PUBLIC

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION
OFFICE OF ADMINISTRATIVE LAW JUDGES

ORIGINAL

In the Matter of:

IMPAX LABORATORIES, INC.,

a corporation.

Docket No. 9373

RESPONDENT IMPAX LABORATORIES, INC.'S REPLIES TO COMPLAINT COUNSEL'S PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW

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IMPAX'S GENERAL RESPONSES TO ALL PROPOSED FINDINGS OF FACT

1. Many of Complaint Counsel's proposed findings of fact are not facts but are instead a mixture of argument, legal conclusions, unsupported assertions, and mischaracterizations of the evidence. Respondent Impax Laboratories, Inc. objects to all such findings.

2. Very few of Complaint Counsel's proposed findings of fact reference the testimony elicited at trial. Of 1,492 proposed findings, 891 (or 60 percent) do not cite trial testimony in any way. Such findings should be accorded little or no weight.

3. Many of Complaint Counsel's proposed findings of fact rely solely on testimony from Investigational Hearings, a proceeding at which Respondent had no opportunity to cross-examine any of the witnesses. All such testimony should be accorded little or no weight, particularly in instances where the witness appeared at trial and testified differently or where Complaint Counsel chose not to elicit the same testimony from the witness at trial.

4. Many of Complaint Counsel's proposed findings of fact are basely solely on hearsay or on exhibits with no sponsoring witness. Other proposed findings are general in nature and refer only to groups of findings that are much narrower than the broad proposition which they supposedly support. These proposed findings should be disregarded.

5. Complaint Counsel's proposed findings based solely on the testimony or the report of an expert violate this Court's Order on Post-Trial Briefs, dated November 17, 2017, ("Order on Post-Trial Briefs") to the extent that the findings address factual propositions that should be proven by fact witnesses or reliable exhibits. Respondent reserves the right to file a motion to strike.

6. Pursuant to the Court's Order on Post-Trial Briefs, Respondent's replies "use the same outline headings as used by [Complaint Counsel] in its opening proposed findings of fact."

Order on Post-Trial Briefs at 4. Respondent does not endorse or adopt the positions taken by Complaint Counsel in those headings.

IMPAX'S REPLIES TO COMPLAINT COUNSEL'S PROPOSED FINDINGS OF FACT

I. Jurisdictional facts

1. Impax Laboratories, Inc. ("Impax") is a for-profit corporation with its principal place of business at 30831 Huntwood Avenue, Hayward, California. (JX-001 at 001 (¶ 1); Koch, Tr. 251). Along with its Hayward headquarters, Impax operates out of its facilities in Middlesex, New Jersey, among other locations. (JX-001 at 001 (¶ 2)).

RESPONSE TO FINDING NO. 1:

Respondent has no specific response.

2. Impax engages in the business of, among other things, developing, manufacturing, and marketing pharmaceutical drugs. (JX-001 at 001, 02 (¶¶ 3, 6); Koch, Tr. 219-20).

RESPONSE TO FINDING NO. 2:

Respondent has no specific response.

3. Impax is a corporation as "corporation" is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44. (JX-001 at 001 (¶ 4)).

RESPONSE TO FINDING NO. 3:

Respondent has no specific response.

4. Impax has engaged, and continues to engage, in commerce and activities affecting commerce in each of the fifty states in the United States and the District of Columbia, as the term "commerce" is defined by Section 1 of the Federal Trade Commission Act, 15 U.S.C. § 44. (JX-001 at 001 (¶ 5)).

RESPONSE TO FINDING NO. 4:

Respondent has no specific response.

5. The Federal Trade Commission ("FTC") has jurisdiction over the subject matter of this proceeding and over Impax. (JX-001 at 002 (¶ 7)).

RESPONSE TO FINDING NO. 5:

Respondent has no specific response.

II. Competition between brand and generic drugs

A. Federal law facilitates approval of generic drugs

6. The Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 et seq., as amended by the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act") and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, 21 U.S.C. §§ 355(b)(2), 355(j) and 35 U.S.C. § 271(e), establishes procedures designed to facilitate competition from lower-priced generic drugs, while maintaining incentives for pharmaceutical companies to invest in developing new drugs. (JX-001 at 002-03 (¶ 12); Snowden, Tr. 347-48).

RESPONSE TO FINDING NO. 6:

Respondent has no specific response.

7. The Hatch-Waxman Act facilitates competition from lower-priced generic drugs through an abbreviated process for generic approval. A company seeking to market a new pharmaceutical product must file a New Drug Application ("NDA") with the U.S. Food and Drug Administration ("FDA") demonstrating the safety and efficacy of the new product. (JX-001 at 003 (¶ 13)). These NDA-based products generally are referred to as "brand-name drugs" or "branded drugs." (JX-001 at 003 (¶ 14)).

RESPONSE TO FINDING NO. 7:

Respondent has no specific response.

8. To market a generic product, companies like Impax file an Abbreviated New Drug Application, or ANDA, to initiate the FDA approval process. (JX-001 at 003 (¶ 17); Snowden, Tr. 348). An ANDA filer does not need to demonstrate the safety and efficacy of its generic product, but instead demonstrates that its generic drug is therapeutically equivalent to the brand-name drug that it references and for which it seeks to be a generic substitute. (JX-001 at 003-04 (¶¶ 18-19); CX4002 (Smolenski, IHT at 56-57)). Upon showing that the generic drug is therapeutically equivalent to the already-approved branded drug, the generic company may rely on the studies submitted in connection with the already approved branded drug's NDA to establish that the generic drug is safe and effective. (JX-001 at 003-04 (¶ 19); Snowden, Tr. 348).

RESPONSE TO FINDING NO. 8:

Respondent has no specific response.

9. The FDA assigns a generic drug an "AB" rating if it is therapeutically equivalent to a brand-name drug. (JX-001 at 004 (¶ 20)). An AB-rated generic drug is the same as a brand-name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use. (JX-001 at 004 (¶ 20)). A generic drug also must contain identical amounts of the same active ingredient(s) as the brand-name drug, although its inactive ingredients may vary. (JX-001 at 004 (¶ 20)).

RESPONSE TO FINDING NO. 9:

Respondent has no specific response.

10. To maintain incentives for pharmaceutical companies to invest in developing new drugs, the Hatch-Waxman Act establishes a series of additional procedures that a generic company must satisfy before it can get approval of its ANDA drug, if the brand company owns patents that might arguably cover the generic product. To notify ANDA filers about potentially relevant patents, the FDA requires brand-name drug manufacturers to identify any patents that the manufacturer believes reasonably could be asserted against a generic manufacturer that makes, uses, or sells a generic version of the branded drug. (JX-001 at 003 (¶ 15)). The manufacturer must submit these patents for listing in an FDA publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the Orange Book) within 30 days of issuance of the patent. (JX-001 at 003 (¶ 16); Snowden, Tr. 349).

RESPONSE TO FINDING NO. 10:

Respondent has no specific response.

11. When a brand-name drug is covered by patent(s) listed in the Orange Book, a company that intends to market a generic version of that drug before the patent(s) expire must make a "Paragraph IV certification" in its ANDA certifying that the patent(s) are invalid, unenforceable, and/or will not be infringed by the generic drug. (JX-001 at 004 (¶ 21); CX4026 (Nguyen, Dep. at 30-31); CX4002 (Smolenski, IHT at 32)). If a generic company makes a Paragraph IV certification, it must notify the patent holder of its certification. (JX-001 at 004 (¶ 22); CX4026 (Nguyen, Dep. at 24)).

RESPONSE TO FINDING NO. 11:

Respondent has no specific response.

12. If the patent holder initiates a patent infringement suit against the company within 45 days of receiving such notice, the FDA may not grant final approval of the ANDA until the earliest of (1) patent expiry, (2) district court resolution of the patent litigation in favor of the generic company, or (3) the expiration of an automatic 30-month stay. (JX-

001 at 004 (¶ 23); CX4026 (Nguyen, Dep. at 24-25)). This is commonly referred to as the "30-month stay." (CX4026 (Nguyen, Dep. at 25)).

RESPONSE TO FINDING NO. 12:

Respondent has no specific response.

13. When a generic drug otherwise meets the FDA's criteria for approval, but final approval is blocked by a statute or regulation such as the Hatch-Waxman 30-month stay, the FDA will tentatively approve the relevant ANDA. (JX-001 at 005 (¶ 24); CX4022 (Mengler, Dep. at 111)). Tentative approval does not permit an ANDA filer to market its generic version of the drug. (JX-001 at 005 (¶ 25)). The FDA can issue final approval of a tentatively-approved drug once the relevant 30-month stay has expired. (JX-001 at 005 (¶ 26)). Getting final approval is generally considered a formality in this situation. (Koch, Tr. 340-41 ("it's pretty routine and rubber stamp from the time of a tentative approval to final approval")).

RESPONSE TO FINDING NO. 13:

Respondent has no specific response.

14. As an incentive for generic companies to challenge patents that may be invalid, unenforceable, or not infringed, the Hatch-Waxman Act gives the first generic company or companies filing an ANDA containing a Paragraph IV certification (the "first filer") a period of protection from competition with other ANDA filers, referred to as the "180-day exclusivity" or "first-filer exclusivity" period. (JX-001 at 005 (¶ 27); Snowden, Tr. 414). The FDA cannot approve any other ANDA generic product until the exclusivity period ends 181 days after the first filer enters the market. (CX5000 at 033 (¶ 73) (Noll Report); Snowden, Tr. 414).

RESPONSE TO FINDING NO. 14:

Respondent has no specific response to the first sentence of Complaint Counsel's Proposed Finding No. 14. The second sentence of Proposed Finding No. 14 is incomplete and inaccurate. First-filer exclusivity can be forfeited, and the FDA can therefore approve other ANDA generic products sooner than 181 days after the first filer enters the market, if, for example, a first-filer does not launch its product within a certain period of time or it does not receive tentative approval from the FDA. (Snowden, Tr. 414-15, 417; JX-003-002 (Second Set of Joint Stipulations ¶ 7); CX5000-033 (Noll Rep. ¶ 73) (explaining that to "take advantage of

the exclusivity period, the generic firm must enter the market at least six months before the challenged patents on the brand-name drug expire")).

15. The 180-day exclusivity period can be "very valuable" to a generic company. (Koch, Tr. 232-33; *see also* Snowden, Tr. 414 (describing exclusivity period as a "benefit")). First-filer exclusivity provides the generic company with "six months of runway before another entrant will be reviewed or approved." (Koch, Tr. 232). Generic companies, like Impax, "can make a substantial portion of their profits" during that "six-month runway." (Koch, Tr. 232).

RESPONSE TO FINDING NO. 15:

Respondent has no specific response.

B. State law encourages substitution of AB-rated generic drugs for brand drugs

16. All 50 states and the District of Columbia have drug substitution laws that encourage and facilitate substitution of lower-cost AB-rated generic drugs for branded drugs. (CX5000 at 030 (¶ 66) (Noll Report) (citing summary from State Regulation of Generic Substitution); CX3162 at 018 n.83 (Impax White Paper) (quoting amicus brief in *Mylan Pharm. Inc. v. Warner Chilcott Public Ltd.*) ("all states facilitate competition through laws that allow a pharmacist to substitute an AB-rated generic drug when presented with a prescription for its brand equivalent"); JX-003 at 011 (¶ 72)).

RESPONSE TO FINDING NO. 16:

Respondent has no specific response.

17. State substitution laws were enacted in part because the pharmaceutical market does not function well. (*See* RX-547 at 027 (¶ 50 n.64) (Addanki Report) (citing FDA Orange Book)). In a well-functioning market, a consumer selects and pays for a product after evaluating the product's price and quality. In the prescription drug market, however, a patient can obtain a prescription drug only if the doctor writes a prescription for that particular drug. (JX-001 at 007 (¶ 11).

RESPONSE TO FINDING NO. 17:

The first sentence of Complaint Counsel's Proposed Finding No. 17 is inaccurate, misleading, and not supported by the cited evidence. Dr. Addanki's expert report does not state that state substitution laws were enacted because the pharmaceutical market does not function

well. The cited footnote from Dr. Addanki's report is a quotation from the FDA's Orange Book describing the creation of the Orange Book itself, which states in relevant part, "To contain drug costs, virtually every state has adopted laws and/or regulations that encourage the substitution of drug products. These state laws generally require either that substitution be limited to drugs on a specific list (the positive formulary approach) or that it be permitted for all drugs except those prohibited by a particular list (the negative formulary approach)." (RX-547.0027 (Addanki Rep. ¶ 50 n.64)).

The second sentence of Proposed Finding No. 17 is not supported by any record evidence and should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Respondent has no specific response to the third sentence of Proposed Finding No. 17.

> 18. The doctor who selects the drug, however, does not pay for it and generally has little incentive to consider price when deciding which drug to prescribe. (CX5000 at 029 (¶ 64) (Noll Report)). Because a clinician's primary concerns are efficacy and safety, most healthcare providers usually do not consider pricing when selecting appropriate medications for patients. (CX5002 at 063 (¶ 177) (Savage Report); Savage, Tr. 770-71). In many instances, physicians are largely unaware of prices when prescribing medications. (CX5002 at 064 (¶ 180) (Savage Report); Savage, Tr. 770-71; *see also* Michna, Tr. 2187-88; Michna, Dep. at 148-49).

RESPONSE TO FINDING NO. 18:

Complaint Counsel's Proposed Finding No. 18 is inaccurate and misleading. When there are multiple equally-safe and effective options to address a patient's needs, doctors take into account the patient's out-of-pocket costs when selecting among treatment options. (RX-549.0006-07, 20-23 (Michna, Rep. ¶¶ 21, 49-53)). Insurance coverage for a particular medication, including the amount of co-pay or other out-of-pocket costs, depends on where a medication is located on an insurance company's formulary. (Bingol, Tr. 1323-24; Michna, Tr.

2140-42; Addanki, Tr. 2218). Accordingly, formulary placement can play a key role in doctors' prescribing decisions when choosing between equally-safe and effective long-acting opioids. (Michna, Tr. 2148; CX4046 (Michna, Dep. at 115-16); CX4044 (Addanki, Dep. at 148); RX-549.0006-07, 21 (Michna Rep. ¶¶ 21, 51)).

In fact, Complaint Counsel's economic expert, Professor Noll, admitted that doctors make prescribing decisions based on price and formulary tiering, among other issues. (Noll, Tr. 1505-06). Dr. Savage, Complaint Counsel's medical expert, similarly admitted that "the copay is one variable that may be considered" when making prescription choices—"clinical determinations are usually the first consideration and then copays." (CX4041 (Savage, Dep. at 138); *see* Savage, Tr. 772 (availability of insurance coverage for a medication would affect Dr. Savage's clinical decision-making)).

Doctors are aware of drug prices when prescribing medications based on numerous sources of information. (Michna, Tr. 2122-23). For example, when they enter a "drug order in the system, as [they are] ready to print it or electronically send the prescription to the pharmacy, [they] will get an immediate feedback as to whether that's a covered medication for that insurance company, also what level of additional pay that the patient has to pay at the pharmacy." (Michna, Tr. 2122-23). Doctors also receive feedback directly from patients, pharmacists, and drug manufacturers regarding drug costs and formulary tiering. (Michna, Tr. 2123; CX4046 (Michna, Dep. at 115-16)). Dr. Savage personally is not aware of drug prices because formulary tiering and what patients pay in copays "truly is outside [her] experience" since she is "a consultant in [her] practice area" and does not "do the direct management of the patients [or] deal with insurance companies," which she leaves to "the staff physicians." (CX4041 (Savage, Dep. at 117-18)).

Finally, the citations to Dr. Michna's testimony are inaccurate and misleading. Dr. Michna did not testify that he is unaware of prices when prescribing medications; just the opposite. (Michna, Tr. 2122-23, 2148; CX4046 (Michna, Dep. at 115-16)). Dr. Michna made the same point in the cited portions of his testimony. (Michna, Tr. 2187-88 (discussing fluctuations in price and explaining "I'd be aware of it if there's dramatic changes"); CX4046 (Michna, Dep. at 148-49) ("I don't trawl the daily cost of all the pharmaceutical products, but I have a general idea.")).

19. Instead, the patient, or in most cases a third-party payer such as a public or private health insurer, pays for the drug. (CX5000 at 031 (¶ 67) (Noll Report)). But these purchasers have little input over what drug is actually prescribed, because physicians ultimately select and prescribe appropriate drug therapies. (CX5002 at 063 (¶ 177) (Savage Report)).

RESPONSE TO FINDING NO. 19:

Respondent does not dispute that third-party payors often pay for drugs, but the first sentence of Complaint Counsel's Proposed Finding No. 19 is not supported by the cited evidence. The cited portion of Professor Noll's report discusses policies to control drug costs, including "rules about physician prescribing behavior and patient cost reimbursement by entities that pay for prescription drugs." (CX5000-031 (Noll Rep. ¶ 67)). The cited portion of the report does not discuss who pays for drugs in most instances.

The second sentence of Proposed Finding No. 19 is inaccurate, misleading, and not supported by the cited evidence. The exhibit cited, a paragraph from Dr. Savage's report, does not discuss third-party payors or their input. (CX5002-063 (Savage Rep. ¶ 177)). The exhibit, moreover, actually notes that clinicians will "consciously consider costs" when they are "aware that the patient will need to pay out of pocket." (CX5002-063 (Savage Rep. ¶ 177)). The second sentence is also inconsistent with the record. Dr. Michna—who, unlike Dr. Savage, directly

manages patients, (CX4041 (Savage, Dep. at 117))—takes the costs of medications, including formulary placement, into account when choosing among equally safe and effective medication options. (*See* Michna, Tr. 2121-22, 2148; CX4046 (Michna, Dep. at 115-16); RX-549.0006-07, 21 (Michna Rep. ¶¶ 21, 51)). Other doctors do the same. (CX4046 (Michna, Dep. at 115-16); RX-549.0006-07, 021 (Michna Rep. ¶¶ 21, 51)).

> 20. State substitution laws are designed to correct this market imperfection by shifting the drug selection choice from physicians to pharmacists and patients who have greater financial incentives to make price comparisons. (CX5000 at 030 (¶¶ 65-66) (Noll Report); RX-547 at 027 (¶ 50 n.64) (Addanki Report) (quoting FDA Orange Book) ("To contain drug costs, virtually every state has adopted laws and/or regulations that encourage the substitution of products.")).

RESPONSE TO FINDING NO. 20:

Complaint Counsel's Proposed Finding No. 20 is inaccurate and mischaracterizes the cited exhibits. None of the cited exhibits provide that state substitution laws were designed to correct a market imperfection or to shift drug selection choices from one entity to another. Professor Noll's report states that insurance companies and the government "have put in place three policies that increase the influence of price on drug choice and encourage use of generics," including generic substitution laws. (CX5000-030 (Noll Rep. ¶ 65)). Dr. Addanki's report quotes the FDA Orange Book, which states only, "To contain drug costs, virtually every state has adopted laws and/or regulations that encourage the substitution of products." (RX-547.0027 (Addanki Rep. ¶ 50 n.64)).

> 21. Under these laws, if a prescription is written for the branded product, a pharmacist could substitute the AB-rated generic for the brand. (CX5000 at 030 (¶ 66) (Noll Report); RX-547 at 026-27 (¶ 50) (Addanki Report); Reasons, Tr. 1219; JX-003 at 011 (¶ 72)).

RESPONSE TO FINDING NO. 21:

Respondent has no specific response.

22. An AB rating is fundamental to automatic substitution. If the generic drug is not AB-rated to the brand drug, a pharmacist cannot substitute the generic drug. (CX5000 at 030 (¶ 66) (Noll Report); JX-003 at 011 (¶ 72)).

RESPONSE TO FINDING NO. 22:

Respondent has no specific response to the first sentence of Complaint Counsel's Proposed Finding No. 22. The second sentence of Proposed Finding No. 22 is inaccurate and misleading. A pharmacist may substitute a non-AB-rated generic for a branded drug if the physician writes the chemical name of the drug, rather than the brand name, on the prescription. (JX-003-011 (¶ 72) (Second Set of Joint Stipulations)).

C. Competition from lower-priced generic drugs saves American consumers billions of dollars a year

23. The Hatch-Waxman Act and state substitution laws have succeeded in facilitating generic competition and generating large savings for patients, health care plans, and federal and state governments. *See* CCF ¶¶ 24-26, below.

RESPONSE TO FINDING NO. 23:

The proposed summary finding should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Additionally, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondent's replies to those findings.

24. It is well known that generic entrants typically charge lower prices than branded drug sellers. (CX5000 at 048 (¶ 104) (Noll Report); CX2607 at 012 (¶ 29) (Lortie Decl.) (competition among multiple generics drives downs the price of generics to levels at which brands cannot compete). The first one or two generic products are typically offered at a 10% to 25% discount to the branded product. (CX5000 at 048 (¶ 104) (Noll Report)). Subsequent generic entry creates greater price competition with discounts reaching 80% or more off the brand price. (CX5000 at 048 (¶ 104) (Noll Report); CX6055 at 010 (FTC study of reverse payments) (generally takes about a year for generic marketplace to mature based on recent generic launches, and generics then sell at an average of 85% lower than the pre-entry branded drug price)).

RESPONSE TO FINDING NO. 24:

Respondent has no specific response to the first sentence of Complaint Counsel's Proposed Finding No. 24 other than to note that while generic drugs generally are priced lower than branded drugs, that is not always the case. (Hoxie, Tr. 2795 (claiming generics do not always sell at a discount to the brand)).

The second sentence of Proposed Finding No. 24 violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents."

The third sentence of Proposed Finding No. 24 is incomplete and misleading. The first cited document (CX5000-048) is expert testimony inappropriately cited for a factual proposition. The second cited document (CX6055-010) is an FTC document advocating for Congressional legislation prohibiting all so-called "pay-for-delay" agreements. The document cites no data or statistics in support of the proposition advanced by Complaint Counsel. (CX6055-010). Finally, the cited document acknowledges that the proposition advanced by Complaint Counsel is based on assumptions about demand and pricing meant to "simplif[y] the analysis," even though prices actually vary. (CX6055-014).

25. Generic drug entry before patent expiration can save consumers billions of dollars. (CX6055 at 005 (FTC study of reverse payments)).

RESPONSE TO FINDING NO. 25:

Complaint Counsel's Proposed Finding No. 25 is incomplete and misleading. The cited exhibit (CX6055-005) is an FTC document advocating for Congressional legislation prohibiting all so-called "pay-for-delay" agreements. The cited document does not state that entry by a single generic company, or entry with respect to single product, can result in the purported savings. The document instead discusses the entire universe of pharmaceutical products and

"pay-for-delay" agreements collectively. (CX6055-005). The document, moreover, cites no data, statistics, or other analysis in support of the proposition advanced by Complaint Counsel. (CX6055-005).

The Proposed Finding also ignores the uncertainty of the purported savings, as courts can enjoin generic companies from competing if they enter before patent expiration. (Snowden, Tr. 503-04; Figg, Tr. 1871, 1904-05). And the Proposed Finding ignores the risks to generic drug companies of entry before patent expiration, including billions of dollars in patent-infringement damages, (Hoxie, Tr. 2782), and bankruptcy (Koch, Tr. 287 (generic entry before patent expiration can be a "bet-the-company" undertaking and can "take the solvency of the company entirely"); CX4030 (Hsu, Dep. at 43) ("the risk can be huge depending on the size of the product and depending on whether we're first to file")).

26. Because of these price advantages and cost savings, many third-party payers of prescription drugs (e.g., health insurance plans and Medicaid programs) have adopted policies to encourage the substitution of AB-rated generic drugs for their branded counterparts. (CX5000 at 030-32 (¶¶ 65, 67-69) (Noll Report); CX6052 at 084-85 (FTC Authorized Generics Report)).

RESPONSE TO FINDING NO. 26:

Respondent has no specific response.

D. Competition from an authorized generic typically has a significant financial impact on the generic first filer

27. To offset some of the lost profits resulting from declining branded product sales after generic entry, brand companies frequently launch authorized generics. An authorized generic, or AG, is chemically identical to the brand drug, but is sold as a generic product, typically through either the brand company's subsidiary or through a third party. (JX-001 at 005 (¶ 31)). A brand company can market a generic version of its own brand product at any time, including during the first filer's exclusivity period. (JX-001 at 005 (¶ 28)). For a brand company to market a generic version of its own brand product, no ANDA is necessary because the brand company already has approval to sell the drug under its NDA. (JX-001 at 005 (¶ 29)).

RESPONSE TO FINDING NO. 27:

The first sentence of Complaint Counsel's Proposed Finding No. 27 is unsupported by any record evidence and should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-Trial Briefs at 2). Respondent has no specific response to the second, third and fourth sentences of Proposed Finding No. 27.

> 28. Brand companies typically launch AGs when the first generic product enters. (CX6052 at 086 (FTC Authorized Generics Report) (When brands sell an AG, they "almost always launch AGs simultaneously with or shortly after ANDA-generic entry"); CX4025 (Bingol, Dep. at 34-35) (launching an AG when a generic enters helps the brand "retain as much market share as you could versus losing it to generics")). Launching at the same time as the first generic entrant can be lucrative because there is competition coming only from the first-filer, and entering immediately can give the brand company a first-mover advantage that remains even after additional generic products are sold. (CX6052 at 081, 107 (FTC Authorized Generics Report) ("early generic entrants, whether first-filers or AGs, are able to retain a large portion of their market share even after potentially many other ANDA-generics enter following the 180-day exclusivity period")). Brand companies do not generally sell an AG prior to the first generic's entry, because that would cannibalize branded sales and start the decline in branded product sales before an ANDA-generic enters. (CX6052 at 086-87 (FTC Authorized Generics Report)).

RESPONSE TO FINDING NO. 28:

The first sentence of Complaint Counsel's Proposed Finding No. 28 is inaccurate and misleading. The only document cited to support the proposition regarding "typical" behavior (CX6052) is a report from the FTC itself, which was drafted in part by members of Complaint Counsel. (CX6052-002). The evidence at trial indicated that brand companies launch authorized generics "from time to time," but do not always utilize authorized generics. (Koch, Tr. 233). Indeed, the record contradicts the Proposed Finding's claims that all brand companies act the same way. Endo "never seriously considered taking any further steps to prepare for or to do [an authorized generic of Opana ER] because we really didn't want to." (CX4019 (Lortie, Dep. at

118-19); *see also* Bingol, Tr. 1337 ("I don't recall specific forecasts about an authorized generic."); Bingol, Tr. 1338-39 (an authorized generic "was never, to my knowledge . . . fully realized as a plan or an idea"); CX4031 (Bradley, Dep. at 198) ("I don't recall having any conversation with any colleagues regarding the launch of an authorized generic.")). In fact, Endo intended to replace its original Opana ER product with a reformulated product "and that would be the only product that we had on the market." (CX4019 (Lortie, Dep. at 117-18); *see* Bingol, Tr. 1338).

Respondent has no specific response to the second and third sentences of Proposed Finding No. 28.

> 29. Competition from an authorized generic has a significant financial impact on the first filer. (CX6052 at 047 (FTC Authorized Generics Report) (first filer's revenues fall 40-52% when facing an AG); CX6055 at 007 (FTC study on reverse payments) ("AG competition can substantially reduce the revenues a first-filer generic earns during its 180 days of marketing exclusivity."); CX4020 (Reasons, Dep. at 53) (as an additional competitor to the generic, an AG can result in lost market share and/or a lower price)).

RESPONSE TO FINDING NO. 29:

Complaint Counsel's Proposed Finding No. 29 is misleading and not supported by the cited evidence. The first exhibit cited in Proposed Finding No. 29 discusses "wholesale expenditures," not actual first-filer revenue. (CX6052-047). The second exhibited cited in Proposed Finding No. 29 (CX6055-005) is an FTC document advocating for Congressional legislation prohibiting all so-called "pay-for-delay" agreements. The document simply references an interim version of CX6052 and offers no other data, statistics, or analysis in support of the quoted language. (CX6055-007, 014). Finally, the third exhibit cited in Proposed Finding No. 29 does not mention "significant financial impacts." (CX4020 (Reasons, Dep. at 53)).

30. Moreover, a first filer's first-mover advantage can be undercut if it faces an AG at launch, resulting in lost revenues even after the first-filer exclusivity period has ended. (CX6052 at 119 (FTC Authorized Generics Report)).

RESPONSE TO FINDING NO. 30:

Complaint Counsel's Proposed Finding No. 30 is incomplete and misleading because it ignores record evidence that there are multiple advantages to being a first-filer, including getting on the market as early as possible, which is not undercut by the presence of an authorized generic. (Mengler, Tr. 528-29; CX4030 (Hsu, Dep. at 76-77)). Generic companies like Impax derive value "by selling the drug [] with or without an" authorized generic. (Mengler, Tr. 528-29).

31. A first filer's revenues could be as much as 62% lower in the 30 months after the end of the 180-day exclusivity period if facing an AG. (CX6052 at 005 (FTC Authorized Generics Report)).

RESPONSE TO FINDING NO. 31:

Respondent has no specific response.

32. If a brand manufacturer agrees to refrain from launching an authorized generic, it can more than double the first filer's revenues during the 180-day exclusivity period. (CX6052 at 008 (FTC Authorized Generics Report)). This financial impact is well known in the pharmaceutical industry. (CX6052 at 159-60 (FTC Authorized Generics Report)).

RESPONSE TO FINDING NO. 32:

The first sentence of Proposed Finding No. 32 is misleading and incomplete. The only document cited to support the Proposed Finding (CX6052) is a report from the FTC itself, which was drafted in part by members of Complaint Counsel. (CX6052-002). The first sentence of the Proposed Finding, moreover, ignores the fact that brand companies can and do compete with generic products on price, even if there is no Authorized Generic product on the market during the 180-day exclusivity period. (Bingol, Tr. 1327; Engle, Tr. 1703-04, 1718 (being non-AB

rated "doesn't impact the ability to sell. We -- Impax was still able to sell"); CX4037 (Smolenski, Dep. at 155)). The second sentence of Proposed Finding No. 32 is not supported by the cited evidence. The cited document does not discuss whether any form of financial impact is well known in the pharmaceutical industry. (CX6052-159-60).

III. Opana ER was a successful and rapidly growing brand drug

33. In 2010, Endo was "was really a company based on two products . . . Lidoderm and Opana." (CX4011 (Holveck, IHT at 11-12, 16)). Together, Lidoderm and the Opana franchise accounted for 63% of Endo's revenues. (CX3214 at 148 (Endo 2010 10-K)). Behind Lidoderm, Opana ER was Endo's "second biggest selling product." (Bingol, Tr. 1263).

RESPONSE TO FINDING NO. 33:

Respondent has no specific response.

34. Oxymorphone is in a class of drugs known as opioids, which have long been used to relieve pain. (JX-001 at 006 (¶ 2)). Oxymorphone is a semi-synthetic opioid, originally developed over 100 years ago and first approved by the FDA in 1960. (JX-001 at 006 (¶ 1); CX5002 at 037 (¶ 104) (Savage Report); CX3247 (NDA No. 011738 "Numorphan"); CX6050 at 004 (FDA presentation: Regulatory History of Opana ER)).

RESPONSE TO FINDING NO. 34:

Respondent has no specific response.

35. Opana ER is an extended-release formulation of oxymorphone. (JX-001 at 006 (¶ 3)). Unlike immediate-release drugs, extended-release medications like Opana ER have special coatings or ingredients that control how fast the active ingredient is released from the pill into the patient's body. (CX5002 at 034 (¶ 96) (Savage Report)). Compared to an immediate-release oxymorphone formulation, Opana ER provides longer-lasting, 12-hour pain relief that allows the patient to take fewer pills each day. (CX3163 at 008 (¶ 8) (Impax Answer); CX5002 at 038 (¶ 106) (Savage Report)).

RESPONSE TO FINDING NO. 35:

Respondent has no specific response.

36. The FDA approved Opana ER (NDA No. 021610) in June 2006 "for the relief of moderate to severe pain in patients requiring continuous, around-the-clock opioid

treatment for an extended period of time." (JX-001 at 006 (¶ 4)). It is used to treat pain for a wide variety of conditions, ranging from chronic back problems to cancer. (JX-001 at 006 (¶ 5)).

RESPONSE TO FINDING NO. 36:

Respondent has no specific response.

37. In July 2006, Endo launched Opana ER as the only extended-release version of oxymorphone on the market. (JX-001 at 006 (¶¶ 6, 8); CX6050 at 006, 08 (FDA Regulatory History of Opana ER)). Endo ultimately sold Opana ER in seven dosage strengths (5, 7.5, 10, 15, 20, 30, and 40 mg). (JX-001 at 006 (¶ 7)).

RESPONSE TO FINDING NO. 37:

Respondent has no specific response.

38. Opana ER was originally launched in four dosage strengths (5, 10, 20 and 40 mg). (CX3273 at 002 (¶ 4) (Bingol Decl.)). In April 2008, Opana ER was launched in three additional dosage strengths (7.5, 15, and 30 mg). (CX3273 at 002 (¶ 4) (Bingol Decl.)). The most commercially significant strengths for Opana ER were the 5 mg, 10 mg, 20mg, 30 mg, and 40 mg strengths, which in 2010 accounted for approximately 94% of the unit sales of Opana ER. (CX3273 at 002-03 (¶ 4) (Bingol Decl.)).

RESPONSE TO FINDING NO. 38:

Respondent has no specific response.

39. As Endo's second best-selling drug, Opana ER was Endo's "flagship branded product." (CX2607 at 005 (¶ 16) (Lortie Decl.); Bingol, Tr. 1263). After a modest start of $5 million in sales in 2006, sales grew to $172 million in 2009. (CX2607 at 004 (¶ 13) (Lortie Decl.)). Endo's 2009 sales of Opana ER amounted to 12% of its total annual revenue. (CX3160, Endo Pharmaceuticals Holdings Inc. SEC 2009 Form 10-K (Feb. 26, 2010), at 052).

RESPONSE TO FINDING NO. 39:

Respondent has no specific response other than to clarify that Mr. Lortie's declaration was written in August 2013, and it discussed Opana ER "going forward," not at the time of the Endo-Impax settlement. (CX2607-005; *see also* Bingol, Tr. 1264 ("all the products that they had, you know, each one was important in its own way")).

40. Sales reached approximately $240 million in 2010 (CX2607 at 004 (¶ 13) (Lortie Decl.), the earliest year that generics could have entered and the year of the Endo-Impax settlement agreement. (RX-364 (SLA); RX-365 (DCA); JX-001 at 007 (¶ 16)).

RESPONSE TO FINDING NO. 40:

Respondent has no specific response.

41. In 2011, sales for Opana ER were approximately $384 million. (CX2607 at 004 (¶ 13) (Lortie Decl.)). Endo had expected that upward sales trend to continue into 2012. (CX2607 at 005 (¶¶ 15-16) (Lortie Decl.)).

RESPONSE TO FINDING NO. 41:

Respondent has no specific response to the first sentence of Complaint Counsel's Proposed Finding No. 41. The second sentence of Proposed Finding No. 41 is inaccurate and not supported by the cited evidence. The cited declaration actually states that "[n]et sales for Opana ER decreased in 2012 because of product shortages and supply disruptions caused by problems with Endo's suppliers," resulting in a decrease of almost $90 million. (CX2607-004-05 & n.2). The cited portions of the declaration say nothing about sales trends or Endo's expectations with respect to the same.

42. In terms of prescriptions, within a year and a half of its launch, over 25,000 prescriptions for Opana ER were being written on a monthly basis. In the 18 months thereafter, the number of prescriptions had more than doubled such that over 60,000 prescriptions for Opana ER were written on a monthly basis in 2010. (CX3273 at 005 (¶ 10) (Bingol Decl.)).

RESPONSE TO FINDING NO. 42:

Respondent has no specific response.

43. Opana ER experienced a 40% growth in the number of prescriptions in the fourth quarter 2009 compared with that same period in 2008, notwithstanding that the overall sales of long-acting opioid products had declined by 1% for that same period. (CX3273 at 005 (¶ 10) (Bingol Decl.)).

RESPONSE TO FINDING NO. 43:

Respondent has no specific response other than to note that Mr. Bingol stated that "the overall LAO [long-acting opioid] market was down one percent," and that he said nothing about sales. (CX3273-005).

44. The Opana franchise, including Opana ER, was an important product that made a significant contribution to the growth and success of Endo's business. (CX3273 at 005 (¶ 11) (Bingol Decl.); Bingol, Tr. 1263-64). From 2008 through 2009, Opana ER accounted for 11.3% and 11.8% (respectively) of Endo's total revenues. Assuming no generic entry, the Opana franchise and was forecasted to represent 13.8% of Endo's total revenues in 2010. (CX2564 at 014 (Mar. 2010 Endo 10-year outlook)).

RESPONSE TO FINDING NO. 44:

Respondent has no specific response.

45. Not only was Opana ER still growing in 2010, but it continued to be a very profitable product for Endo. The importance of the Opana franchise to the success and growth of Endo's business is reflected by the extent to which the brand contributes profits to Endo's overall business. In 2009, and as Endo projected for 2010 (assuming no generic entry), the Opana franchise contributed more than 40% of its net sales to the overall company. (CX3273 at 006 (¶ 13) (Bingol Decl.)).

RESPONSE TO FINDING NO. 45:

Respondent has no specific response.

46. Endo projected that its Opana ER sales of would continue to contribute significantly to the revenues and profitability of the company thereby continuing to support the growth of Endo's business. (CX3273 at 006 (¶ 15) (Bingol Decl.); Bingol, Tr. 1263-64).

RESPONSE TO FINDING NO. 46:

Respondent has no specific response.

A. Opana ER was an attractive target for generic firms

47. Several attributes of Opana ER made it a potentially lucrative target for generic substitutes, including the size of the market opportunity (*see* CCF ¶¶ 48-49, below), and the lack of meaningful patent protection (*see* CCF ¶¶ 50-57, below).

RESPONSE TO FINDING NO. 47:

The proposed summary finding should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Additionally, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondent's replies to those findings.

48. The size of the branded product is "obviously" an important factor in determining whether to develop a generic product. (CX4021 (Ben-Maimon, Dep. at 17-18)). Indeed, when Impax assesses the value of potential market opportunity for a new generic drug, the size of the corresponding branded product's sales provides the "best" and "most accurate" estimate. (Reasons, Tr. 1219-20).

RESPONSE TO FINDING NO. 48:

The first sentence of Complaint Counsel's Proposed Finding No. 48 is not supported by the cited evidence. Dr. Ben-Maimon testified that "[o]bviously *market size*" was one of many factors considered when selecting a generic to develop. (CX4021 (Ben-Maimon, Dep. at 17-18) (emphasis added)). She said nothing about the "size of the branded product." Respondent has no specific response to the second sentence of Proposed Finding No. 48 other than to note the quotations attributed to Mr. Reasons are questions by Complaint Counsel. (Reasons, Tr. 1219-20).

49. Therefore, Opana ER's rapid growth and profitability made it an exciting opportunity for Impax and other generic firms. (Koch, Tr. 300; CX2607 at 008-009 (Lortie Decl. ¶ 24).

RESPONSE TO FINDING NO. 49:

Respondent has no specific response.

50. Additionally, the lack of meaningful patent protection for Opana ER made it an easy target for generic companies. When Endo launched Opana ER in 2006, it only listed

> a single patent, No. 5,128,143 (the "'143 patent"), in the Orange Book covering Opana ER. (CX3242 at 003 (2007 Endo letter to the FDA)). The '143 patent was not a meaningful, long-term barrier to generic competition, because it was set to expire in September 2008. (CX3242 at 003 (2007 Endo letter to the FDA)).

RESPONSE TO FINDING NO. 50:

The first sentence of Complaint Counsel's Proposed Finding No. 50 is not supported by any record evidence and should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). The first sentence of the Proposed Finding also represents an improper legal conclusion regarding the strength of the patent protection. Respondent has no specific response to the second sentence of Proposed Finding No. 50. Respondent does not dispute that the '143 patent was set to expire in September 2008, but the third sentence of Proposed Finding No. 50 states an improper legal conclusion regarding the strength of the patent protection.

> 51. Against this patent backdrop, Impax initially filed an Abbreviated New Drug Application ("ANDA") for a generic version of Opana ER (No. 79-087) in June 2007. (JX-001 at 007 (¶ 11)). Based on Opana ER's increasing profitability and the absence of meaningful patent protection, the filing of ANDAs by several generic companies was inevitable. Impax was the first of many generics to file a Paragraph IV certification. (CX2607 at 008-09 (Lortie Decl. ¶¶ 24-25)).

RESPONSE TO FINDING NO. 51:

Respondent has no specific response to the first sentence of Complaint Counsel's Proposed Finding No. 51. The second sentence of Proposed Finding No. 51 is not supported by any record evidence and should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Respondent has no specific response to the third sentence of Proposed Finding No. 51.

52. On October 2, 2007, Endo listed Patent No. 7,276,250 (the "'250 patent") relating to a mechanism for controlling the release of a drug's active ingredient over an extended period of time. (JX-001 at 006 (¶ 9); CX3520 (U.S. Patent No. 7,276,250 Abstract)). That patent expires in 2023 (JX-001 at 006 (¶ 10); CX3208 at 006, 07 (Smolenski/Camargo email)).

RESPONSE TO FINDING NO. 52:

Respondent has no specific response.

53. On October 19, 2007, Endo listed in the Orange Book two additional patents pertaining to a controlled release mechanism—No. 5,662,933 (the "'933 patent") and No. 5,958,456 (the "'456 patent"). (JX-001 at 006 (¶ 9); CX3249 (U.S. Patent No. 5,662,933 Abstract); CX0303 at 35 (U.S. Patent No. 5,958,456 Abstract)). The '933 and '456 patents expired in September 2013. (JX-001 at 006 (¶ 10)).

RESPONSE TO FINDING NO. 53:

Respondent has no specific response.

54. Those patents had been issued by the U.S. Patent and Trademark Office up to a decade earlier—in 1997 and 1999, respectively. (CX0303 at 006 (¶¶ 22, 23) (*Endo v. Impax* complaint)).

RESPONSE TO FINDING NO. 54:

Respondent has no specific response.

55. Endo failed to list the '456 and '933 patents in the Orange Book within 30 days of the FDA approving Endo's NDA for Opana ER as required under 21 C.F.R. § 314.53. (JX-001 at 003 (¶ 16), 006 (¶¶ 4, 9)).

RESPONSE TO FINDING NO. 55:

Complaint Counsel's Proposed Finding No. 55 improperly states a proposed legal conclusion, not a fact.

56. Following Endo's listing of additional patents in the Orange Book in October 2007, Impax amended its ANDA to include Paragraph IV certifications for the '250, '933, and '456 patents, attesting that Impax's product did not infringe the patents and/or that the patents were invalid. (JX-001 at 007 (¶ 12)).

RESPONSE TO FINDING NO. 56:

Respondent has no specific response.

57. Eventually, at least eight companies submitted ANDAs seeking approval to market a generic version of Opana ER, including Impax and Actavis. (CX2607 at 008-09 (Lortie Decl. ¶ 24)). Each company included a Paragraph IV certification asserting that its proposed generic product did not infringe Endo's patents and/or that Endo's patents were invalid or unenforceable. (CX2607 at 008-09 (Lortie Decl. ¶ 24); *see also* CX3449 (Impax Paragraph IV certification for the '933 patent); CX3451 (Impax Paragraph IV certification for the '250 patent); CX3450 (Impax Paragraph IV certification for the '456 patent)).

RESPONSE TO FINDING NO. 57:

Respondent has no specific response.

B. Endo projected generic entry as early as June 2010 and knew that generic competition would decimate its Opana ER sales

58. Endo was concerned that the generic companies targeting Opana ER would enter the market as early as 2010, rapidly eroding Opana ER's profitability for Endo. Endo predicted that generic entry would occur sometime between mid-2010—when Impax could receive FDA approval for Opana ER at the end of the 30-month stay against Impax's ANDA—and mid-2011—when Endo estimated any appeal in the Impax litigation would be complete and when Endo had licensed another generic company to enter. (*See* CCF ¶¶ 59-66, below). Endo knew that generic entry would take an overwhelming majority of Opana ER sales (*see* CCF ¶¶ 67-70, below), and would have a substantial impact on Endo's business (*see* CCF ¶ 714, below).

RESPONSE TO FINDING NO. 58:

The proposed summary finding should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Additionally, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondent's replies to those findings.

59. Based on the dates of Impax's Paragraph IV certification and subsequent litigation by Endo, the automatic 30-month stay precluding the FDA from granting final

approval for Impax's ANDA would expire in June 2010. (JX-001 at 005, 07 (¶¶ 15-16, 26)); *see also* CCF ¶¶ 94-118, below).

RESPONSE TO FINDING NO. 59:

Respondent has no specific response.

60. Endo was aware of this key date and had long forecasted the possibility of generics launching in the middle of 2010. (CX4025 (Bingol, Dep. at 24-26) (as early as 2008, Endo had identified and was planning around the possibility that Impax could launch a generic at risk in mid-2010); CX2573 at 004 (Feb. 2010 EN3288 Commercial Update) (noting that Impax could launch at risk any time after June 2010); CX2564 at 094 (Mar. 2010 Endo 10-year outlook) (projecting July 2010 generic entry)).

RESPONSE TO FINDING NO. 60:

Respondent has no specific response.

61. By May 2010, Endo was repeatedly forecasting that a generic version of Opana ER would launch in July 2010. (CX3017 at 001-03, 05-06 (May 2010 Endo internal email thread and attached Opana ER P&L model scenarios); CX3009 at 003 (May 2010 Endo Opana ER P&L model scenarios)). The FDA tentatively approved Impax's ANDA on May 13, 2010, and Impax could launch as soon as it got final approval from the FDA, which was generally a formality after getting tentative approval (JX-001 at 007 (¶ 17); Snowden, Tr. 417-18 ("Impax was almost certain to get final approval at the conclusion of the 30-month stay"); Koch, Tr. 340-41 ("it's pretty routine and rubber stamp from the time of tentative approval to final approval"); CX5007 at 022 (¶ 42) (Hoxie Rebuttal Report)).

RESPONSE TO FINDING NO. 61:

The first sentence of Complaint Counsel's Proposed Finding No. 61 is inaccurate and misleading. None of the cited documents indicate that a generic version of Opana ER "would launch in July 2010." The forecasts were based on "many" assumptions and Endo was looking at "any possible scenario." (CX4025 (Bingol, Dep. at 59); Bingol, Tr. 1310 ("We have to consider all scenarios")). They were "based on scenarios that we had created, I mean, the accuracy of which are always debatable." (Bingol, Tr. 1303). And many of the assumptions were actually total unknowns. (Bingol, Tr. 1307 ("JUDGE CHAPPELL: Okay. Well, I don't

want you to guess[], so according to this document, whatever those claims were you didn't know. THE WITNESS: Well, we would be -- that's correct."); Cuca, Tr. 662-63).

In the case of Opana ER, Endo's "base case" and "latest best estimate" did not assume generic entry in 2010. (CX4035 (Cuca, Dep. at 62) (discussing CX3009)). Indeed, in the spring of 2010, Endo knew "there had been ANDAs filed for generic versions of Opana ER," but believed "there was not imminently at that point going to be a generic." (Cuca, Tr. 643; *see* RX-086 at 9-10 (Impax was "not likely to launch at risk")). But Endo still forecast different scenarios regarding the future of its Opana ER product to "analyze the full range of potential outcomes." (Cuca, Tr. 663-64).

While respondent does not dispute that the FDA tentatively approved Impax's ANDA on May 13, 2010, or that final approval was likely after that point, the claim in the second sentence of Proposed Finding No. 61 that Impax could launch as soon as it got final approval is inaccurate and not supported by the cited evidence. While Impax would be permitted by the FDA to launch as soon as it received final approval, the FDA's approval is only one of numerous factors affecting whether Impax "could launch" at any given time, including patent litigation, manufacturing readiness, and Impax internal approvals. (Koch, Tr. 276-77; Snowden, Tr. 426; CX4021 (Ben-Maimon, Dep. at 34); Engle, Tr. 1783-85).

> 62. Even if Impax did not launch as soon as it received final FDA approval in June 2010 following expiration of the 30-month stay, Endo identified other key dates for a potential generic launch ranging from later in 2010 to, at the latest, the middle of 2011. (*See* CCF ¶¶ 63-66, below).

RESPONSE TO FINDING NO. 62:

The proposed summary finding should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Additionally,

the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondent's replies to those findings.

> 63. For example, Endo expected that a decision in the patent litigation would probably occur in August/September 2010 and that Impax could launch at risk ahead of an appellate decision. (CX2576 at 001 (Bingol/Kelnhofer email) (district court decision would "likely be rendered in the August/September [2010] time frame")).

RESPONSE TO FINDING NO. 63:

Complaint Counsel's Proposed Finding No. 63 is inaccurate and misleading. The estimate of an August/September 2010 decision was in response to a question asking about "the *earliest* date" a competitor could "start shipping the generic." (CX2576 (emphasis added); CX4025 (Bingol, Dep. at 175-76) (discussing CX2576 and explaining there were "a lot of scenarios, and that one scenario is that it could be as earl[y] as June." "So we don't know, but these are some potential stakes in the ground that we put to monitor")).

> 64. The other date that Endo frequently forecasted for generic Opana ER entry was mid-2011. (CX1106 at 005 (July 2009 Endo presentation re 2010 Opana Brand Strategic Plan) ("Generic OPANA ER may not be available until early to mid-2011"); CX1320 at 007 (Feb. 2010 Endo Three-Year Plan) (Opana ER "Key Assumption" of "Generic entrant July 2011")).

RESPONSE TO FINDING NO. 64:

Complaint Counsel's Proposed Finding No. 64 is incomplete and misleading in its suggestion that Endo "frequently" forecast a particular date. The Proposed Finding cites only two documents, one of which is marked "DRAFT Not Approved by Management." (CX1106-003; *see* Bingol, Tr. 1298-99 (discussing identical "draft" language: "JUDGE CHAPPELL: . . . it says it's a draft. Why would he have presented a draft to anybody?")). The second (CX1320) assumed generic entry for purposes of the specific forecast, and gives no indication that the assumption was applied more broadly. (CX1320-007).

65. Endo expected that an appellate decision on the infringement case would be issued by June 2011. (Feb. 2010 Bingol/Kelnhofer email) ("If [Impax] wait[s] for the appeal to play out, it will likely happen around June of next year.")).

RESPONSE TO FINDING NO. 65:

Complaint Counsel's Proposed Finding No. 65 is inaccurate and misleading to the extent it intended to cite CX2576. The estimate of a June 2011 Federal Circuit decision was in response to a question asking about "the *earliest* date" a competitor could "start shipping the generic." (CX2576 (emphasis added); CX4025 (Bingol, Dep. at 175-76) (discussing CX2576 and explaining there were "a lot of scenarios" and that Mr. Bingol was "simply looking at numbers of scenarios that could play out and the influencing factors in those scenarios . . . But as I point out below, there are many scenarios to play out, and we really don't know")).

66. The middle of 2011 was also when Endo had licensed another generic company, Actavis, which was the first-to-file generic on two dosage strengths of generic Opana ER, to begin selling generic Opana ER. (CX2607 at 009 (¶ 25) (Lortie Decl.); CX0309 at 002 (Analyst update discussing Actavis settlement)). Actavis was the first-to-file generic on those two dosage strengths and could launch in July 2011. (CX2607 at 009 (¶ 25) (Lortie Decl.); CX0309 at 002). But Impax had first-filer exclusivity on the remaining five dosages, so Actavis had to wait until Impax had used first-filer exclusivity before it could launch those dosages. (JX-001 at 007 (¶ 14); CX2607 at 009 (¶ 25) (Lortie Decl.); *see also* CCF ¶¶ 99-102, below).

RESPONSE TO FINDING NO. 66:

Respondent has no specific response.

67. For Endo, Impax's entry was paramount because Impax held first-filer exclusivity for the five dosage strengths of Opana ER that comprised over 95% of Endo's Opana ER sales. (JX-001 at 007 (¶¶ 13, 14)). Impax's impending launch therefore presented a substantial risk to Endo's Opana ER monopoly.

RESPONSE TO FINDING NO. 67:

Respondent does not dispute that the five dosages of Opana ER for which Impax held first-filer exclusivity comprised over 95 percent of Endo's Opana ER's sales. The remainder of

the first sentence of Complaint Counsel's Proposed Finding No. 67 is not supported by the cited evidence. The second sentence of Proposed Finding No. 67 should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2).

> 68. Endo considered generic entry a "worst case scenario." (CX4025 (Bingol Dep., at 74-76)). Endo knew that when Impax entered, it would have an immediate and substantial adverse effect on sales of branded Opana ER, because branded Opana ER would quickly lose unit sales to the lower-priced generic product. (*See* CCF ¶ 69-71, below).

RESPONSE TO FINDING NO. 68:

The first sentence of Complaint Counsel's Proposed Finding No. 68 is incomplete and misleading. Mr. Bingol testified that when conducting projections in order to estimate the future performance of Opana ER, "an entry of a generic is -- we would consider that to be a fairly negative impact to the overall business and somewhat of a worst-cast scenario. So you want to plan for that and show that potential impact. Whether or not it comes to pass is another question. . . . [F]orecasts, especially these types of assumptions, aren't always probability based. You can't really know." (CX4025 (Bingol, Dep. at 74-76)).

The second sentence of Proposed Finding No. 68 purports to summarize and incorporate other findings and should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Additionally, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondent's replies to those findings.

69. In terms of Endo's revenues for Opana ER, which had been growing prior to 2010, generic entry threatened to cut dollar sales drastically. In 2010, Endo projected that generic entry would cut sales from $215 million in the year before generic launch to $34.8 million in the year after. (CX1320 at 003, 05, 07 (Feb. 2010 Endo Three-Year Plan); CX2564 at 016, 94 (Mar. 2010 Endo 10 Year Outlook and Valuation)). At a different point, Endo projected lost sales at approximately $20 million per month when generics launched. (CX4025 (Bingol, Dep. at 48, 187-88); CX1106 at 005 (July 2009 Endo Opana Brand Strategic Plan) ("Each month that generics are delayed beyond June 2010 is worth $20 million in net sales per month.")). Loss of sales to a generic product made generic entry a "worst-case scenario" for Endo for Opana ER. (CX4025 (Bingol, Dep. at 74-76)).

RESPONSE TO FINDING NO. 69:

The first sentence of Complaint Counsel's Proposed Finding No. 69 is not supported by any record evidence and should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2).

The second sentence of Proposed Finding No. 69 is incomplete and misleading. Endo did not "project" a loss in sales, it simply assumed lost sales for purposes of the particular forecasts. (CX1320-007 (describing "assumptions"); CX2564-094 (describing "assumptions")). It was Endo's practice to forecast different scenarios regarding the future of its Opana ER product to "analyze the full range of potential outcomes." (Cuca, Tr. 663-64). Endo did not know if any of the many different assumptions contained in its forecasts would come true. (Cuca, Tr. 662-63). Endo simply forecasted "a number of different potential outcomes over the course of years," the accuracy of which were "always debatable." (Bingol, Tr. 1292, 1303).

The third sentence of Proposed Finding No. 69 is incomplete and misleading in its suggestion that "Endo" calculated something even though the document is marked "DRAFT Not Approved by Management." (CX1106-005; *see* Bingol, Tr. 1298-99 (discussing identical "draft" language: "JUDGE CHAPPELL: . . . it says it's a draft. Why would he have presented a draft to anybody?")).

The fourth sentence of Proposed Finding No. 69 is incomplete and misleading. Mr. Bingol testified that when conducting projections in order to estimate the future performance of Opana ER, "an entry of a generic is -- we would consider that to be a fairly negative impact to the overall business and somewhat of a worst-cast scenario. So you want to plan for that and show that potential impact. Whether or not it comes to pass is another question. . . . [F]orecasts, especially these types of assumptions, aren't always probability based. You can't really know." (CX4025 (Bingol, Dep. at 74-76)).

> 70. The revenue declines would be primarily driven by loss of branded unit sales. In fact, Endo expected to lose 80–85% of its market share volume once a generic version of Opana ER launched. (CX3273 at 008 (Bingol Decl.) (forecasting a loss of 80% market share); CX1320 at 007 (Feb. 2010 Endo Three-Year Plan.) (Opana ER "Key Assumption" that "15% brand volume remains after 3 months" following generic entry); CX4025 (Bingol, Dep. at 28) ("Generics will typically erode the brand significantly, often within the first two to three months.")). Endo believed that prescriptions of Opana ER would fall from 200,500 prescriptions in the full quarter before generic entry to 29,100 in the full quarter after generic launch. (CX1320 at 007 (Feb. 2010 Endo Three-Year Plan)).

RESPONSE TO FINDING NO. 70:

The first sentence of Complaint Counsel's Proposed Finding No. 70 is not supported by any record evidence and should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2).

The second sentence of Proposed Finding No. 70 is incomplete and misleading. Mr. Bingol was referring to a decline in Endo's 3.4 percent market share in the "Long Acting Opioid Market." (CX3273-003; Bingol, Tr. 1318-19).

The third sentence of Proposed Finding No. 70 is incomplete and misleading. Endo did not "believe" there would be a fall in prescriptions, it simply assumed lost prescriptions for purposes of the particular forecasts. (CX1320-007 (describing "assumptions"); CX2564-094

(describing "assumptions")). It was Endo's practice to forecast different scenarios regarding the future of its Opana ER product to "analyze the full range of potential outcomes." (Cuca, Tr. 663-64). Endo did not know if any of the many different assumptions contained in its forecasts would come true. (Cuca, Tr. 662-63). Endo simply forecasted "a number of different potential outcomes over the course of years," the accuracy of which were "always debatable." (Bingol, Tr. 1292, 1303).

71. The substantial economic effect that generics would have on Opana ER sales was expected to negatively impact Endo's business in a number of ways beyond just revenue loss. For example, Endo heavily relied on Opana ER revenues to fund significant R&D efforts, and Endo projected the dramatic reduction in Opana ER revenues could force it to reduce its research and development programs. (CX3273 at 009 (¶ 20) (Bingol Decl.)). After loss of Opana ER sales due to an Impax launch, Endo planned to scale back and possibly abandon some ongoing development efforts. (CX2607 at 021-22 (¶ 51) (Lortie Decl.)). Reduced Opana ER revenues from an Impax launch could also lead to workforce reductions, unused business units, and idle capacity. (CX3273 at 009 (¶ 21) (Bingol Decl.); CX2607 at 021 (¶ 51) (Lortie Decl.)).

RESPONSE TO FINDING NO. 71:

Complaint Counsel's Proposed Finding No. 71 is incomplete and misleading. Mr. Lortie's declaration states unequivocally that "generic sales have had a relatively small effect on Opana ER." (CX2607-010-11 ("Endo has not had to significantly discount its branded Opana ER CRF beyond previous discount rates and loss of market share has been relatively mild")).

C. To protect its franchise, Endo planned to reformulate Opana ER, but needed time to do so

72. With the threat of generic entry looming, Endo wanted to protect and extend its Opana franchise, including the substantial profits from Opana ER. (CX1002 at 004 (Mar. 2010 Endo presentation re Corporate Development & Strategy Departmental Offsite) (Endo planned to aggressively protect the Opana ER franchise)). Endo planned to use several tactics, including introducing a new version of Opana ER and an authorized generic, to ensure it retained market share. *See* CCF ¶¶ 73-90, below; (CX2564 at 099 (Mar. 2010 Endo 10-Year Outlook and Valuation); CX3007 at 003 (June 2010 Endo pricing proposal for authorized generic version of Opana ER)); CX2573 at 005 (Feb. 2010 Endo presentation re EN3288 Commercial Update)). To successfully execute its

plan, Endo needed to introduce the new Opana ER before generic entry—which could ensure that the new drug product would capture sales potentially lost to generics. *See* CCF ¶¶ 73, 75-80, below.

RESPONSE TO FINDING NO. 72:

The first sentence of Complaint Counsel's Proposed Finding No. 72 is incomplete and misleading. The cited document (CX1002) states only that Endo would "[a]ppropriately protect the Opana and Lidoderm franchises, including by aggressively defending against paragraph IV challenges." (CX1002-004).

The second sentence is incomplete and misleading because it ignores the testimony of Demir Bingol, Endo's Senior Director of Marketing and the person responsible for marketing Endo's Opana ER products. Mr. Bingol testified that an authorized generic "was never, to my knowledge . . . fully realized as a plan or an idea." (Bingol, Tr. 1338-39; *see* Bingol, Tr. 1337 ("I don't recall specific forecasts about an authorized generic."); CX4019 (Lortie, Dep. at 118-19) ("we never seriously considered taking any further steps to prepare for or to do [an authorized generic] because we really didn't want to."); CX4031 (Bradley, Dep. at 198) ("I don't recall having any conversation with any colleagues regarding the launch of an authorized generic.")). Endo had no intention of launching both an authorized generic and a reformulated version of Opana ER. (Bingol, Tr. 1338; CX4019 (Lortie, Dep. at 117-18) (Endo "intended to replace one product with the other, and that would be the only product that we had on the market.")).

The third sentence of Proposed Finding No. 72 in not supported by any record evidence and should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). To the extent the Proposed Finding purports to incorporate and summarize other findings, the individual findings cited do not

support the proposed summary finding and are unreliable for the reasons set out in Respondent's replies to those findings.

73. Since 2007, Endo had been working on a reformulated "crush resistant" version of Opana ER ("Reformulated Opana ER") to replace the original version. (CX3214 at 015 (Endo SEC Form 10-K for 2011); CX3199 at 046 (Opana Brand Single Strategy Plan)). Reformulated Opana ER was also referred to in planning as EN3288 and Revopan. (RX-007 at 0001 (Endo Narrative for 3Q 2010 Earnings Call); CX3214 at 015 (Endo SEC Form 10-K for 2011) ("In December 2007, we entered into a license, development and supply agreement with Grünenthal GMBH for the exclusive clinical development and commercialization rights in Canada and the United States for a new oral formulation of long-acting oxymorphone, which is designed to be crush resistant.")). Introducing a reformulated product was a potential way for Endo to preserve its lucrative Opana ER franchise even after generics became available for Original Opana ER. (CX3205 at 001 (Dec. 13, 2007 Endo memo on Grunenthal ADF formulation of Oxymorphone) ("There is also a life cycle management (LCM) imperative for Endo's Opana ER franchise. . . . To ensure we continue to protect the franchise in the face of loss of regulatory exclusivity in June 2009, a TRF formulation of ER will be important to secure. Without this LCM strategy, Opana ER is expected to lose about 70% of its sales within six months if generic entry occurs.")).

RESPONSE TO FINDING NO. 73:

Respondent has no specific response.

74. Reformulating the product would extend the life of brand through additional patent protection and other possible roadblocks for potential generic competitors. (CX2724 at 005 (Jan. 2010 Endo presentation on Commercial Strategy Scenarios for EN3288/Reformulated Opana ER) (forecasting up to four years of "organic exclusivity" and retaining all Opana ER sales if launched with labeling claims and ahead of generics); CX3205 at 001 (Dec. 13, 2007 Endo memo on Grunenthal ADF formulation of Oxymorphone); CX3251 (U.S. Patent No. 8,309,060 B2, disclosing an "abuse-proofed, thermoformed dosage form" containing an active ingredient with abuse potential)).

RESPONSE TO FINDING NO. 74:

Respondent has no specific response.

75. Endo knew that a successful transition to Reformulated Opana ER was dependent on its launch relative to the launch of generic Original Opana ER. In 2007, Endo's "Priority #1" was to "Beat Generics by 1 Year." (CX2578 at 009 (Dec. 11, 2007 Endo re Opana Brand LCM Update)). Launching Reformulated Opana ER ahead of generic entry was the "[m]ost important criteria for maximum asset value, as this will allow Endo to

convert from one branded product to another." (CX2578 at 009 (Opana Brand LCM Update)). Endo forecasted peak year sales of more than $199 million in 2016 if Reformulated Opana ER beat generics and was first to market. (CX2578 at 009 (Opana Brand LCM Update)). If, however, Reformulated Opana ER was launched after generic entry and generics were not removed, estimated peak annual sales in 2016 were $10 million and the present value of sales was $18 million. (CX2578 at 008 (Opana Brand LCM Update)). If Endo did not get Reformulated Opana ER approved in a timely manner, Endo predicted significant erosion of the oxymorphone franchise. (CX1106 at 004 (Endo presentation re 2010 Opana Brand Strategic Plan); CX2724 at 006 (Jan. 2010 Endo presentation re EN3288 Commercial Strategy Scenarios) (generic entry would result in steep drop in Opana ER sales unless EN3288 were approved with tamper resistance claims ahead of generic entry)). If Endo launched Reformulated Opana ER at the same time as generic oxymorphone ER hit the market, Reformulated Opana ER would capture at most 30% to 32% of its Original Opana ER sales. (CX1320 at 024 (Feb. 2010 Endo Three-Year Plan) ("Oxymorphone TRF conversion from OPANA ER base volume: 30-32% conversion of base volume; Conversion curve begins at launch (July 2011); Peak conversion (30%) reached in 40 months"); CX1320 at 007 (forecasting rapid generic erosion upon generic entry in July 2011); CX1320 at 003 (projecting only $11.9 million in Oxy TRF revenues for 2011)).

RESPONSE TO FINDING NO. 75:

The first sentence of Proposed Finding No. 75 is not supported by any record evidence and should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). The second, third, fourth, and fifth sentences of Proposed Finding No. 75 are incomplete and misleading in their suggestion that "Endo" "knew" or "forecasted" anything. The cited document is a draft from 2007, just after original Opana ER launched. (CX2578-009 ("draft"); *see* Bingol, Tr. 1298-99 (discussing "draft" language: "JUDGE CHAPPELL: . . . it says it's a draft. Why would he have presented a draft to anybody?")).

Respondent has no specific response to the sixth sentence of Proposed Finding No. 75 other than to note that it too is predicated in part on a draft document. (CX1106-004 ("DRAFT Not Approved by Management")).

Finally, the seventh sentence of Proposed Finding No. 75 is incomplete and misleading. Endo did not conclude that reformulated Opana ER would capture any percentage of sales, it simply assumed a conversion rate for purposes of the particular forecasts. (CX1320-007, 024 (describing "assumptions")). It was Endo's practice to forecast different scenarios regarding the future of its Opana ER product to "analyze the full range of potential outcomes." (Cuca, Tr. 663-64). Endo did not know if any of the many different assumptions contained in its forecasts would come true. (Cuca, Tr. 662-63). Endo simply forecasted "a number of different potential outcomes over the course of years," the accuracy of which were "always debatable." (Bingol, Tr. 1292, 1303).

> 76. Introducing a Reformulated Opana ER meant that the generics that planned to come to market would not be AB-rated to the reformulated product version. Without the AB rating, generic versions of Opana ER also would be automatically substitutable only to the old version of Opana ER ("Original Opana ER"), which Endo planned to remove from the market. (CX1108 at 008 (Opana ER Switch to Revopan) (noting plan to stop shipping Opana ER by October 2011)).

RESPONSE TO FINDING NO. 76:

While Respondent does not dispute that the cited document indicated that Endo had a "current planning assumption" to stop shipping original Opana ER at some point after it launched a reformulated product, the remainder of Complaint Counsel's Proposed Finding No. 76 is not supported by the cited evidence. (CX1108-008).

> 77. By structuring the launch of Reformulated Opana ER in a specific way, Endo thought it could inoculate its franchise from significant competition from generic versions of Original Opana ER. Endo planned to implement the transition by removing Original Opana ER from the market after introducing Reformulated Opana ER. (CX1108 at 008, 13 (Revopan Board Update) (noting plan to launch Revopan in February 2011 and stop shipping Opana ER by October 2011)).

RESPONSE TO FINDING NO. 77:

The first sentence of Proposed Finding No. 77 in not supported by any record evidence and should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Respondent has no specific response to the second sentence of Proposed Finding No. 77.

78. Because of the time necessary to transition between formulations and the quickly-approaching possibility of generic entry, Endo wanted to introduce Reformulated Opana ER as soon as possible. (CX4025 (Bingol, Dep. at 32); Bingol, Tr. 1295 ("the quicker you get to market, the better")). At the time of the settlement negotiations, Endo had not yet filed its application for a reformulated version of Opana ER with the FDA. (CX3189 at 001-02 (Aug. 9, 2010 Endo press release announcing filing of Reformulated Opana ER NDA with the FDA)). Endo expected to file its application for Reformulated Opana ER with the FDA around the third quarter of 2010, but potentially as soon as late June 2010. (CX2575 at 004 (May 6, 2010 Endo presentation: EN3288 Review)). Depending on the form of the application, Endo anticipated that FDA approval would take between four and 10 months. (CX2575 at 004 (May 6, 2010 Endo presentation: EN3288 Review)). Endo targeted a launch of Reformulated Opana ER around March 2011, but estimated it could be as soon as December 2010 or later than June 2011. (CX3038 at 001 (Apr. 2, 2010 Endo email from Brian Hogan to Roberto Cuca and attachment); *see also* CX2573 at 004 (Feb. 24, 2010 Endo presentation: EN3288 Commercial Update) (projected May 2011 launch); CX2724 at 005 (Jan. 27, 2010 EN3288 Commercial Strategy Scenarios) (projected launch between January and September 2011)). Launching as far ahead of generic entry as possible would allow Endo to separate the reformulated brand product from potential generics with a reasonable amount of time to make the conversion and create the most value. (CX4025 (Bingol, Dep. at 63); CX2578 at 009 (Endo presentation re Opana Brand LCM Update)).

RESPONSE TO FINDING NO. 78:

The first sentence of Complaint Counsel's Proposed Finding No. 78 is not supported by the cited evidence. None of the cited testimony discusses the time necessary to transition between formulations. Mr. Bingol, moreover, testified that Endo "plan[ned] for different eventualities" and analyzed "different scenarios" and different "assumption[s]" about launch. (CX4025 (Bingol, Dep. at 31-32)). And while Mr. Bingol had a personal goal for the launch of

reformulated Opana ER, he worked in marketing, and there is no evidence that Mr. Bingol had any role in deciding whether or when to launch a product. (Bingol, Tr. 1308 (JUDGE CHAPPELL: . . . You're a marketing person; right? THE WITNESS: Correct.")). In fact, the evidence is clear that Endo actually intended to transition to a reformulated version of Opana ER at the very end of 2012. (CX4017 (Levin, Dep. at 99-101, 131) (Endo's Chief Financial Officer); RX-094.0003 (planned launch in roughly September 2012, with conversion by end of the year)). And Endo's original budget for 2012 projected original Opana ER sales into the fourth quarter of 2012. (RX-108.0002 at 10; RX-094.0006 ("Prior to March [2012], it would have been reasonable to assume that prescriptions of old formulation [Opana ER] would have occurred in Q4 2012.")). Professor Noll admitted that such a strategy would have permitted Endo to carry out the "late switch" plan and avoid any payments to Impax under the SLA. (*See* CX4039 (Noll, Dep. at 124) (testifying that zero-payment outcome "would have required entry along about the 1st of September of 2012")).

Respondent has no specific response to the second sentence of Proposed Finding No. 78. The third sentence of Proposed Finding No. 78 is misleading and not supported by the cited evidence. The cited document (CX2575) does not state that Endo "expected" to file an application at any time. The document instead included a "recommendation" that Endo "target filing date 3Q2010." (CX2575-005). The document moreover, was still being revised and had not been forwarded to senior management. (CX2575-001).

The fourth sentence of Proposed Finding No. 78 is incomplete and misleading because it ignores the testimony of Demir Bingol, Endo's Senior Director of Marketing and the author of the cited exhibit (CX2575). Mr. Bingol testified that "EN3288 Review" presentations were based "on scenarios that we had created, I mean, the accuracy of which are always debatable."

(Bingol, Tr. 1303). Endo always forecast "a number of different potential outcomes over the course of years." (Bingol, Tr. 1292).

Respondent has no specific response to the fifth sentence of Proposed Finding No. 78. The sixth sentence of Proposed Finding No. 78 is incomplete and misleading because Mr. Bingol testified "for this asset it was important to try to have your follow-on formulations, products, improvements, whatever would separate this product from potential generics *or* with a reasonable amount of time to make the conversion." (CX4025 (Bingol, Dep. at 64) (emphasis added); *see also* CX2578-009 (a "draft" document from 2007, just after original Opana ER launched); Bingol, Tr. 1298-99 (discussing "draft" language: "JUDGE CHAPPELL: . . . it says it's a draft. Why would he have presented a draft to anybody?")).

79. Endo not only wanted to begin this transition between formulations as soon as possible, but also to make the transition as "smooth a[s] possible." (CX4019 (Lortie Dep. at 33). Endo's desire for a smooth transition was driven in part by an understanding that patients cannot be switched immediately from one long-acting opioid to another because physicians are "very careful as they adjust dosages" for patients. (CX4019 (Lortie, Dep. at 39)). Endo's plan was "for an orderly and phased transition from one product to the other so [it] made sure [it wasn't] leaving any current patients in a difficult situation." (CX4019 (Lortie, Dep. at 39-40)).

RESPONSE TO FINDING NO. 79:

Complaint Counsel's Proposed Finding No. 79 is incomplete and misleading because it ignores Mr. Lortie's testimony, which explained that Endo several times changed its plans with respect to reformulated Opana ER. (CX4019 (Lortie, Dep. at 161); *see also* CX4019 (Lortie, Dep. at 11-12) (dates were "assumptions at that point," but that "[t]here was some subsequent work that needed to be done")).

80. This transition would take time. Generally, it takes six to nine months to transition a market from an original branded product to a reformulated branded product. (Mengler, Tr. 530-31; CX4019 (Lortie, Dep. at 41-42) (noting that the process of switching patients to a reformulation could take months)).

RESPONSE TO FINDING NO. 80:

Complaint Counsel's Proposed Finding No. 80 is incomplete and misleading because it misstates Mr. Mengler's testimony. Mr. Mengler testified that the time to transition "would depend on the type of product, on the other, you know circumstances" and that "six to nine [months] in general doesn't seem unreasonable." (Mengler, Tr. 531).

81. Endo anticipated that it could receive final FDA approval by January 2011. (CX1108 at 004 (Revopan Product Summary) (noting a January 7, 2011 PDUFA date). PDUFA is typically a date referencing when Endo expects the FDA will decide on the approvability of its product. (CX4019 (Lortie, Dep. at 10)). *See also* CX3038 at 001 (Apr. 2, 2010 Endo email from Brian Hogan to Roberto Cuca and attachment); CX2573 at 004 (Feb. 24, 2010 Endo presentation: EN3288 Commercial Update) (projected May 2011 launch); CX2724 at 005 (Jan. 27, 2010 EN3288 Commercial Strategy Scenarios) (projected launch between January and September 2011)).

RESPONSE TO FINDING NO. 81:

Complaint Counsel's Proposed Finding No. 81 is incomplete and misleading because it ignores the testimony of Mr. Lortie, who testified that any dates in the cited document (CX1108) were "assumptions at that point," but that "[t]here was some subsequent work that needed to be done." (CX4019 (Lortie, Dep. at 11-12) (discussing CX1108)).

82. With generic entry forecasted to occur as early as June 2010, Endo would be unable to obtain FDA approval for Reformulated Opana ER and convert the market before Impax might have entered with its generic version of Original Opana ER. (CX2724 at 001 (Jan. 27, 2010 email re: EN3288 Potential Launch Scenarios) ("Obviously the scenario in which we were trying to launch ahead of generics is seeming less likely.")). The reverse-payment settlement allowed Endo the time it needed to reformulate before Impax launched its generic version of Original Opana ER. (RX-364 at 0002 (SLA § 1.1 "Effective Date"); CX2583 at 032 (Endo presentation to Moody's)).

RESPONSE TO FINDING NO. 82:

The first sentence of Complaint Counsel's Proposed Finding No. 82 is incomplete and misleading because it ignores the testimony of Mr. Bingol, the author of the cited document (CX2724). Mr. Bingol explained that forecast was based on "many" assumptions and Endo was

looking at "any possible scenario." (CX4025 (Bingol, Dep. at 59); Bingol, Tr. 1310 ("We have to consider all scenarios")). They were "based on scenarios that we had created, I mean, the accuracy of which are always debatable." (Bingol, Tr. 1303). And many of the assumptions were actually total unknowns. (Bingol, Tr. 1307 ("JUDGE CHAPPELL: Okay. Well, I don't want you to guess[], so according to this document [CX2724], whatever those claims were you didn't know. THE WITNESS: Well, we would be -- that's correct."); Cuca, Tr. 662-63).

In the case of Opana ER, Endo's "base case" and "latest best estimate" did not assume generic entry in 2010. (CX4035 (Cuca, Dep. at 62) (discussing CX3009)). Indeed, in the spring of 2010, Endo knew "there had been ANDAs filed for generic versions of Opana ER," but believed "there was not imminently at that point going to be a generic." (Cuca, Tr. 643; *see* RX-086 at 9-10 (Impax was "not likely to launch at risk")). Endo still forecast different scenarios regarding the future of its Opana ER product to "analyze the full range of potential outcomes." (Cuca, Tr. 663-64).

The second sentence of Proposed Finding No. 82 is not supported by the cited evidence. (RX-364; CX2583-032 (stating only that "a phased withdrawal of Opana ER and launch of Revopan . . . was facilitated by the Impax settlement and Penwest transaction")).

> 83. In July 2010, Endo filed a supplemental New Drug Application (No. 201655) for a Reformulated Opana ER. (JX-001 at 011 (¶ 48)). Endo originally expected final FDA approval in January 2011 (CX2528 at 009) (Endo presentation re Revopan Launch Readiness Review)), but approval was delayed due to certain deficiencies in the methods used in the bioequivalence studies (RX-011 (Jan. 7, 2011 FDA complete response letter)). The FDA ultimately approved the application in December 2011. (JX-001 at 011 (¶ 48)). Endo began selling Reformulated Opana ER in February 2012. (CX1107 at 006 (¶ 19) (Lortie Decl.)).

RESPONSE TO FINDING NO. 83:

Respondent has no specific response other than to clarify that Mr. Lortie testified that any dates regarding FDA approval were merely "assumptions at that point," but that "[t]here was some subsequent work that needed to be done." (CX4019 (Lortie, Dep. at 11-12)).

D. Endo also planned to launch an authorized generic in the event of an at-risk generic launch

84. Endo had strong financial incentives to launch an AG version of oxymorphone ER upon entry of generic versions of oxymorphone ER. Endo expected to earn $25 million in AG sales (compared to a $71 million decline in Opana ER sales) during 2010 if Impax launched its generic oxymorphone ER on July 1, 2010. (CX1314 (June 2010 email from Cuca to Levin)). In other financial analyses, Endo estimated that an Impax launch in July 2010 would cause Endo to lose about $46 million in "Product Contribution" in 2010, but that Endo could recoup approximately $18 million by launching an AG. (CX3009 at 003 (June 2010 Opana ER Combined P&L scenarios, "Combined P&L" tab)).

RESPONSE TO FINDING NO. 84:

Proposed Finding No. 84 is incomplete, inaccurate, and misleading. Mr. Cuca, the author of the cited email (CX1314), testified that the figures came from "assuming some specified erosion assumption." (CX4035 (Cuca, Dep. at 66) (discussing CX1314)). Mr. Cuca also testified that under those assumptions, "the bottom-line effect" of a theoretical Impax launch—Endo's income before taxes, which considers revenues and expenses together—would only be $2 million at the "more aggressive end of the range of cost savings" and $13.5 million if Endo was "less aggressive about cost savings." (CX4035 (Cuca, Dep. at 67) (discussing CX1314)). Similarly in the second cited document (CX3009), Endo did not "estimate" reductions, it merely "assumed" it for purposes of the forecast. (CX3009-003 (describing "assumptions" regarding "erosion" and "reduction in allocation")). In fact, Endo's "base case" and "latest best estimate" did not assume generic entry in 2010. (CX4035 (Cuca, Dep. at 62) (discussing CX3009)).

Mr. Cuca explained that Endo forecast different scenarios regarding the future of its Opana ER product to "analyze the full range of potential outcomes," but did not know if any of the many different assumptions in its forecasts would come true. (Cuca, Tr. 662-64; *see* CX4025 (Bingol, Dep. at 180) (an authorized generic is "another scenario that you go through, just like when you're making an assumption around potential launch dates"); Bingol, Tr. 1292, 1303 (Endo simply forecasted "a number of different potential outcomes over the course of years," the accuracy of which were "always debatable.")).

> 85. Endo intended to launch an authorized generic if Impax entered with generic oxymorphone ER. (CX2576 at 003 (email from Endo National Account Executive Kayla Kelnhofer) ("We will launch on word/action of first generic competitor."); CX2581 at 001 (Feb. 2010 Opana Lifecycle Management Team Meeting Minutes) ("Endo is prepared to launch an authorized generic if another generic is approved first."); CX2573 at 004 (February 2010 Endo presentation "EN3288 Commercial Update") (Endo planned a "Launch of authorized generic" in the event that Impax launched at risk); CX3007 at 003 (Endo oxymorphone ER price proposal) ("If Impax launches, Endo will launch its authorized generic . . . .")).

RESPONSE TO FINDING NO. 85:

Complaint Counsel's Proposed Finding No. 85 is inaccurate, incomplete, and misleading. Brian Lortie, Endo's Senior Vice President for Pain Solutions, testified that Endo "never seriously considered taking any further steps to prepare for or to do [an authorized generic of Opana ER] because we really didn't want to." (CX4019 (Lortie, Dep. at 118-19)). Demir Bingol, Endo's Senior Director of Marketing and the person responsible for marketing Endo's Opana ER products, testified that an authorized generic "was never, to my knowledge . . . fully realized as a plan or an idea." (Bingol, Tr. 1338-39; *see* Bingol, Tr. 1337 ("I don't recall specific forecasts about an authorized generic.")). And Mark Bradley, Endo's Senior Director of Corporate Finance at the time of settlement, testified, "I don't recall having any conversation

with any colleagues regarding the launch of an authorized generic." (CX4031 (Bradley, Dep. at 198)).

The cited evidence does not reflect that "Endo" "intended" to do anything. The exhibits include (1) a single statement by an "account executive on our managed markets team," (CX4025 (Bingol, Dep. at 174, 179) (discussing CX2576, testifying that he did not "know what their conversation meant or why they wrote those things")); (2) a statement about authorized generics in the context of *crush-resistant Opana ER*, (CX2581 (discussing EN3288); CX4025 (Bingol, Dep. at 183) (discussing CX2581, explaining language meant that "mentally we have all options on the table to be commercially successful, and this is one of these levers we could pull if we had to, and at this point no steps were taken, and I don't recall that any ever were.")); (3) a draft document, (CX2573-004 ("DRAFT Not Approved by Management"); Bingol, Tr. 1298-99 (discussing identical "draft" language: "JUDGE CHAPPELL: . . . it says it's a draft. Why would he have presented a draft to anybody?")); and (4) a "proposal," (CX3007-003). Finally, all of the hypothetical scenarios at issue in these documents discuss a possible authorized generic in response to what would necessarily be an at-risk generic launch in 2010. No documents or testimony address whether, let alone suggest that, Endo would launch an authorized generic under other circumstances, such as in response to Impax (or another generic) launching pursuant to a settlement license.

> 86. By late 2009, Endo began preparing for an authorized generic launch in summer 2010. Endo designed AG oxymorphone ER tablets in October and November 2009, and received labels for its AG by May 4, 2010. (CX2998 at 001 (October 2009 Endo email chain) ("We have $ in the budget to buy tooling this year for potentially bringing generic Opana ER to the market sometime in the future. I'd like to spend that money this year, but we need to decide on the tablet design quickly – like the end of the month.); CX2999 at 001 (November 2009 Endo email chain) ("I would like a decision before Thanksgiving on design for potential generic Opana ER."); CX3005 (May 2010 Endo email attaching oxymorphone ER labels)).

RESPONSE TO FINDING NO. 86:

Complaint Counsel's Proposed Finding No. 86 is inaccurate and misleading in its suggestion that Endo's actions reflected a decision or intention to launch an authorized generic, much less in summer 2010. In fact, the cited documents reflect the exact opposite. (CX2998-001 ("We have $ in the budget to buy tooling this year for potentially bringing generic Opana ER to the market sometime in the future. I'd like to spend that money this year."); CX2999-002 (same); CX3005 (saying nothing about an authorized generic, launch, or timing)).

87. In February 2010, Endo informed drug wholesalers that Endo would launch an AG immediately upon Impax's launch. (CX2576 at 003 (Feb. 2010 email from Endo National Account Executive Kayla Kelnhofer) ("We will launch on word/action of first generic competitor. We are hearing as early as June this year (not confirmed) let me ask around and verify.")).

RESPONSE TO FINDING NO. 87:

Complaint Counsel's Proposed Finding No. 87 is incomplete and misleading. The Proposed Finding is based on a single document, which included a single email exchange with a single Endo customer by a single "account executive on our managed markets team." (CX4025 (Bingol, Dep. at 174) (discussing CX2576)). There is no evidence suggesting that the single account executive had any role in deciding whether or when a product would launch. Demir Bingol, Endo's Senior Director of Marketing, testified that he did not "know what their conversation meant or why they wrote those things." (CX4025 (Bingol, Dep. at 179)).

Indeed, Mr. Bingol testified that an authorized generic "was never, to my knowledge . . . fully realized as a plan or an idea." (Bingol, Tr. 1338-39; *see* Bingol, Tr. 1337 ("I don't recall specific forecasts about an authorized generic.")). Brian Lortie, Endo's Senior Vice President for Pain Solutions, similarly testified that Endo "never seriously considered taking any further steps to prepare for or to do [an authorized generic of Opana ER] because we really didn't want to."

(CX4019 (Lortie, Dep. at 118-19); *see* CX4031 (Bradley, Dep. at 198) ("I don't recall having any conversation with any colleagues regarding the launch of an authorized generic.")).

Finally, the hypothetical scenario at issue in this document discusses a theoretical authorized generic in response to what would necessarily be an at-risk generic launch in 2010. No documents or testimony address, let alone suggest, whether Endo would launch an authorized generic under any other circumstance.

88. Endo created new SKUs for its generic oxymorphone ER and, as of May 26, 2010, had made one batch of each strength of oxymorphone ER. (CX3002 at 001, 05 (May 2010 Endo email chain and Change Control Report); CX3003 (May 2010 Endo email chain) ("We made 1 batch of each strength.")).

RESPONSE TO FINDING NO. 88:

Respondent has no specific response other than to clarify that Endo did not create new SKUs; rather, Novartis, Endo's agent, created new SKUs as a result of an "unrecoverable error" in its own SAP software. (CX3002-001, 05).

89. Endo personnel reported that Endo had manufactured enough generic oxymorphone ER to support a June 2010 AG launch. (CX3003 ("[I]f we launch in June we would be able to support the current generic ER forecast. We would make an additional batch of both the 20 mg and the 40 mg in July.")).

RESPONSE TO FINDING NO. 89:

Complaint Counsel's Proposed Finding No. 89 is misleading. The hypothetical scenario at issue in this document discusses a theoretical authorized generic in response to what would necessarily be an at-risk generic launch in 2010. No documents or testimony address, let alone suggest, whether Endo would launch an authorized generic under any other circumstance.

90. In May 2010, Endo was assessing which customers to target with an AG launch, and on June 2, 2010, Endo employees submitted a pricing proposal for the AG. (CX2577 at 001 (May 21, 2010 email) ("As we begin thinking about what customers to go after with an AG of Opana ER, can you run an analysis on Impax and Sandoz to understand

what market share they have across specific customers . . . I am trying to assess as part of the customer targeting exercise, which customers Impax and Sandoz value the most and will be less willing to lose so we can prioritize customers appropriately."); CX3007 at 003 (Endo price proposal stating "If Impax launches, Endo will launch its authorized generic" and setting prices)).

RESPONSE TO FINDING NO. 90:

Complaint Counsel's Proposed Finding No. 90 is incomplete and misleading. The cited evidence does not support the proposition that Endo employees actually submitted pricing proposals to customers, as Complaint Counsel attempts to suggest. The pricing proposal was an internal Endo proposal. (CX2577-001). Proposed Finding No. 90 also ignores the testimony of Brian Lortie, Endo's Senior Vice President for Pain Solutions, who testified that Endo "never seriously considered taking any further steps to prepare for or to do [an authorized generic of Opana ER] because we really didn't want to." (CX4019 (Lortie, Dep. at 118-19); *see also* Bingol, Tr. 1337 ("I don't recall specific forecasts about an authorized generic."); Bingol, Tr. 1338-39 (an authorized generic "was never, to my knowledge . . . fully realized as a plan or an idea"); CX4031 (Bradley, Dep. at 198) ("I don't recall having any conversation with any colleagues regarding the launch of an authorized generic.")). In fact, Endo intended to replace its original Opana ER product with a reformulated product "and that would be the only product that we had on the market." (CX4019 (Lortie, Dep. at 117-18); *see* Bingol, Tr. 1338).

Finally, Proposed Finding No. 90 is misleading. The hypothetical scenarios at issue in these documents discuss a theoretical authorized generic in response to what would necessarily be an at-risk generic launch in 2010. No documents or testimony address, let alone suggest, whether Endo would launch an authorized generic under any other circumstance.

91. In the past, Endo has launched authorized generics of brand-name drugs Lidoderm, Fortesta, and Voltran gel. (CX5001 at 026 (¶ 50) (Bazerman Report); CX6044 at 034, 41, 57 (2017 FDA Listing of Authorized Generics)).

RESPONSE TO FINDING NO. 91:

To the extent Complaint Counsel's Proposed Finding No. 91 purports to rely on expert testimony, it violates this Court's Order on Post-Trial Briefs by improperly citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents."

Proposed Finding No. 91, moreover, is not supported by the cited evidence. The only cited evidence apart from the improperly-cited expert report (CX6044) does not support the proposition that Endo had launched authorized generics "in the past" when it settled with Impax. In fact, the document shows the exact opposite: Endo had never launched an authorized generic at the time of settlement. (CX6044-034, 041, 057).

92. Endo and Impax settled the infringement case on June 8, 2010, and three days later Endo employees concluded that Endo could make arrangements to destroy its generic oxymorphone ER inventory. (RX-364 at 0002 (SLA) (defining "Effective Date"); CX3000 (June 11, 2010 Endo email) ("Arrangements can be made to destroy the generic Oxymorphone ER inventory.").

RESPONSE TO FINDING NO. 92:

Respondent has no specific response.

IV. Impax posed a significant competitive threat to Endo's Opana ER franchise

93. Prior to the Impax-Endo Settlement Agreement, Impax was considering an at-risk launch of generic oxymorphone ER to compete against Endo's Opana ER franchise. (Koch, Tr. 247; CX4014 (Hsu, IHT at 130); CX3274 (May 13, 2010 email chain); CCF ¶¶ 94-213, below)).

RESPONSE TO FINDING NO. 93:

Complaint Counsel's Proposed Finding No. 93 is incomplete and misleading. The cited documents do not suggest that Impax was considering launching oxymorphone ER at risk. Rather, Impax, like all companies, prepares forecasts for many different purposes. Its forecasts

model possible outcomes based on a range of assumptions. (Engle, Tr. 1766-67; CX4002 (Smolenski, IHT at 85)).

In the case of oxymorphone ER, Impax attempted to "look[] at different various scenarios" and tried "very hard to . . . describe the possible outcomes under any number of different assumptions." (Koch, Tr. 299-300; *see* Mengler, Tr. 553 (financial projections did not "imply or mean that any legal decision ha[d] been made to clear the way for a launch"); Mengler, Tr. 584 (forecasting "alert[s] the board as to the product being out there that might get to the point of an at-risk launch, so that was it")). This modelling is intended to inform and facilitate decision-making regarding possible launches and launch dates; it does not reflect any decision regarding launch dates. (Engle, Tr. 1720 ("describing forecasting as a "tool" and a "starting point, which senior management can use to make their judgments and decisions"); Engle, Tr. 1771 (Engle not involved in launch decisions); Mengler, Tr. 553 (financial modelling based on assumed launch date does not "imply or mean that any legal decision ha[d] been made to clear the way for a launch."); Koch, Tr. 299-300 (Impax merely tried to "look[] at different various scenarios" and attempt "very hard to . . . describe the possible outcomes under any number of different assumptions.")). Indeed, in the case of oxymorphone ER, Impax modelled a set of assumptions involving a June 2010 launch date even when that date remained an "obvious[] controversial element." (CX0514-001).

The testimony cited in the Proposed Finding reflects that Impax "considered" an at-risk launch only as part of this general decision-making process and routine forecasting. Mr. Koch testified that Impax considered an at-risk launch in the sense that it "evaluated" it. (Koch, Tr. 247). Elsewhere in Mr. Koch's testimony, he confirmed that Impax never intended to launch oxymorphone ER at-risk. (Koch, Tr. 324-25 ("JUDGE CHAPPELL: Are you a hundred percent

certain you would be aware of whether or not Impax planned an at-risk launch of Opana ER? WITNESS: Absolutely. I would have a key role in that. JUDGE CHAPPELL: Do you know in fact whether Impax intended an at-risk launch of Opana ER? . . . THE WITNESS: I do know. JUDGE CHAPPELL: Did they intend to do an at-risk launch of Opana ER? THE WITNESS: No."); *see also* Koch, Tr. 310 (Impax would only consider an at-risk launch after a favorable court ruling)).

And in the cited testimony of Dr. Hsu, Impax's founder and CEO at the time the SLA was executed, Dr. Hsu explained that evaluating an at-risk launch was part of a larger process that looks at all options in making a launch decision, in order to be able to defend any potential course of action to Impax's Board of Directors later on. (CX4041 (Hsu, IHT at 129-30) ("We could settle, we could launch at risk, we could do many other things, and as the job of CEO, I just have to, you know, lay out everything, get prepared so I don't get accused by the board and say, well, wait a minute, how come you didn't prepare for plan B?"); CX4041 (Hsu, IHT at 130) ("Q: So, as of May 13th, 2010, Impax was at least considering the possibility of an at-risk launch for Oxymorphone ER? A. Yes, that's one of the options, absolutely.")). Moreover, contemporaneous documents make clear that such "evaluation" of all possible "options" does not suggest an at-risk launch was likely to occur, or that Impax intended to launch oxymorphone ER at risk. To the contrary, in contemporaneous documents, Dr. Hsu noted that "[i]t's unlikely we will launch Opana ER this year (I actually prefer not to launch this year for obvious reason[s])." (RX-297.0002; *see* CX2929-001 (Dr. Hsu further explained that that "mostly likely we will make launch decision based on court decision on the PI.")).

With respect to at-risk launches generally, the decision-making process is especially involved, because Impax is "incredibly conservative," (CX4021 (Ben-Maimon, Dep. at 34); *see*

Koch, Tr. 287), and it "is very important for [Impax] to have a . . . risk-free launch" in the vast majority of cases, (CX4014 (Hsu, IHT at 117))—as Impax's meager track record of actually launching at-risk reflects, (*see* Snowden, Tr. 424, 426 (aside from limited oxycodone launch after favorable district court decision, in a single dose, and with a cap on sales, Impax had not pursued any other at-risk launches at the time of Endo-Impax settlement)).

Had Impax seriously considered launching oxymorphone ER at-risk, it would have sought Board approval—a prerequisite at Impax for any at-risk launch (Koch, Tr. 276-77 ("every at-risk launch is a board-level decision"); Snowden, Tr. 426; CX4030 (Hsu, Dep. at 128); CX4021 (Ben-Maimon, Dep. at 160))—well before tentative FDA approval of its ANDA. (Koch, Tr. 333-34, 341). Yet Impax's senior management never even recommended an at-risk launch of oxymorphone ER to the Impax Board of Directors regarding, nor was the Impax Board of Directors ever asked to vote on such an at-risk launch. (Koch, Tr. 299; Snowden, Tr. 470-71; CX4030 (Hsu, Dep. at 85); JX-001-009 (¶ 29) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity)).

Finally, to the extent Proposed Finding No. 93 purports to summarize and incorporate other findings, it should be disregarded because the individual findings cited do not support the Proposed Finding and are unreliable for the reasons set out in Respondent's replies to those findings.

A. Impax's generic application

94. In June 2007, Impax filed an Abbreviated New Drug Application ("ANDA") (No. 79-087) for a generic version of Original Opana ER ("generic oxymorphone ER"). (JX-001 at 007 (¶ 11)).

RESPONSE TO FINDING NO. 94:

Respondent has no specific response.

95. Impax's ANDA included a Paragraph III certification for Patent Number 5,128,143 ("the '143 patent"). A Paragraph III certification meant that Impax's ANDA would be eligible for FDA approval upon the '143 patent's expiration in September 2008. (CX2967 at 017 (July 2007 Impax letter to FDA)).

RESPONSE TO FINDING NO. 95:

Respondent has no specific response.

96. As of June 2007, the '143 patent was the only patent listed in the Orange Book as covering Opana ER. (CX2967 at 014, 017 (July 2007 Impax letter to FDA); CCF ¶ 50, above).

RESPONSE TO FINDING NO. 96:

Respondent has no specific response.

97. In October of 2007, however, Endo listed three additional patents in the Orange Book as covering Opana ER: U.S. Patent Nos. 7,276,250 ("the '250 patent"), 5,662,933 ("the '933 patent"), and 5,958,456 ("the '456 patent"). Endo listed the '250 patent in the Orange Book on October 2, 2007, and the '933 and '456 patents on October 19, 2007. The '933 and '456 patents expired in September 2013. The '250 patent expires in February 2023. (JX-001 at 006 (¶¶ 9-10)).

RESPONSE TO FINDING NO. 97:

Respondent has no specific response.

98. The '250, '933, and '456 patents all pertain to the controlled-release mechanism of the oxymorphone formulation. (JX-003 at 002 (¶ 6) (discussing the '456, '933, and '250 patents)).

RESPONSE TO FINDING NO. 98:

Respondent has no specific response.

99. On November 23, 2007, the FDA accepted Impax's ANDA with an amendment to include Paragraph IV certifications for the '250, '933, and '456 patents. (CX3163 at 010 (¶ 37) (Impax Answer); JX-001 at 007 (¶ 12)).

RESPONSE TO FINDING NO. 99:

Respondent has no specific response.

100. With respect to the amendment for the '250, '933 and '456 patents, Impax's Paragraph IV notice asserted that its ANDA product did not infringe these patents and/or that the patents were invalid. (JX-001 at 007 (¶ 12); CX2714 at 002 (Impax's Paragraph IV Notice)). As a matter of routine, Impax made sure that the information it included in the Paragraph IV notification was "truthful." (CX4026 (Nguyen, Dep. at 31)).

RESPONSE TO FINDING NO. 100:

Respondent has no specific response of the first sentence of Complaint Counsel's Proposed Finding No. 100. The second sentence of Proposed Finding No. 100 is incomplete because it ignores the fact that while Impax believes "in its opinion and to the best of its knowledge" that patents identified in Paragraph IV notifications are invalid, unenforceable, or will not be infringed, (JX-003-002 (¶7) (Second Set of Joint Stipulations)), courts can disagree with Paragraph IV certifications and deem the patents valid and infringed, an outcome Impax had experienced prior to its suit against Endo, (Snowden, Tr. 412-13).

101. Impax was the first company to file an ANDA with Paragraph IV certifications for the 5, 10, 20, 30, and 40 mg dosages of Opana ER. Thus, Impax was eligible for first-filer exclusivity (a "180-day exclusivity period") for these dosages. (JX-001 at 007 (¶¶ 13-14)). These dosages were the most profitable dosages for Endo, comprising over 95% of Endo's Opana ER sales. (JX-001 at 007 (¶ 13)).

RESPONSE TO FINDING NO. 101:

Respondent has no specific response.

102. Because Impax was eligible for first-filer exclusivity, the FDA could not grant final approval for other companies' generic oxymorphone ER ANDAs in those dosage strengths until 180 days after Impax started selling its generic product. In other words, no other generic company could compete with its own oxymorphone ER product for those dosage strengths until 180 days after Impax began selling its generic product. (JX 001 at 002 (¶ 7); Mengler, Tr. 522-23; CCF ¶¶ 14-15, above).

RESPONSE TO FINDING NO. 102:

The Complaint Counsel's Proposed Finding No. 102 is incomplete and inaccurate. First-filer exclusivity can be forfeited, and the FDA can therefore approve other ANDA generic

products sooner than 181 days after the first filer enters the market, if, for example, a first-filer does not launch its product within a certain timeframe or it does not receive tentative approval from the FDA. (Snowden, Tr. 414-15, 417; JX-003-002 (Second Set of Joint Stipulations ¶ 7); CX5000 at 033 (Noll Rep. ¶ 73) (explaining that to "take advantage of the exclusivity period, the generic firm must enter the market at least six months before the challenged patents on the brand-name drug expire")).

To the extent Proposed Finding No. 102 purports to summarize and incorporate other findings, it should be disregarded because the individual findings cited do not support the Proposed Finding and are unreliable for the reasons set out in Respondent's replies to those findings.

103. Impax's first-to-file exclusivity was very valuable because, as a generic company, Impax can make "a substantial portion of their profits" during the six months of first-filer exclusivity. (Koch, Tr. 232).

RESPONSE TO FINDING NO. 103:

Respondent has no specific response.

104. Impax did not forfeit its 180-day exclusivity rights for generic oxymorphone ER at any point, either during or subsequent to the patent litigation. (Snowden, Tr. 484; *see also* CX1107 at 009 (¶ 25) (Lortie Decl.)).

RESPONSE TO FINDING NO. 104:

Respondent has no specific response.

105. Although no other ANDA filer for generic oxymorphone ER could enter during Impax's 180-day exclusivity, as the holder of the approved NDA for Opana ER, Endo could market an authorized generic ("AG") version of Opana ER during Impax's exclusivity period. (Mengler, Tr. 523; CX4003 (Snowden, IHT at 27); JX-001 at 5 (¶ 28)).

RESPONSE TO FINDING NO. 105:

Respondent has no specific response.

106. In December 2007, Impax sent Endo a notice of its Paragraph IV certifications for the '250, '933, and '456 patents. In its notice, Impax asserted that its ANDA product did not infringe Endo's patents. (CX2714 at 002 (Impax's Paragraph IV Notice); CX3163 at 010 (¶ 38) (Impax Answer)).

RESPONSE TO FINDING NO. 106:

Respondent has no specific response.

B. The *Endo v. Impax* patent infringement litigation and the ensuing 30-month stay

107. In January 2008, Endo sued Impax in the District of Delaware, alleging that Impax's ANDA for the 5, 10, 20, 30, & 40 mg dosages of generic oxymorphone ER infringed the '456 and '933 patents. (JX-001 at 007 (¶ 15); CX3163 at 010 (¶ 39) (Impax Answer)). Endo did not allege that Impax's product infringed the '250 patent. (CX0304 at 002 (¶ 5) (*Endo v. Impax*, complaint)).

RESPONSE TO FINDING NO. 107:

Respondent has no specific response.

108. The patent infringement lawsuit triggered a statutory stay (commonly referred to as a "30-month stay") on the FDA's ability to approve Impax's ANDA. (JX-001 at 007 (¶ 15)).

RESPONSE TO FINDING NO. 108:

Respondent has no specific response.

109. The 30-month stay meant that the FDA could not approve Impax's ANDA for generic oxymorphone ER until the earlier of the expiration of 30 months or the resolution of the patent dispute in Impax's favor. (JX-001 at 007 (¶ 15)). The 30-month stay was set to expire on June 14, 2010. (JX-001 at 007 (¶ 16)).

RESPONSE TO FINDING NO. 109:

Respondent has no specific response.

110. Impax desired an early trial date for the patent litigation and sought to transfer the patent litigation to the District of New Jersey. (Snowden, Tr. 357-58). The court granted Impax's request and transferred the patent litigation case to the District of New Jersey. (Snowden, Tr. 357-58).

RESPONSE TO FINDING NO. 110:

Respondent has no specific response.

111. On May 13, 2010, near the end of the 30-month stay, the FDA granted tentative approval of Impax's ANDA for all dosage strengths of generic oxymorphone ER. (JX-001 at 007 (¶¶ 16-17); Snowden, Tr. 356-57).

RESPONSE TO FINDING NO. 111:

Respondent has no specific response.

112. Tentative approval means that an ANDA application satisfies all the FDA requirements for approval, but cannot be granted final approval for some patent or exclusivity reason, such as a 30-month stay. (Snowden, Tr. 417). Going from tentative approval to final approval was "pretty routine" and tantamount to a "rubber stamp." (Koch, Tr. 340-41; *see also* Snowden, Tr. 417-18). Thus, once tentative approval was granted, Impax expected to receive FDA final approval on June 14, 2010, the expiration date of the 30-month stay. (Koch, Tr. 341; Snowden, Tr. 417-18).

RESPONSE TO FINDING NO. 112:

Respondent has no specific response.

113. On May 19, 2010, the Court set the patent infringement trial for five days between June 3, 2010 and June 17, 2010. (CX2759 at 019-20, 022 (*Endo v. Impax*, docket)).

RESPONSE TO FINDING NO. 113:

Respondent has no specific response, other than to note that the Court set the patent infringement trial for six days between June 3, 2010, and June 17, 2010. (CX2759-020).

114. On June 3, 2010, the Impax-Endo patent infringement trial began. (CX2759 at 020, 022 (*Endo v. Impax*, docket)).

RESPONSE TO FINDING NO. 114:

Respondent has no specific response.

115. On June 8, 2010, before the end of trial, Impax and Endo entered the Impax-Endo Settlement Agreement, which settled the patent litigation. (JX-001 at 007 (¶ 18)). As part of this agreement, the parties executed a Settlement and License Agreement ("SLA") and a Development and Co-Promotion Agreement ("DCA"). (JX-003 at 005 (¶ 26); RX-364 (SLA); RX-365 (DCA)).

RESPONSE TO FINDING NO. 115:

Respondent has no specific response to the first sentence of Complaint Counsel's Proposed Finding No. 115. The second sentence of Proposed Finding No. 115 is misleading. The Settlement and License Agreement settled the patent litigation. (RX-364.0001; JX-001-007-09 (¶¶ 19, 33) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity)). The Development and Co-Promotion Agreement was a "stand-alone legal document[]." (CX4017 (Levin, Dep. at 157-58); *see* Koch, Tr. 313-14 (Impax assessed and considered DCA and SLA as standalone agreements "all the time"); CX4036 (Fatholahi, Dep. at 138-39)). It concerned a potential treatment for Parkinson's disease using a combination of levodopa-ester and carbidopa. (JX-003-010 (¶ 67) (Second Set of Joint Stipulations)). Accordingly, both Endo and Impax assessed the Development and Co-Promotion Agreement independently from the Settlement and License Agreement. (Koch, Tr. 313 (Impax's CEO "was very clear that each agreement should be evaluated on their own merits as a standalone agreement"); CX4001 (Koch, IHT at 41) (DCA was "a separate negotiation that came up during settlement negotiations"); Mengler, Tr. 586; CX4017 (Levin, Dep. at 159); CX4031 (Bradley, Dep. at 196)).

116. At the time of the Impax-Endo Settlement Agreement, the outcome of the patent infringement suit was uncertain. (JX-001 at 008 (¶ 20)).

RESPONSE TO FINDING NO. 116:

Respondent has no specific response.

117. As part of the Impax-Endo Settlement Agreement, Impax agreed not to launch its generic oxymorphone ER product until January 1, 2013. (RX-364 at 0001-02, 09 (SLA §§ 1.1, 4.1(a)) (granting license and defining the "Commencement Date")).

RESPONSE TO FINDING NO. 117:

Complaint Counsel's Proposed Finding No. 117 is incomplete. Under the Impax-Endo Settlement Agreement, Impax received a license to launch its generic oxymorphone ER product *no later than* the date certain of January 1, 2013. However, Impax's settlement license also permitted it to launch free from patent risk earlier under certain circumstances, specified in the agreement. (*See* RX-364.0001-02, 09 (SLA §§ 1.1, 4.1(a)) (defining the "Commencement Date" for license granted with several alternatives)).

118. On June 14, 2010, Impax received final approval for Impax's ANDA for generic oxymorphone ER for the 5, 10, 20, and 40 mg dosage strengths. (JX-001 at 008 (¶ 21)). This approval occurred upon expiry of the 30-month stay under 21 U.S.C. § 355(j)(5)(B)(iii). (JX-001 at 008 (¶ 21)).

RESPONSE TO FINDING NO. 118:

Respondent has no specific response.

119. Upon receiving final FDA approval, Impax would have been legally permitted to launch its generic oxymorphone ER product at risk absent the SLA. (CX3157 at 020 (Impax quota requests to DEA) ("Because obtaining Final Approval following expiration of our 30-month stay is the only legal or regulatory hurdle we have, we will be in a position to launch the products on 6/15/2010.")). "At-risk launch" means launching a generic product prior to final resolution of a patent infringement litigation. (Koch, Tr. 246).

RESPONSE TO FINDING NO. 119:

The first sentence of Complaint Counsel's Proposed Finding No. 119 is misleading to the extent it suggests that, because an at-risk launch after receiving FDA approval would have been "legal" under FDA requirements, such a launch would have remained legal or was without legal risks. As with any at-risk launch, there is always a risk that relevant patent litigation will

determine that the launch infringed a valid patent. (RX-548.0039-40 (Figg Rep. ¶¶ 85-86)). The second sentence of Proposed Finding No. 119 is incomplete because it ignores the fact that an at-risk launch can occur outside the context of active litigation, including any time a generic company launches a product, without a license, before relevant patents expire. (Bingol, Tr. 1282). An at-risk launch can also occur when relevant patents are pending, but not yet approved or the subject of litigation. (CX4014 (Hsu, IHT at 116) (every Impax license "agreement has to cover all the patent[s], not just the patent [at issue] today, but cover all future patent[s] as well," "otherwise you end up with [a] launch [of] the product and still have to be under [patent] risk, and that doesn't really help us"); Figg, Tr. 1938).

120. An at-risk launch can occur any time after FDA final approval, including (1) before a district court decision, (2) after a district court decision but before an appellate decision by the Federal Circuit, or (3) even after a Federal Circuit opinion if the case is remanded or otherwise continues. (Hoxie, Tr. at 2810-11; CX4021 (Ben-Maimon, Dep. at 133-34); Nguyen, Dep. at 47-48)). An at-risk launch involves more risk prior to a district court decision and significantly less risk after the generic receives a favorable decision from either the district court or the Federal Circuit. (Hoxie, Tr. at 2810-11; CX4021 (Ben-Maimon, Dep. at 133-34)).

RESPONSE TO FINDING NO. 120:

Respondent has no specific response to the first sentence of Complaint Counsel's Proposed Finding No. 120. The second sentence of Proposed Finding No. 120 is misleading and not supported by the cited evidence. The cited testimony of Dr. Ben-Maimon does not state that companies face "significantly less risk" when launching a product at-risk following a court decision, but rather that "risk goes down *to some extent*." (CX4021 (Ben-Maimon, Dep. at 134) (emphasis added)).

C. Impax had financial incentives to launch as soon as possible

121. In the absence of its settlement with Endo, Impax had strong financial incentives to launch oxymorphone ER as soon as possible to prevent Endo from destroying the

market opportunity for generic oxymorphone ER. (CCF ¶¶ 122-26; *see also* RX-547 at 0064 (¶ 121) (Addanki Report) ("Impax was concerned about a potential switch to some new version of Opana ER"); CX5001 at 033-34 (¶ 62) (Bazerman Report) (discussing Impax's financial incentives for launching before a reformulated product)).

RESPONSE TO FINDING NO. 121:

The proposed summary finding should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Additionally, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondent's replies to those findings.

To the extent Proposed Finding No. 121 purports to rely on expert testimony, it violates this Court's Order on Post-Trial Briefs by improperly citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." But even if Professor Bazerman's expert report were considered, Professor Bazerman did not actually analyze whether Impax should (or would) have launched at-risk before a reformulated product. He did not analyze whether Impax was more likely than not to launch at risk and did not analyze the risks to Impax in doing so. (Bazerman, Tr. 921-22). Professor Bazerman admitted, moreover, that the large potential penalties for launching at-risk—as much as ten times the generic company's profits—mean that any generic company must make its launch decisions with care. (Bazerman, Tr. 922).

122. Impax wanted to launch oxymorphone ER "as early as possible." (CX4030 (Hsu, Dep. at 28)). Impax was aware that delaying a launch beyond market formation of oxymorphone ER could mean "lost/delayed sales." (CX0505 at 001 (May 14, 2010 Mengler email); *see also* CX2685 at 003 (Impax's Global Launch Strategy BOD Presentation) ("Launching, even days after market formation, significantly limits the opportunity" for Impax's new products)). A market's formation can occur on the date Impax receives final FDA approval when the product has first-to-file 180-day exclusivity. (CX2685 at 003 (Impax's Global Launch Strategy BOD Presentation)).

RESPONSE TO FINDING NO. 122:

The first sentence of Complaint Counsel's Proposed Finding No. 122 is incomplete and misleading. The record evidence is clear that Impax wanted to launch oxymorphone ER as early as possible, but only if it could do so *free from patent risk*. (CX4014 (Hsu, IHT at 116-17) (it "is very important for [Impax] to have a . . . risk-free launch"); CX4026 (Nguyen, Dep. at 160) (Impax "wanted always to get on the market as quickly as possible and stay in the market")). Impax always seeks "freedom to operate" without patent risks. (CX4026 (Nguyen, Dep. at 155-58)). Indeed, Impax is "incredibly conservative." (CX4021 (Ben-Maimon, Dep. at 34)). In the words of Impax's founder and CEO at the time the SLA was executed, if Impax launches while still under patent risk, "you end up with [a] launch [of] the product and still have to be under [patent] risk, and that doesn't really help us." (CX4014 (Hsu, IHT at 116)). Launching at-risk can be a bet-the-company risk for a small pharmaceutical firm like Impax, (Koch, Tr. 287; CX4030 (Hsu, Dep. at 43)), and as Impax's CFO at the time of settlement explained, Impax would not "risk [its] business on any one particular situation, product, lawsuit, and we were very careful," (Koch, Tr. 287). As a result of this incredibly conservative approach, Impax had only launched at-risk once at the time of the SLA, and only under exceptional circumstances. (Snowden, Tr. 424, 426 (aside from limited oxycodone launch after favorable district court decision, in a single dose, and with a cap on sales, Impax had not pursued any other at-risk launches at the time of Endo-Impax settlement)).

The second sentence of Proposed Finding No. 122 is not supported by the cited evidence and is misleading. The May 2010 email (CX0505) does not discuss market formation and states simply that "the cost of Jan '11 is lost/delayed sales." (CX0505-001). The December 2013

Board presentation (CX2685) does not discuss oxymorphone ER or the impact of delaying a launch of the same. (CX2685-003).

Respondent has no specific response to the third sentence of Proposed Finding No. 122.

123. Impax was also concerned about a decrease in Impax's profits if Endo switched the Opana ER market to a reformulated product. (Mengler, Tr. 526-27, 568 ("reformulation strategy was potentially damaging to Impax' [*sic*] business")). A reformulation by Endo presented a significant risk to Impax because sales of Impax's generic would be largely driven by Endo's brand sales, due to automatic substitution at pharmacies and insurance reimbursement preferences for generics. (CCF ¶¶ 16-22, above (discussing substitution); CX4022 (Mengler, Dep. at 104)). Mr. Mengler, the president of Impax's generic division in 2010, explained that "the way generic drugs are sold is by having a substitute, and if there's no substitute, I get nothing." (Mengler, Tr. 527).

RESPONSE TO FINDING NO. 123:

The first sentence of Complaint Counsel's Proposed Finding No. 123 is inaccurate, incomplete, and misleading. Mr. Mengler testified he was concerned that reformulation would subvert "the benefits to the American consumer for getting a generic version of what would have been an important drug and also I benefit, too, in the way I make money is by selling generic drugs." (Mengler, Tr. 526-27). The quotation attributed to Mr. Mengler was actually a question from Complaint Counsel, in response to which Mr. Mengler explained that the interests of Impax's business and those of consumers were aligned. (*See* Mengler, Tr. 568 ("Q: So in addition to the benefits to consumers, you felt that this reformulation strategy was potentially damaging to Impax'[s] business; is that right? A: That luckily for us in the generic industry those are the same thing, but yes.")).

To the extent the second sentence of Proposed Finding No. 123 purports to incorporate and summarize other findings, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondent's replies to those findings. The only piece of evidence cited in support of the second sentence of Proposed

Finding No. 123 (CX4022) does not support the Proposed Finding because it does not discuss reformulation, risks, substitution, or anything else in the Proposed Finding. (CX4022 (Mengler, Dep. at 104)).

Respondent has no specific response to the third sentence of Proposed Finding No. 123.

124. If Endo successfully converted the market from Original Opana ER to Reformulated Opana ER before Impax could enter with its generic version, Impax might get "nothing" in terms of generic Opana ER sales. (Mengler, Tr. 527 (if Endo launched Reformulated Opana ER before Impax launched generic Opana ER the market for generic Opana ER could disappear); *see also* CX5007 at 023 (¶ 43) (Hoxie Rebuttal Report)).

RESPONSE TO FINDING NO. 124:

Complaint Counsel's Proposed Finding No. 124 is inaccurate and not supported by the cited evidence. Mr. Mengler did not testify about any "market" being "converted" or "disappearing." To the extent the proposed finding relies on CX5007 (Hoxie Report), the proposed finding should be disregarded because it violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." (*See* Court, Tr. 1859 ("[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.")).

The record evidence, moreover, is clear that even though the FDA forced Endo to cease selling its original formulation of Opana ER before Impax launched its generic product, (CX4017 (Levin, Dep. at 138-39, 155); RX-100.0001; RX-094.0004), Impax has still been able to sell the original formulation of oxymorphone ER. (JX-003-006, 08 (¶¶ 40, 59) (Second Set of Joint Stipulations)).

125. Impax's suspicions of Endo's plan to the switch the Opana ER market were confirmed when Endo submitted its NDA for Reformulated Opana ER to the FDA on July 7, 2010. (CX0117 at 002 (Aug. 9, 2010 email chain discussing Endo's new application); (CX3243 at 004 (FDA Approval Letter for Endo NDA 201655)).

RESPONSE TO FINDING NO. 125:

Respondent has no specific response.

126. Thus, but for the Impax-Endo Settlement Agreement, Impax would have been financially motivated to launch as soon as possible to ensure it would enjoy its first-filer exclusivity ahead of Endo's planned switch to a new formulation. (*See* CCF ¶¶ 121-25, above).

RESPONSE TO FINDING NO. 126:

The proposed summary finding should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Additionally, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondent's replies to those findings.

D. Prior to the Impax-Endo Settlement Agreement, Impax was preparing for a launch of generic oxymorphone ER as early as June 14, 2010

1. One of Impax's Company Goals for 2010 was to successfully manage a launch of generic oxymorphone ER

127. Each year, Impax sets "Company Key Goals." (CX4030 (Hsu, Dep. at 22-23); Koch, Tr. 249). These goals are based on "a lot of discussion" and meetings with the Impax management teams and ultimately received approval from Impax's CEO. (CX4030 (Hsu, Dep. at 22-23)). Impax Division Heads would use the Company Key Goals to ensure they had the plans and resources to accomplish their particular part of the Key Goals. (Koch, Tr. 249; CX4018 (Koch, Dep. at 110)). The Company Key Goals would then be circulated to company management and used to set yearly Management By Objective ("MBOs"). (CX2562 at 001 (2010 Company Key Goals); Koch, Tr. 251).

RESPONSE TO FINDING NO. 127:

Respondent has no specific response to the first sentence of Complaint Counsel's Proposed Finding No. 127. The second sentence of Proposed Finding No. 127 is inaccurate and misleading. Dr. Hsu testified that "[t]here's no official approval process," but rather "as the CEO, I have to agree with the key goal we put together." (CX4030 (Hsu, Dep. at 23)).

Respondent has no specific response to the third and fourth sentences of Proposed Finding No. 127.

128. MBOs are an important tool in setting executive compensation, determining bonus calculations, and corporate planning. (Koch, Tr. 249-51; Camargo, Tr. 1000-01; CX4023 (Hildenbrand, Dep. at 197-98); CX2562 at 002 (2010 Company Key Goals) (Hsu instructing management to use the goals in setting "quantitative targets and to map out executive plans for achieving them"); *see, e.g.* CX3069 at 002 (2010 Supply Chain MBOs) (tying achievement of each goal to targeted and obtained salary percentages)). MBOs are more quantitative and division-oriented than the Company Key Goals. (*Compare* CX2562 at 001-02 (2010 Company Key Goals) *with* CX3069 at 002 (2010 Supply Chain MBOs)).

RESPONSE TO FINDING NO. 128:

Respondent has no specific response.

129. In February 2010, Impax's CEO, Larry Hsu, widely distributed Impax's 2010 Company Key Goals to management personnel. (CX2562 at 001 (2010 Company Key Goals)).

RESPONSE TO FINDING NO. 129:

Respondent has no specific response other than to note that the cited evidence does not support the proposition that Dr. Hsu's distribution was "wide" in comparison to any other communication or any other Company Key Goals document.

130. One of Impax's "Company Key Goals" for 2010 was to successfully manage the new product launch of oxymorphone ER. (CX2562 at 002 (2010 Company Key Goals)). According to the Company Key Goals, Impax's "financial success" in 2010 would "hinge heavily on [its] success in several key products," including oxymorphone ER. (CX2562 at 002 (2010 Company Key Goals)).

RESPONSE TO FINDING NO. 130:

Respondent has no specific response.

2. Prior to the Impax-Endo Settlement Agreement, Impax considered an at-risk launch

131. Consistent with the Company Key Goals, Impax was actively considering whether to launch its oxymorphone ER product in 2010, either upon final FDA approval or after a district court decision. (Koch, Tr. 247 ("whether [or not] Impax should launch generic Opana at risk was under consideration"); CX2929 at 001 ("most likely we will make a launch decision based on court decision on the PI")).

RESPONSE TO FINDING NO. 131:

Complaint Counsel's Proposed Finding No. 131 is incomplete, misleading, and not supported by the cited evidence. The cited document does not refer to considerations of a launch upon final FDA approval; to the contrary, it suggested Impax's decision-making would be informed by the way the patent litigation proceeded, not the manner in which the FDA approval process unfolded. The cited testimony of Mr. Koch does not state that Impax was "actively considering" an at-risk launch. Instead, Mr. Koch agreed in the affirmative with Complaint Counsel's question whether such a launch was "under consideration" at Impax at that time. The quotation attributed to Mr. Koch was actually a question from Complaint Counsel.

In the case of oxymorphone ER, Impax attempted to "look[] at different various scenarios" and tried "very hard to . . . describe the possible outcomes under any number of different assumptions." (Koch, Tr. 299-300; *see* Mengler, Tr. 553 (financial projections did not "imply or mean that any legal decision ha[d] been made to clear the way for a launch"); Mengler, Tr. 584 (forecasting "alert[s] the board as to the product being out there that might get to the point of an at-risk launch, so that was it")). This modelling is intended to inform and facilitate decision-making regarding possible launches and launch dates; it does not reflect any decision regarding launch dates. (Engle, Tr. 1720 ("describing forecasting as a "tool" and a "starting point, which senior management can use to make their judgments and decisions"); Engle, Tr. 1771 (Engle not involved in launch decisions); Mengler, Tr. 553 (financial modelling based on

assumed launch date does not "imply or mean that any legal decision ha[d] been made to clear the way for a launch."); Koch, Tr. 299-300 (Impax merely tried to "look[] at different various scenarios" and attempt "very hard to . . . describe the possible outcomes under any number of different assumptions.")). Indeed, in the case of oxymorphone ER, Impax modelled a set of assumptions involving a June 2010 launch date even when that date remained an "obvious[] controversial element." (CX0514-001).

The testimony cited in the Proposed Finding reflects that Impax "considered" an at-risk launch only as part of this general decision-making process and routine forecasting. Mr. Koch testified that Impax considered an at-risk launch in the sense that it "evaluated" it. (Koch, Tr. 247). Elsewhere in Mr. Koch's testimony, he confirmed that Impax never intended to launch oxymorphone ER at-risk. (Koch, Tr. 324-25 ("JUDGE CHAPPELL: Are you a hundred percent certain you would be aware of whether or not Impax planned an at-risk launch of Opana ER? WITNESS: Absolutely. I would have a key role in that. JUDGE CHAPPELL: Do you know in fact whether Impax intended an at-risk launch of Opana ER? . . . THE WITNESS: I do know. JUDGE CHAPPELL: Did they intend to do an at-risk launch of Opana ER? THE WITNESS: No."); *see also* Koch, Tr. 310 (Impax would only consider an at-risk launch after a favorable court ruling)).

And in the cited testimony of Dr. Hsu, Impax's founder and CEO at the time the SLA was executed, Dr. Hsu explained that evaluating an at-risk launch was part of a larger process that looks at all options in making a launch decision, in order to be able to defend any potential course of action to Impax's Board of Directors later on. (CX4041 (Hsu, IHT at 129-30) ("We could settle, we could launch at risk, we could do many other things, and as the job of CEO, I just have to, you know, lay out everything, get prepared so I don't get accused by the board and

say, well, wait a minute, how come you didn't prepare for plan B?"); CX4041 (Hsu, IHT at 130) ("Q: So, as of May 13th, 2010, Impax was at least considering the possibility of an at-risk launch for Oxymorphone ER? A. Yes, that's one of the options, absolutely.")). Moreover, contemporaneous documents make clear that such "evaluation" of all possible "options" does not suggest an at-risk launch was likely to occur, or that Impax intended to launch oxymorphone ER at risk. To the contrary, in contemporaneous documents, Dr. Hsu noted that "it's unlikely we will launch Opana ER this year (I actually prefer not to launch this year for obvious reason[s])." (RX-297.0002; *see* CX2929-001 (Dr. Hsu further explained that that "mostly likely we will make launch decision based on court decision on the PI.")).

With respect to at-risk launches generally, the decision-making process is especially involved, because Impax is "incredibly conservative," (CX4021 (Ben-Maimon, Dep. at 34); *see* Koch, Tr. 287), and it "is very important for [Impax] to have a . . . risk-free launch" in the vast majority of cases, (CX4014 (Hsu, IHT at 117))—as Impax's meager track record of actually launching at-risk reflects, (*see* Snowden, Tr. 424, 426 (aside from limited oxycodone launch after favorable district court decision, in a single dose, and with a cap on sales, Impax had not pursued any other at-risk launches at the time of Endo-Impax settlement)).

Had Impax seriously considered launching oxymorphone ER at-risk, it would have sought Board approval—a prerequisite at Impax for any at-risk launch (Koch, Tr. 276-77 ("every at-risk launch is a board-level decision"); Snowden, Tr. 426; CX4030 (Hsu, Dep. at 128); CX4021 (Ben-Maimon, Dep. at 160))—well before tentative FDA approval of its ANDA. (Koch, Tr. 333-34, 341). Yet Impax's senior management never even recommended an at-risk launch of oxymorphone ER to the Impax Board of Directors, nor was the Impax Board of Directors ever asked to vote on such an at-risk launch. (Koch, Tr. 299; Snowden, Tr. 470-71;

CX4030 (Hsu, Dep. at 85); JX-001-009 (¶ 29) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity)).

132. At the time of the Impax-Endo Settlement Agreement, there was no set procedure governing the analysis and decision-making process for Impax's decisions to launch at risk. (CX2704 at 009-10 (Impax Objection and Response to Interrogatory No. 9); CX4026 (Nguyen, Dep. at 53); CX4022 (Mengler, Dep. at 46)). Nevertheless, there are steps Impax would have taken prior to authorization for an at-risk launch. (CX2704 at 009-10 (Impax's Objection and Response to Interrogatory No. 9)).

RESPONSE TO FINDING NO. 132:

Respondent has no specific response.

133. For instance, an at-risk launch decision would begin with an evaluation by the New Products Committee, who would evaluate the science, the legal elements, and the market opportunity. (Koch, Tr. 276). The New Products Committee would work with Marketing to forecast a launch date and Marketing would share those forecasts with teams responsible for the manufacturing and distribution of the new product. (CX4023 (Hildenbrand, Dep. at 41-43); CX4028 (Camargo, Dep. at 25); Camargo, Tr. 957-58). The New Products Committee could also recommend additional diligence by the research and development and legal teams. (Koch, Tr. 276).

RESPONSE TO FINDING NO. 133:

Respondent has no specific response to the first sentence of Complaint Counsel's Proposed Finding No. 133.

The second sentence of Proposed Finding No. 133 is incomplete, inaccurate, and misleading. Impax strives to have every product in its generic pipeline "launch ready" at the earliest date allowed by the Hatch-Waxman Act. (CX4023 (Hildenbrand, Dep. at 60-61); CX4030 (Hsu, Dep. at 85-86)). The goal of this approach is to give Impax management a full range of potential launch dates as options, and to avoid missing out on an opportunity to launch under favorable conditions because the product is not ready. (CX4030 (Hsu, Dep. at 86); CX4023 (Hildenbrand, Dep. at 140)). In order to accomplish this goal, Impax begins working towards launch preparedness eighteen months before the earliest possible launch date allowed by

the Hatch-Waxman Act. (Camargo, Tr. 952-53, 958; CX4023 (Hildenbrand, Dep. at 79)). This process is routine, consistent with industry practice, and is the same for all products. (CX4023 (Hildenbrand, Dep. at 30); Koch, Tr. 271; CX3278-101).

Forecasting a launch date as part of this process does not mean that Impax has decided whether or when to launch a product. Todd Engle, Impax's Vice President of Sales and Marketing, would forecast potential launch dates based on the earliest possible date allowed by the Hatch-Waxman Act. (Engle, Tr. 1767, 1769, 1772-73). Mr. Engle and the teams on which he worked did not make a decision regarding whether (or when) to launch at risk, or even whether senior management should recommend an at-risk launch to Impax's Board of Directors. (Engle, Tr. 1754-55).

The New Products Committee, moreover, does not decide whether or when Impax will launch a product, including whether or when Impax will launch a product at risk. Impax's Board of Directors makes that decision; it must approve any at-risk launch management recommends. (Koch, Tr. 276-77, 286). Even if the Board approves a potential at-risk launch, it may do so with limitations on the extent of the launch, and senior management may decline to act on the Board's approval based on changes in market dynamics or the underlying patent litigation. (Koch, Tr. 276-77, 286; CX4026 (Nguyen, Dep. at 56) ("even after Board approval, senior management still has the decision to pull the trigger or not")).

Respondent has no specific response to the third sentence of Proposed Finding No. 133.

134. Management team members would also formulate a risk analysis profile for at-risk launches. (Koch, Tr. 276). This risk analysis profile, also called a risk-launch analysis, included a legal analysis involving the status and merits of the patent litigation and potential risk of patent damages. (CX2704 at 010-11 (Impax Objection and Response to Interrogatory No. 9); CX3274 at 001 (Oct. 13, 2010 email chain)). The risk-launch analysis would also consider the potential rewards of an at-risk launch, such as estimated potential profits that might be earned from the launch. (CX2704 at 011 (Impax Objection

and Response to Interrogatory No. 9); *see, e.g.,* CX2695 at 009 (Impax Risk Scenarios for Avodart)).

RESPONSE TO FINDING NO. 134:

Respondent has no specific response to Complaint Counsel's Proposed Finding No. 134 other than to note that Mr. Koch testified that he and "division heads" of certain operations would formulate a risk analysis profile. (Koch, Tr. 276). Mr. Koch did not mention Impax management.

135. Furthermore, an at-risk launch would be evaluated by Impax's Executive Committee. (Koch, Tr. 256). Impax's Executive Committee included the CEO, the President of the Brand Division, the President of the Generics Division, the Vice President of Operations, and the CFO. (Koch, Tr. 219; CX4018 (Koch, Dep. at 140-41)). This Committee was also called the G5. (Koch, Tr. 219).

RESPONSE TO FINDING NO. 135:

Respondent has no specific response.

136. Impax's Executive Committee would need to approve all recommendations about at-risk launches before the recommendations were presented to the Board of Directors for a vote on whether or not to launch at risk. (Koch, Tr. 256, 277-78).

RESPONSE TO FINDING NO. 136:

Respondent has no specific response.

137. For oxymorphone ER, some members of the Executive Committee and other senior managers regularly reviewed forecasts that contained both "upside" and "base case" launch scenarios. (*See, e.g.,* CX5000 at 165-67, 231-38 (¶ 371 & App. D) (Noll Report) (summarizing 27 key forecasts)). A "base case" scenario was always more conservative than the "upside" scenario. (Koch, Tr. 225). In these forecasts, the upside scenario for oxymorphone ER generally assumed a June 2010 launch; the base scenario generally assumed an oxymorphone ER launch in July 2011. (CX2819 at tab "June Forecast Bottles" (June 2009 Monthly Forecast); CX3228 at tab "July Forecasty [*sic*] Bottles" (July 2009 Monthly Forecast); CX2820 at tab "Aug Forecast Bottles" (Aug. 2009 Monthly Forecast); CX2821 at tab "Sept Forecast Bottles" (Sep. 2009 Monthly Forecast); CX2822 at tab "Oct Forecast bottles" (Oct. 2009 Monthly Forecast); CX3229 at tab "Nov forecast Bottles" (Nov. 2009 Monthly Forecast); CX3225 at tab "Dec Forecast bottles" (Dec. 2009 Monthly Forecast); CX2824 at tab "Jan Forecast Bottles"

(Jan. 2010 Monthly Forecast); CX3226 at tab "Feb10 Forecast Bottles" (Feb. 2010 Monthly Forecast); CX3230 at tab "March 10 Forecast Bottles" (Mar. 2010 Monthly Forecast); CX3227 at tab "Apr10 Forecast Bottles" (Apr. 2010 Monthly Forecast); CX2829 at tab "may 10 Forecast bottles" (May 2010 Monthly Forecast); *see also* CX5000 at 165-67, 231-38 (¶ 371 & App. D) (Noll Report) (summarizing 27 key forecasts)).

RESPONSE TO FINDING NO. 137:

The first sentence of Complaint Counsel's Proposed Finding No. 137 violates this Court's Order on Post-Trial Briefs by improperly citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." Respondent has no specific response to the second sentence of Proposed Finding No. 137.

The third sentence of Proposed Finding No. 137 is incomplete and misleading. The forecasts cited must be understood in the context of Impax's larger process for getting every product in its generic pipeline "launch ready" at the earliest date allowed by the Hatch-Waxman Act. (CX4023 (Hildenbrand, Dep. at 60-61); CX4030 (Hsu, Dep. at 85-86)). In order to do so, Impax uses an eighteen-month planning horizon. (Camargo, Tr. 952-53, 958; CX4023 (Hildenbrand, Dep. at 79)). Forecasting and preparing for the earliest possible launch date is the same for all products. (CX4023 (Hildenbrand, Dep. at 30)).

Todd Engle, Impax's Vice President of Sales and Marketing, created the forecasts that included potential launch dates. (Engle, Tr. 1769-70). "Base case" assumptions were simply a "starting point. I have to start modeling out some point, and . . . I try to think if everything possibly could go really well, what would the optimistic be, to kind of put a range, put guardrails on the range of possibilities." (Engle, Tr. 1769-70). "Upside" assumptions are "the most . . . optimistic version where everything would go in the opportune situation." (Engle, Tr. 1770).

In the case of oxymorphone ER, Mr. Engle used June 2010 as an upside assumption simply because "that was the date of the expiration of the thirty-month stay." (Engle, Tr. 1770).

He did not account for risk in any way, and specifically did not consider any regulatory or legal risk associated with a potential launch of oxymorphone ER. (Engle, Tr. 1770-71). The expiration of the thirty-month stay is the target launch date Impax routinely uses in its launch-preparedness efforts for its products. (CX4023 (Hildenbrand, Dep. at 60-61); CX4030 (Hsu, Dep. at 85-86)).

Mr. Engle did not make decisions regarding whether (or when) to launch at risk, or even whether senior management should recommend an at-risk launch to Impax's Board of Directors. (Engle, Tr. 1754-55, 1771). Nor does Mr. Engle and the Marketing department make risk assessments regarding a launch on the forecasted date, or otherwise take into account the status of related litigation. (Engle, Tr. 1774-77). Marketing's forecasting and planning work helps assess "what it would take to be in a position to launch," so that Impax can work towards that goal and keep all options open for management (or, in the case of an at-risk launch, the Board and management) to select a launch date. (CX4037 (Smolenski, Dep. at 116); Koch, Tr. 299-300; *see* Engle, Tr. 1754-55; CX4002 (Smolenski, IHT at 120); CX4038 (Engle, Dep. at 197-98)).

138. Upon receiving tentative FDA approval on May 13, 2010, Chris Mengler, Impax's President of Generics, instructed the head of Operations and to "move on with our next step of preparation for launch." (CX2929 (May 2010 email chain)).

RESPONSE TO FINDING NO. 138:

Complaint Counsel's Proposed Finding No. 138 is incomplete and misleading. The full statement found in the cited evidence is, "Let's move on with our next step of preparation for launch . . . *the court stuff[] should occur timely enough for us to build inventory*." (CX2929-001 (emphasis added; ellipsis in original)). The document also states that Impax "likely [] will make launch decision based on court decision on the PI." (CX2929-001). These omitted portions

suggest that, while Impax was moving forward with routine launch preparedness efforts, its decisions regarding launch timing would depend on a separate assessment of patent risks.

The record, moreover, is clear that Impax strives to have every product in its generic pipeline "launch ready" at the earliest date allowed by the Hatch-Waxman Act. (CX4023 (Hildenbrand, Dep. at 60-61); CX4030 (Hsu, Dep. at 85-86)). In order to do so, Impax uses an eighteen-month planning horizon. (Camargo, Tr. 952-53, 958; CX4023 (Hildenbrand, Dep. at 79)). To that end, Impax's Operations team had actually been working on oxymorphone ER launch preparedness since 2009. (Camargo, Tr. 969, 1004). Yet the Supply Chain Group engaged in those preparation efforts acknowledged that the "odds of launching [in June 2010] when the 30-month stay expires may be low." (RX-181.0001; *see* Camargo, Tr. 1009-10 ("it didn't seem likely to me that we would actually launch" in mid-2010 because the company "tended to shy away from" at-risk launches and oxymorphone ER would have been an at-risk launch given the ongoing litigation)).

The later in the eighteen-month horizon, the more Impax may adjust operational launch preparedness efforts to reflect current thinking at the company. (CX4023 (Hildenbrand, Dep. at 27)). Accordingly, by May 25, 2010, the Operations team had stopped their oxymorphone ER preparation efforts completely and shifted capacity to other projects, (CX2904-001 (May 25, 2010 email chain in which Chuck Hildenbrand tells Joe Camargo and others, "I don't see the OXM happening in June, lets replace it with more MDD")), and the Operations team never undertook a full launch inventory build in support of an oxymorphone ER launch, (Camargo, Tr. 1020).

> 139. On May 14, 2010, Dr. Hsu also instructed Mr. Mengler, the Generic Division President, to "alert BOD [board of directors] with potential oxymorphine [sic] launch," even though "we will have a special Board conference call when we do decide to launch at risk on a later date." (CX0008 at 002 (May 2010 email chain); *see also* Mengler,

Tr. 547). Todd Engle, a senior member of Impax's Sales and Marketing team, then provided Dr. Hsu and Mr. Mengler a risk-launch analysis for oxymorphone ER that he prepared in conjunction with Meg Snowden, Impax's most senior in-house counsel. (CX2753 at 001, 004-28 (May 14, 2010 Engle email and attached Risk Analysis); CX3274 at 001 (May 13, 2010 Impax email chain)). The analysis projected that in its first six months on the market, Impax would earn $53 million in profit if it did not face an AG or between $23.4 million and $28.5 million if it did face an AG. (CX2753 at 004).

RESPONSE TO FINDING NO. 139:

The first sentence of Complaint Counsel's Proposed Finding No. 139 is incomplete and misleading because it ignores Dr. Hsu's testimony providing context for the quoted language. Dr. Hsu "want[ed] to alert the board that we are considering this is one of the scenario[s] so that if we do come up with a final recommendation to the board, there will be no surprise. . . . [T]his is very typical." (CX4030 (Hsu, Dep. at 82); *see* Mengler, Tr. 584 (Mr. Mengler sought to "alert the board as to the product being out there that might get to the point of an at-risk launch, so that was it")). Indeed, it is Impax's normal practice to update the Board of Directors on various scenarios that could impact products in the company's pipeline, ensuring that the Board is not caught off guard regarding any future course. (Koch, Tr. 301; CX4041 (Hsu, IHT at 129-30)).

The second sentence to Proposed Finding No. 139 is also misleading. First, Ms. Snowden is not Impax's "most senior in-house counsel." Ms. Snowden is the Vice president, intellectual property litigation and licensing. (Snowden, Tr. 343). Further, never did Mr. Engle state that he created the referenced analysis "in conjunction witih Meg Snowden." During his deposition, Mr. Engle testified that "I probably had some correspond -- I think -- Meg Snowden has been on some of these e-mails. So Meg probably has looked at the model, (CX4038 (Engle, Dep. 92)).

Respondent has no specific response to the third sentence of Proposed Finding No. 139.

140. On May 17, 2010, after Impax had received tentative approval, Endo informed the court that it was aware of "indications" that Impax was making and stockpiling product

for a potential launch. (CX3309 at 016 (*Endo v. Impax*, transcript of May 14, 2010 teleconference with court) (arguing Impax was "going down that road")). Endo proposed that, even after Impax obtained final FDA approval, Impax should agree to refrain from launching until a district court ruling. (CX3309 at 015-16 (*Endo v. Impax*, transcript of May 14, 2010 teleconference with court)).

RESPONSE TO FINDING NO. 140:

Complaint Counsel's Proposed Finding No. 140 is inaccurate, misleading, and not supported by the cited evidence. The transcript actually reflects that counsel for Endo stated, "we might well be able to agree that there wouldn't be a launch until after the trial or after a decision on the merits. Unless Impax has already made product and stockpiled, it's -- I mean they have to get final approval, they have to get to June 14th, they have to get product ready. The indications we had was that they were actually going down that road. But then maybe then talking to Mr. Chin, we can work out something." (CX3309-015-16).

141. Impax opposed Endo's preliminary injunction proposal. (CX3309 at 016 (*Endo v. Impax*, May 14, 2010 transcript of teleconference with court)). Impax argued that it should not be required to delay a launch beyond the end of the 30-month stay and that, barring a court order, it "will have the right to launch the [oxymorphone ER] product upon final approval in mid-June." (CX3309 at 010-11 (Endo v. Impax, transcript of May 14, 2010 teleconference with court)).

RESPONSE TO FINDING NO. 141:

Complaint Counsel's Proposed Finding No. 141 is not supported by the cited evidence, which reflects only that Impax was initially unwilling to give up its "statutory right" to launch upon receiving FDA approval without further consultation with opposing counsel. Specifically, the cited document actually reflects the following exchange: "THE COURT: Okay. All right. From Impax's point of view, what do you think we should do next? MR. CHIN: Your Honor, this is Roger Chin. The -- it's not our motion, so I'm not quite sure if I can speak to that issue. I certainly today could not say that we would agree not to launch on June 14th. It's our statutory right to launch the product after final approval. But I would be happy to chat separately with

plaintiff's counsel and see what we can work out with respect to scheduling. But ultimately it's their motion." (CX3309-016). The record is likewise unambiguous that, after conferring with opposing counsel, Impax agreed not to launch a product until after trial. (Snowden, Tr. 471-73; RX-251). And as Complaint Counsel's own expert, Professor Max Bazerman, testified, creating a credible threat that Impax might launch at risk improves Impax's potential negotiation outcomes, even if it is a form of bluffing. (Bazerman, Tr. 920-21).

> 142. On May 20, 2010, Impax informed the court that it would not launch until the "last day of trial as presently scheduled," June 17, 2010. (Snowden, Tr. 471-73; RX-251 (Impax letter to court)). Internal Impax documents from this date indicate executive management recommended "obtaining board approval for an at risk launch" and to be prepared to launch on June 14, 2010. (CX3348 at 004 (May, 20, 2010 launch planning document); *see also* CCF ¶¶ 163-64, below).

RESPONSE TO FINDING NO. 142:

Respondent has no specific response to the first sentence of Complaint Counsel's Proposed Finding No. 142. The second sentence of Proposed Finding No. 142 is inaccurate, misleading, and not supported by the cited evidence. The cited evidence (CX3348) was prepared by Todd Engle, Impax's Vice President of Sales and Marketing, and does not reflect "executive management" recommendations of any kind, least of all recommendations that the Impax Board should approve an at-risk launch. (Engle, Tr. 1774, 1777 ("this committee actually doesn't produce any recommendations")).

The cited document is instead a "Launch Planning Committee" document. The Launch Planning Committee holds quarterly meetings intended to keep products in the eighteen-month development pipeline on schedule for planning purposes. (Engle, Tr. 1771). The Launch Planning Committee does not make decisions regarding whether to launch a product at risk, or even whether senior management should recommend an at-risk launch. (Engle, Tr. 1754-55, 1774 ("this particular committee doesn't make that decision. It is about preparing for launch");

CX4037 (Smolenski, Dep. at 116) (Launch Planning Committee reviews "what it would take to be in a position to launch" and does not hold "meeting[s] to decide to launch")).

Mr. Engle drafted and circulated the cited exhibit (CX3348) before a Launch Planning Committee meeting in order to describe where products were in their development process and create a dialogue about next steps. (Engle, Tr. 1771-72). The cited exhibit reflected Mr. Engle's "thinking walking into th[e] meeting" and did not reflect the thinking of executive management at that time. (Engle, Tr. 1777). As in other launch-preparedness planning documents, and as is Impax's standard practice, Mr. Engle picked a projected launch-ready date for oxymorphone ER based on the earliest possible date Impax could launch the product, which in the case of oxymorphone ER was the expiration of the thirty-month stay. (Engle, Tr. 1772-73, 1775-76). He conducted no risk assessment and did not assess the status of any litigation or settlement discussions. (Engle, Tr. 1774-75, 1776-77; *see* CX3347; CX3348). In these quarterly Planning Committee documents, Mr. Engle did not recommend an at-risk launch, but rather flagged "the next logical step" on the basis of his own launch date assumptions. (Engle, Tr. 1753-54, 1773-74, 1776-77). Mr. Engle testified that these thoughts on logical next steps never "went anywhere." (Engle, Tr. 1777).

To the extent the second sentence of Proposed Finding No. 142 purports to summarize and incorporate other findings, the individual findings cited do not support the Proposed Finding and are unreliable for the reasons set out in Respondent's replies to those findings.

> 143. On May 21, 2010, Endo filed its motion for preliminary injunction. (CX2759 at 020 (Patent Litigation Docket)). To support this motion, Endo presented evidence to the Court that assumed Impax would "make an at risk launch of a generic substitute for Opana ER around the June 2010 time frame." (CX3273 at 002 (¶ 2) (Bingol Decl.)). Endo described the impact of such an at-risk launch on Endo's Opana business as "dramatic" and a "substantial loss." (CX3273 at 009 (¶¶ 20-21) (Bingol Decl.)).

RESPONSE TO FINDING NO. 143:

Respondent has no specific response to the first sentence of Complaint Counsel's Proposed Finding No. 143. The second sentence of Proposed Finding No. 143 is inaccurate, misleading, and not supported by the cited evidence. The cited exhibit states in relevant part that a particular declarant had "been asked to assume that Impax will make an at-risk launch of a generic substitute for Opana ER around the June 2010 time frame and to describe the impact of such an at-risk launch on Endo's Opana business" for the purpose of the declaration, but that "Endo has been anticipating and planning for a launch of a generic substitute for Opana ER . . . no earlier than September 2013." (CX3273-002).

In fact, the record is clear that in mid-2010, Endo knew "there had been ANDAs filed for generic versions of Opana ER," but believed "there was not imminently at that point going to be a generic." (Cuca, Tr. 643). Indeed, when Impax suggested during settlement negotiations that it might launch at risk at the end of the Hatch-Waxman Act's thirty-month stay, Endo's lawyer laughed at the suggestion. (Snowden, Tr. 424; CX4032 (Snowden, Dep. at 26)). Endo's lawyer responded that "Impax never launches at risk. . . . That's not a realistic date." (Snowden, Tr. 424). Endo's internal documents make the same point, stating that at the time of settlement Impax was "not likely to launch at risk" because it had never done so before. (RX-086 at 9-10 (third-party market intelligence firm noted that "Impax tends not to launch at risk")).

The third sentence of Proposed Finding No. 143 is incomplete and misleading because it ignores the testimony of Demir Bingol, Endo's Senior Director of Marketing and the author of the cited exhibit (CX3273). Mr. Bingol testified that forecasts regarding the possible impacts of a theoretical generic launch were of "debatable" accuracy. (Bingol, Tr. 1303). Mr. Bingol also

testified that Endo forecast "a number of different potential outcomes over the course of years. As a brand leader . . . you have to plan for all the contingencies." (Bingol, Tr. 1292).

144. On the same day, Ted Smolenski, Impax's Director of Portfolio Management, circulated a five-year forecast to Impax's CFO, Art Koch. (CX2831 at 001, 003 (May 21, 2010 email attaching May 2010 five-year forecast)). A five-year forecast is typically updated quarterly and relied upon by senior management for long-range business planning. (Engle, Tr. 1719-20). The May 21, 2010 five-year forecast assumed only two possible launch date scenarios: either June 2010 (upside) or July 2011 (base). (CX2831 at 001, 003 (May 21, 2010 email attaching May 2010 five-year forecast)).

RESPONSE TO FINDING NO. 144:

Respondent has no specific response to the first and second sentences of Complaint Counsel's Proposed Finding No. 144. The third sentence of Proposed Finding No. 144 is incomplete and misleading because it ignores the testimony of Todd Engle, Impax's Vice President of Sales and Marketing and the individual who created the cited document (CX2831). Mr. Engle testified that the document was "a first draft" and he tried "to give a good range of possibilities and recognizing the fact that I don't know everything and . . . senior management may have other information I don't have, so it's a starting point, which they can use to make their judgments and their decisions." (Engle, Tr. 1719-21). Specifically, "base case" assumptions were simply a "starting point. I have to start modeling out some point, and . . . I try to think if everything possibly could go really well, what would the optimistic be, to kind of put a range, put guardrails on the range of possibilities." (Engle, Tr. 1769-70). "Upside" assumptions are "the most . . . optimistic version where everything would go in the opportune situation." (Engle, Tr. 1770).

In the case of oxymorphone ER, Mr. Engle used June 2010 as an upside assumption simply because "that was the date of the expiration of the 30-month stay." (Engle, Tr. 1770). He did not account for risk in any way, and specifically did not consider any regulatory or legal risk

associated with a potential launch of oxymorphone ER. (Engle, Tr. 1770-71). Mr. Engle, moreover, does not make the decision regarding whether (or when) to launch at risk, or even whether senior management should recommend an at-risk launch to Impax's Board of Directors. (Engle, Tr. 1754-55, 1771). Forecasting and planning work helps assess "what it would take to be in a position to launch," so that Impax can work towards that goal and keep all options open for management (or, in the case of an at-risk launch, the Board and management) to select a launch date. (CX4037 (Smolenski, Dep. at 116); Koch, Tr. 299-300; *see* Engle, Tr. 1754-55; CX4002 (Smolenski, IHT at 120); CX4038 (Engle, Dep. at 197-98)). The limited significance of launch dates assumed in such routine forecasts is reflected in the fact that the date chosen for Impax's oxymorphone ER was an "obvious[] controversial element" of the forecast. (CX0514-001; *see* Koch, Tr. 301 (management updated the Board of Directors on various scenarios so the Board was not caught off guard regarding any future course)).

> 145. By the May 2010 Board of Directors meeting, the oxymorphone ER plan for the Generics Division that was presented to the Board assumed a 2010 "at-risk launch." (CX2662 at 012 (May 2010 board of directors presentation); Koch, Tr. 337-38; Mengler, Tr. 553). Mr. Mengler's presentation to the Board noted that the plan for oxymorphone ER as presented at the February Board meeting anticipated "No launch" in 2010. For the May 2010 Board meeting, however, the "Current Assumption" changed to an "At-Risk Launch" for oxymorphone ER. (CX2662 at 008, 012 (May 2010 board of directors presentation); Koch, Tr. 337-38; Mengler, Tr. 549-53). Based on this change of assumption, Impax expected to earn $28.8 million in 2010 from oxymorphone ER, with sales beginning in June. (CX2662 at 013, 015 (May 2010 board of directors presentation)).
>
> **RESPONSE TO FINDING NO. 145:**

Complaint Counsel's Proposed Finding No. 145 is incomplete, inaccurate, and misleading. Mr. Mengler, the individual responsible for drafting the cited document (CX2662), testified that the document contained only his "assumptions" and those assumptions applied only "to the [sales] numbers." (Mengler, Tr. 552-53; *see* Koch, Tr. 338 (document described Mr.

Mengler's assumptions)). His assumptions with respect to possible sales numbers did not "imply or mean that any legal decision has been made to clear the way for a launch. It just says, when you see the slide with the numbers . . . that says 'oxymorphone' with dollars. That's all that this is saying." (Mengler, Tr. 553). Mr. Mengler testified that "it's impossible to know for sure what we were thinking about a potential launch or launch timing" based on the document. (Mengler, Tr. 551). Indeed, Impax merely tried to "look[] at different various scenarios" and attempt "very hard to . . . describe the possible outcomes under any number of different assumptions." (Koch, Tr. 299-300).

Indeed, Mr. Mengler mentioned oxymorphone ER at the May 2010 Board meeting to put oxymorphone ER "on the radar" of the Board. (Mengler, Tr. 548). He sought to "alert the board as to the product being out there that might get to the point of an at-risk launch, so that was it." (Mengler, Tr. 584). Larry Hsu, Impax's CEO at the time, explained that senior management "want to alert the board that we are considering this is one of the scenario[s] so that if we do come up with a final recommendation to the board, there will be no surprise. . . . [T]his is very typical." (CX4030 (Hsu, Dep. at 82)). This was consistent with Impax's normal practices. Senior management annually updated the Board of Directors on various scenarios that could impact products in the company's pipeline, ensuring that the Board is not caught off guard regarding any future course. (Koch, Tr. 301; *see* CX4014 (Hsu, IHT at 129-30) ("We could settle, we could launch at risk, we could do many other things, and as the job of CEO, I just have to, you know, lay out everything, get prepared so I don't get accused by the board and say, well, wait a minute, how come you didn't prepare for plan B?")).

146. At the May 2010 Board meeting, Mr. Mengler also "expressed the view that Oxymorphone [ER] was a good candidate for an at-risk launch." (CX2663 at 001 (May 2010 board of directors meeting minutes)). Everyone at the meeting agreed that oxymorphone ER was "a great market opportunity" for Impax. (Koch, Tr. 259; CX4018

(Koch, Dep. at 121)) It was understood that the Executive Committee might "come back to the Board seeking an at-risk launch." (Koch, Tr. 301).

RESPONSE TO FINDING NO. 146:

The first sentence of Complaint Counsel's Proposed Finding No. 146 is incomplete and misleading because it ignores the testimony of Arthur Koch, Impax's CFO at the time and the individual who drafted the cited document (CX2663). Mr. Koch testified that there was "no discussion of an at-risk launch by any [one]," "I regret that I used the words 'at-risk launch' [in the minutes]. It's confusing the readers. There was no discussion of an at-risk launch." (Koch, Tr. 295).

Mr. Mengler similarly testified that he mentioned oxymorphone ER at the Board meeting only to "alert the board as to the product being out there that might get to the point of an at-risk launch, so that was it." (Mengler, Tr. 584). Larry Hsu, Impax's CEO at the time, explained that senior management "want to alert the board that we are considering this is one of the scenario[s] so that if we do come up with a final recommendation to the board, there will be no surprise. . . . [T]his is very typical." (CX4030 (Hsu, Dep. at 82)). The record, moreover, is clear that Mr. Mengler did not make a recommendation for an at-risk launch, did not discuss the risk or benefits of an at-risk launch, and did not ask the Board to approve an at-risk launch at the May 2010 Board meeting. (Koch, Tr. 295; Mengler, Tr. 584-85). Finally, a passing reference to Mr. Mengler's comment is in stark contrast with documents associated with meetings where an at-risk launch actually was recommended. Those minutes reflect lengthy, in-depth discussions, and a presentation analyzing the proposed launch, and a formal resolution. (CX3223; CX2689).

The second sentence of Proposed Finding No. 146 is incomplete and misleading. Mr. Koch testified that oxymorphone "presented a great opportunity" because "Oxymorphone was a very rapidly growing product, and we had a tentative approval or we had an application that was

going to be successful." (Koch, Tr. 295). There is no evidence indicating that oxymorphone ER's opportunity had anything to do with an at-risk launch, as Proposed Finding No. 146 attempts to imply.

The third sentence of Proposed Finding No. 146 is inaccurate, misleading, and misrepresents the cited evidence. Mr. Koch actually testified that Mr. Mengler shared information about oxymorphone ER with the Board because "*we were unsure of what direction we were to ultimately take* and we didn't want the case -- we didn't want to come back to the board seeking an at-risk launch with them never having heard of it before, so almost at the earliest time we can think of, we would scope out for them the market profile. And this -- and that was what Chris was doing here." (Koch, Tr. 301 (emphasis added)). Mr. Koch did not testify what "everyone at the meeting" understood or whether the Executive Committee would come back to the board with any recommendation.

147. The discussion about the oxymorphone ER opportunity was memorialized by Arthur Koch, Impax's CFO, in the Board of Directors meeting minutes. (Koch, Tr. 257-59; CX2663 at 004 (May 2010 board of directors meeting minutes)). Mr. Koch takes notes during the Board meeting with a view to prepare the meeting minutes. Based on these notes, Mr. Koch prepares a draft, which he circulates to the CEO. When he is comfortable that the minutes accurately reflect the Board meeting discussions, he circulates the minutes to the Board of Directors. (Koch, Tr. 254-55). The Board then votes to approve the minutes at the next meeting and the minutes then become a permanent corporate record of the deliberations of Impax's officers. (Koch Tr. 255-56).

RESPONSE TO FINDING NO. 147:

Respondent has no specific response.

3. Before entering into the Impax-Endo Settlement Agreement, Impax continually projected oxymorphone ER entry dates as early as June 2010 and prior to January 2013

148. Impax's internal projections and forecasts consistently assumed a generic oxymorphone ER entry as early as June 2010 and prior to January 2013. (CX5000 at 165-67, 231-38 (¶ 371 & App. D) (Noll Report) (summarizing 27 key forecasts)). Their

projections and forecasts were built off of the best information available to Impax at that time. (Koch, Tr. 223-24; CX4029 (Sica, Dep. at 27)).

RESPONSE TO FINDING NO. 148:

The first sentence of Complaint Counsel's Proposed Finding No. 148 violates this Court's Order on Post-Trial Briefs by improperly citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents."

Respondent has no specific response to the second sentence of Proposed Finding No. 148 other than to clarify that Mr. Koch and Mr. Sica were testifying about financial forecasts generally, and not any particular forecast or any particular assumption therein. (Koch, Tr. 223-24; CX4029 (Sica, Dep. at 27)). Different forecasts at Impax serve different purposes, and the purpose of a particular forecast will affect the assumptions chosen for modeling. (Engle, Tr. 1766-67).

149. The Impax employees creating the forecasts were aware that these forecasts often would be sent to Impax's senior management, Impax's Executive Committee, and/or Impax's Board of Directors. (CX4029 (Sica, Dep. at 27-28)). Impax personnel relied on these forecasts for budgeting, planning, and making management decisions. (Engle, Tr. 1710; Camargo, Tr. 958-60, 964; Koch, Tr. 223-24; CX4018 (Koch, Dep. at 18-19)).

RESPONSE TO FINDING NO. 149:

Respondent has no specific response.

150. Impax created and relied on a number of different types of forecasts that consistently assumed a generic oxymorphone ER entry as early as June 2010 and prior to January 2013. Three types of forecasts that Impax used were the 1) monthly demand forecasts; 2) forecasts used at the Quarterly Launch Planning Meetings; and 3) five-year forecasts. (Camargo, Tr. 958 (discussing monthly forecasts); Engle, Tr. 1719-20, 1755-56 (discussing five-year forecasts and Quarterly Launch Planning Meetings); *see also* CCF ¶¶ 151-54, 158-66, below).

RESPONSE TO FINDING NO. 150:

The first sentence of Complaint Counsel's Proposed Finding No. 150 is not supported by any evidence and violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Respondent has no specific response to the second sentence of Proposed Finding No. 150 other than to note that to the extent the Proposed Finding purports to summarize and incorporate other findings, those findings do not support the Proposed Finding and are unreliable for the reasons set out in Respondent's replies to those findings.

> 151. For instance, Impax's Marketing team prepared demand forecasts that it sent to the Operations and Supply Chain groups every month. (CX4023 (Hildenbrand, Dep. at 14-15); Camargo, Tr. 958). These forecasts, which were also called market or monthly forecasts, would typically contain projections for all products Impax expected to launch in an 18-month planning window. (CX4023 (Hildenbrand, Dep. at 14-15); Camargo, Tr. 958)).

RESPONSE TO FINDING NO. 151:

Respondent has no specific response to the first sentence of Complaint Counsel's Proposed Finding No. 151. The second sentence of Proposed Finding No. 151 is inaccurate and not supported by the cited evidence. Neither Mr. Hildenbrand nor Mr. Camargo testified that the marketing forecasts contained projections for products "Impax expected to launch" at any particular time, including within eighteen months. Rather, the record is clear that Impax uses an eighteen-month planning horizon to have every product in its generic pipeline "launch ready" at the earliest date allowed by the Hatch-Waxman Act. (CX4023 (Hildenbrand, Dep. at 60-61, 79); Camargo, Tr. 952-53, 958; CX4030 (Hsu, Dep. at 85-86)). But forecasting a launch date based on the eighteen-month planning horizon does not mean that Impax expects or has decided when to launch a product. (Engle, Tr. 1754-55). Todd Engle, Impax's Vice President of Sales and Marketing, testified that he would forecast potential launch dates based on the earliest possible

date allowed by the Hatch-Waxman Act. (Engle, Tr. 1767, 1769, 1772-73). But Mr. Engle would not make risk assessments regarding a launch on the forecasted date, or otherwise take into account the status of related litigation. (Engle, Tr. 1774-75, 1776-77). Marketing's forecasting and planning work helps assess "what it would take to be in a position to launch," so that Impax can work towards that goal and keep all options open for management (or, in the case of an at-risk launch, the Board and management) to select a launch date. (CX4037 (Smolenski, Dep. at 116); *see* Engle, Tr. 1754-55; CX4002 (Smolenski, IHT at 120); CX4038 (Engle, Dep. at 197-98)).

152. These monthly forecasts were used by Impax's Operations group to plan for the eventual launch of a generic product. (CX4023 (Hildenbrand, Dep. at 14-15) ("production planning originates with a market forecast"); Camargo, Tr. 958 ("Q. The supply chain group bases its launch planning off ... these monthly forecasts. A. Yes.")).

RESPONSE TO FINDING NO. 152:

Respondent does not dispute that Impax's Operations group uses monthly forecasts to assist in its launch preparedness efforts, but these efforts do not always result in the launch of a generic product, as Impax engages in launch preparedness efforts as a matter of course for all products it could theoretically market within eighteen months. (CX4023 (Hildenbrand, Dep. at 60-61, 79); Camargo, Tr. 952-53, 958; CX4030 (Hsu, Dep. at 85-86)).

153. During 2009-2010, Kevin Sica was generally responsible for sending Marketing's monthly forecasts to the Operations group. (Camargo, Tr. 1004; *see, e.g.* CX3055 (Jan. 9, 2009 email attaching monthly forecast)). Mr. Sica was Impax's Sales Operations Planning Manager from 2008 through 2013. (CX4029 (Sica, Dep. at 6-7, 14)). In this role, Mr. Sica was responsible for sales planning and forecasting for generic products in Impax's pipeline. (CX4029 (Sica, Dep. at 7-9)).

RESPONSE TO FINDING NO. 153:

Respondent has no specific response.

154. When a new product entered the 18-month planning window, the Operations group would kick off its pre-launch preparation activities. (Camargo, Tr. 958-59). To start, the Operations group would take information about the new product from the monthly forecasts, including the intended launch date, and enter the information into Impax's enterprise resource planning system ("ERP"). (Camargo, Tr. 959-61).

RESPONSE TO FINDING NO. 154:

Respondent has no specific response other than to note that the phrase "intended launch date" is derived from Complaint Counsel's question at trial. Impax's Operations group referred instead to a "launch-ready" date. (*See, e.g.*, CX2914-003).

155. ERP is a computer system that allows a company, like Impax, to plan the many aspects of a product launch. (Camargo, Tr. 959-61). During the 2009-2010 time-frame, Impax's enterprise resource planning system was called PRMS. (Camargo, Tr. 959-60).

RESPONSE TO FINDING NO. 155:

Respondent has no specific response.

156. PRMS assisted Impax's Operations group with the planning necessary to be ready to launch on the target launch date, the date of each product's planned actual product launch. (Camargo, Tr. 960-61, 982; CX4023 (Hildenbrand, Dep. at 17, 27)).

RESPONSE TO FINDING NO. 156:

Complaint Counsel's Proposed Finding No. 156 is incomplete and misleading because the use of a target launch date by Operations does not mean that the particular product is slated for an "actual product launch" on that date. (CX4023 (Hildenbrand, Dep. at 39-40, 84-85); Engle, Tr. 1754-55, 1771).

Instead, the record indicates that Impax strives to have every product in its generic pipeline "launch ready" at the earliest date allowed by the Hatch-Waxman Act. (CX4023 (Hildenbrand, Dep. at 60-61); CX4030 (Hsu, Dep. at 85-86); Camargo, Tr. 982; CX4028 (Camargo, Dep. at 59)). This ensures that Impax has the ability meaningfully to consider all options for a product. (CX4014 (Hsu, IHT at 86)). In order to accomplish this, Impax begins

working towards launch preparedness eighteen-months before the earliest possible launch date. (Camargo, Tr. 952-53, 958; CX4023 (Hildenbrand, Dep. at 79)). This process is routine, consistent with industry practice, and is the same for all products. (CX4023 (Hildenbrand, Dep. at 30); Koch, Tr. 271; CX3278-101)). The target launch dates used in this process do not reflect a decision regarding whether or when to launch a product. Instead, Todd Engle, Impax's Vice President of Sales and Marketing, would forecast potential launch dates based on the earliest possible date allowed by the Hatch-Waxman Act. (Engle, Tr. 1767, 1769, 1772-73). Mr. Engle and the teams on which he worked did not make a decision regarding whether (or when) to launch at risk, or even whether senior management should recommend an at-risk launch to Impax's Board of Directors. (Engle, Tr. 1771, 1754-55). The date of a "product's planned actual product launch," if at risk, would only be decided by Impax senior management after approval from the Board of Directors. (Koch, Tr. 276-77, 286; CX4026 (Nguyen, Dep. at 56)).

157. For example, Impax used PRMS to plan for the purchasing of raw materials, to allocate labor and plant capacity necessary to manufacture the product, and to assess the safety stock needed to launch a product. (Camargo, Tr. 958-59, 964-65).

RESPONSE TO FINDING NO. 157:

Respondent has no specific response.

158. Prior to entering into the Impax-Endo Settlement Agreement, every Impax monthly demand forecast sent to the Operations group and inputted into PRMS assumed a generic oxymorphone ER launch date of June 2010 or July 2010. (CX2819 at tab "June Forecast Bottles" (June 2009 Monthly Forecast); CX3228 at tab "July Forecasty [*sic*] Bottles" (July 2009 Monthly Forecast); CX2820 at tab "Aug Forecast Bottles" (Aug. 2009 Monthly Forecast); CX2821 at tab "Sept Forecast Bottles" (Sep. 2009 Monthly Forecast); CX2822 at tab "Oct Forecast bottles" (Oct. 2009 Monthly Forecast); CX3229 at tab "Nov forecast Bottles" (Nov. 2009 Monthly Forecast); CX3225 at tab "Dec Forecast bottles" (Dec. 2009 Monthly Forecast); CX2824 at tab "Jan Forecast Bottles" (Jan. 2010 Monthly Forecast); CX3226 at tab "Feb10 Forecast Bottles" (Feb. 2010 Monthly Forecast); CX3230 at tab "March 10 Forecast Bottles" (Mar. 2010 Monthly Forecast); CX3227 at tab "Apr10 Forecast Bottles" (Apr. 2010 Monthly Forecast); CX2829 at tab "may 10 Forecast bottles" (May 2010 Monthly Forecast); *see also*

CX5000 at 165-67, 231-38 (¶ 371 & App. D) (Noll Report) (summarizing 27 key forecasts); Camargo Tr. 953-54, 958-59, 964-65 (discussing Operation and Supply Chain's use of monthly forecasts)).

RESPONSE TO FINDING NO. 158:

Complaint Counsel's Proposed Finding No. 158 is incomplete and misleading because it ignores the actual language in the initial forecast cited, which set out Impax's assumptions and noted that any estimate of a mid-2010 launch of oxymorphone ER was "the best case scenario; therefore we should not plan on being ready 3 months early." (CX2819-001).

Todd Engle, Impax's Vice President of Sales and Marketing, created the forecasts. In the case of oxymorphone ER, Mr. Engle used June 2010 as an upside assumption simply because "that was the date of the expiration of the thirty-month stay." (Engle, Tr. 1770). He did not account for risk in any way, and specifically did not consider any regulatory or legal risk associated with a potential launch of oxymorphone ER. (Engle, Tr. 1770-71). Forecasts regarding possible launch dates, while routine, were consequently an "obvious[] controversial element" of any Impax projection. (CX0514-001).

Mr. Engle and the Marketing team did not make decisions regarding whether (or when) to launch at risk, or even whether senior management should recommend an at-risk launch to Impax's Board of Directors. (Engle, Tr. 1754-55, 1771). Marketing's forecasting and planning work helps assess "what it would take to be in a position to launch," so that Impax can work towards that goal and keep all options open for management (or, in the case of an at-risk launch, the Board and management) to select a launch date. (CX4037 (Smolenski, Dep. at 116); Koch, Tr. 299-300; *see* Engle, Tr. 1754-55; CX4002 (Smolenski, IHT at 120); CX4038 (Engle, Dep. at 197-98)).

159. Using the planned launch date from the monthly forecast, the Operations group calculated backwards to determine the key milestones it needed to accomplish to be ready to launch oxymorphone ER. (Camargo, Tr. 983, 985).

RESPONSE TO FINDING NO. 159:

Respondent has no specific response.

160. The Product Launch Checklist is a planning document that contains "a checklist of significant activities that needed to be completed to ensure that Impax was launch-ready by the date provided by Impax management." (Camargo, Tr. 962; *see also* CX4028 (Camargo, Dep. at 173)).

RESPONSE TO FINDING NO. 160:

Complaint Counsel's Proposed Finding No. 160 is inaccurate and misleading because the quotation attributed to Mr. Camargo is actually a question from Complaint Counsel. Proposed Finding No. 160 is also inaccurate because the eighteen-month forecasts, including estimated launch-ready dates, came from the Marketing Department, not Impax management. (Camargo, Tr. 958, 1004).

161. The Product Launch Checklist is sent in advance of all product launch coordination meetings. (CX4028 (Camargo, Dep. at 173); Camargo, Tr. 962). The launch coordination meetings are led by the Supply Chain group, and are generally held monthly for the purpose of ensuring that everybody had a common understanding of the planned launch-ready dates for products and what tasks needed to be completed to meet the planned launch-ready dates. (Camargo, Tr. 962-63).

RESPONSE TO FINDING NO. 161:

Respondent has no specific response.

162. As of May 2010, Impax's Launch Planning Checklist assumed a launch ready date of June 14, 2010 for oxymorphone ER. (CX3078 at 003 (May 11, 2010 Product Launch Checklist)).

RESPONSE TO FINDING NO. 162:

Respondent does not dispute Complaint Counsel's Proposed Finding No. 162, but notes that the Proposed Finding is incomplete and misleading. Impax strives to have every product in its generic pipeline "launch ready" at the earliest date allowed by the Hatch-Waxman Act. (CX4023 (Hildenbrand, Dep. at 60-61); CX4030 (Hsu, Dep. at 85-86)). Joseph Camargo, Impax's Vice President of Supply Chain, testified that despite using that estimated launch-ready date, the "odds of launching [in June 2010] when the 30-month stay expires may be low." (RX-181.0001; *see* Camargo, Tr. 1009-10 ("it didn't seem likely to me that we would actually launch" in mid-2010 because the company "tended to shy away from" at-risk launches)). As of May 25, 2010, the Operations team had stopped their oxymorphone ER preparation efforts completely and shifted capacity to other projects. (CX2904-001 (May 25, 2010, email chain in which Chuck Hildenbrand tells Joe Camargo and others, "I don't see the OXM happening in June, lets replace it with more MDD")). And, by June 2010, the date on which Impax anticipated to be fully "Launch Ready" still remained "TBD." (CX2914-003; CX4023 (Hildenbrand, Dep. at 209)).

> 163. Other Impax forecasts also projected an oxymorphone ER launch on June 14, 2010. For example, Impax conducted quarterly launch planning meetings. (Mengler, Tr. 556-58). The quarterly launch planning meetings were generally chaired by a representative from Marketing, and brought together representatives from various Impax groups, including Legal, Regulatory, Marketing, and Operations, to discuss and plan for product launches. (CX4023 (Hildenbrand, Dep. at 68-69); *see, e.g.* CX3348 at 001 (May 20, 2010 quarterly launch planning meeting agenda)).

RESPONSE TO FINDING NO. 163:

The first sentence of Complaint Counsel's Proposed Finding No. 163 is unsupported by any record evidence and should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific

references to the evidentiary record." (Order on Post-trial Briefs at 2). Respondent has no specific response to the second and third sentences of Proposed Finding No. 163.

> 164. In the months prior to the Impax-Endo Settlement Agreement, the launch planning documents prepared for the quarterly launch planning meetings assumed an oxymorphone ER projected launch date of June 14, 2010. (CX0204 at 002-03 (Feb. 1, 2010 launch planning document); CX3348 at 003 (May 20, 2010 quarterly launch planning meeting agenda)).

RESPONSE TO FINDING NO. 164:

Complaint Counsel's Proposed Finding No. 164 is incomplete and misleading in its characterization of the document prepared in connection with quarterly launch planning meetings. Todd Engle, Impax's Vice President of Sales and Marketing, drafted and circulated the cited documents (CX0204; CX3348) before Launch Planning Committee meetings to describe where products were in their development process and create a dialogue about next steps. (Engle, Tr. 1771-72). The cited exhibits reflected Mr. Engle's "thinking walking into th[e] meeting" and did not reflect the thinking of Impax as a whole or executive management at that time. (Engle, Tr. 1777).

As he did with other documents designed to assist with launch preparedness efforts, Mr. Engle selected the launch date for oxymorphone ER found in these documents based on the expiration of the thirty-month stay since it was the earliest possible date Impax theoretically could launch the product. (Engle, Tr. 1772-73, 1775-76). He conducted no risk assessment and did not assess the status of any litigation or settlement discussions. (Engle, Tr. 1774-75, 1776-77; *see* CX3347; CX3348). The expiration of the thirty-month stay is the target launch date Impax routinely uses in its launch-preparedness efforts for its products. (CX4023 (Hildenbrand, Dep. at 60-61); CX4030 (Hsu, Dep. at 85-86)).

Moreover, Mr. Engle did not recommend any actual launch date in those quarterly Planning Committee documents, but rather flagged "the next logical step" for launch preparedness on the basis of his own launch date assumptions. (Engle, Tr. 1753-54, 1773-74, 1776-77). Mr. Engle testified that these thoughts on logical next steps never "went anywhere." (Engle, Tr. 1777).

165. Impax also prepared and relied on longer-range forecasts that projected Impax's needs over a five-year horizon. A five-year forecast is typically updated quarterly and relied upon by senior management for long-range business planning. (Engle, Tr. 1719-20). For example, the five-year forecasts were relied upon to make critical decisions about capacity needs to support products that were planned for the future and other capital expenditures. (CX4028 (Camargo, Dep. at 21-22); CX4022 (Mengler, Dep. at 26)).

RESPONSE TO FINDING NO. 165:

Respondent has no specific response.

166. In the months prior to the Impax-Endo Settlement Agreement, all of the five-year forecasts assumed launch date scenarios as early as June 2010 and well in advance of January 2013. For example, the May 21, 2010 five-year forecast assumed only two possible launch date scenarios: either June 2010 (upside) or July 2011 (base). (CX2831 at 003 (May 21, 2010 email attaching May 2010 five-year forecast)). Such assumptions "triggered a lot of other things in the company, like bonus calculations" and influenced the budgeting and planning process. (Mengler, Tr. 550).

RESPONSE TO FINDING NO. 166:

The first sentence of Complaint Counsel's Proposed Finding No. 166 is unsupported by any record evidence and should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2).

The second sentence of Proposed Finding No. 166 is an incomplete and misleading characterization of the document cited because it ignores the testimony of Todd Engle, Impax's Vice President of Sales and Marketing and the individual who created the cited document

(CX2831). Mr. Engle testified that the document was "a first draft" and he tried "to give a good range of possibilities and recognizing the fact that I don't know everything and . . . senior management may have other information I don't have, so it's a starting point, which they can use to make their judgments and their decisions." (Engle, Tr. 1719-21). Specifically, "base case" assumptions were simply a "starting point. I have to start modeling out some point, and . . . I try to think if everything possibly could go really well, what would the optimistic be, to kind of put a range, put guardrails on the range of possibilities." (Engle, Tr. 1769-70). "Upside" assumptions are "the most . . . optimistic version where everything would go in the opportune situation." (Engle, Tr. 1770). More generally, this and other Impax five-year plans must be understood in the context of their larger purpose at the company: forecasting a range of possibilities regarding potential and current Impax products. (Engle, Tr. 1720; CX4002 (Smolenski, IHT at 85) (financial forecasts prepared "for planning purposes to understand what the scenario would look like")). They assist senior management in making decisions, but do not contain all relevant information, and certainly do not reflect any decisions. (Engle, Tr. 1719-21).

In the case of CX2831, Mr. Engle used June 2010 as an upside assumption for oxymorphone ER simply because "that was the date of the expiration of the 30-month stay." (Engle, Tr. 1770). He did not account for risk in any way, and specifically did not consider any regulatory or legal risk associated with a potential launch of oxymorphone ER. (Engle, Tr. 1770-71). Mr. Engle, moreover, does not make the decision regarding whether (or when) to launch at risk, or even whether senior management should recommend an at-risk launch to Impax's Board of Directors. (Engle, Tr. 1754-55, 1771).

The third sentence of Proposed Finding No. 166 is inaccurate and not supported by the cited evidence. In the cited testimony, Mr. Mengler was not discussing CX2831, May 2010 five-

year forecast assumptions, or even five year forecasts generally. Rather, he was discussing the specific February 2010 sales budget base plan assumptions laid out in a Board of Directors' presentation (CX2662). (Mengler, Tr. 550-51 ("Q: And so in February, the sales budget was assuming no launch of generic oxymorphone ER; right? A: The base -- it's a -- yeah. It's important to keep this sort of in a context with our budgeting process and planning process, so what this says is that the base plan, as presented to the board, that triggered a lot of other things in the company, like bonus calculations and things of that nature, did not include an oxymorphone launch. Just from this, it's impossible to know for sure what we were thinking about a potential launch or launch timing, but what we can say with certainty is that this plan as presented in February didn't have any numbers in it, any dollar sales in it.")).

> 167. There are a few forecasts, called "generic new product launch projections," that identify a March 2013 entry date for oxymorphone ER. (*See, e.g.,* CX2828 at 001 (Apr. 5, 2010 email distributing generic new product launch projections to Impax managers)). March 2013 represents the date that is six months before expiration of the patents listed by Endo in the Orange Book. These generic new product launch projections always included the date six months before last patent expiration as a matter of course for all Impax products, regardless of the actual planned launch date. (CX4037 (Smolenski, Dep. at 64-65) ("Q. And the base case launch six months before last patent expiry, you said that was a standard assumption that was applied across all products at Impax? A. Yeah. . . .")). There is no evidence that any of the forecasts with a March 2013 entry date were used by Impax to make management decisions for launch planning.

RESPONSE TO FINDING NO. 167:

Respondent has no specific response to the first sentence of Complaint Counsel's Proposed Finding No. 167. The second sentence of Proposed Finding No. 167 cites no support and should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2).

The third sentence of Proposed Finding No. 167 is inaccurate and not supported by the cited evidence. In the cited testimony, Mr. Smolenski said nothing about "actual planned launch dates" or how generic new drug product launch projections related to them. (CX4037 (Smolenski, Dep. at 64-65)). Nor did Mr. Smolenski state that generic new drug product launch projections applied to all Impax products, explaining instead that they applied to products involving Paragraph IV challenges. (CX4037 (Smolenski, Dep. at 65) ("assumption we would launch later" applied to "products that were Paragraph IV challenges")).

Finally, the third and fourth sentences are inconsistent with the larger context provided by Mr. Smolenski regarding the way these assumptions and hypothetical launch dates were used at Impax. Mr. Smolenski testified that "when forecasting products, it's really hard to accurately predict when a product will launch. So what we try to do is just kind of bracket with a very optimistic case that had some assumptions behind it and then bracket it on the more conservative side and make an assumption we would launch later." (CX4037 (Smolenski, Dep. at 65)). Finally, "launch projections" discussing oxymorphone ER and the March 2013 "bracket" *were* in fact circulated to Impax management, including the CEO and CFO. (CX2828-001, 003 (circulating "Generic new product launch projection 2010-04-05.xls" to Larry Hsu, Art Koch and others with the note "see attached for latest launch projections")). Complaint Counsel cites no basis for its suggestion that such high level Impax personnel did not consider these launch projections in making decisions regarding launch planning. Nor did Complaint Counsel ask Mr. Koch or Dr. Hsu whether and for what purpose either may have used this or similar documents in making launch planning decisions.

4. Impax prepared to manufacture generic oxymorphone ER

168. Impax took concrete steps to be ready to launch oxymorphone ER as early as 2010. (CCF ¶¶ 174-213, below).

RESPONSE TO FINDING NO. 168:

The proposed summary finding should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Additionally, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondent's replies to those findings.

169. Operations and Supply Chain's MBO goals for 2010 included achieving a "new product launch on the day of ANDA approval" for the oxymorphone ER product. (CX2899 at 002 (2010 Operations MBOs); CX3069 at 002 (2010 Supply Chain MBOs); Camargo, Tr. 1001-02). Operations oversees the planning, manufacturing, and packaging of products that Impax produces internally to ensure that Impax is "launch-ready." (Camargo, Tr. 961-62). The Supply Chain group fell within Operations (collectively "Operations group") and was responsible for coordinating with the Marketing group the resources necessary to meet customer demand for Impax products. (CX4023 (Hildenbrand, Dep. at 10-11); Camargo, Tr. 951, 961-62).

RESPONSE TO FINDING NO. 169:

The first sentence of Complaint Counsel's Proposed Finding No. 169 is incomplete, inaccurate, and misleading. The full quotation from the cited evidence actually reads, "Achieve new product launch on the day of ANDA approval *without putting Company into unnecessary financial or legal risks*." (CX2899-002; CX3069-002 (emphasis added)). Joseph Camargo, Impax's Vice President of Supply Chain, testified that achieving the stated objective meant receiving sign off on a process validation report and being ready to execute a launch inventory build if management so instructed. (Camargo, Tr. 1033-34). The stated objective was also consistent with Impax's efforts to have every product in its generic pipeline "launch ready" at the earliest date allowed by the Hatch-Waxman Act. (CX4023 (Hildenbrand, Dep. at 60-61); CX4030 (Hsu, Dep. at 85-86)).

Respondent has no specific responses to the second and third sentences of Proposed Finding No. 169.

> 170. Achieving a new product launch on the day of ANDA approval required the Operations group to meet the demand forecasted by the Sales and Marketing teams, to complete process validation for manufactured product, to ensure that the product was packaged and available to ship, and to confirm that Impax had achieved all of the internal and FDA quality assurance goals. (CX4023 (Hildenbrand, Dep. at 35-36)). Inherent in this objective is the allocation of resources towards launch preparation and the commitment of labor and plant capacity for manufacturing. (CX4023 (Hildenbrand, Dep. at 43-44); *see also* CCF ¶¶ 174-213, below).

RESPONSE TO FINDING NO. 170:

Respondent has no specific response to the first sentence of Complaint Counsel's Proposed Finding No. 170. The second sentence of Proposed Finding No. 170 incorrectly summarizes and thus is not supported by the cited testimony. Mr. Hildenbrand did not testify about meeting any objective, any inherent allocations, or commitments necessary to do the same. (*See* CX4023 (Hildenbrand Dep. at 43-44) ("Q: … I believe you said new product launches often had a greater potential for opportunity cost because they took up more resources; is that correct? . . . A: Let me try to restate what I was attempting to convey, that in first-to-file situations of large-volume products, they offered a potential for using an inordinate amount of both labor and plant capacity, that could cause, therefore, disruption to other products requiring adjustments in planning.")). To the extent the second sentence of Proposed Finding No. 170 purports to summarize and incorporate other findings, the individual findings cited do not support the Proposed Finding and are unreliable for the reasons set out in Respondent's replies to those findings.

> 171. The Operations group achieved this MBO in 2010 by being launch-ready as of the targeted oxymorphone ER launch date, June 14, 2010. (Camargo, Tr. 1001-02; CX4028 (Camargo, Dep. at 208-11)). For the purposes of performance assessments and bonus calculations, the Operations group succeeded in meeting this goal, even though Impax did

not launch oxymorphone ER until 2013, due to the Impax-Endo Settlement Agreement. (Camargo, Tr. 1001-02; CX4028 (Camargo, Dep. at 208-11); CCF ¶¶ 203-04, 208-09, below).

RESPONSE TO FINDING NO. 171:

Complaint Counsel's Proposed Finding No. 171 is incomplete and misleading in its selective paraphrasing of the testimony of Joseph Camargo, Impax's Vice President of Supply Chain. Mr. Camargo testified that achieving the stated objective meant only receiving sign off on a process validation report and being ready to execute a launch inventory build if management so instructed. (Camargo, Tr. 1033-34). That aim was consistent with Impax's efforts to have every product in its generic pipeline "launch ready" at the earliest date allowed by the Hatch-Waxman Act. (CX4023 (Hildenbrand, Dep. at 60-61); CX4030 (Hsu, Dep. at 85-86)). Mr. Camargo, moreover, was testifying about his personal performance and bonus assessment, not Impax employees more generally. (Camargo, Tr. 1000-01).

To the extent Proposed Finding No. 171 purports to summarize and incorporate other findings, the individual findings cited do not support the Proposed Finding and are unreliable for the reasons set out in Respondent's replies to those findings.

172. Manufacturing generic oxymorphone ER required the allocation of "an inordinate amount of both labor and plant capacity" towards the oxymorphone ER product and away from other Impax products. (CX4023 (Hildenbrand, Dep. at 43-44)). Oxymorphone's status as a controlled substance added complexities and required additional resources to manufacture the product. (CX4023 (Hildenbrand, Dep. at 140-41)).

RESPONSE TO FINDING NO. 172:

The first sentence of Complaint Counsel's Proposed Finding No. 172 is inaccurate and misleading. Mr. Hildenbrand was not testifying about oxymorphone, but rather the potential requirements of large-volume, first-to-file products. His actual testimony states, "in the first-to-file situations of large-volume products, they offered a potential for using an inordinate amount

of both labor and plant capacity, that could cause, therefore, disruption to other products requiring adjustments in planning." (CX4023 (Hildenbrand, Dep. at 43-44)). In fact, Mr. Hildenbrand rejected Complaint Counsel's suggestion that the specific production of oxymorphone ER required "a substantial amount of resources," stating only that it would require "[n]ot insignificant" resources. (CX4023 (Hildenbrand, Dep. at 140)).

Respondent has no specific response to the second sentence of Proposed Finding No. 172.

> 173. As a small, resource-constrained company, Impax had to make difficult decisions about how to allocate its manufacturing capacity. (CX4038 (Engle, Dep. at 189-91, 192)). Despite the potential impact on the production of other products, the Operations group began preparations for the launch of generic oxymorphone ER in June 2010. (Camargo, Tr. 969).

RESPONSE TO FINDING NO. 173:

The first sentence of Complaint Counsel's Proposed Finding No. 173 is not supported by the cited evidence. Mr. Engle did not testify that Impax was a small, resource-constrained company, or that Impax had to make "difficult decisions" about manufacturing capacity. Mr. Engle actually testified that "I think they [Impax] do that [make decisions about how to allocate resources] every day. I think it's a constant process of making judgments, what to make, when to make it. . . . It's just the nature of demand planning and production scheduling, equipment availability, people availability." (CX4038 (Engle, Dep. at 192)).

The second sentence of Proposed Finding No. 173 is incomplete, misleading, and not supported by the cited evidence. Mr. Camargo did not testify that preparing oxymorphone ER had a potential impact on the production of other products. He testified only that in 2009, the supply chain group began planning for the launch of oxymorphone ER because it had entered Impax's eighteen-month planning window, (Camargo, Tr. 969), just as Impax does for all

products when they enter the eighteen-month planning window. (CX4023 (Hildenbrand, Dep. at 30)). Moreover, contemporaneous operational documents make clear that, for form "beg[inning] preparations for the launch of generic oxymorphone ER in June 2010," by May 25, 2010, the Operations team had *stopped* their oxymorphone ER preparedness efforts completely and shifted capacity to other projects. (CX2904-001 (May 25, 2010, email chain in which Mr. Hildenbrand tells Mr. Camargo and others, "I don't see the OXM happening in June, lets replace it with more MDD")).

a) Impax worked with federal agencies and outside parties to purchase raw materials for manufacturing

174. Oxymorphone, the active pharmaceutical ingredient ("API") for Opana ER and generic oxymorphone ER, is a controlled substance. (JX-001 at 006 (¶ 8); Camargo, Tr. 965). This means that purchasing oxymorphone is regulated by the Drug Enforcement Agency ("DEA"). (Camargo, Tr. 965; CX4027 (Anthony, Dep. at 13-14, 150-51)).

RESPONSE TO FINDING NO. 174:

Respondent has no specific response to Complaint Counsel's Proposed Finding No. 174 other than to clarify that the purchase of oxymorphone *API* is regulated by the Drug Enforcement Agency, not the purchase of all products colloquially referred to as "oxymorphone," like oxymorphone ER.

175. Impax could only purchase API after receiving quota from the DEA. (Camargo, Tr. 965-66). Quota is the amount of a controlled substance, like oxymorphone, that the DEA permits a company to purchase in a particular year. (Camargo, Tr. 965-66). Quota can be granted for different purposes, including research and development and commercial sale. (Camargo, Tr. 966). A company like Impax could only purchase as much API as the amount of quota the DEA grants, and it could only use that quota for the purpose identified in the DEA grant. (Camargo, Tr. 966). Thus, if a company sought quota to manufacture a product that would be sold commercially, the company would need to seek and be granted quota specifically for commercial manufacturing. (Camargo, Tr. 966).

RESPONSE TO FINDING NO. 175:

Respondent has no specific response.

176. In March 2009, Impax requested oxymorphone quota from the DEA to be used for commercial manufacturing in 2010. (CX4027 (Anthony, Dep. at 68-69)). In December 2009, the DEA denied this request because Impax's submission did not justify the need for the requested quota. (CX2874 at 005 (Dec. 23, 2009 letter from the DEA); CX4027 (Anthony, Dep. at 95)).

RESPONSE TO FINDING NO. 176:

Respondent has no specific response.

177. After this initial denial, in January 2010 Impax employees were instructed to follow up with DEA "aggressively" to get the quota because the planned launch for oxymorphone ER was only "five months away." (CX2866 at 001 (Jan. 12, 2010 email chain)).

RESPONSE TO FINDING NO. 177:

Complaint Counsel's Proposed Finding No. 177 is misleading and not supported by the cited evidence. The cited evidence (CX2866) does not contain an instruction to any employee, but rather a comment by Chris Mengler as follows: "Note that our currently planned launch is only five months away, so we need to follow up aggressively." (CX2866 at 001). Complaint Counsel never asked Mr. Mengler about this comment at trial, deposition, or during his investigational hearing. And when Complaint Counsel asked John Anthony, one of the recipients of the email and the individual at Impax who was responsible for DEA quota requests, about Mr. Mengler's statement, Mr. Anthony indicated Mr. Mengler's remark carried no particular importance. (CX4027 (Anthony Dep. at 136) ("Q: Do you know why you needed to follow up aggressively? A: Well, Chris Mengler, everything he did he wanted to be done quickly or aggressively. He's talking about the product launch, so just going along with what

would be normal requirement to get that procurement quota. And they were always, the procurement quotas were always done as quickly as possible by me.")).

> 178. On January 18, 2010, Impax submitted an additional request to the DEA for oxymorphone commercial manufacturing quota. (CX2876 at 001 (Jan. 22, 2010 email chain); JX-001 at 008 (¶ 25)). To support its quota request, Impax submitted a forecast to DEA listing its target commercial launch of oxymorphone ER as June 2010. (CX2916 at 017 (forecast sent to DEA)). Impax made sure that the forecasts it sent to the DEA were "reasonably accurate" and a "very good representation" of what Impax believed it "would sell in a certain time frame." (CX4038 (Engle, Dep. at 145-46)).

RESPONSE TO FINDING NO. 178:

Respondent has no specific response to the first and second sentences of Complaint Counsel's Proposed Finding No. 178. The third sentence of the proposed finding is misleading and inconsistent with the record in its characterization of submissions to the DEA. While Mr. Engle testified that he was "pretty comfortable the forecasts submitted to the DEA would have merit," he also explained that John Anthony and Mark Shaw, not Mr. Engle, were responsible for and dealt with DEA submissions and quota requests. (CX4038 (Engle, Dep. at 145-46)). At deposition, Mr. Anthony explained that Impax had to justify its requested amount of quota by showing a need for the amount requested to support commercial sales. (CX4027 (Anthony, Dep. at 56-57)). Impax was limited in its ability to make such a showing for oxymorphone ER, since Impax had not yet launched the product, and so had no history of commercial sales. (CX4027 (Anthony, Dep. at 59-60)). At least initially, Impax was also hesitant to seek letters of intent from customers to support its request to the DEA, given that Impax had not yet received FDA approval. (CX4027 (Anthony, Dep. at 120)). Impax therefore submitted a forecast as supporting documentation, (*see* CX3157 at 15-16 (Letter to DEA explaining the absence of letters of intent to support additional quota request and identifying forecast and other supporting documentation in lieu of such letters)), which Mr. Anthony described as offering the DEA an "estimate" of the

amount of product Impax "hoped" to sell as a way of justifying Impax's request for quota. (CX4027 (Anthony, Dep. at 123)).

The forecast Mr. Anthony ultimately submitted as part of Impax's quota request was therefore a truthful and accurate estimate of representation of what Impax *hoped* to sell, and the DEA understood it as such. (CX4027 (Anthony, Dep. at 123)). Moreover, Mr. Anthony—Impax's Senior Director of DEA Compliance for eleven years and a former DEA employee (CX4027 (Anthony, Dep. at 8 & 65)—did not believe the DEA took such supporting estimates "at face value to be a hundred percent accurate," but rather took them "into consideration." (CX4027 (Anthony, Dep. at 123) ("Q: Do you know how DEA would use this chart to make a decision about quota to grant? A: They would take it into consideration. Whether or not they take it at face value to be a hundred percent accurate, it's mostly an estimate of what they hope to be able to sell.")). Consistent with this, Mr. Anthony testified that there would be no ramifications for Impax if such estimates were inaccurate. (*See* CX4027 (Anthony, Dep. at 115-17 & 85-88)). That the launch dates and other aspects of the forecast submitted to the DEA reflected only best estimates of what Impax hoped to sell is supported by the fact that, in later forecasts, the launch date for oxymorphone ER remained an "obviously controversial element." (CX0514-001).

> 179. Impax also supported its quota request with an email from Meg Snowden, Impax's head in-house counsel. (CX3157 at 020 (Impax submissions to DEA)). In this email provided to the DEA, Ms. Snowden represented that Impax "would be in a position to launch [oxymorphone ER] on 6/15/2010" and that obtaining final approval was "the only legal or regulatory hurdle" Impax faced before an at-risk launch. (CX3157 at 020 (Impax submissions to DEA)).

RESPONSE TO FINDING NO. 179:

Respondent has no specific response to the first sentence of Proposed Finding No. 179. The second sentence of Proposed Finding No. 179 is misleading, incomplete, and incorrectly

characterizes the email from Ms. Snowden that was submitted as an attachment to Impax's quota request. (CX3157). First, nowhere in the cited email—or in any other portion of CX3157—is there a reference to an at-risk launch. While the communication acknowledges the ongoing patent litigation, it does not speak to any patent litigation damages risk at all. Instead, it states that Impax does not expect the patent litigation to end in the near future, but that "we do not need [a court decision] in order to obtain FDA approval or launch." (CX3157-020). It is in this context, and in the letter's larger context of providing documentation to support Impax's ability to sell oxymorphone ER and therefore acquire oxymorphone API quota, that Ms. Snowden notes that FDA approval is the "only legal/regulatory hurdle." (*See* CX3157-015-16).

180. In March 2010, the DEA partially granted Impax's January quota request. (CX2870 at 002 (Mar. 3, 2010 letter from the DEA) (allowing procurement of additional 147 kg of oxymorphone "to support commercial manufacturing efforts (validation and launch)"); CX2868 at 001 (Mar. 9, 2010 email chain); JX-001 at 008 (¶ 26)).

RESPONSE TO FINDING NO. 180:

Respondent has no specific response.

181. Impax purchased all of the API it was authorized to purchase under the March 2010 DEA quota allotment. (Camargo, Tr. 976-77). This oxymorphone API was enough to manufacture product sufficient for an initial launch of oxymorphone ER in 2010. (Camargo, Tr. 979-80; CX4028 (Camargo, Dep. at 172)). Impax, however, needed to request more quota and purchase more API to sustain the oxymorphone ER product after its launch. (CX2898 at 001 (May 12, 2010 email); CX4028 (Camargo, Dep. at 172)).

RESPONSE TO FINDING NO. 181:

Respondent has no specific response to the first sentence of Complaint Counsel's Proposed Finding No. 181. The second sentence of Proposed Finding No. 181 is vague and ambiguous as to the size of the hypothetical launch for which Impax's oxymorphone ER API was supposedly sufficient, what "initial launch," as opposed to launch means, and as to when in 2010 this hypothetical launch was to occur. All of these factors could affect the amount of API

Impax needed. The second sentence is also misleading and unsupported by the cited testimony of Joseph Camargo. Mr. Camargo never mentioned a possible launch in 2010. Mr. Camargo testified that Impax was "short of" API as of May 12, 2010, but "could have made some of the additional batches if we got the word to do so." (CX4028 (Camargo, Dep. at 172)). Specifically, Impax did not have "the desired amount" of API and it was "not optimal" for a theoretical launch because "normally we have an agreed-upon amount of inventory at the time of launch. And that would have required post PV inventory build lots. And . . . we didn't have enough at this point in time to complete all those batches. So we would have been launching with less than the targeted amount of inventory." (CX4028 (Camargo, Dep. at 172-73); *see* Camargo, Tr. 979-80 (API would leave Impax "a bit under our target amount of three months of inventory")). Respondent has no specific response to the third sentence of Proposed Finding No. 181.

> 182. To receive additional commercial manufacturing quota for 2010, John Anthony, the Impax employee responsible for seeking quota from the DEA, advised that Impax would need to submit "Letters of Intent" ("LOIs"). (CX2868 at 001 (Mar. 9, 2010 email); CX4027 (Anthony, Dep. at 139)). Letters of intent are written statements by pharmaceutical customers that "prove to the DEA that the Impax customers will order the Oxymorphone [requested by Impax] in quantities that exceed the Procurement Quota already granted." (CX2864 at 001 (Apr. 2, 2010 email chain and LOI)).

RESPONSE TO FINDING NO. 182:

Respondent has no specific response to the first sentence of Complaint Counsel's Proposed Finding No. 182. The second sentence of Proposed Finding No. 182 is inaccurate and misleading because it ignores the testimony of John Anthony, the author of the quoted language, who explained that letters of intent are only "an indication that the customer was willing to consider purchasing a finished product from Impax," and "are not legal documents that bind the customer into any specific quantity of purchase." (CX4027 (Anthony, Dep. at 59) (expressly rejecting suggestion that letters of intent are "as accurate as possible"); *see* Engle, Tr. 1788

(letters of intent do not contain "pricing or any agreement")). Indeed, potential customers are "reluctant to sign such documents" and have to be "reassured that, you know, this is in no way binds them, because the market might change, the business environment might change, and it might be unfavorable for them in the future . . . to purchase from us." (CX4027 (Anthony, Dep. at 59-60)). In providing such letters, customers generally understand the purpose of the letters is to support DEA quota requests, not to create future commercial obligations. (*See* Engle, Tr. 1797 (describing a letter of intent as "a form letter listing the different strengths and the packages size, and it asks the customer for their good-faith estimate, is if Impax were to have this product, how much of the product would you be likely to buy, based on their own forecast of how much they need or how much they sell, with the -- the idea is that it's a good-faith estimate to secure additional quota from DEA.")).

> 183. Impax's January 2010 quota request to the DEA had not included any LOIs. (CX2876 at 003 (Jan. 11, 2010 Impax email string)). Impax had been concerned that disclosing its marketing intentions to customers would put Impax at a competitive disadvantage to Endo. (CX2876 at 003 (Jan. 11, 2010 email); CX4027 (Anthony, Dep. at 130-31); *see also* CX2576 at 001-02 (in Feb. 2010, Endo sought "reconnaissance from McKesson" to determine Impax's oxymorphone launch timeline); CX2864 at 005 (in Mar. 2010 McKesson sent Impax an LOI). Impax's desire to maintain secrecy for its launch plans is consistent with an actual intention to launch, rather than mere bluffing. (Bazerman, Tr. 930-31; *see also* CX5001 at 033-34 (¶¶ 62-63) (Bazerman Report) (discussing Impax's desire to make money from generic Opana ER in 2010 or 2011)).

RESPONSE TO FINDING NO. 183:

Respondent has no specific response to the first and second sentences of Complaint Counsel's Proposed Finding No. 183.

The third sentence of Proposed Finding No. 183 is not supported by the cited evidence. To the extent Complaint Counsel purports to cite Professor Bazerman's testimony and expert report for factual propositions, it violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or

documents." Moreover, Professor Bazerman did not testify that Impax had an "actual intention to launch" or that any of Impax's actions was consistent with such an intent. He stated only that maintaining confidentiality is inconsistent with bluffing. (Bazerman, Tr. 930-31).

184. Despite these earlier concerns about secrecy, in order to receive additional quota that could sustain the launch of oxymorphone ER, Impax also began working with customers to obtain LOIs as justification for an additional quota request. (CX2868 at 001 (Mar. 9, 2010 Impax email) ("Impax must submit 'Letters of Intent to Purchase' signed by customers . . . to receive additional 2010 Procurement Quota."); CX2864 at 001-05 (Apr. 2010 email chain attaching LOIs); CX2882 (Apr. 2010 email chain attaching LOI)). To secure LOIs, Impax had to tell customers that "Impax is preparing the launch" of oxymorphone ER in 2010. (CX4038 (Engle, Dep at 153-54); CX4027 (Anthony, Dep. at 81)).

RESPONSE TO FINDING NO. 184:

Respondent has no specific response to Complaint Counsel's Proposed Finding No. 184, other than to note that none of the cited evidence supports the proposition that Impax had "concerns for secrecy."

185. By April 12, 2010, Impax had received LOIs from four customers. (CX2882 at 001 (Apr. 2010 email chain and LOI) (attaching Walgreens' letter of intent; referencing ABC's, Cardinal's, and McKesson's letters of intent)). The customer commitments in these LOIs represented 88% of the total generic oxymorphone ER demand Impax expected in 2010. (CX2882 at 001 (Apr. 2010 email chain and LOI)).

RESPONSE TO FINDING NO. 185:

Respondent has no specific response to the first sentence of Complaint Counsel's Proposed Finding No. 185. The second sentence of Proposed Finding No. 185 is an incomplete and inaccurate characterization of the letters of intent. First, there is no record support for the proposition that these documents reflect "customer commitments," rather than "good-faith estimate[s]"—prepared for the express purpose of assisting Impax in procuring DEA quota—of "how much of the product [the customer] would be likely to buy" if Impax were to sell it. (Engle, Tr. 1797 (describing a letter of intent as "a form letter listing the different strengths and

the packages size, and it asks the customer for their good-faith estimate, is if Impax were to have this product, how much of the product would you be likely to buy, based on their own forecast of how much they need or how much they sell, with the -- the idea is that it's a good-faith estimate to secure additional quota from DEA."); CX4027 (Anthony, Dep. at 59) (letters of intent are "indication[s] that the customer was willing to consider purchasing a finished product from Impax" and "are not legal documents that bind the customer into any specific quantity of purchase."); CX4027 (Anthony, Dep. at 59) (expressly rejecting the suggestion from Complaint Counsel that letters of intent are "as accurate as possible"); *see* Engle, Tr. 1788 (noting that letters of intent do not contain "pricing or any agreement")).

186. On April 15, 2010, Impax submitted an additional supplemental request for oxymophone quota to the DEA, which included the LOIs from Impax's customers. (CX3157 at 035-37 (Apr. 15, 2010 Impax letter to DEA); CX2881 at 002-03 (June 15, 2010 letter from DEA granting Impax's request); JX-001 at 009 (¶ 27)).

RESPONSE TO FINDING NO. 186:

Respondent has no specific response.

187. After the Impax-Endo Settlement Agreement was executed, the DEA granted Impax's April 2010 quota request. (CX2881 at 002-03 (June 15, 2010 letter from DEA granting Impax's request); JX-001 at 009 (¶ 30); Camargo, Tr. 992-93). However, the Impax-Endo Settlement Agreement had nullified Impax's plans to use this 2010 oxymorphone quota. (Camargo, Tr. 992-93).

RESPONSE TO FINDING NO. 187:

Respondent has no specific response.

b) Impax manufactured enough oxymorphone ER for a launch as early as June 2010

188. The steps Impax took towards an at-risk oxymorphone ER launch also included manufacturing product. (CX4023 (Hildenbrand, Dep. at 41-42, 155)). In fact, Operations met its 2010 MBOs for an oxymorphone ER launch by manufacturing generic oxymorphone ER product during 2010. (CX2899 at 002 (2010 Operations Objectives &

Results) (head of operations sharing accomplishments, including "Oxymorphone: approved & ready to launch same day but settled (achieved goal)"); Koch, Tr. 247, 251-52 (describing goals of "successfully launching" oxymorphone ER); CX2562 at 002 (2010 Company Key Goals); Camargo, Tr. 1001-02).

RESPONSE TO FINDING NO. 188:

The first sentence of Complaint Counsel's Proposed Finding No. 188 is misleading and not supported by the cited evidence. Mr. Hildenbrand did not testify about Impax taking any steps toward an at-risk launch. He testified generally about the steps necessary to prepare a new product, and the fact that Impax had completed process validation for oxymorphone ER in 2010. (CX4023 (Hildenbrand, Dep. at 41-42, 155)). Process validation need not be repeated once it is successfully completed and, as a result, the process validation Impax conducted in 2010 could (and did) support a launch after 2010. (*See* CX4010 (Mengler, IHT at 71) ("it's a one and done, once you have done process validation")).

The second sentence of Proposed Finding No. 188 is incomplete and misleading. The actual objective in the cited MBO documents stated, "Achieve new product launch on the day of ANDA approval *without putting Company into unnecessary financial or legal risks*." (CX2899-002; CX3069-002 (emphasis added)). Joseph Camargo, Impax's Vice President of Supply Chain, testified that achieving the stated objective meant receiving sign off on a process validation report and being ready to execute a launch inventory build if management so instructed, which it never actually did in the case of oxymorphone ER. (Camargo, Tr. 1033-34). The stated objective was also consistent with Impax's efforts to have every product in its generic pipeline "launch ready" at the earliest date allowed by the Hatch-Waxman Act. (CX4023 (Hildenbrand, Dep. at 60-61); CX4030 (Hsu, Dep. at 85-86)).

189. Oxymorphone ER entered Impax's 18-month production window in January 2009. (Camargo, Tr. 1004; CX4028 (Camargo, Dep. at 29-40, 75-80); CX4029 (Sica, Dep. at 36-37)).

RESPONSE TO FINDING NO. 189:

Respondent has no specific response.

190. By October 2009, Impax had added oxymorphone ER to its Product Launch Checklist. (CX2915 at 001, 03 (Oct. 2009 Product Launch Checklist)).

RESPONSE TO FINDING NO. 190:

Respondent has no specific response.

191. As of March 2010, Impax had received enough quota and purchased enough API to enable it to complete process validation for generic oxymorphone ER and launch with "just under three months of inventory." (CX4028 (Camargo, Dep. at 172-73); *see also* Camargo, Tr. 975-76). Impax, however, desired additional oxymorphone quota from the DEA to sustain demand for the product after launching. (CX4028 (Camargo, Dep. at 172-73); CX2898 at 001 (May 12, 2010 email re: Launch Planning) ("Impax submitted an additional request in April 2010 for quota "needed to sustain the product shortly after launch.")).

RESPONSE TO FINDING NO. 191:

The first sentence of Proposed Finding No. 191 is incomplete and misleading. As of May 2010, Impax did not have "the desired amount" of API and it was "not optimal" for a theoretical launch because "normally we have an agreed-upon amount of inventory at the time of launch. And that would have required us to complete all of the post PV inventory build lots. And . . . we didn't have enough at this point in time to complete all those batches. So we would have been launching with less than the targeted amount of inventory." (CX4028 (Camargo, Dep. at 172-73); *see* Camargo, Tr. 979-80 (API would leave Impax "a bit under our target amount of three months of inventory")).

The second sentence of Proposed Finding No. 191 is not supported by the cited evidence. The cited evidence does not state that Impax "desired" additional quota to sustain demand for an actual launch. The cited documents state only that Impax would need additional quota in order

to be in a position to launch with "the targeted amount of inventory." (CX4028 (Camargo, Dep. at 172-73); *see* CX2898).

192. To sell commercial drug products, pharmaceutical manufacturers are required by the FDA to complete process validation. Through process validation, manufacturers seek to demonstrate that their manufacturing process can be scaled up to manufacture commercial size batches, that the process is repeatable, and that the product created is of a satisfactory quality. (Camargo, Tr. 967; CX4023 (Hildenbrand, Dep. at 136-37)). The time it takes to complete process validation can vary from a month to an entire year, depending on the product specifications. (CX4023 (Hildenbrand, Dep. at 144)).

RESPONSE TO FINDING NO. 192:

Respondent has no specific response other than to clarify that process validation can be completed any time before launch and, once successfully completed, need not be repeated. (CX4010 (Mengler, IHT at 71) ("it's a one and done, once you have done process validation")).

193. Process validation concludes with the approval of a "PV summary report," which is reviewed and approved by various departments within Impax. (CX4028 (Camargo, Dep. at 171); CX4023 (Hildenbrand, Dep. at 136-37)). Process validation must be complete before a product is launched. (Camargo, Tr. 967).

RESPONSE TO FINDING NO. 193:

Respondent has no specific response.

194. The batches that are manufactured as part of process validation can be sold commercially as part of the launch inventory. (Camargo, Tr. 967; CX4023 (Hildenbrand, Dep. at 137-38)). However, if process validation batches are not sufficient to meet projected demand, Impax will manufacture additional product for a launch. (Camargo, Tr. 967-68).

RESPONSE TO FINDING NO. 194:

Respondent has no specific response.

195. The terms "inventory build" and "launch inventory build," as used by Impax personnel, include process validation batches among the commercial product needed for the initial launch. (CX4023 (Hildenbrand, Dep. at 137-39); CX2898 (May 12, 2010 Camargo email); Camargo Tr. 967-68; CX4028 (Camargo, Dep. at 51-52)).

RESPONSE TO FINDING NO. 195:

Complaint Counsel's Proposed Finding No. 195 is inaccurate. The evidence is clear that the phrase "launch inventory build" refers to the product "manufactured after the PV summary report is signed off on." (Camargo, Tr. 968 ("Q. The launch inventory build is the additional product manufactured when the process validation batches are not enough to meet your expected needs to launch the product, correct? A. That's correct, and they would be manufactured after."); CX4028 (Camargo, Dep. at 51-52) (same); CX2898 (despite process validation complete, "we will not commence the launch inventory build until we receive direction to do so from senior mgmt.")).

196. As of May 11, 2010, using the API it already had on hand, Impax aimed to complete manufacturing of the launch inventory build by May 28, 2010. (Camargo Tr. 985-86).

RESPONSE TO FINDING NO. 196:

Complaint Counsel's Proposed Finding No. 196 is inaccurate and misleading. The cited testimony says nothing about using the API on hand to do anything, but rather speaks to theoretical goals in one document that Mr. Camargo noted was not necessarily up to date. (Camargo, Tr. 985-86). Looking beyond this snippet of testimony about a single line item in a single Excel spreadsheet, the record—including several contemporaneous documents—actually indicates that Impax stopped its launch preparedness efforts in May 2010. (*See, e.g.*, CX2904-001 (May 25, 2010 email chain in which Chuck Hildenbrand tells Joe Camargo and others, "I don't see the OXM happening in June, lets replace it with more MDD")). For example, as early as May 7, 2010, the Supply Chain Group reported that they would not begin a launch inventory build until they were instructed by senior management. (RX-186.0004 ("We are then await [sic] management decision to proceed with 8-lot launch inventory build."); Camargo, Tr. 1016-17

("At that point, we need management decision and direction to proceed with the launch inventory build.")). Again on May 12, 2010, Mr. Camargo indicated that "we will not commence the launch inventory build until we receive direction to do so from senior management." (CX2898). The plan was to wait for directions from senior management before beginning a launch inventory build. (Camargo, Tr. 1017).

On May 25, 2010, Impax's senior director of operations, Chuck Hildenbrand, instructed Mr. Camargo, to shift manufacturing resources to another product, noting that "I don't see the OXM happening in June." (CX2904-001; Camargo, Tr. 1017-18). Mr. Camargo responded that he had already "advised the team that it was unlikely that we would make the Oxymorphone." (CX2904-001; *see* Camargo, Tr. 1020 ("I had been given no direction at that point in time to actually execute the product launch, and it seemed unlikely to me that we would ever do that")). And according to a June 8, 2010, planning document, the date on which Impax anticipated to be "Launch Ready" still remained "TBD." (CX2914-003; CX4023 (Hildenbrand, Dep. at 209)).

197. By May 12, 2010, Impax had manufactured eight lots of the launch inventory build. (Camargo, Tr. 978, 986-87; CX2898 (May 12, 2010 email re: Launch Planning)). This included the process validation inventory build lots, which Impax intended to sell. (Camargo, Tr. 967-68; CX4023 (Hildenbrand, Dep. at 138-39)). After manufacturing these lots, Impax had $1,652,710 worth of oxymorphone API remaining. (CX0421 at 001 (June 21, 2010 email)).

RESPONSE TO FINDING NO. 197:

The first sentence of Complaint Counsel's Proposed Finding No. 197 is inaccurate and not supported by the cited evidence. The document says nothing about manufacturing a launch inventory build, much less that Impax had already undertaken a launch inventory build. In fact, it *says the opposite*: "we will not commence the launch inventory build until we receive direction to do so from senior management." (CX2898-001; *see* Camargo, Tr. 1016-17 ("At that point, we need management decision and direction to proceed with the launch inventory

build.")). The testimony cited in the first sentence of the Proposed Finding speaks only to (1) theoretical goals in a single line item in a single Excel spreadsheet that Mr. Camargo noted was not necessarily up-to-date, (Camargo Tr. 985-86), and (2) the process validation batches Impax had completed, (Camargo, Tr. 978). While process validation batches potentially could be sold, they are not part of a "launch build" or "launch build inventory," (Camargo, Tr. 968 ("Q. The launch inventory build is the additional product manufactured when the process validation batches are not enough to meet your expected needs to launch the product, correct? A. That's correct, and they would be manufactured after"); CX4028 (Camargo, Dep. at 51-52) (same)).

The second sentence of Proposed Finding No. 197 is inaccurate and not supported by the cited evidence. The cited evidence says nothing about Impax intentions with respect to any oxymorphone ER process validation lots.

Respondent has no specific response to the third sentence of Proposed Finding No. 197 other than to clarify that "these lots" refers to the process validation lots, not any launch inventory build.

198. As of May 12, 2010, Impax expected to complete testing on all launch inventory batches by June 11, 2010. (Camargo, Tr. 978, 986-87; CX3078 (May 11, 2010 email attaching updated Product Launch Checklist). Impax was planning for a launch with just under three months of inventory. (CX2898 (May 12, 2010 email)).

RESPONSE TO FINDING NO. 198:

The first sentence of Complaint Counsel's Proposed Finding No. 198 is incomplete and misleading. The record indicates that as early as May 7, 2010, the Supply Chain Group had completed process validation but reported that they would not begin a launch inventory build or any other steps with respect to launch inventory until they were instructed by senior management. (RX-186.0004 ("We are then await [sic] management decision to proceed with 8-lot launch inventory build."); Camargo, Tr. 1016-17 ("At that point, we need management

decision and direction to proceed with the launch inventory build.")). Again on May 12, 2010, Mr. Camargo indicated that "we will not commence the launch inventory build until we receive direction to do so from senior management." (CX2898-001). The plan was to wait for directions from senior management before beginning a launch inventory build. (Camargo, Tr. 1017).

On May 25, 2010, Impax's Senior Director of Operations, Chuck Hildenbrand, instructed Mr. Camargo to shift manufacturing resources to another product, noting that "I don't see the OXM happening in June." (CX2904-001; Camargo, Tr. 1017-18). Mr. Camargo responded that he had already "advised the team that it was unlikely that we would make the Oxymorphone." (CX2904-001; *see* Camargo, Tr. 1020 ("I had been given no direction at that point in time to actually execute the product launch, and it seemed unlikely to me that we would ever do that")). And according to a June 8, 2010, planning document, the date on which Impax anticipated to be "Launch Ready" still remained "TBD." (CX2914-003; CX4023 (Hildenbrand, Dep. at 209)).

The second sentence of Proposed Finding No. 198 is inaccurate, misleading, and not supported by the cited evidence. The cited document (CX2898) does not state that Impax was planning for a launch with just under three months of inventory, only that if Impax theoretically were to launch, it would have to do so with less than three months inventory. (CX2898-001). The cited document also makes clear that the Operations team would "not commence the launch inventory build until we receive direction to do so from senior mgmt." (CX2898-001).

Mr. Camargo also testified that Impax was "short of" API, but "could have made some of the additional batches if we got the word to do so." (CX4028 (Camargo, Dep. at 172)). Specifically, Impax did not have "the desired amount" of API and it was "not optimal" for a theoretical launch because "normally we want to have an agreed-upon amount of inventory at the time of launch. And that would have required post PV inventory build lots. And . . . we didn't

have enough at this point in time to complete all those batches. So we would have been launching with less than the targeted amount of inventory." (CX4028 (Camargo, Dep. at 172-73); *see* Camargo, Tr. 979-80 (API would leave Impax "a bit under our target amount of three months of inventory")).

199. On May 13, 2010, the day Impax received tentative FDA approval, CEO Larry Hsu instructed the head of Impax's Operations department to "move on with our next step of preparation for launch." (CX2929 at 001 (May 2010 Impax email chain)). At that point, the team needed only about two more weeks to finalize the launch inventory manufacturing. (CX2929 at 001 (May 2010 Impax email chain)). This included making six lots of product in addition to the product that was manufactured as part of process validation once the PV summary report was finalized. (CX2929 at 001 (May 2010 Impax email chain); CX2898 (May 12, 2010 Camargo email) (PV batches were already manufactured)).

RESPONSE TO FINDING NO. 199:

The first and second sentences of Complaint Counsel's Proposed Finding No. 199 are incomplete and misleading. The full statement quoted in the first sentence is, "Let's move on with our next step of preparation for launch . . . *the court stuff[] should occur timely enough for us to build inventory*." (CX2929-001 (emphasis added; ellipsis in original)). The quoted language attributed to Dr. Hsu, moreover, was actually written by Chris Mengler. With respect to timing, the document actually states that "*[i]f we elect to move forward*, it will take about 2 weeks to complete mfg and 1-2 weeks, if we push for QC/QA release." (CX2929-001 (emphasis added)). Finally, the document also indicates that Impax "likely [] will make launch decision based on court decision on the PI." (CX2929-001).

The Proposed Finding selectively quotes and characterizes the document in an effort to avoid the documents' plain language indicating that Impax's launch preparation efforts were on hold, pending additional information regarding the patent litigation. This is supported by extensive evidence that, as of May 2010, Impax had stopped its oxymorphone launch

preparedness efforts—before ever starting a launch build—and shifted those resources to a different product. (*See, e.g.*, CX2904-001 (May 25, 2010, email chain in which Chuck Hildenbrand tells Joe Camargo and others, "I don't see the OXM happening in June, lets replace it with more MDD")).

Mr. Camargo explained that the Operations team did not believe a launch of oxymorphone was likely "given the situation where it would have been a[n] at-risk launch, and we had no history of launching products at risk due to . . . what could happen if were to lose in the litigation, so . . . I had been given no direction at that point in time to actually execute the product launch, and it seemed unlikely to me that we would ever do that." (Camargo, Tr. 1020). The Operations team never undertook a full launch inventory build in support of an oxymorphone ER launch. (Camargo, Tr. 1020).

Respondent has no specific response to the third sentence of Proposed Finding No. 199.

200. By May 20, 2010, the PV summary report had been approved and process validation was complete. (Camargo, Tr. 978-79, 990; CX3348 at 003 (May 20, 2010 Launch Planning Document); CX4023 (Hildenbrand, Dep. at 157)).

RESPONSE TO FINDING NO. 200:

Respondent has no specific response.

201. The manufactured process validation batches were then prepared for commercial sale. Impax brite-stocked some of the batches of product. (CX3348 at 003 (May 20, 2010 Launch Planning Document); CX3053 at 001 (June 2010 email chain listing manufactured oxymorphone inventory). Brite stock is product that is manufactured and placed in bottles but not labeled. (CX4001 (Koch, IHT at 157-58, 233); Camargo, Tr. 995). The remainder of the manufactured product was finished goods – goods that are bottled and labeled. (Koch, Tr. 253-54; Camargo, Tr. 995).

RESPONSE TO FINDING NO. 201:

The first sentence of Complaint Counsel's Proposed Finding No. 201 is not supported by any record evidence and should be disregarded because it violates the Court's Order on Post-

Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2).

Respondent has no specific response to the second, third, and fourth sentences of Proposed Finding No. 201 other than to clarify that there is no cited evidence supporting when the brite-stocking occurred. The cited evidence states only that *by* May 20, some batches had been brite-stocked. The record is clear that the Operations team had already stopped their oxymorphone ER preparation efforts. (RX-186.0004 (May 7, 2010, email noting awaiting management instruction before further preparation); CX2898-001 (same on May 12, 2010); CX2904-001 (by May 25, 2010, Operations had shifted resources to another product "advised the team that it was unlikely that we would make the Oxymorphone")).

202. In sum, prior to the Impax-Endo Settlement Agreement, Impax had manufactured over four months of supply for the 5 mg tablets, over three months for the 10 mg tablets, over one month for the 20 mg tablets, and two months for the 40 mg tablets. (CX4028 (Camargo, Dep. 164-65)).

RESPONSE TO FINDING NO. 202:

Complaint Counsel's Proposed Finding No. 202 is inaccurate and not supported by the cited evidence. Mr. Camargo testified that if Impax "us[ed] the API available" to conduct a launch inventory build it would have product to last a certain number of months. (CX4028 (Camargo, Dep. at 164-65); CX3063). In the case of the 20mg tablet, Impax would need "1 PV lot *plus 2 inventory build lots* [to] cover[] demand through late July (1+ months of coverage)." (CX3063-001 (emphasis added)). For the 40 mg tablet, Impax would need "2 PV lots *plus 6 inventory build lots* [to] cover[] demand through mid Aug (1+ months of coverage)." (CX3063-002 (emphasis added)). There is no evidence that Impax undertook any launch inventory build. (CX2898-001 ("we will not commence the launch inventory build until we receive direction to

do so from senior management"); Camargo, Tr. 1016-17, 1020 ("At that point, we need management decision and direction to proceed with the launch inventory build.")).

c) Impax had to discard over $1.3 million of manufactured oxymorphone ER product

203. As the Opana ER settlement discussions progressed, Impax's preparations for a June 2010 oxymorphone ER launch were postponed. (CX3062 (May 26, 2010 Mengler email) (instructing Operations to postpone packaging oxymorphone ER); CX0320 at 001 (May 26, 2010 email to Mengler with initial term sheets from Endo)). Eventually, Impax's efforts to complete manufacturing of the launch inventory batches were stopped "in view of [the Endo/Impax] settlement." (CX2542 (June 9-10, 2010 email chain on oxymorphone quota); Camargo, Tr. 989, 991; *compare* CX2914 at 003 (June 8, 2010 Product Launch Checklist) (listing oxymorphone ER as "DROPPED" because of the settlement) *with* CX3078 at 003 (May 11, 2010 Product Launch Checklist) (listing oxymorphone ER "Launch Ready" date as Jun. 14, 2010)).

RESPONSE TO FINDING NO. 203:

The first sentence of Complaint Counsel's Proposed Finding No. 203 is inaccurate, misleading, and not supported by the cited evidence. CX3062 does not contain an instruction to any employee, refer to any settlement discussions, or make any reference to a launch of oxymorphone ER. It simply states, "No rush to pack oxym." (CX3062). This is consistent with the numerous emails about halting oxymorphone launch preparedness efforts well before Impax and Endo began discussing settlement in 2010. (*See, e.g.*, RX-186.0004 (May 7, 2010, email: "We are then await [sic] management decision to proceed with 8-lot launch inventory build."); Camargo, Tr. 1016-17 ("At that point, we need management decision and direction to proceed with the launch inventory build."); CX2898-001 (May 12, 2010, email: "we will not commence the launch inventory build until we receive direction to do so from senior management.")).

The second sentence of Proposed Finding No. 203 is inaccurate and misleading. It offers a misleadingly selective quotation from CX2542, which reflects Impax withdrawing a pending DEA quota request—not Impax aborting some ongoing launch preparation or launch build

effort—to "create good will" with the DEA. The second sentence also selectively quotes one-word answer from Mr. Camargo's trial testimony, (Camargo, Tr. 989), ignoring the more in depth discussion of this issue in Mr. Camargo's contemporaneous documents and elsewhere in his trial testimony. (*See, e.g.*, CX2905 ("launch inventory build was ready to start should management give the go-ahead."); Camargo, Tr. 1016-17 ("At that point [May 12, 2010], we need management decision and direction to proceed with the launch inventory build.")). The record further reflects that, as of May 24, 2010, Mr. Camargo has already "advised the team that it was unlikely that we would make the Oxymorphone." (CX2904-001).

204. But for the settlement, Impax would have been "ready to launch [on the] same day" as ANDA approval in June 2010. (CX2899 at 002 (2010 Operations MBOs); CX4028 (Camargo, Dep. at 205-06)).

RESPONSE TO FINDING NO. 204:

Complaint Counsel's Proposed Finding No. 204 is incomplete, inaccurate, and misleading. The cited document (CX2899) states that the Operations team's objective was to, "Achieve new product launch on the day of ANDA approval *without putting Company into unnecessary financial or legal risks*." (CX2899-002; CX3069-002 (emphasis added)). Joseph Camargo, Impax's Vice President of Supply Chain, testified that achieving the stated objective meant receiving sign off on a process validation report and being ready to execute a launch inventory build if management so instructed. (Camargo, Tr. 1033-34). The stated objective was also consistent with Impax's efforts to have every product in its generic pipeline "launch ready" at the earliest date allowed by the Hatch-Waxman Act. (CX4023 (Hildenbrand, Dep. at 60-61); CX4030 (Hsu, Dep. at 85-86)).

Impax, moreover, would not have actually been "ready to launch" until it manufactured the launch inventory build, which required management authorization. Yet as early as May 7,

2010, the Supply Chain Group had stopped preparedness efforts because it had not received instructions from management. (RX-186.0004 ("We are then await [sic] management decision to proceed with 8-lot launch inventory build."); Camargo, Tr. 1016-17 ("At that point, we need management decision and direction to proceed with the launch inventory build.")). Again on May 12, 2010, Mr. Camargo indicated that "we will not commence the launch inventory build until we receive direction to do so from senior management." (CX2898-001). This meant that the plan was to wait for directions from senior management before beginning a launch inventory build. (Camargo, Tr. 1017).

And by May 25, 2010, the Operations group had shifted its resources to another product, noting that "I don't see the OXM happening in June." (CX2904-001; Camargo, Tr. 1017-18). Mr. Camargo explained that he had already "advised the team that it was unlikely that we would make the Oxymorphone." (CX2904-001). Mr. Camargo testified that "given the situation where it would have been a[n] at-risk launch, and we had no history of launching products at risk due to . . . what could happen if were to lose in the litigation, so . . . I had been given no direction at that point in time to actually execute the product launch, and it seemed unlikely to me that we would ever do that." (Camargo, Tr. 1020).

> 205. Ultimately, the Executive Committee never asked the Impax Board one way or the other to reach a decision for an at-risk launch of oxymorphone ER. (JX-003 at 011 (¶ 70); Koch, Tr. 332; Snowden, Tr. 470; CX2704 at 018-19 (Impax Objection and Response to Interrogatory No. 10)). Before the Board was asked to make any at-risk launch decision, Impax entered the Impax-Endo Settlement Agreement on June 8, 2010. (JX-001 at 009 (¶ 33); Koch, Tr. 299, 333-35).
>
> **RESPONSE TO FINDING NO. 205:**

Respondent has no specific response to the first sentence of Complaint Counsel's Proposed Finding No. 205. The second sentence of Proposed Finding No. 205 is inaccurate and not supported by the cited evidence in its attempt to suggest the Executive Committee was

planning to ask, and but for the Impax-Endo Settlement would have asked, the Board to make an at-risk launch decision. The record is clear that senior management never decided to recommend an at-risk launch such that they would need to ask the Board anything. (Mengler, Tr. 547-48, 584; CX4002 (Smolenski, IHT at 99) ("there was never a 'final decision' to launch")). In fact, Impax senior management did not believe a limited at-risk launch was a good business strategy for oxymorphone ER. (Snowden, Tr. 503-04).

Arthur Koch, Impax's CFO at the time of settlement, testified that Impax never intended to launch oxymorphone ER at-risk launch. (Koch, Tr. 324-25 ("JUDGE CHAPPELL: Are you a hundred percent certain you would be aware of whether or not Impax planned an at-risk launch of Opana ER? WITNESS: Absolutely. I would have a key role in that. JUDGE CHAPPELL: Do you know in fact whether Impax intended an at-risk launch of Opana ER? . . . THE WITNESS: I do know. *JUDGE CHAPPELL: Did they intend to do an at-risk launch of Opana ER? THE WITNESS: No.*" (emphasis added))). And in contemporaneous documents, Impax's founder and CEO at the time of settlement, Dr. Larry Hsu, made the same point: "*it's unlikely we will launch Opana ER this year (I actually prefer not to launch this year for obvious reason[s]).*" (RX-297.0002 (emphasis added)).

206. For Impax, a "big amount" of unsellable and discarded product was product worth more than a million dollars. (CX4004 (Engle, IHT at 134)). Scrapping large amounts of product could possibly get members of the sales and marketing team "in trouble." (CX4004 (Engle, IHT at 134)).

RESPONSE TO FINDING NO. 206:

Complaint Counsel's Proposed Finding No. 206 is an incomplete and misleading characterization of Mr. Engle's testimony during his investigational hearing. During that proceeding, Mr. Engle spoke about discarding "product because it expired *because [he] over-projected*" the amount of the product that needed to be manufactured. (CX4004 (Engle, IHT at

134) (emphasis added)). Later in the proceeding, Mr. Engle clarified that discarding product because Impax sought to be prepared for all possible outcomes "falls under the category of cost of doing business in weighing all your options and all your -- your options, your risks," and that no one "got in trouble" as a result of discarded oxymorphone ER. (CX4004 (Engle, IHT at 181)). Mr. Engle also testified that write offs of this magnitude were not unusual at Impax, and provided another example of when Impax incurred a $1.5 million loss as a "cost of doing business." (CX4004 (Engle, IHT at 182) (citing caprofen example, and noting other situations in which this likely occurred)).

At trial, Mr. Engle reiterated this point when he testified unambiguously that "[t]hrowing away product or discarding product in about a 1.5 million range happens frequently and it—it's not unusual." (Engle, Tr. 1785-86). Other witness testimony supports the fact that discarding products or materials was "a matter of course pretty much every month." (Camargo, Tr. 1020-21, 1033; *see* Koch, Tr. 273 (discarding and writing off product is a routine and "small cost" of doing business)). For example, over $1 million in non-oxymorphone ER products was written off in April 2010, and $560,000 worth of non-oxymorphone ER product was written off in June 2010. (CX2905-003; CX2896-002-03; Camargo, Tr. 1023-24)). Impax also discarded and wrote off roughly $25 million in finished product in 2017. (Engle, Tr. 1786).

> 207. Forecasting and planning by Impax personnel tried to be accurate to minimize the chance that Impax would have to throw away large amounts of manufactured product because the product expired before being sold. (CX4004 (Engle, IHT at 133-34)). Operations was evaluated on the cost of products that had to be discarded. (CX2899 at 003 (2010 Operations Objectives) (discussing COGS and cost of rejected batches); CX4023 (Hildenbrand, Dep. at 198)).

RESPONSE TO FINDING NO. 207:

Respondent has no specific response to the first sentence of Complaint Counsel's Proposed Finding No. 207. The second sentence of Proposed Finding No. 207 is incomplete and

misleading because it ignores the testimony of Mr. Hildenbrand, who explained that the evaluation related only to "variable pay[and] Bonus targets," not Operations' overall performance. (CX4023 (Hildenbrand, Dep. at 198)). Even then, whether the discarding of product will impact bonus compensation depends on the reason for discarding the product, and that if such a loss occurs as a result of generally accepted costs of doing business, it generally will not negatively affect compensation. (CX4023 (Hildenbrand, Dep. at 199-200) ("if a decision is made whether it [is] due to risk or opportunity to not to launch, we don't get approval, whatever it is, but we were ready to have that loss counted against us" before the product was ever made)). As Impax's CEO at the time of the settlement explained, "in order to make sure whatever the discussion or the decision is meaningful, you have to have a supply ready. Then you can talk about [possible launches]. . . . [Y]ou have to have material ready. Then you decide which way you want to go." (CX4030 (Hsu, Dep. at 86)). This is "routine" and consistent with industry practice. (Koch, Tr. 271; CX3278-101). Indeed, "it's much less expensive, in terms of the company's financial goals, to prepare a small cost item to be prepared for the launch into a large market." (Koch, Tr. 270-71).

> 208. Nevertheless, Impax discarded approximately $1.4 million in manufactured oxymorphone ER product, including brite stocked and finished goods, due to the Impax-Endo Settlement Agreement. (CX2899 at 003 (2010 Operations Objectives); Camargo, Tr. 993-98; CX2896 at 002 (Monthly Report—July 2010); CX0421 at 001-02 (June 21, 2010 Impax email chain) (discussing how to treat oxymorphone ER that had been produced); CX3053 at 001-02 (June 4, 2010 Impax email chain) (listing book value of manufactured oxymorphone ER)). While it was typical for Impax to discard some product or materials in inventory every month, a disposal of this "big amount" of manufactured oxymorphone ER product was not a common practice. (*See* CX4004 (Engle, IHT at 133-34)). Impax was forced to discard this product because it would expire before it could be sold in 2013. (CX3164 at 017-18 (Impax Response to Request for Admission Nos. 38 and 39)).

RESPONSE TO FINDING NO. 208:

Complaint Counsel's Proposed Finding No. 208 is inaccurate and misleading. The first sentence is misleading because the referenced product was not discarded "due to the Impax-Endo Settlement Agreement." The Settlement and License Agreement did not require Impax to discard any materials; these materials were discarded because of expiration dates. (Camargo, Tr. 998). Indeed, Impax was able to use much of the API it had purchased for its 2013 launch. (Camargo, Tr. 1022).

The second sentence of Proposed Finding No. 208 is an inaccurate and misleading characterization of Mr. Engle's testimony during his investigational hearing. During that proceeding, Mr. Engle spoke about discarding "product because it expired *because [he] over-projected*" the amount of the product that needed to be manufactured. (CX4004 (Engle, IHT at 134) (emphasis added)). Later in the proceeding, Mr. Engle clarified that discarding product because Impax sought to be prepared for all possible outcomes "falls under the category of cost of doing business in weighing all your options and all your -- your options, your risks," and that no one "got in trouble" as a result of discarded oxymorphone ER. (CX4004 (Engle, IHT at 181)). Mr. Engle also testified that write offs of this magnitude were not unusual at Impax, and provided another example of when Impax incurred a $1.5 million loss as a "cost of doing business." (CX4004 (Engle, IHT at 182) (citing caprofen example, and noting other situations in which this likely occurred)).

At trial, Mr. Engle reiterated this point when he testified unambiguously that "[t]hrowing away product or discarding product in about a 1.5 million range happens frequently and it—it's not unusual." (Engle, Tr. 1785-86). Other witness testimony supports the fact that discarding products or materials was "a matter of course pretty much every month." (Camargo, Tr. 1020-

21, 1033; *see* Koch, Tr. 273 (discarding and writing off product is a routine and "small cost" of doing business)). For example, over $1 million in non-oxymorphone ER products was written off in April 2010, and $560,000 worth of non-oxymorphone ER product was written off in June 2010. (CX2905-003; CX2896-002-03; Camargo, Tr. 1023-24)). Impax also discarded and wrote off roughly $25 million in finished product in 2017. (Engle, Tr. 1786).

Respondent has no specific response to the third sentence of Complaint Counsel's Proposed Finding No. 208.

> 209. In addition to the manufactured product, Impax was also left with more than $1.6 million in oxymorphone API with a 2011 expiration date. (CX2888 at 002 (June 21, 2010 Smith email re OXM)). It is unclear what, if anything, Impax did with this remaining oxymorphone API. (CX2928 at 015 (Impax Response to Interrogatory No. 20)).

RESPONSE TO FINDING NO. 209:

Respondent has no specific response to the first sentence of Complaint Counsel's Proposed Finding No. 209. The second sentence of Proposed Finding No. 209 is inaccurate and misleading. The record indicates that Impax worked "to extend the exp[iration] dating of the API" so that it could be used through at least 2013. (CX0421). Impax succeeded, never discarded the API, and eventually used it to manufacture finished products. (Camargo, Tr. 1022).

> 210. The cost of Impax's rejected and discarded product in 2010, including the oxymorphone ER product, was 2.7% of COGS. (CX2899 at 003 (2010 Operations Objectives); CX4028 (Camargo, Dep. at 209-11)). The 2010 MBOs for Operations aimed to "[a]chieve a cost of rejected batch rate of 2.5% or less of COGS." (CX2899 at 003 (2010 Operations Objectives); CX4023 (Hildenbrand, Dep. at 198)). This metric measured the percentage of COGS, or the cost of goods sold, that were not used productively. (CX4023 (Hildenbrand, Dep. at 195)).

RESPONSE TO FINDING NO. 210:

Complaint Counsel's Proposed Finding No. 210 is incomplete and misleading because it ignores the fact that the cited document (CX2899) actually excluded oxymorphone ER when

assessing whether the relevant objective was met. (CX2899-002). That brought the cost of discarded product in 2010 to 2.1 percent of COGS. (CX2899-003). Mr. Hildenbrand explained that it did so because, in essence, Impax expects this type of loss as a cost of preparedness efforts: "if a decision is made whether it [is] due to risk or opportunity to not to launch, we don't get approval, whatever it is, but we were ready to have that loss counted against us" before the product was ever made, then it could be deducted from the relevant COGS evaluation. (CX4023 (Hildenbrand, Dep. at 198)). As Impax's CEO at the time of settlement explained, "in order to make sure whatever the discussion or the decision is meaningful, you have to have a supply ready. Then you can talk about [possible launches]. . . . [Y]ou have to have material ready. Then you decide which way you want to go." (CX4030 (Hsu, Dep. at 86)). Discarding and writing off products under these circumstances is a routine and "small cost" of doing business. (Koch, Tr. 273).

> 211. Impax's Senior Vice President of Operations for seven years, Chuck Hildenbrand, could not recall any other instance where the Operations team successfully manufactured product for a launch date, the product received FDA approval, and yet the product had to be destroyed because the company decided not to launch. (CX4023 (Hildenbrand, Dep. at 8, 95-97)).

RESPONSE TO FINDING NO. 211:

Complaint Counsel's Proposed Finding No. 211 is an incomplete, inaccurate, and misleading description of Mr. Hildenbrand's testimony. Mr. Hildenbrand was asked, "on how many occasions did operations manufacture product for a launch date the company decided not to launch and the product had to be destroyed?" (CX4023 (Hildenbrand, Dep. at 95-96)). Mr. Hildenbrand testified that he had "no ability to kind of give you an exact number" or an estimate, but that the company had at least done so with respect to a methylphenidate product. (CX4023 (Hildenbrand, Dep. at 96)). Moreover, nothing the evidence cited (or the record generally)

supports the characterization of the oxymorphone ER process validation batches as "successfully manufactured product for a launch date." (*See* Camargo, Tr. 968 ("Q. The launch inventory build is the additional product manufactured when the process validation batches are not enough to meet your expected needs to launch the product, correct? A. That's correct, and they would be manufactured after"); CX4028 (Camargo, Dep. at 51-52) (same)).

212. Furthermore, the total value of the discarded oxymorphone product ($1.4 million) was approximately 250% of all of the other inventory losses that Impax incurred during June 2010 ($560,000) and was far greater than the combined losses for the first five months of 2010. (CX2896 at 002-03 (Aug. 10, 2010 Monthly Report); Camargo, Tr. 1024).

RESPONSE TO FINDING NO. 212:

Complaint Counsel's Proposed Finding No. 212 is inaccurate, not supported by the cited evidence, and misleading in its attempt to portray the discarding of oxymorphone ER product as unusual. The record is clear that "[t]hrowing away product or discarding product in about a 1.5 million range happens frequently and it—it's not unusual." (Engle, Tr. 1785-86). This included over $1 million in non-oxymorphone ER products being written off in April 2010, and $560,000 worth of non-oxymorphone ER product being written off in June 2010, which together are more than the discarded oxymorphone ER product. (CX2905-003; CX2896-002-03; Camargo, Tr. 1023-24)). In March 2011, Impax had over $2 million in non-oxymorphone raw materials and packaging at risk of destruction in a single location. (CX2922-003; Camargo, Tr. 1027-28). This included $618,000 of new bulk inventory at high-risk of destruction. (CX2922-007; Camargo, Tr. 1030). It also included $1.16 million in finished goods at risk of destruction. (CX2922-010; Camargo, Tr. 1032-33). In 2017, Impax discarded roughly $25 million in finished product. (Engle, Tr. 1786).

213. The Operations group was only able to meet the 2010 MBO regarding rejected product by excluding the oxymorphone ER product from the normal COGS calculation. (CX2899 at 003 (2010 Operations Objectives)).

RESPONSE TO FINDING NO. 213:

Complaint Counsel's Proposed Finding No. 213 is inaccurate, incomplete, and misleading. Mr. Hildenbrand explained that Impax excluded oxymorphone ER form the calculation because, in essence, Impax expects this type of loss as a cost of preparedness efforts: "if a decision is made whether it [is] due to risk or opportunity to not to launch, we don't get approval, whatever it is, but we were ready to have that loss counted against us" before the product was ever made, then it could be deducted from the relevant COGS evaluation. (CX4023 (Hildenbrand, Dep. at 198)). As Impax's CEO at the time of settlement explained, "in order to make sure whatever the discussion or the decision is meaningful, you have to have a supply ready. Then you can talk about [possible launches]. . . . [Y]ou have to have material ready. Then you decide which way you want to go." (CX4030 (Hsu, Dep. at 86)). Discarding and writing off products under these circumstances is a routine and "small cost" of doing business. (Koch, Tr. 273).

V. Impax and Endo engaged in discussions to settle the Opana ER patent litigation

A. Impax and Endo had previously discussed settlement and a side deal in 2009, but those negotiations went nowhere

214. Impax and Endo first discussed the possibility of settlement in the fall of 2009. (CX0310 at 003-04 (Impax CID Response); CX1301 at 110-12 (Endo CID Response)). From the start, the settlement discussions also covered a "potential transaction" and "potential areas of mutual business interest." (CX0310 at 003 (Impax CID Response); CX1301 at 110 (Endo CID Response)).

RESPONSE TO FINDING NO. 214:

Complaint Counsel's Proposed Finding No. 214 is incorrect, inconsistent with the record, and unsupported by the cited evidence. Specifically, CX1301 (Endo's CID Response), reflects

several Impax-Endo settlement communications that occurred before October 14, 2009, when the first communication regarding any "potential transaction" or "potential areas of mutual business interest" took place. (*See* CX1301-110).

> 215. In order to facilitate the settlement discussions, including the parties' evaluation of a potential side deal, Impax and Endo executed a confidential disclosure agreement ("CDA") on October 13, 2009. (RX-359 at 0006 (Oct. 13, 2009 emails between Doug Macpherson and Meg Snowden); CX1816 at 002-04 (executed CDA); RX-284 at 0001 (Nov. 3, 2009 emails from Cobuzzi and Mengler)). In the CDA, Impax and Endo "recognize and agree that any statements made by the parties or their counsel are part of settlement discussions" and that they cannot use any information exchanged "for any purpose whatsoever other than settling the parties' current disputes." (CX1816 at 003-04 (CDA ¶ 9)).

RESPONSE TO FINDING NO. 215:

To the extent that Complaint Counsel's Proposed Finding No. 215 suggests the October 13, 2009, CDA was executed "in order to facilitate the settlement discussions," it is incorrect and not supported by the cited evidence. (Nor does RX-284 contain "Nov. 3, 2009 emails from Cobuzzi to Mengler" described in the parenthetical for that exhibit).

The executed CDA indicates on its face that the parties entered into the agreement "in view of the . . . stated intentions" that they "are interested in entering into discussions which would involve the mutual exchange of information relating to a possible business transaction (the "Transaction") and which will include information that is confidential to the respective parties." (CX1816-002 (CDA preamble)). Nowhere does the CDA suggest the purpose of the agreement was "to facilitate settlement discussions." The cited portions of the CDA provide only that the discussions about a possible business transaction are "part of settlement discussions." (CX1816-003 (CDA ¶ 9)).

> 216. Under the CDA and as part of the settlement talks in October and November 2009, Impax and Endo discussed partnering together on a deal concerning Endo's migraine drug, Frova, as part of a potential settlement of the patent infringement

litigation. (RX-284 at 0001 (Nov. 3, 2009 emails from Cobuzzi and Mengler); CX0310 at 004 (Impax CID Response)).

RESPONSE TO FINDING NO. 216:

Complaint Counsel's Proposed Finding No. 216 is incomplete and misleading. Impax and Endo communicated regarding a potential collaboration [redacted], well before any settlement discussions with Endo had begun. (*See* RX-234 (*in camera*); CX2927-020; RX-393.0014 (*in camera*)). While the parties discussed a potential settlement and "a potential brand agreement related to Frova" in October 2009, (CX0310-004), this does not suggest that the potential Frova collaboration was "part of a potential settlement of the patent infringement litigation." The other document Complaint Counsel cites (RX-284) is a May 19, 2010, email providing information regarding IPX-066. This is not the document Complaint Counsel's parenthetical suggests it is and does not support the Proposed Finding.

217. During the fall 2009 settlement talks, Impax and Endo also discussed potential generic license entry dates. (CX4003 (Snowden, IHT at 56-57)). Meg Snowden, Impax's Vice President of Intellectual Property Litigation and Licensing, proposed to Guy Donatiello, Endo's Senior Vice President of Intellectual Property, that Impax should be able to enter around July 2011 or possibly December 2011 or January 2012 (the mid-point between the expiration of the 30-month stay (June 2010) and the expiration of the asserted patents (August 2013)). (CX4003 (Snowden, IHT at 56-57)). Mr. Donatiello rejected Ms. Snowden's proposal, arguing that the entry date should be around the midpoint between the conclusion of litigation through appeal and patent expiration. (CX4003 (Snowden, IHT at 56-57)).

RESPONSE TO FINDING NO. 217:

Respondent has no specific response, except to point out that the expiration of the asserted patents was September 2013, not August 2013. (JX001-06 (¶10)). Further, Ms. Snowden did not testify as to the specific dates discussed as cited in the second sentence of Proposed Finding No. 217. Those are assumptions devised by Complaint Counsel.

218. Settlement discussions ceased following a final teleconference on December 7, 2009. (CX1301 at 112 (Endo CID Response)). Discussions on any side business deal ended as well. (CX0310 at 003-04 (Impax CID Response); Snowden, Tr. 495 (discussion around Frova never resulted in a deal)).

RESPONSE TO FINDING NO. 218:

Respondent has no specific response.

B. After Impax received tentative approval, settlement discussions began again

219. Settlement negotiations resumed in May 2010 after Endo learned that the FDA tentatively approved Impax's ANDA for generic oxymorphone ER. (CX0310 at 004 (Impax CID Response); CX1301 at 112 (Endo CID Response); CX0513 at 001 (May 13, 2010 Impax internal email from Michelle Wong re tentative approval)).

RESPONSE TO FINDING NO. 219:

Respondent does not dispute that Endo and Impax reinitiated settlement negotiations in May 2010, but the cited evidence does not support the assertion that settlement negotiations were reinitiated after (or because) Endo learned of tentative approval.

220. On May 13, 2010, the FDA granted tentative approval to Impax's ANDA for generic oxymorphone ER. (CX0513 at 001 (May 13, 2010 Impax internal email from Michelle Wong re tentative approval); JX-001 at 007 (¶ 17)). Tentative approval meant that the FDA had determined that Impax's ANDA would be ready for final approval upon the expiration of the 30-month stay on June 14, 2010. (JX-001 at 005, 007 (Stipulation of Law ¶ 24, Stipulation of Fact ¶¶ 15-16)). The FDA's May 13, 2010 grant of tentative approval also affirmed Impax's first-filer eligibility for the 5, 10, 20, 30, and 40 mg dosage strengths of generic Opana ER. (CX4003 (Snowden, IHT at 67-68); CX4022 (Mengler, Dep. at 120-21); CX2662 at 13 (May 2010 Mengler presentation to the Impax Board of Directors) ("FTF Exclusivity Preserved – TA Prior to 30 Months")).

RESPONSE TO FINDING NO. 220:

Respondent has no specific response.

221. On Friday May 14, 2010, Impax issued a press release announcing the FDA's grant of tentative approval of its ANDA for generic oxymorphone ER. (CX3245 at 001 (Impax press release)).

RESPONSE TO FINDING NO. 221:

Respondent has no specific response.

222. By that time, Impax knew that Endo already had agreed to a 2011 entry date for at least one 2011 generic oxymorphone ER. (CX4003 (Snowden, IHT at 56-57)). On February 20, 2009, Endo announced it had reached its first settlement concerning generic Opana ER in its patent infringement suit against Actavis. The following business day, news of the Actavis settlement was made public and circulated among Impax's top executives. (CX0309 at 001-02 (internal Impax email attaching analyst report on Endo's settlement with Actavis)). Impax knew that Endo had granted Actavis a license to the asserted patents beginning on July 15, 2011, which was approximately midway between the 2009 expiration of Endo's new dosage form exclusivity and the expiration of the asserted patents in August 2013. (CX0309 at 001-02).

RESPONSE TO FINDING NO. 222:

Respondent has no specific response.

223. Thus, at the time Impax obtained tentative approval on May 13, 2010, Impax was thinking about trying to get a settlement with Endo with a generic entry date in January 2011, rather than launching at risk in June 2010. (CX0505 at 001 (May 13-14, 2010 Mengler-Hsu e-mail chain)).

RESPONSE TO FINDING NO. 223:

Complaint Counsel's Proposed Finding No. 223 is not supported by the cited evidence. The cited document (CX0505) says nothing about an at-risk launch, and certainly not an at-risk launch in June 2010. With respect to Impax's "thinking," the document states "I want to consider pros and cons on postponing the launch of Oxymorphone in January 2011." (CX0505-001).

224. But Chris Mengler, President of Impax's Generics Division, was concerned about postponing Impax's generic oxymorphone ER launch. As he informed Larry Hsu, Impax's CEO, "the cost of Jan '11 is lost/delayed sales – you know what they [s]ay about a bird in the hand..." (CX0505 at 001) (May 14, 2010 Mengler email)). But when Dr. Hsu asked Mr. Mengler "What if we can settle with Endo for January 2011 launch with No AG?", Mr. Mengler replied: "Settlement ---- different story. I'd love that !!!!" (CX0505 at 001 (emphasis in original)).

RESPONSE TO FINDING NO. 224:

The first sentence of Complaint Counsel's Proposed Finding No. 224 is inaccurate and unsupported by any record evidence. The only document cited in Proposed Finding No. 224 (CX0505) says nothing about Mr. Mengler's concerns. Rather, the document indicates that Dr. Hsu stated, "I want to consider pros and cons on postponing the launch of Oxymorphone in January 2011." (CX0505-001). Mr. Mengler responded that "the cost of Jan '11 is lost/delayed sales." (CX505-001).

Respondent has no specific response to the second and third sentences of Proposed Finding No. 224.

> 225. Impax's tentative approval for generic Opana ER also got the attention of Endo. The day Impax's press release was issued, Endo's head of investor relations forwarded the Impax press release to Endo's CEO Dave Holveck and CFO Alan Levin. (CX1307 at 001 (May 14, 2010 email from Blaine to Holveck/Levin). Endo's outside counsel contacted the president of Penwest, its Opana ER business partner, to discuss a potential settlement with Impax (CX1301 at 112 (Endo CID Response)).

RESPONSE TO FINDING NO. 225:

Respondent has no specific response to Complaint Counsel's Proposed Finding No. 225 other than to clarify that the evidence cited in support of the second sentence (CX1301) indicates Endo's outside counsel contacted Penwest only to provide an "[u]pdate on discussions with Impax regarding potential settlement," not any other aspect of a potential settlement. (CX1301-112).

> 226. On Monday May 17, 2010, Mr. Donatiello reached out to Ms. Snowden via both voicemail and email to re-start settlement discussions. (RX-316 at 0001 (May 17, 2010 Snowden/Donatiello email chain); CX4003 (Snowden, IHT at 83-84)). That afternoon, Ms. Snowden and Mr. Donatiello discussed a potential settlement for the first time since December 2009. (CX0310 at 004 (Impax CID Response)). Mr. Mengler then assumed the role of primary negotiator for Impax. (Mengler, Tr. at 524-25; Snowden Tr. at 366).

RESPONSE TO FINDING NO. 226:

Respondent has no specific response.

227. From the beginning of the renewed negotiations, Endo offered compensation in exchange for Impax's agreement to stay off the market until 2013. (CX0320 (May 26, 2010 Endo term sheets)).

RESPONSE TO FINDING NO. 227:

Complaint Counsel's Proposed Finding No. 227 is inaccurate, misleading, and not supported by the cited evidence. The cited document (CX0320) does not state that Endo offered "compensation" in exchange for "Impax's agreement to stay off the market." The term sheet was an initial draft of terms to settle patent litigation. Indeed, the record is clear that at no point during the parties' settlement discussions did the parties discuss Impax accepting any term for delayed entry. (Mengler, Tr. 567; *see* CX4018 (Koch, Dep. at 74 ("We didn't agree to stay out. We agreed to a specific launch date in return for eliminating the uncertainty of patent litigation")). And the testimony at trial indicated that Endo had no intention of compensating Impax. (Cuca, Tr. 666). In fact, Alan Levin, one of Endo's lead negotiators, does not recall any discussion about the No-Authorized Generic term, or any link between the term and commencement date. (CX4017 (Levin, Dep. at 156-57); *see also* CX4012 (Donatiello, IHT at 172-73) (no provisions in SLA linked to commencement date)).

228. On May 26, 2010, Endo sent Impax its first written settlement offer, comprised of two term sheets. (CX0320 (May 26, 2010 Endo term sheets)). Endo proposed a generic licensed entry date of March 10, 2013 and offered a six-month No-AG provision and a side deal in the form of an option agreement with a $10 million upfront payment relating to a Parkinson's disease treatment under development by Impax, code-named IPX-066. (CX0320 at 002-03, 009-10).

RESPONSE TO FINDING NO. 228:

Respondent has no specific response to the first sentence of Complaint Counsel's Proposed Finding No. 228. Respondent has no specific response to the second sentence of Proposed Finding No. 228 other than to clarify that the cited evidence does not support the proposition that the suggested Parkinson's collaboration was a "side deal." The record is clear that the Development and Co-Promotion Agreement, was a "stand-alone legal document[]." (CX4017 (Levin, Dep. at 157-58); *see* Koch, Tr. 313-14 (Impax assessed and considered DCA and SLA as standalone agreements "all the time"); CX4036 (Fatholahi, Dep. at 138-39)). Accordingly, both Endo and Impax assessed the Development and Co-Promotion Agreement independently from the Settlement and License Agreement. (Koch, Tr. 313 (Impax's CEO "was very clear that each agreement should be evaluated on their own merits as a standalone agreement"); CX4001 (Koch, IHT at 41) (DCA was "a separate negotiation that came up during settlement negotiations"); Mengler, Tr. 586; CX4017 (Levin, Dep. at 159); CX4031 (Bradley, Dep. at 196)).

229. Mr. Donatiello sent the term sheets to Mr. Mengler and Ms. Snowden following a discussion of their contents that morning and more than week of discussions and a significant exchange of information pertaining to IPX-066. (CX0320 at 001 (May 26, 2010 Endo term sheets); RX-272 at 0001-03 (May 19-22, 2010 Paterson/Cobuzzi email exchange and attached list of IPX-066 data made available to Endo)).

RESPONSE TO FINDING NO. 229:

Respondent has no specific response to Complaint Counsel's Proposed Finding No. 229 other than to clarify that the cited evidence does not support the proposition that Mr. Donatiello, Mr. Mengler, and Ms. Snowden had more than a week of discussions.

1. Endo offered a No-AG provision

230. Endo's offer included a provision giving Impax an "Exclusivity Period" of 180 days for each of the dosages for which Impax held first-to-file exclusivity (5, 10, 20, 30, and 40 mg), during which Impax's license "would be exclusive as to all but (i) Opana ER®-branded products that are not sold as generic products and (ii) generic products covered by prior license agreement executed as of the effective date of the License Agreement with Impax." (CX0320 at 009-10 (May 26, 2010 Endo term sheets)). Due to Impax's first-filer exclusivity, an authorized generic sold under Endo's brand license was the only other generic that could have competed with Impax during its first 180 days on the market. (CX4003 (Snowden, IHT at 27); *see also* Mengler, Tr. 523). This "No-AG" provision guaranteed that Impax would be the only generic for its first 180 days on the market and would not face competition from an Endo authorized generic. (Snowden, Tr. 392; CX0320 at 009-10; CX4003 (Snowden, IHT at 111-13)).

RESPONSE TO FINDING NO. 230:

Respondent has no specific response to the first sentence of Complaint Counsel's Proposed Finding No. 230. The second sentence of Proposed Finding No. 230 is inaccurate, misleading, and not supported by the cited evidence. Ms. Snowden and Mr. Mengler did not state that an authorized generic was "the only other generic that could have competed with Impax" during its exclusivity period. Rather, both testified that the FDA could not approve additional oxymorphone ANDAs for the relevant dosage strengths during the exclusivity period, so long as Impax did not forfeit its exclusivity. (Mengler, Tr. 522-23; CX4003 (Snowden, IHT at 27, 113 (discussing identified strengths and "Endo products")).

The third sentence of Proposed Finding No. 230 is incomplete and misleading. Ms. Snowden testified only that assuming Impax did not forfeit its exclusivity, the FDA could not approve additional oxymorphone ANDAs for the relevant dosage on which it was the first filer. (CX4003 (Snowden, IHT at 27, 112-13 (discussing identified strengths and "Endo products"); Mengler, Tr. 522-23). The record is replete, however, with evidence that generic oxymorphone ER would still compete with generic and branded versions of many different long-acting opioids. (Savage, Tr. 732 (when a patient seeks treatment for chronic pain in the first instance, doctors

can prescribe any long-acting opioid); RX-083.0003 at 35 (highlighting real-world switching patterns between oxymorphone-based products and drugs including fentanyl, oxycodone, and morphine)). Demir Bingol, Endo's Senior Director of Marketing and the Endo employee responsible for knowing with which products oxymorphone-based products compete, testified that "all long-acting opioid formulations," including generics that are not actively marketed, are direct competitors. (Bingol, Tr. 1271, 1313).

This competition plays out through, among other things, "effective targeting of your messaging to your clinicians," "rebates that you offer payers in order to ensure that you have a competitive place on formularies," and "certain competitors coming and going that your product becomes a natural next choice." (Bingol, Tr. 1284). With respect to formularies in particular, manufacturers compete on price to secure favorable formulary placement vis-à-vis competitors. (Bingol, Tr. 1324-25). This includes rebates by brand companies in order to compete with generic products on price. (Bingol, Tr. 1327; Engle, Tr. 1718; CX4037 (Smolenski, Dep. at 155)). And it can mean that generic long-acting opioids, like oxymorphone ER, are excluded from formulary coverage in favor of other long-acting opioids. (Noll, Tr. 1546; RX-017.0001; RX-017.0002 at 11).

> 231. Consistent with Dr. Hsu and Mr. Mengler's desire for a No-AG provision (CX0505 at 001), the No-AG provision was favorably received by Impax. (CX4022 (Mengler, Dep. 190-91) (Mr. Mengler reviewing the May 26 term sheets and testifying he would be "happy" with a No-AG clause); *see also* CX4014 (Hsu, IHT at 68) ("obviously if you have a choice, with AG, without AG, you prefer to get the no AG")). For Mr. Mengler, obtaining a No-AG provision is "among the more important things" in a settlement negotiation and was beneficial to Impax. (Mengler, Tr. 526). A six-month No-AG provision remained part of the terms contemplated by the parties throughout the negotiations (CX1305 at 001 (May 27, 2010 Mengler email) (proposing launch date of "1/1/13 with no authorized generic"); CX0406 at 001 (June 2, 2010 Mengler email) ("We enter jan 1 2013 with no ag")) and was included in the final agreement executed by the parties. (RX-364 at 0010-11 (SLA § 4.1(c))).

RESPONSE TO FINDING NO. 231:

The first sentence of Complaint Counsel's Proposed Finding No. 231 is not supported by the cited evidence. The cited evidence does not identify a "desire for a No-AG provision" by Dr. Hsu or Mr. Mengler. (CX0505-001 (discussing possibility of settlement generally and noting an interest in a no-AG commitment)). Nor does any of the cited evidence discuss Impax's reception of a No-Authorized Generic provision at the time of negotiations.

The second sentence of Proposed Finding No. 231 is incomplete and misleading because it selectively quotes Mr. Mengler. Mr. Mengler actually testified that "most important is, you know, early entry. Then, you know, there's a few -- what's important is the best possible deal that gets the product on the market as quickly as possible and maximizes the value to Impax shareholders, so early entry and no-AG are certainly among the more important things, yes." (Mengler, Tr. 526). Mr. Mengler further explained that a No-Authorized Generic provision was not particularly valuable because Impax derives value "by selling the drug [] with or without an" authorized generic. (Mengler, Tr. 528-29). And Dr. Hsu, Impax's CEO at the time of settlement, explained that getting on the market as early as possible is what matters. Impax did not value the absence of an authorized generic if it meant delaying its own product. (CX4030 (Hsu, Dep. at 76-77)).

Respondent has no specific response to the third sentence of Proposed Finding No. 231.

2. Endo offered a side deal for IPX-066 with a $10 million upfront payment

232. After settlement discussions resumed on May 17, 2010, Impax and Endo immediately began discussing a potential joint development agreement for the first time since the 2009 settlement discussions had disbanded. (CX0310 at 004 (Impax CID Response); CX4003 at 024 (Snowden, IHT at 89-90)). In conjunction with the first discussion of a potential transaction on May 19, 2010 (CX2966 at 002 (Impax-Endo email chain and presentation)), Mr. Donatiello confirmed to Ms. Snowden and

Mr. Mengler that the confidential disclosure agreement the parties entered as part of settlement negotiations in the fall of 2009 was still effective. (CX1816 at 001).

RESPONSE TO FINDING NO. 232:

Respondent has no specific response.

233. Between May 17 and 26, 2010, Impax and Endo held two conference calls and exchanged numerous emails and materials regarding a product known as IPX-066. (CX2966 (May 19, 2010 emails noting conference call and attaching presentation on "IPX066: Licensing Opportunity for Parkinson's Disease" and science poster); RX-272 at 0001-03, 0005-08 (May 19-22, 2010 Paterson/Cobuzzi email exchange and attached list of IPX-066 data made available to Endo); CX1301 at 112-13 (Endo CID Response); CX0310 at 004-05 (Impax CID Response)).

RESPONSE TO FINDING NO. 233:

Respondent has no specific response.

234. IPX-066 was the name for Impax's treatment for Parkinson's disease that was in Phase III of clinical development —the last stage of development before submitting an application for approval to the FDA. (RX-076 at 0001-02 (Endo draft OEW for IPX-066); CX4022 (Mengler, Dep. at 161-62)). IPX-066 was a combination of levodopa and carbidopa, a standard combination treatment for Parkinson's disease. (RX-076 at 0002, 0005-06 (Endo draft OEW for IPX-066)). Though many carbidopa-levodopa products, including generics, were already on the market, Impax believed that its formulation would be a superior product. (RX-076 at 0009 (Endo draft OEW for IPX-066); CX2966 at 036-38 (Impax presentation: IPX066: Licensing Opportunity for Parkinson's Disease)).

RESPONSE TO FINDING NO. 234:

Respondent has no specific response to the first or second sentences of Complaint Counsel's Proposed Finding No. 234. The third sentence of Proposed Finding is incomplete and misleading. The cited evidence indicates that Endo also believed IPX-066 would be superior than existing carbidopa-levodopa treatments. (RX-076.0009 (Endo evaluation worksheet noting that "[t]he data available for IPX066 suggests this agent will be superior to Sinemet and Stalevo in terms of PK/PD and thus in terms of efficacy"; noting also that the drug could be marketed to

primary care physicians because "there is more push by payors for the ongoing management of PD patients to be administered by PCP's")).

> 235. On May 19, 2010, David Paterson, Impax's Vice President of Business Development, provided initial written materials on IPX-066 to Robert Cobuzzi, Endo's Senior Vice President of Corporate Development, including a presentation entitled "IPX066: Licensing Opportunity For Parkinson's Disease." (CX2966 at 001, 003 (Impax-Endo email chain and presentation)). The presentation described Impax as "[s]eeking a resourceful European partner." (CX2966 at 009 (Impax-Endo email chain and presentation)). At the time, Endo was predominantly a U.S. company with a minimal international presence. (CX3216 at 026-38, 063 (May 3, 2010, Endo 10-Q for Q1'2010) (discussing license and collaboration agreements and U.S. sales efforts); *see also* CX2534 at 002 (June 6, 2010 emails from Koch and Cobuzzi) (Cobuzzi stating that "of course" it's not a problem that the side deal for IPX-203 would be for the U.S. market only)). The presentation touted the clinical benefits of IPX-066 over Sinemet, the leading carbidopa-levodopa brand product, and projected launch in the U.S. in the second half of 2012. (CX2966 at 038, 040-45, 73 (Impax-Endo email chain and presentation)).

RESPONSE TO FINDING NO. 235:

Respondent has no specific responses to the first, third, and fourth sentences of Complaint Counsel's Proposed Finding No. 235. The second sentence of Proposed Finding No. 235 is incomplete and misleading in its attempt to suggest that Impax sought to partner with Endo outside the United States. The record makes clear that Impax provided Endo with the presentation, as well as a data room with additional information regarding IPX-066, because the information had been put together as a result of Impax's separate efforts to secure a European partner for the product. (Snowden, Tr. 403-04; CX4032 (Snowden, Dep. at 142-43) ("Impax told Endo that -- that there was a data room available for IPX066 because Impax was in the process of working on an ex-US licensing arrangement for that and that Endo would be able to understand the opportunity for this [IPX-203] Parkinson's product.")). Those already-collected materials aided Endo "tremendously" in its assessment of IPX-203, the actual subject of the executed Development and Co-Promotion Agreement. (Cobuzzi, Tr. 2625).

236. On May 22, 2010, Dr. Paterson provided Dr. Cobuzzi and a number of additional Endo employees with access to a "data room" with "a large amount of IPX 066 related documents." (RX-272 at 0001-02 (May 19-22, 2010 Paterson/Cobuzzi email exchange)). The documents covered: (i) intellectual property/legal; (ii) chemistry, manufacturing, and controls ("CMC"); (iii) commercial; (iv) regulatory; (v) clinical; (vi) clinical pharmacology; and (vii) Impax's unredacted confidential presentation on IPX-066. (RX-272 at 0001(May 19-22, 2010 Paterson-Cobuzzi email exchange)).

RESPONSE TO FINDING NO. 236:

Respondent has no specific response.

237. On May 26, 2010, one of the two term sheets Mr. Donatiello sent to Impax proposed an option agreement concerning IPX-066 "and all improvements, modifications, derivatives, formulations and line extensions thereof." (CX0320 at 002 (May 26, 2010 Endo term sheets)). The term sheet gave Endo the option to receive either the right to co-promote the product within the U.S. or to purchase an exclusive license to the product in the U.S. (CX0320 at 003). Endo would pay Impax a $10 million "Option Fee" upon signing the agreement and a $5 million milestone fee upon the FDA's acceptance of the NDA for the product. (CX0320 at 003).

RESPONSE TO FINDING NO. 237:

Respondent has no specific response.

238. If Endo elected the co-promotion option, Endo's right to co-promote IPX-066 would be limited to "areas outside the practice of neurology." (CX0320 at 004 (May 26, 2010 Endo term sheets)). Endo would receive a fee of 50% of net sales prescribed by those outside the practice of neurology. (CX0320 at 004).

RESPONSE TO FINDING NO. 238:

Respondent has no specific response.

239. If Endo elected the license option, Endo would pay Impax a one-time fee equal to five times the average of the product's projected sales for its first three years post-approval. (CX0320 at 004-05 (May 26, 2010 Endo term sheets)). In return, Impax would grant Endo an exclusive license to IPX-066 and any formulations or line extensions to IPX-066 for use in humans in the U.S. (CX0320 at 002, 004).

RESPONSE TO FINDING NO. 239:

Respondent has no specific response.

C. Endo sought to delay Impax's entry until 2013 because each month of delay was worth $20 million and Endo needed sufficient time to switch the market to Reformulated Opana ER

240. It was lucrative for Endo to delay Impax's generic entry as long as possible. Due to Impax's first-filer eligibility, no other generic could launch a generic version of Opana ER in the 5, 10, 20, 30, or 40 mg dosage strengths until 180 days after Impax launched. (CX4003 (Snowden, IHT at 112-13, 167)). Thus, the longer Endo could delay Impax's entry, the longer Endo could delay all generic entry. Endo calculated that "[e]ach month that generics are delayed beyond June 2010 is worth ~$20 million in net sales per month." (CX1106 at 005 (Endo presentation: 2010 Opana Brand Strategic Plan)). Endo estimated that if Impax launched its generic in July 2010, Endo would lose approximately $100MM in branded Opana ER sales during the first six months Impax was on the market. (CX3445 at 001, 002 (native) (June 1, 2010 internal Endo email with attached Opana ER P&L spreadsheet)). Endo estimated that it would lose 85% of its branded Opana ER sales within three months of generic entry. (CX1320 at 007 (Feb. 11, 2010 Endo Three-Year Plan)).

RESPONSE TO FINDING NO. 240:

The first and third sentences of Complaint Counsel's Proposed Finding No. 240 are unsupported by any evidence and should be disregarded because they violate the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2).

Respondent has no specific response to the second sentence of Proposed Finding No. 240 other than to clarify that other ANDA filers could launch a generic version of Opana ER in the relevant dosage strengths if Impax were to forfeit its first-filer exclusivity. (CX4003 (Snowden, IHT at 112-13)).

The fourth sentence of Proposed Finding No. 240 is incomplete, inaccurate, and misleading because it attempts to suggest "Endo" calculated something even though the document is marked "DRAFT Not Approved by Management." (CX1106-005; *see* Bingol, Tr. 1298-99 (discussing identical "draft" language: "JUDGE CHAPPELL: . . . it says it's a draft. Why would he have presented a draft to anybody?")).

The fifth sentence of Proposed Finding No. 240 is incomplete and misleading because it ignores the testimony of Demir Bingol, Endo's Senior Director of Marketing and the individual often responsible for Endo forecasts, including the cited exhibit (CX3445). Mr. Bingol testified that Endo always forecast "a number of different potential outcomes over the course of years," but that the accuracy of such forecasts were "debatable." (Bingol, Tr. 1292, 1303). Endo did not know if any of the many different assumptions contained in its forecasts would come true. (Cuca, Tr. 662-63). Endo forecast different scenarios regarding the future of its Opana ER product to "analyze the full range of potential outcomes." (Cuca, Tr. 663-64).

The sixth sentence of Proposed Finding No. 240 is incomplete and misleading because it ignores the plain language of the document. Endo did not "estimate" that it would lose 85 percent of sales, it simply assumed it for purposes of the forecast. (CX1320-007 (noting "Key Assumptions" including generic entry and "15% brand volume remains after 3 months")). Endo did not know if any of the many different assumptions contained in its forecasts would come true. (Cuca, Tr. 662-63).

The sixth sentence of Proposed Finding No. 240 also ignores the testimony of Mr. Bingol, who testified that Endo always forecast "a number of different potential outcomes over the course of years," but that the accuracy of such forecasts were "debatable." (Bingol, Tr. 1292, 1303). In fact, the other cited exhibit in Proposed Finding No. 240 (CX3445) assumed lost sales of less than 50 percent over six months. (CX3445-001, 02 (native)).

> 241. Endo also aimed to keep Impax off the market until 2013 in order to have enough time to switch Opana ER from its then-marketed version ("Original Opana ER," NDA No. 021610) to a reformulated version ("Reformulated Opana ER," NDA No. 201655). Though not disclosed publicly at the time of the settlement negotiations (CX4005 (Levin, IHT Day 1 at 72)), Endo had long been planning to introduce a new "tamper-resistant" version of Opana ER. (CX3214 at 015 (Endo SEC Form 10-K for 2011) ("In December 2007, we entered into a license, development and supply agreement with Grünenthal GMBH for the exclusive clinical development and commercialization rights in Canada

and the United States for a new oral formulation of long-acting oxymorphone, which is designed to be crush resistant.")).

RESPONSE TO FINDING NO. 241:

The first sentence of Complaint Counsel's Proposed Finding No. 241 is unsupported by any record evidence and should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Respondent has no specific response to the second sentence of Proposed Finding No. 241.

242. Reformulating the product would extend the life of the brand through additional patent protection and other possible roadblocks for potential generic competitors. (CX2724 at 005 (Jan. 2010 Endo presentation on Commercial Strategy Scenarios for EN3288/Reformulated Opana ER) (forecasting up to four years of "organic exclusivity" and retaining all Opana ER sales if launched with labeling claims and ahead of generics); CX3205 at 001 (Dec. 13, 2007 Endo memo on Grunenthal ADF formulation of Oxymorphone) ("There is also a life cycle management (LCM) imperative for Endo's Opana ER franchise. . . . To ensure we continue to protect the franchise in the face of loss of regulatory exclusivity in June 2009, a TRF formulation of ER will be important to secure. Without this LCM strategy, Opana ER is expected to lose about 70% of its sales within six months if generic entry occurs."); CX3251 (U.S. Patent No. 8,309,060 B2, disclosing an "abuse-proofed, thermoformed dosage form" containing an active ingredient with abuse potential)).

RESPONSE TO FINDING NO. 242:

Respondent has no specific response.

243. At the time of the settlement negotiations, Endo had not yet filed its application for a reformulated version of Opana ER with the FDA. (CX3189 at 001-02 (Aug. 9, 2010 Endo press release announcing filing of Reformulated Opana ER NDA with the FDA). Endo expected to file its application for Reformulated Opana ER with the FDA around the third quarter of 2010, but potentially as soon as late June 2010. (CX2575 at 004 (May 6, 2010 Endo presentation: EN3288 Review)). Depending on the form of the application, Endo anticipated that FDA approval would take between four and 10 months. (CX2575 at 004 (May 6, 2010 Endo presentation: EN3288 Review)). Endo targeted a launch of Reformulated Opana ER around March 2011, but estimated it could be as soon as December 2010 or later than June 2011. (CX3038 at 001 (Apr. 2, 2010 Endo email from Brian Hogan to Roberto Cuca and attachment); *see also* CX2573 at 004 (Feb. 24, 2010 Endo presentation: EN3288 Commercial Update) (projected May 2011 launch); CX2724

at 005 (Jan. 27, 2010 EN3288 Commercial Strategy Scenarios) (projected launch between January and September 2011)).

RESPONSE TO FINDING NO. 243:

Respondent has no specific response to the first sentence of Complaint Counsel's Proposed Finding No. 243.

The second sentence of Proposed Finding No. 243 is misleading and not supported by the cited evidence. The cited document (CX2575) does not state that Endo "expected" to file an application at any time. The document instead included a "recommendation" that Endo "target filing date 3Q2010." (CX2575-005). The document moreover, was still being revised and had not been forwarded to senior management. (CX2575-001).

The third sentence of Proposed Finding No. 243 is incomplete and misleading because it ignores the testimony of Demir Bingol, Endo's Senior Director of Marketing and the author of the cited exhibit (CX2575). Mr. Bingol testified that "EN3288 Review" presentations were based "on scenarios that we had created, I mean, the accuracy of which are always debatable." (Bingol, Tr. 1303). Endo always forecast "a number of different potential outcomes over the course of years." (Bingol, Tr. 1292).

Respondent has no specific response to the fourth sentence of Proposed Finding No. 243.

244. Endo understood that the timing of the reformulation was the key to its financial success. Endo forecasted that if it launched Reformulated Opana ER in advance of generic entry, it could not only retain its Original Opana ER sales, but actually grow brand sales for at least five more years. (CX2724 at 001, 006 (Jan. 27, 2010 Endo email from Demir Bingol to CEO Dave Holveck and attached presentation: EN3288 Commercial Strategy Scenarios) (projecting Opana ER sales to grow from less than $200 million to greater than $300 million by 2015 if Endo launched Reformulated Opana ER with labeling claims and ahead of generics)).

RESPONSE TO FINDING NO. 244:

The first sentence of Complaint Counsel's Proposed Finding No. 244 is unsupported by any record evidence and should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2).

The second sentence of Proposed Finding No. 244 is incomplete and misleading because it ignores the testimony of Mr. Bingol, the author of the cited email (CX2724). Mr. Bingol testified that the estimates were based on "many" assumptions and Endo was looking at any possible scenario. (CX4025 (Bingol, Dep. at 59); Bingol, Tr. 1310 ("We have to consider all scenarios")). Indeed, Mr. Bingol explained that the forecast, like the other forecasts his department created, "was based on scenarios that we had created, I mean, the accuracy of which are always debatable." (Bingol, Tr. 1303). And many of the assumptions were actually total unknowns. (Bingol, Tr. 1307 ("JUDGE CHAPPELL: Okay. Well, I don't want you to guess[], so according to this document [CX2724], whatever those claims were you didn't know. THE WITNESS: Well, we would be -- that's correct.")). Endo did not know if any of the many different assumptions contained in its forecasts would come true. (Cuca, Tr. 662-63). Endo forecast different scenarios regarding the future of its Opana ER product to "analyze the full range of potential outcomes." (Cuca, Tr. 663-64).

245. By contrast, if Endo launched after generic oxymorphone ER was already on the market, it forecast that it would capture only "~25% of all existing oxymorphone business." (CX2724 at 001, 006 (Jan. 27, 2010 Endo email from Demir Bingol to CEO Dave Holveck re EN3288 Potential Launch Scenarios) (projecting Reformulated Opana ER sales of just over $100 million in 2015 if launched "after the advent of generics")). If Endo launched Reformulated Opana ER at the same time as generic oxymorphone ER hit the market, Reformulated Opana ER would capture at most 30% to 32% of its Original Opana ER sales. (CX1320 at 024 (Feb. 2010 Endo Three-Year Plan) ("Oxymorphone TRF conversion from OPANA ER base volume: 30-32% conversion of base volume; Conversion curve begins at launch (July 2011); Peak conversion (30%) reached in 40

months"); CX1320 at 007 (forecasting rapid generic erosion upon generic entry in July 2011); CX1320 at 003 (projecting only $11.9 million in Oxy TRF revenues for 2011)).

RESPONSE TO FINDING NO. 245:

The first sentence of Complaint Counsel's Proposed Finding No. 245 is incomplete and misleading because it ignores the testimony of Mr. Bingol, the author of the cited email (CX2724). Mr. Bingol testified that the estimates were based on "many" assumptions and Endo was looking at any possible scenario. (CX4025 (Bingol, Dep. at 59); Bingol, Tr. 1310 ("We have to consider all scenarios")). Indeed, Mr. Bingol explained that the forecast, like the other forecasts his department created, "was based on scenarios that we had created, I mean, the accuracy of which are always debatable." (Bingol, Tr. 1303). And many of the assumptions were actually total unknowns. (Bingol, Tr. 1307 ("JUDGE CHAPPELL: Okay. Well, I don't want you to guess[], so according to this document [CX2724], whatever those claims were you didn't know. THE WITNESS: Well, we would be -- that's correct.")). Indeed, Endo did not know if any of the many different assumptions contained in its forecasts would come true. (Cuca, Tr. 662-63). Endo forecast different scenarios regarding the future of its Opana ER product to "analyze the full range of potential outcomes." (Cuca, Tr. 663-64).

The second sentence of Proposed Finding No. 245 is not supported by the cited evidence. The cited exhibit (CX1320) does not calculate or determine what Reformulated Opana ER would actually accomplish upon launch. Rather, it simply assumed the conversion rate for purposes of that particular forecast. (CX1320-024 (describing "[b]ase assumptions")). As noted, Endo did not know if any of the many different assumptions contained in its forecasts would come true. (Cuca, Tr. 662-63). Endo simply forecasted "a number of different potential outcomes over the course of years," the accuracy of which were "always debatable." (Bingol, Tr. 1292, 1303).

D. The parties negotiated the Endo Credit as a "make good" provision to protect Impax from degradation of the Opana ER market

246. Though Endo had not publicly disclosed its plans for Reformulated Opana ER, Impax suspected Endo might switch to a new formulation before Impax could enter under the proposed 2013 entry date. (Mengler, Tr. 528, 568). Impax feared "that Endo had a strategy in place that would have led to the elimination of the Opana ER market, destroying . . . all of [its] value and [its] ability to sell the generic." (CX4010 (Mengler, IHT at 21)). Impax was aware that "there was a strategy in place for these super high-potency opioid products . . . to switch to a tamper-resistant formulation" and that introduction of a new formulation "may have led to the withdrawal of the initial product for safety reasons, which would have completely destroyed [Impax's] market." (CX4010 (Mengler, IHT at 35); see also Mengler, Tr. 568). Impax came to "believe[] that that was [Endo's] strategy." (CX4010 (Mengler, IHT at 35)).

RESPONSE TO FINDING NO. 246:

Respondent has no specific response.

247. Impax was suspicious of Endo's plans as early as December 2009, when Endo management disclosed that Endo was working on tamper-resistant opioids. (CX2540 at 001 (Dec. 4, 2009 internal Impax email circulating excerpts from Endo management meeting)). Impax's suspicions were strengthened by additional Endo management statements during a conference call to discuss Q1'2010 earnings. (CX0216 at 001 (May 27, 2010 internal Impax email circulating excerpts from Endo earnings call transcript) (stating that "at this point we don't have any let's say announcements" regarding whether they would launch a new form of Opana ER before September 2012 and reiterating that Endo had investments in the TRF space and "that's certainly something we continue to be interested in down the road")).

RESPONSE TO FINDING NO. 247:

Complaint Counsel's Proposed Finding No. 247 is not supported by the cited evidence. Neither of the cited exhibits (CX2540; CX0216) discuss Impax's suspicions with respect to reformulation or anything else. Both documents are emails from Ted Smolenski, who simply forwarded excerpts of Endo statements on various topics.

248. If Endo did reformulate Opana ER, the market for Impax's generic oxymorphone ER product could disappear before Impax could launch its product upon the proposed 2013 license entry date. (CX4010 (Mengler, IHT at 21) (Endo's reformulation strategy "would have led to the elimination of the Opana ER market, destroying ... all of [Impax's] value and [Impax's] ability to sell the generic."); CX4014 (Hsu, IHT at 90)

(Endo reformulating Opana ER "definitely has a significant impact on us. No question at all.")). Mr. Mengler felt reformulation would "subvert the value of the deal [he] was trying to put together." (Mengler, Tr. at 526-27). Such a move would cost Impax the benefit of both the No-AG provision and its first-filer exclusivity. (CX4010 (Mengler, IHT at 33, 42 ("So, if I negotiate a settlement and then the product goes away, that's a really bad thing." The Endo Credit, at least, allowed Impax to "get something" from the settlement agreement if Endo switched the market)).

RESPONSE TO FINDING NO. 248:

Respondent has no specific response to the first sentence of Complaint Counsel's Proposed Finding No. 248. The second sentence of Proposed Finding No. 248 is incomplete and misleading because it selectively quotes Mr. Mengler's full answer. He explained that the "subversion of the benefits" was "the benefits to the American consumer for getting a generic version of what would have been an important drug and also I benefit, too, in the way I make money is by selling generic drugs, so." (Mengler, Tr. 527).

The third sentence of Proposed Finding No. 248 is not supported by the cited evidence. Mr. Mengler said nothing about a No-Authorized Generic provision or first-filer exclusivity, let alone their loss. His actual testimony stated, "the best way that we can add value . . . the best thing I can do to create sustaining value to the business is to consistently bring products to market and continue to supply them. . . . So, if I negotiate a settlement and then the product goes away, that's a really bad thing." (CX4010 (Mengler, IHT at 33); *see* CX4010 (Mengler, IHT at 42) (Endo Credit intended to "create somewhat of an incentive to keep the product out there"); Mengler, Tr. 528-29 (Impax derives value "by selling the drug [] with or without an" authorized generic)). Dr. Hsu, Impax's CEO at the time of settlement, similarly testified that getting on the market as early as possible is what matters. Impax did not value the absence of an authorized generic if it meant delaying its own product. (CX4030 (Hsu, Dep. at 76-77)).

249. Impax raised its concerns with Endo, but Endo denied it had any plans to move the Opana ER market. (Mengler, Tr. 531-32; CX4010 (Mengler, IHT at 41-42)).

Mr. Mengler told Mr. Levin he thought Endo had "a secret plan to damage the market." (CX0217 at 001 (June 2, 2010 email from Mengler to Smolenski)). Mr. Levin denied that Endo was planning to reformulate, assuring Mr. Mengler: "'Chris, I promise we have no plans to not continue to pursue our existing formulation.'" (CX0117 at 002 (Aug. 9, 2010 email from Mengler re Endo's announcement of application for Reformulated Opana ER)); *see also* CX4010 (Mengler, IHT at 41) ("Sitting this close, looked me right in the eye, and told me, 'We are absolutely not switching this product. I promise you, Chris.'")).

RESPONSE TO FINDING NO. 249:

Respondent has no specific response.

250. Despite Endo's proclamations that it did not plan to move the Opana ER market, Impax sought contractual provisions to address the possibility. Impax's fear "that Endo had a strategy in place that would have led to the elimination of the Opana ER market" was a "very significant business issue[]" that would have been a "deal-breaker[]" for Impax. (CX4010 (Mengler, IHT at 20-21)). As Impax "learned more about the market, something that didn't protect us from the downside was becoming a deal-breaker." (CX4010 (Mengler, IHT at 44)).

RESPONSE TO FINDING NO. 250:

Respondent has no specific response.

1. Initially, Impax sought a market degradation acceleration trigger

251. Impax first proposed to address its concern with an acceleration trigger for market degradation. After receiving Endo's May 26th term sheets, Impax responded by proposing a January 1, 2013 license entry date, with the No-AG provision and "certain acceleration triggers, including market degradation to any alternate product." (CX1305 at 001 (May 27, 2010 email from Mengler to Levin)).

RESPONSE TO FINDING NO. 251:

Respondent has no specific response, except to clarify that Endo had already offered the No-AG provision in Endo's opening term sheet. (*See* CX0320 (May 26, 2010 email to Mengler with initial term sheets from Endo)).

252. An acceleration provision for market degradation would allow Impax to launch its generic oxymorphone ER product earlier than January 1, 2013 in the event that Opana ER brand sales fell by a certain amount or percentage. (CX4010 (Mengler, IHT at 33-34)). Impax wanted a market acceleration provision as "protection in case Endo had any

intentions of moving the market to a next-generation product." (CX4032 (Snowden, Dep. at 104)). Impax had included similar provisions in other patent settlements with brand companies. (CX4003 (Snowden, IHT at 121-22)).

RESPONSE TO FINDING NO. 252:

The second sentence of Complaint Counsel's Proposed Finding No. 252 is an incomplete and misleading quotation from Ms. Snowden's testimony, which is as follows: "Q. And do you remember what was the rationale that Impax provided as to why it wanted that acceleration trigger?... A. As a corporate designee, Impax said it wanted that as protection in case Endo had any intentions of moving the market to a next-generation product. ***Impax said it was important in -- when agreeing to an entry date, that there's a robust market to launch its generic into and, therefore, it needed this protection of the market in case that's what Endo had in mind***." (CX4032 (Snowden, Dep. at 104) (emphasis added)).

2. Endo refused, and the discussions turned to a "make good" provision

253. Endo rejected Impax's request for a market acceleration trigger. (CX4032 (Snowden, Dep. at 104); Snowden, Tr. 385; CX4014 (Hsu, IHT at 85-87) (Endo "fiercely" opposed the accelerated entry concept)). Endo insisted "that they had no interest in moving the market and they weren't planning to." (CX4032 (Snowden, Dep. at 106)). Endo's rejection of an acceleration trigger increased Impax's concern that Endo was going to switch the market. (Mengler, Tr. 568). Mr. Mengler's response to Endo was that "if you're not telling me the truth, you're going to pay me what I would have made anyway." (CX4010 (Mengler, IHT at 36)); *see also* CX4026 (Nguyen, Dep. at 165-66) (the "gist" of the Endo Credit was "Mr. Mengler basically telling Endo to put its money where its mouth was")).

RESPONSE TO FINDING NO. 253:

Respondent has no specific response to the first and second sentences of Complaint Counsel's Proposed Finding No. 253. The third sentence of Proposed Finding No. 253 is incomplete and misleading because it ignores the full context of Mr. Mengler's statement. Mr. Mengler testified "the concept was, you know, if you're telling me the truth and the product is really going to grow, well, you know, there will be something in it for you as well and -- but I'm

still coming out and I'm going to take this market out as quickly as I can and sell as much product as I can, but if you're not telling me the truth, you're going to pay me what I would have made anyway." (CX4010 (Mengler, IHT at 36)). This was "a carrot and a stick approach" to incentivize Endo to make investments in its original Opana product and ensure Impax had a measure of control over its generic opportunity. (Koch, Tr. 236-37, 240-41; Snowden, Tr. 386). It was intended to act as "a deterrent to prevent [Endo] from switching the market." (CX4021 (Ben-Maimon, Dep. at 118, 122); *see* CX4037 (Smolenski, Dep. at 244-45) ("intended to disincentivize Endo from" introducing a reformulated product); CX4026 (Nguyen, Dep. at 163-64) (Endo Credit was used to "put [Endo] to [its] word" with respect to reformulation)). The testimony at trial was clear that Mr. Mengler did not view the Endo Credit as a means to generate income; it was instead meant to ensure Impax had a generic opportunity. (Mengler, Tr. 582-83).

254. At an in-person meeting on June 1, 2010, Endo proposed an alternative approach that would do just that: "if the product declines by more than 50%, [Impax] would be entitled to a 'make good' payment such that [Impax's] potential profits would equal to 50%." (RX-387 at 0001 (June 1, 2010 Mengler internal email recapping the "current proposal"); *see also* CX0310 at 005 (Impax CID Response) (disclosing June 1, 2010 in-person meeting between Impax and Endo)).

RESPONSE TO FINDING NO. 254:

Respondent has no specific response.

255. This make-whole provision "was intended to insulate" Impax from the risk that Endo would discontinue the product prior to Impax's launch. (CX4035 (Cuca, Dep. at 81-82); *see also* Cuca, Tr. 617). If Endo did destroy the market for Impax's product, Mr. Mengler wanted Impax "to be made whole for the profits that we would have otherwise achieved." (Mengler, Tr. at 533). The provision would "come up with a number that [Impax] would have made . . . if [it] had a generic in that six-month period." (CX4010 (Mengler, IHT at 36-37)). If "the market changed substantially before the date that the parties agreed that Impax could launch," the provision "would be a way of making Impax whole." (Cuca, Tr. 617; CX4035 (Cuca, Dep. at 69-70 ("If sales of Opana ER had decreased," the provision would "kind of fix that . . . [b]y making a true-up payment to Impax... The true-up payment would correct for the loss in the value of the market that had occurred before the generic entry date.")).

RESPONSE TO FINDING NO. 255:

The first sentence of Complaint Counsel's Proposed Finding No. 255 is incomplete, misleading, and not supported by the cited evidence. Mr. Cuca's statement was actually, "Impax became concerned that the value to them of the market at that generic entry date could be different than what they had previously expected or assumed, and so the provision was intended to insulate them from that sort of risk or reduce the effect of the impact." (CX4035 (Cuca, Dep. at 81-82)). Mr. Cuca testified at trial that "I don't know that anyone was anticipating a change in the marketplace, but the provision was designed to insulate against a substantial decrease in sales of the innovator product." (Cuca, Tr. 615, 617).

Respondent has no specific response to the second sentence of Proposed Finding No. 255.

The third sentence of Proposed Finding No. 255 lacks foundation because Mr. Mengler testified that "I forget the detailed mechanisms of the royalty and stuff and the detailed math of this, you know, credit calculation. I would have to refresh my memory." (CX4010 (Mengler, IHT at 36-37) (being asked then about "generally what your best recollection is")). Mr. Mengler also testified that his general understanding was that the Endo Credit was "based on pricing and share and just assumptions like that, just basically a calculation that would have said, you know, we're going to take your peak sales and do some math to it and come up with a number that we would have made." (CX4010 (Mengler, IHT at 37).

Respondent has no specific response to the fourth sentence of Proposed Finding No. 255.

256. Mr. Mengler worried that the 50% "make-good" trigger proposed by Endo was too low, but felt that a "similar arrangement with, say a 75% number might be quite attractive." (RX-387 at 0002 (June 1, 2010 Mengler internal email recapping the "current proposal")). Endo was resistant to a higher trigger, and on June 2, 2010, Mr. Mengler told Mr. Levin that Impax was "still not comfortable with the 50% trigger and wonder if your

insistence is due to a known strategy to reduce the market. This may be a sticking point." (CX1308 at 001 (June 2, 2010 email from Mengler to Levin)).

RESPONSE TO FINDING NO. 256:

Respondent has no specific response.

257. Despite Impax's reservations, the parties reached an agreement in principle, including a make whole payment, on the afternoon of June 3, 2010. (CX3334 at 001 (Levin reporting that Endo had "reached a handshake agreement with Impax); CX4012 (Donatiello, IHT at 139) ("Endo and Impax reached an agreement in principal [*sic*] around midday on June 3rd."); CX0114 at 001 (June 3, 2010, email from Mengler reporting that "[i]t seems all parties internally are good to go")). After Endo had agreed to the make whole payment provision, Impax "stop[ped] pursuing an earlier launch date." (CX4018 (Koch Dep. at 71)).

RESPONSE TO FINDING NO. 257:

Respondent has no specific response to the first sentence of Complaint Counsel's Proposed Finding No. 257. The second sentence of Proposed Finding No. 257 is inaccurate, misleading, and not supported by the cited evidence. Mr. Koch actually testified that "What we did was **stop pursuing an earlier launch date *because we were met with no willingness to consider that*** and [Impax] pursued the carrot and the stick" instead. (CX4018 (Koch, Dep. at 71) (emphasis added); *see* Koch, Tr. 239 (Impax "met complete resistance to the concept of an earlier launch date"); Mengler, Tr. 565-67 (Endo was "adamant about 2013 and not getting anything into 2012" and "was certainly digging in their heels with that date"); Noll, Tr. 1599-1600 ("Impax's attempt to get an earlier date met with complete resistance.")). Mr. Koch did not testify that Impax stopped pursuing an earlier launch date after Endo agreed to anything, least of all a "make whole payment."

Moreover, the record directly contradicts the second sentence of Proposed Finding No. 257. After the parties began crafting the Endo Credit, the licensed entry dates the parties discussed (and the date they ultimately agreed up) got earlier, not later. (RX387.0001-02 (June

1, 2010, summary of terms with proposed license date of February 1, 2013, and Endo Credit); CX1301-113 (noting June 1, 2010, negotiations between parties about Endo Credit and royalty provisions); CX2626 (June 8, 2010, executed settlement agreement including same Endo Credit threshold, but January 1, 2013, license date); CX4032 (Snowden, Dep. at 96-97) (Impax continued to pursue 2011 entry date even "after the January 2013 discussions")).

The record also makes clear that Impax did not discuss or accept the Endo Credit—what Complaint Counsel calls a "make whole payment"—in exchange for a later license date. (Mengler, Tr. 567-68; CX4012 (Donatiello, IHT at 172-73) (no provisions in SLA linked to commencement date); CX4010 (Mengler, IHT at 45) ("there was no quid pro quo")). Mr. Mengler, the Impax negotiator of the settlement agreement, testified that Impax "absolutely" would have accepted an earlier license date if it had been possible. (Mengler, Tr. 567).

3. Impax and Endo each negotiated to make the "make whole" payment as favorable for themselves as possible

> 258. After reaching agreement in principle, Impax and Endo turned to crafting a provision that achieved the purpose of delivering a "make-whole" payment to Impax that would approximate what Impax would have expected to make during its six-month No-AG exclusivity period. (CX4035 (Cuca, Dep. at 69-70, 82-83, 93)). The parties worked to ensure that the provision would actually work to produce a "sensible result." (CX4035 (Cuca, Dep. at 95-96 (a sensible result would "insulate Impax from the effect of Endo . . . withdrawing or effectively withdrawing Opana ER from the market ahead of the date on which the parties had agreed that Impax would launch their generic version of Opana ER"))).

RESPONSE TO FINDING NO. 258:

The first sentence of Complaint Counsel's Proposed Finding No. 258 is inaccurate and not supported by the cited evidence. Mr. Cuca did not testify that Impax and Endo "turned to crafting" anything, let alone a "make-whole" payment, after reaching an agreement in principle. Nor does the cited evidence say anything about approximating earnings during a "six-month No-AG exclusivity period." Mr. Cuca testified that "Impax became concerned that the value to them

of the market at that generic entry date could be different than what they had previously expected or assumed, and so the provision was intended to insulate them from that sort of risk or reduce the effect of the impact." (CX4035 (Cuca, Dep. at 81-82)). The "goal was to assess the market for Opana ER that existed before the generic entry date and account for any changes that had occurred to that market to decrease the market." (CX4035 (Cuca, Dep. at 69).

The cited evidence, moreover, directly contradicts Complaint Counsel's assertion that Endo and Impax "turned to crafting" the Endo Credit after reaching a tentative agreement on June 3, 2010. The parties had been negotiating the Endo Credit provision since at least June 1, 2010. (CX4035 (Cuca, Dep. at 73); RX387.0001-02 (June 1, 2010, summary of terms including Endo Credit); CX1301-113 (noting June 1, 2010, negotiations between parties about Endo Credit and royalty provisions); CX2626 (June 8, 2010, executed settlement agreement including same Endo Credit threshold)).

The second sentence of Proposed Finding No. 258 is incomplete, inaccurate, and misleading. Mr. Cuca, Endo's Vice President of Financial Planning and Analysis and the author of the Endo Credit, actually explained that "I would pick a number that seemed like it could be a potential outcome and run it through the formula and make sure it produced a sensible result." (Cuca, Tr. 629). But that process "would have been about five minutes of work with maybe one or two sets of numbers that I would have just to, again, make sure the provision worked, and once I was satisfied with that, that would have been the end of it." (Cuca, Tr. 630-31). The record, moreover, is clear that Impax never analyzed or forecasted whether it would receive a payment under the Endo Credit. (Mengler, Tr. 582; CX4038 (Engle, Dep. at 187-88)). Endo similarly did not forecast any payment under the Endo Credit at the time of settlement. (Cuca,

Tr. 631, 673; CX4017 (Levin, Dep. at 96-98); Noll, Tr. 1649 (neither Endo nor Impax forecast or planned for a payment under the settlement)).

259. Each party negotiated to make the provision more financially favorable for themselves. (*See* CCF ¶¶ 260-69, below).

RESPONSE TO FINDING NO. 259:

The proposed summary finding should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Additionally, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondent's replies to those findings.

260. In a teleconference, Mr. Mengler told Mr. Levin that Impax would accept the alternative of the make-whole payment in place of an acceleration trigger, but all assumptions would have to be in Impax's favor and Endo would have to agree to "aggressive numbers." (Snowden, Tr. 386).

RESPONSE TO FINDING NO. 260:

Respondent has no specific response other than to clarify that Ms. Snowden did not testify about a "make-whole payment," only a "credit." (Snowden, Tr. 386).

261. Roberto Cuca, Endo's Vice President of Financial Planning & Analysis, was tasked with developing the Endo Credit provision on behalf of Endo. (CX4035 (Cuca, Dep. at 68-69); Cuca, Tr. 612, 614-15). Mr. Cuca's "goal was to make the provision be as beneficial to Endo as possible." (CX4035 (Cuca, Dep. at 96)). Mr. Cuca looked for ways to "improve the economic effect of this provision to Endo." (CX4035 (Cuca, Dep. at 96-97)).

RESPONSE TO FINDING NO. 261:

Respondent has no specific response.

262. Endo drafted the first iteration of the make-whole provision, which it included in the first draft of the SLA it sent on Friday June 4, 2010. (CX0323 at 001, 012 (June 4,

2010 email from Mr. Donatiello sending attached draft SLA; draft SLA § 4.4)). Under Endo's initial proposal, Endo's obligation to pay Impax a cash amount would be triggered if the amount of oxymorphone active pharmaceutical ingredient ("API") shipped in the Opana ER strengths for which Impax was first to file fell below a set threshold from the peak consecutive three-month sales period between the SLA's effective date and the fourth quarter of 2012. (CX0323 at 006-07, 12 (June 4, 2010 draft SLA § 4.4 and definitions of "Pre-Impax Amount," "Three Month Shipment Amount," and "Trigger Threshold")).

RESPONSE TO FINDING NO. 262:

Respondent has no specific response other than to clarify that the draft settlement agreement did not contain the term "make-whole provision." (CX0323-012).

263. The amount Endo would be obligated to pay, however, depended on Impax's sales during its six-month No-AG exclusivity period. The lower Impax's net profits during the exclusivity period, the lower the amount Endo was obligated to pay; if Impax did not or could not launch and sell generic oxymorphone ER, then the amount Endo would have to pay Impax would be $0. (CX0323 at 006-07, 12 (June 4, 2010 draft SLA § 4.4 and definitions of "Impax's Net Profit," "Impax Product," "Exclusivity Period, "Pre-Impax Amount," and "Trigger Threshold") ("If the Pre-Impax Amount is less than the Trigger Threshold, then Endo shall pay Impax an amount equal to the product of (a) Impax's Net Profit on the Impax Product during the Exclusivity Period and (b) the Trigger Threshold, divided by (c) the Pre-Impax Amount.")).

RESPONSE TO FINDING NO. 263:

Complaint Counsel's Proposed Finding No. 263 is incomplete and misleading because Impax's profits were relevant under the draft settlement provision only under certain circumstances. The draft Endo Credit provision made clear that, "If the Pre-Impax Amount is not less than the Trigger Threshold, then Endo shall not pay anything under this Section," no matter what Impax realized in terms of profits. (CX0323-012).

264. Because the amount Endo would have to pay Impax was directly tied to Impax's sales of generic oxymorphone ER, Endo's initial formulation failed to address the primary purpose of including a make-whole provision, which was to provide Impax with the profits it had expected to make during its exclusivity period in the event that the market declined or disappeared prior to Impax's licensed entry date. (CX4026 (Nguyen, Dep. at 165-66) (the "gist" of the Endo Credit was "Mr. Mengler basically telling Endo to put its money where its mouth was"); (CX4010 (Mengler, IHT at 36) (Mr. Mengler told

Endo that "if you're not telling me the truth [about switching the market], you're going to pay me what I would have made anyway.")).

RESPONSE TO FINDING NO. 264:

Complaint Counsel's Proposed Finding No. 264 is inaccurate and not supported by the cited evidence. Neither Ms. Nguyen nor Mr. Mengler testified about an early formulation of the Endo Credit, or whether such a formulation failed its so-called purpose. Moreover, Proposed Finding No. 264 ignores that the initial draft of the Endo Credit made clear that, "If the Pre-Impax Amount is not less than the Trigger Threshold, then Endo shall not pay anything under this Section," which allowed Endo to avoid any penalty if original Opana ER sales remained robust. (CX0323-012). As the record makes clear, the prospect of a penalty was meant to incentivize Endo to make investments in its original Opana product. (Koch, Tr. 241; Snowden, Tr. 386; CX4021 (Ben-Maimon, Dep. at 118, 122); CX4010 (Mengler, IHT at 37 ("the primary thought" was to "create an environment that would have enabled us to sell the product" in which "Opana ER was, you know, pacing at a $500 million product on January 1 of '13")).

265. On Saturday June 5, 2010, counsel for Impax sent an edit of the draft SLA to Endo. (CX0324 at 001 (June 5, 2010 draft SLA)). Impax named the make-good provision the "Endo Credit." (CX0324 at 045). Impax proposed two major changes. First, Endo's obligation to pay the Endo Credit would be dependent on a decline of 50% or more in Opana ER unit sales rather that API. (CX0324 at 045 (June 5, 2010 draft SLA § 4.4, definitions of "Endo Credit," "Pre-Impax Amount," "Trigger Threshold," and "Quarterly Peak")).

RESPONSE TO FINDING NO. 265:

Respondent has no specific response other than to note that the draft settlement agreement or any edits thereto did not contain the term "make-good provision."

266. Second, if Endo's obligation to pay was triggered, the amount to be paid would not rely on Impax's actual sales of generic oxymorphone ER during its No-AG exclusivity period, but rather on the revenues Impax would have expected to make during the No-AG exclusivity period had Endo not switched the market. (CX0324 at 045

(June 5, 2010 draft SLA § 4.4, definitions of "Endo Credit," "Market Share Value," and "Market Share Factor")). To approximate this expected amount, the formula incorporated the generic substitution rate (90%), the generic price (75% of the WAC brand price), and the length of the exclusivity period (50%, or half a year or 180 days). (CX0324 at 045 (June 5, 2010 draft SLA § 4.4, definitions of "Endo Credit" and "Market Share Factor")).

RESPONSE TO FINDING NO. 266:

Respondent does not dispute the specific terms were included in the cited document, but the cited exhibit does not support the proposition that any payment under such terms would rely on "the revenues Impax would have expected to make" or that the formula approximated those revenues. Moreover, the cited document makes clear that the proposal came from Impax's counsel alone, and was still subject to Impax's review. (CX0324-001 ("Please note that, in the interest of time, the attached documents are being sent contemporaneously to our client and, therefore, remain subject to their further review and comment.")). Finally, the cited document notes that Impax's counsel proposed the edits to the Endo Credit in order "to discuss before adding them to the agreement itself." (CX0324-001).

267. On Sunday, June 6, 2010, Endo responded to Impax's proposal with two additional changes to the make-whole provision. (CX2771 at 001, 005-07, 014 (June 6, 2010 email attaching draft SLA).

RESPONSE TO FINDING NO. 267:

Respondent has no specific response other than to clarify that the cited evidence does not use the term "make-whole provision." (CX2771).

268. First, Endo proposed that its obligation to pay the Endo Credit would be dependent on a decline of 50% or more in Opana ER dollar sales, as calculated by multiplying unit sales by the wholesale acquisition (WAC) cost, instead of unit sales. (CX2771 at 005, 007, 014 (June 6, 2010 draft SLA § 4.4, definitions of "Endo Credit," Pre-Impax Amount," "Prescription Sales," and "Quarterly Peak")). This switch from units to dollars was to make the provision more "sensible," as it was unclear "how you would actually do the calculation with units rather than dollars." (CX4035 (Cuca, Dep. at 103-04); *see also* Cuca, Tr. 628).

RESPONSE TO FINDING NO. 268:

Respondent has no specific response.

269. Second, though Endo largely agreed to Impax's proposed approach for calculating the amount to be paid if the Endo Credit was triggered, Endo wanted the amount to reflect Impax's expected profits during the No-AG exclusivity period, rather than Impax's expected revenues. (CX2771 at 005-06, 14 (June 6, 2010 draft SLA § 4.4, definitions of "Endo Credit," "Market Share Profit Factor," and "Market Share Profit Value")). The effect of this change would be to reduce any amount to be paid to Impax under the Endo Credit. (CX2771 at 005-06, 014 (June 6, 2010 draft SLA § 4.4, definitions of "Endo Credit," "Market Share Profit Factor," and "Market Share Profit Value"); *see also* CX4035 (Cuca, Dep. at 105-06) ("[T]hat is one of the ways that the Endo team would have negotiated to make it more financially favorable to Endo."); Cuca, Tr. 639). Endo believed that incorporating Impax's net profit margin was consistent with the objective of "trying to make them whole at the bottom line, so at their profit line, whereas the prior provision would have made them whole at the revenue line and actually would have advantaged them as compared to what was trying to be achieved." (Cuca, Tr. 638-39).

RESPONSE TO FINDING NO. 269:

Respondent has no specific response.

4. The make-whole provision guaranteed the value of the No-AG: either Impax would earn profits from exclusively selling generic Opana ER during 180-day period or would get the make-whole payment

270. Impax agreed to both changes proposed by Endo. (CX2767 at 004, 006-07, 013 (June 7, 2010 Impax draft SLA § 4.4, definitions of "Endo Credit," "Market Share Profit Factor," "Market Share Profit Value," "Pre-Impax Amount," "Prescription Sales," and "Quarterly Peak"); RX-364 at 0003-06, 12 (SLA § 4.4, definitions of "Endo Credit," "Market Share Profit Factor," "Market Share Profit Value," "Pre-Impax Amount," "Prescription Sales," and "Quarterly Peak")).

RESPONSE TO FINDING NO. 270:

Respondent has no specific response.

271. If Endo did not harm the market for Impax's generic oxymorphone ER before its licensed entry in 2013, Impax would enjoy the benefit of the 180-day No-AG exclusivity provision. (Mengler, Tr. 534). With no authorized generic, Impax would be guaranteed to be the only generic on the market for its first six months, allowing Impax to capture a

greater market share and to charge a higher price. (Snowden, Tr. 392; CX4003 (Snowden, IHT at 111-13); CX4010 (Mengler, IHT at 25); Mengler, Tr. 524).

RESPONSE TO FINDING NO. 271:

The first sentence of Complaint Counsel's Proposed Finding No. 271 is misleading. Mr. Mengler testified only that Impax would benefit from the ability to make additional sales in the absence of an authorized generic. (Mengler, Tr. 533-34). However, the No-AG provision would only benefit Impax in this way if, absent the commitment, Endo would have launched an AG.

The Proposed Finding is also misleading and vague in its use of the phrase "if Endo did not harm the market," and what level of original Opana ER sales growth or reduction this can encompass. For example, if Endo launched reformulated Opana ER late in 2012 but continued to sell original Opana ER into the fourth quarter of that year, Endo "could have moved the market down so in the last quarter it would be down less than 50 percent and they would not have had to pay the credit." (Reasons, Tr. 1228; *see* CX4032 (Snowden, Dep. at 205-06)). If that occurred, Impax would have a much reduced opportunity for its generic version of the original Opana ER. (Mengler, Tr. 583; CX4037 (Smolenski, Dep. at 251-52)). Impax considered it "entirely plausible" that Endo could employ a late switch in products such that there was a reduced generic opportunity for Impax—and thus no benefit from a No-AG provision—while Endo still made no Endo Credit payment. (Mengler, Tr. 589-90; CX4002 (Smolenski, IHT at 50-51, 129, 187-88); Bingol, Tr. 1338 (Endo had no intention of launching both an authorized generic and a reformulated version of Opana ER); CX4019 (Lortie, Dep. at 117-18) (Endo "intended to replace one product with the other, and that would be the only product that we had on the market.")).

The second sentence of Proposed Finding No. 271 is inaccurate, misleading, and not supported by the cited evidence. Mr. Mengler testified that "it's hard to know what would

happen in an individual market" and "it's difficult to predict in an individual market," before speaking about sales and market shares only in general terms and with no reference to Impax. (Mengler, Tr. 524). Ms. Snowden testified that assuming Impax did not forfeit its exclusivity, the FDA could not approve additional oxymorphone ANDAs for the relevant dosage on which it was the first filer. (CX4003 (Snowden, IHT at 27, 112-13 (discussing identified strengths and "Endo products"); *see* Mengler, Tr. 522-23). The record, however, is replete with evidence that generic oxymorphone ER would still compete with generic and branded versions of many different long-acting opioids, even if there was no authorized generic. (Savage, Tr. 732 (when a patient seeks treatment for chronic pain in the first instance, doctors can prescribe any long-acting opioid); RX-083.0003 at 35 (highlighting real-world switching patterns between oxymorphone-based products and drugs including fentanyl, oxycodone, and morphine)). Demir Bingol, Endo's Senior Director of Marketing and the Endo employee responsible for knowing with whom oxymorphone-based products compete, testified that "all long-acting opioid formulations," including generics that are not actively marketed, are direct competitors. (Bingol, Tr. 1271, 1313).

This competition plays out through, among other things, "effective targeting of your messaging to your clinicians," "rebates that you offer payers in order to ensure that you have a competitive place on formularies," and "certain competitors coming and going that your product becomes a natural next choice." (Bingol, Tr. 1284). With respect to formularies in particular, manufacturers compete on price to secure favorable formulary placement vis-à-vis competitors. (Bingol, Tr. 1324-25). This includes rebates by brand companies in order to compete with generic products on price. (Bingol, Tr. 1327; Engle, Tr. 1718; CX4037 (Smolenski, Dep. at 155)). And it can mean that generic long-acting opioids, like oxymorphone ER, are excluded

from formulary coverage in favor of other long-acting opioids. (Noll, Tr. 1546; RX-017.0001; RX-017.0002 at 11).

272. If Endo did reformulate and harm the market for Impax's generic oxymorphone ER product, the Endo Credit would provide Impax with compensation approximating its expected earnings from its six-month No-AG exclusivity period. (Mengler Tr. 533-35; Cuca, Tr. 625 ("the provision was intended to capture a loss of value to Impax' launch and its six months of exclusivity post that launch"); CX4010 (Mengler, IHT at 36); CX4035 (Cuca, Dep. at 68-70)).

RESPONSE TO FINDING NO. 272:

Complaint Counsel's Proposed Finding No. 272 is inaccurate, misleading, and vague in its use of the phrase "if Endo did not harm the market," and what level of original Opana ER sales growth reduction this can encompass. The record is clear that Impax was not guaranteed compensation, even if Endo caused some harm to Impax's generic opportunity. If Endo launched reformulated Opana ER late in 2012 but continued to sell original Opana ER into the fourth quarter of that year, Endo "could have moved the market down so in the last quarter it would be down less than 50 percent and they would not have had to pay the credit." (Reasons, Tr. 1228; *see* CX4032 (Snowden, Dep. at 205-06)). If that occurred, Impax would have a much reduced opportunity for its generic version of the original Opana ER. (Mengler, Tr. 583; CX4037 (Smolenski, Dep. at 251-52)). Impax considered it "entirely plausible" that Endo could employ a late switch in products such that there was a reduced generic opportunity for Impax—and thus no benefit from a No-AG provision—while Endo still made no Endo Credit payment. (Mengler, Tr. 589-90; CX4002 (Smolenski, IHT at 50-51, 129, 187-88); Bingol, Tr. 1338 (Endo had no intention of launching both an authorized generic and a reformulated version of Opana ER); CX4019 (Lortie, Dep. at 117-18) (Endo "intended to replace one product with the other, and that would be the only product that we had on the market.")).

273. The Endo Credit in the executed SLA provided that Endo would be obligated to pay Impax a cash amount if Endo's Original Opana ER dollar sales (as calculated by units multiplied by the WAC price) fell by more than 50% from the "Quarterly Peak" (the highest sales quarter between Q3'2010 and Q3'2012) to the fourth quarter of 2012 (the quarter before Impax would be permitted to launch its generic oxymorphone ER product). (RX-364 at 0003-06, 12 (SLA § 4.4, definitions of "Endo Credit," "Market Share Profit Factor," "Market Share Profit Value," "Pre-Impax Amount," "Prescription Sales," "Quarterly Peak," and "Trigger Threshhold")).

RESPONSE TO FINDING NO. 273:

Respondent has no specific response.

274. If Endo's obligation to pay the Endo Credit was triggered, the amount would approximate the net profits Impax would have expected to make during its six-month No-AG exclusivity period had Endo not moved the market to a new formulation. The provision achieved this by basing the calculation in part on the expected generic substitution rate (90%), the expected generic price (75% of the brand WAC price), Impax's net profit margin (87.5%), and the length of the No-AG exclusivity period (50%, or 180 days expressed as half a year). (RX-364 at 0004 (SLA § 4.4, definitions of "Market Share Profit Value"); *see also* Cuca, Tr. 635-37). By including Impax's net profit margin rather than just looking to Impax's expected revenues, any amount Endo would be required to pay was reduced by 12.5%. (RX-364 at 0004 (SLA § 4.4, definitions of "Market Share Profit Value"); Cuca, Tr. 640-41).

RESPONSE TO FINDING NO. 274:

The first sentence of Complaint Counsel's Proposed Finding No. 274 is not supported by any record evidence and should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). The first sentence of the Proposed Finding No. 274 is also wrong. Actual quarterly peak sales after settlement were $185,691,457. (CX0332-003). If sales dropped just enough to trigger the Endo Credit, for instance, because sales in the last quarter of 2012 were 49 percent of their quarterly peak, this would mean the resulting liability would be roughly $2 million. If sales dropped only to 49.9 percent of their peak, the resulting liability would be roughly $200,000. (RX-364.0003-04 (any Endo Credit payment is the product of (1) 0.2953 times the annualized quarterly peak sales

divided by 100, and (2) the number of percentage points under 50)). There is no evidence to suggest that such potential liabilities under the Endo Credit are approximations of Impax's expected net profits over six months.

Although Respondent does not dispute that the specific terms identified in the second sentence of Proposed Finding No. 274 were included in the settlement agreement, the cited evidence does not support the proposition that those terms ensured Impax would receive a payment approximating net profits in any instance in which the Endo Credit was triggered. They simply meant that annualized quarterly peak sales (after being divided by 100) would be multiplied by a specific figure: 0.2953. (RX-364.0003-04).

Respondent has no specific response to the third sentence of Proposed Finding No. 274.

275. Thus, the Endo Credit was "basically a calculation that would have given . . . an approximation of the profits . . . that Impax would have earned . . . if [Impax] had a generic in that six-month" exclusivity period. (CX4010 (Mengler, IHT at 36-38) (analysis underlying the Endo Credit was "some general market calculations based on how much money I would have made if I was able to . . . sell that as an exclusive for six months")).

RESPONSE TO FINDING NO. 275:

Complaint Counsel's Proposed Finding No. 275 lacks foundation because Mr. Mengler testified that "I forget the detailed mechanisms of the royalty and stuff and the detailed math of this, you know, credit calculation. I would have to refresh my memory." (CX4010 (Mengler, IHT at 36-37) (being asked then about "generally what your best recollection is")). The Proposed Finding is also incomplete and misleading because the record makes clear that "the primary thought" behind the Endo Credit (and the prospect of Endo incurring a penalty thereunder) was to incentivize Endo to make investments in its original Opana ER product and thereby protect Impax's generic opportunity. (CX4010 (Mengler, IHT at 37) ("the primary thought" was to "create an environment that would have enabled us to sell the product" in which

"Opana ER was, you know, pacing at a $500 million product on January 1 of '13"); Koch, Tr. 241; Snowden, Tr. 386; CX4021 (Ben-Maimon, Dep. at 118, 122)).

E. Late in the negotiations, Impax sought an earlier entry date without any additional payment provisions

276. On June 4, 2010, Impax CFO Art Koch and Ms. Snowden replaced Mr. Mengler as Impax's primary negotiators. (CX0507 at 001 (June 4, 2010, Hsu email to Mengler)). At an internal Impax management discussion that day, Mr. Koch and Ms. Snowden were instructed to go back to Endo and ask for a "simple settlement" dropping the payment terms then on the table (No-AG provision, make-whole provision, and side deal) but with a generic license entry date of July 2011—the same date Endo had granted to Actavis. (CX4032 (Snowden, Dep. at 96-99) (Impax proposed "dropping all of that discussion and entering into a simple settlement agreement with the Actavis entry date"); Snowden, Tr. 372-73).

RESPONSE TO FINDING NO. 276:

Respondent has no specific response to the first sentence of Complaint Counsel's Proposed Finding No. 276.

The second sentence of Proposed Finding No. 276 is inaccurate and not supported by the cited testimony. Ms. Snowden did not testify that she was instructed to drop so-called "payment terms." Indeed, Ms. Snowden testified that the Endo Credit and No-Authorized Generic terms were not discussed at the internal Impax meeting at all. (Snowden, Tr. 373). Ms. Snowden also testified that any "simple settlement" "likely" would still contain some kind of acceleration trigger. (Snowden, Tr. 372-73).

277. Mr. Koch and Ms. Snowden proposed the "simple settlement" to Endo, which Endo rejected. (CX4032 (Snowden, Dep. at 99-100); Snowden, Tr. 370-75). Mr. Levin was "very angry" that Mr. Koch and Ms. Snowden were "dismissing the entire deal and deal terms that he had negotiated with Chris Mengler." (CX4032 (Snowden, Dep. at 100); *see also* Snowden, Tr. 376-78). Mr. Levin insisted on a license agreement on "terms he had negotiated with Chris Mengler" and "refused to entertain any discussion around an earlier license date." (CX4032 (Snowden, Dep. at 100-01); *see also* Snowden, Tr. 374-75).

RESPONSE TO FINDING NO. 277:

Respondent has no specific response.

278. Following Mr. Levin's rejection of the earlier entry date, the parties resumed discussing the terms Mr. Levin had negotiated with Mr. Mengler, but with Mr. Koch now negotiating for "better terms on the co-promote deal." (CX4032 (Snowden, Dep. at 102, 197-98); *see also* (CX1311 (June 4, 2010 Levin email to Holveck re "It's not over till the fat lady sings...")).

RESPONSE TO FINDING NO. 278:

Respondent has no specific response.

F. Impax eventually sought a license to future potential patents covering Opana ER

279. Impax and Endo did not discuss the scope of the patent license to be granted to Impax prior to reaching agreement in principle on June 3, 2013. Mr. Mengler, Impax's primary negotiator until June 4, 2010, never "had a discussion with Endo about patents personally." (Mengler, Tr. 524-25, 573; *see also* CX4022 (Mengler, Dep. at 226) (testifying that he never discussed with Endo what intellectual property would be included in the license and that he does not know what "scope of the patent license" means)). When Mr. Koch and Ms. Snowden took over negotiating responsibilities on June 4, 2010, the licensed entry date of January 1, 2013 was already set. (CX4018 (Koch, Dep. at 73-76)). Mr. Koch and Ms. Snowden also did not raise the issue of the scope of the patent license with Endo. (CX4001 (Koch, IHT at 42-43); CX4032 (Snowden, Dep. at 121-22)).

RESPONSE TO FINDING NO. 279:

The first sentence of Complaint Counsel's Proposed Finding No. 279 is not supported by any record evidence and should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2).

Respondent has no specific response to the second sentence of Proposed Finding No. 279.

The third sentence of Proposed Finding No. 279 is inaccurate. No final terms were set until the parties executed their settlement agreement. Indeed, Ms. Snowden testified that Impax

continued to pursue a 2011 license date even "after the January 2013 discussions." (CX4032 (Snowden, Dep. at 96-97)).

The fourth sentence of Proposed Finding No. 279 is not supported by the cited evidence. Mr. Koch testified only that he did not "have a lot of back and forth on [patents] with Endo," not that he never raised the issue of the scope of the patent license. (CX4001 (Koch, IHT at 43); *see* Mengler, Tr. 575 (other Impax employees reviewed the draft settlement agreements, expressed concern about the patent issue, and had discussions between Impax and Endo related to the patents)).

> 280. The responsibility for addressing the scope of patent license fell to Huong Nguyen, Impax's Senior Director of Intellectual Property. (CX4032 (Snowden, Dep. at 121-22); CX4026 (Nguyen, Dep. at 143-44)). Ms. Nguyen first became involved in the settlement talks on June 5, 2010. (CX4026 (Nguyen, Dep. at 141-42); CX0310 at 007). That same day, Impax for the first time proposed broadening the patent license to "any patents and patent applications owned or licensed by Endo . . . that cover or could potentially cover" Impax's generic oxymorphone ER product. (CX0324 at 030 (June 5, 2010 draft SLA § 4.1(a)); *see also* CX4026 (Nguyen, Dep. at 153-55) (testifying that the June 5 SLA draft expanded the scope of the patent license); CX4012 (Donatiello, IHT at 93)).

RESPONSE TO FINDING NO. 280:

The first sentence of Complaint Counsel's Proposed Finding No. 280 is incomplete and misleading. Ms. Snowden testified that Ms. Nguyen and Impax's outside counsel were both involved in the drafting of the license provision, but that Ms. Snowden was personally involved in internal discussions about the language that would ultimately become the license provision. (CX4032 (Snowden, Dep. at 122)).

The second sentence of Proposed Finding No. 280 is incomplete and misleading. Ms. Nguyen testified that "I don't have exact dates" and that the date of June 5 may only be "approximately right for when [she] became involved." (CX4026 (Nguyen, Dep. at 142-43)).

Respondent does not dispute the content of Impax's counterproposal on June 5, 2010, but the cited evidence does not support the proposition that "Impax for the first time proposed broadening the patent license" on that date.

281. In contrast, both Endo's May 26, 2010 term sheet and its initial June 4, 2010 draft of the SLA limited the license to the three patents then listed in the Orange Book for Opana ER (the '933, '456, and '250 patents). (CX0320 at 006, 009-10 (May 26, 2010 Endo term sheets); CX0323 at 006, 010 (June 4, 2010 draft SLA §§ 1.1, 4.1(a))).

RESPONSE TO FINDING NO. 281:

Respondent has no specific response.

282. In settlement negotiations with brand companies, Impax would regularly seek a broad patent license whenever it intended to launch and continue to sell its generic product indefinitely. (CX4026 (Nguyen, Dep. at 155-56)). In negotiating patent licenses, Ms. Nguyen's practice was "to provide the business with as much flexibility as possible." (CX4026 (Nguyen, Dep. at 157)). In any negotiation where the brand company tried to narrow the scope to the patents being litigated, Impax was "very firm," explaining that "'this is not about the patents being litigated. This is about a product, and we want the ability to operate.'" (CX4026 (Nguyen, Dep. at 157-58)).

RESPONSE TO FINDING NO. 282:

Respondent has no specific response.

283. Ms. Nguyen could not recall a settlement with a brand company that limited the license to the asserted patents from her nine years at Impax, during which time she oversaw all but three of Impax's patent litigations. (CX4026 (Nguyen, Dep. at 32-33, 158)).

RESPONSE TO FINDING NO. 283:

Respondent has no specific response.

284. Impax and Endo ultimately included a broader license, including a license to patent applications and future patents, in the final SLA, but they also included a provision in which Impax and Endo agreed "to negotiate in good faith an amendment to the terms of the License" to any patents issued in the future from patent applications that were pending at the time of the agreement. (RX-364 at 0009, 0011 (SLA §§ 4.1(a), 4.1(d))).

RESPONSE TO FINDING NO. 284:

Complaint Counsel's Proposed Finding No. 283 is misleading and incomplete in its discussion of the SLA sections 4.1(a) (the License) and 4.1(d) (referring to additional good faith negotiations to amend the License) without referencing the broad Covenant Not to Sue set forth in SLA section 4.1(b). (RX-364.0009-11 (SLA §§ 4.1(a), 4.1(b), 4.1(d))). No evidence suggests section 4.1(d) has any effect on section 4.1(b)'s Covenant Not to Sue, which covered any patents licensed to Endo or Pennwest that "cover or potentially could cover" the manufacture or sale of Opana ER. (RX-364.0010 (SLA §§ 4.1(b))).

G. Impax switched the side deal subject from IPX-066 to IPX-203 and demanded greater milestone payments

1. Initially, Impax and Endo discussed an IPX-066 side deal

285. As discussed above (¶¶ 232-39), from the outset of the renewed settlement discussions, Impax and Endo began discussing a side deal in which Endo would collaborate with Impax on IPX-066, Impax's treatment for Parkinson's disease that was in the last stage of clinical development prior to be ready to submit an NDA to the FDA.

RESPONSE TO FINDING NO. 285:

The proposed summary finding should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Additionally, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondent's replies to those findings.

286. Dr. Roberto Cobuzzi, Endo's Senior Vice President of Corporate Development, and his team were tasked with evaluating a potential deal with Impax. (Cobuzzi, Tr. at 2514, 2523-24).

RESPONSE TO FINDING NO. 286:

Respondent has no specific response.

287. Endo began work on an Opportunity Evaluation Worksheet ("OEW") to assess a potential collaboration on IPX-066 on May 20, 2010 (CX1006 at 001 (Endo internal email)), but did not complete it prior to sending the term sheet to Impax on May 26, 2010. (CX1704 (May 24, 2010 draft OEW); CX2775 (May 27, 2010 email forwarding the incomplete OEW)).

RESPONSE TO FINDING NO. 287:

Respondent has no specific response.

288. Endo rushed to review IPX-066 and to prepare an offer to Impax. [redacted] (RX-072 at 0004 (May 21, 2010 email to Equinox) (*in camera*). [redacted] (RX-072 at 0004 (emphasis in original) (*in camera*)). [redacted] (RX-072 at 0004 (*in camera*)). [redacted] (RX-072 at 0004 (*in camera*)).

RESPONSE TO FINDING NO. 288:

Complaint Counsel's Proposed Finding No. 288 is misleading and not supported by the cited evidence to the extent that it characterizes the timing of Endo's efforts to prepare an initial DCA term sheet as "rushed." The documents cited indicate that Endo proceeded [redacted] and that the efforts needed to be completed within a certain amount of time, but do not speak to whether or not Endo was "rushed" in preparing its initial term sheet as a result. In fact, Dr. Cobuzzi testified he had sufficient time to analyze IPX-203 in the context of the DCA. (Cobuzzi, Tr. 2543, 2625).

289. On the evening of May 24, 2010, Dr. Cobuzzi pressed Equinox to provide a view of peak sales by the next day so that he could "construct an expression of interest as there is a time delimiter." (CX1009 at 002 (Cobuzzi email to Godolphin)). At the time, Impax had no other suitors for any U.S. collaboration on IPX-066. (CX4036 (Fatholahi, Dep. at 76-77); CX4014 (Hsu, IHT at 48-49)). [redacted]

[redacted] (RX-072 at 0001 (Endo emails with Equinox (*in camera*)). [redacted] (RX-072 at 0001) (*in camera*).

RESPONSE TO FINDING NO. 289:

Complaint Counsel's Proposed Finding No. 289 is incomplete and misleading in its selective description of Equinox's market research. Subsequent portions of the cited document indicate that [redacted] (RX-072.0001). And the sentence Complaint Counsel selectively quotes actually states: [redacted] (RX-072.0001 (emphasis added)). The cited document also refers to [redacted] (RX-072.0004).

290. On May 25, 2010, Dr. Cobuzzi continued to press his team to get a review done quickly, warning R&D employees that "[w]e have very little time for this evaluation – ie, we need to have a perspective by EOB [end of business] *this* Thursday." (CX1007 at 001 (Cobuzzi email re IPX066) (emphasis in original)). Dr. Cobuzzi asked that they not "start sending me a lot of disparaging emails or slandering me personally for the condensed timeline for this review." (CX1007 at 001).

RESPONSE TO FINDING NO. 290:

Respondent has no specific response other than to clarify that the document states "this should not be a difficult evaluation." (CX1007-001; Cobuzzi, Tr. 2548-49 (discussing CX1007 and explaining "I didn't think this was going to be difficult to evaluate" because "[w]e knew the space, we knew the underlying molecules, the carbidopa and levodopa, and we looked at a number of Parkinson's opportunities in the past")).

291. As discussed above (¶ 228, 237-39), on May 26, 2010, Endo sent a term sheet for an IPX-066 side deal to Impax, proposing an option agreement for IPX-066 in which Endo would pay Impax $10 million upfront and $5 million upon the FDA's acceptance of an NDA in exchange for the right to either purchase an exclusive license to the product or to co-promote the product to non-neurologists. (CX0320 at 002-04 (May 26, 2010 Endo term sheets)). Equinox did not send its estimate of the percentage of Parkinson's patients diagnosed (37%) and managed (40%) by non-neurologists until after Endo had sent the term sheet to Impax. (CX1009 at 001, 008 (May 26, 2010 email from Equinox to Cobuzzi attaching "Strategic Insights" presentation)).

RESPONSE TO FINDING NO. 291:

To the extent the first sentence of Complaint Counsel's Proposed Finding No. 291 attempts to incorporate and summarize other findings, it should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Moreover, the individual findings cited are misleading or incomplete for the reasons set out in Respondent's replies to those findings. In any event, the first sentence of Proposed Finding No. 291 is misleading and incomplete in (1) its suggestion that Endo's initial May 26, 2010, term sheet proposed "an IPX-066 side deal," when the term sheet refers to the entire IPX-066 franchise and does not link the potential collaboration to settlement; and (2) its failure to acknowledge that the proposed terms called for Endo to receive 50 percent of all the profits from sales generated by non-neurologist prescriptions. (CX0320).

The second sentence of Proposed Finding No. 291 is incomplete and misleading in its suggestion that Endo did not independently have knowledge about Parkinson's disease or the number of prescriptions written by non-neurologists. The record reflects that Endo had extensive experience vetting potential Parkinson's disease products, which included performing market research on the Parkinson's disease market. (Cobuzzi, Tr. 2548-49).

2. Impax switched the subject of the side deal from IPX-066 (a late-stage product) to "IPX-066a"/IPX-203 (a preclinical product)

292. On May 26 and 27, 2010, after a week of efforts by both parties to enable Endo to review IPX-066 and develop a proposal for the product, Impax informed Endo that it was taking IPX-066 off the table as a product for possible collaboration. (*See* CCF ¶¶ 293-294, below).

RESPONSE TO FINDING NO. 292:

The proposed summary finding should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Additionally, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondent's replies to those findings.

293. On May 26, 2010, Mr. Mengler informed Mr. Levin and Mr. Donatiello on a call that the R&D collaboration would be for a "product tbd," for which Impax wanted Endo to provide $50 million. (CX0502 at 001 (May 26, 2010 Mengler email to Hsu et al. regarding Endo negotiations)).

RESPONSE TO FINDING NO. 293:

Respondent has no specific response.

294. On May 27, 2010, after reviewing Endo's proposed term sheets, Mr. Mengler informed Endo that the R&D collaboration would be for "for a product I designate as 066a. This is our next generation of 066. We have significant data and can name the product at signing." (RX-565 at 0001 (Mengler email to Levin)). Mr. Mengler warned Mr. Levin that "[w]hen I indicated my offer wasn't 'first' but close to 'last' apparently that was mis-interpreted as the initiation of multiple rounds of give and take, something we want to avoid." (RX-565 at 0001). In addition to his demands regarding entry date, a No-AG provision, and an acceleration trigger for market degradation, Mr. Mengler wanted $60 million in upfront and milestone payments for the product to be named at signing. (RX-565 at 0001).

RESPONSE TO FINDING NO. 294:

Respondent has no specific response to the first, second, and third sentences of Complaint Counsel's Proposed Finding No. 294. The fourth sentence of Proposed Finding No.

294 is misleading in its selective paraphrasing, excerpting, and description of the cited document (RX-565). The Proposed Finding refers to the No-Authorized Generic term as an Impax "demand," but Endo had already proposed the exact same term in Endo's initial term sheet the day before. (CX0320-002). The Proposed Finding also omits that only $3 million would be payable at signing, with the rest subject to development milestones, and that Impax would pay Endo a royalty if the Opana ER opportunity expanded by certain metrics. (RX-565.0001).

295. Impax's actual internal code name for "066a" was "IPX-203." (CX3178 (June 4, 2010 Nestor email to Cobuzzi re Information requested); CX2533 at 001 (June 5, 2010 email re: information requested) (IPX-203 is "similar to IPX066 in that it is carbidopa + levodopa with the differences being that they will use an esterified version of levodopa")). Whereas IPX-066 was in the last phase of clinical development before filing with the FDA, IPX-203 was in the earliest pre-clinical or "discovery" stage. (CX1209 at 002 (June 8, 2010 Endo OEW); CX2780 at 026 (June 4, 2010 Impax IPX-203 presentation) [redacted] *see also* CX5003 at 009 (¶ 17) (Geltosky Report)). In the midst of the negotiations, Michael Nestor, President of Impax's Branded Division, warned Mr. Mengler that the project "is not a slam dunk," with at least one scientist thinking "there will be some difficulty with developing the formulation." (RX-387 at 0001 (June 1, 2010 Nestor email to Mengler); CX4033, Nestor Dep. at 116 (the parties "really had no idea as to the success" of IPX-203 because "probability of success with any drug at this point in the development is fairly low")).

RESPONSE TO FINDING NO. 295:

Respondent has no specific response to the first and second sentences of Complaint Counsel's Proposed Finding No. 295. The third sentence of Proposed Finding No. 295 is incomplete and misleading in its selective paraphrasing and excerpting of the cited evidence. Mr. Nestor stated in his email to Mr. Mengler that "Suneel [Gupta, Impax's Chief Scientific Officer] thinks it is doable," and that Mr. Nestor personally "views [the formulation] as part of the development process." (RX-387.0001; Nestor, Tr. 2946). Mr. Nestor testified that when Dr. Gupta, who was renowned for his formulation capabilities, believes something is "doable," that carries a great deal of weight. (Nestor, Tr. 2946 ("Suneel Gupta, for whom I have a great deal of

professional respect, he thought it would be doable, and that was good enough for me"; noting Dr. Gupta has "done a number of product developments where he has basically taken an existing chemical compound and improved it and then had those products come to market and been very successful commercial products"); CX4033 (Nestor, Dep. at 82-83) (describing Dr. Gupta as a renowned formulator)). Finally, Mr. Nestor went on to note in his email to Mr. Mengler that the product might be better than IPX-066, and that he "would hate to have to sell it." (RX-387.0001; Nestor, Tr. 2946-47).

3. Endo agreed to Impax's late product switch to IPX-066a/IPX-203

296. At the June 1, 2010, in-person meeting, Endo agreed to the switch to "066a." (RX-387 at 0001 (June 1, 2010 Mengler internal email recapping the "current proposal"); *see also* CX0406 at 001 (June 2, 2010 Mengler email to Hsu et al.) (describing deal structure "for co-development of 066a"); CX1011 (June 2, 2010 Levin email to Mengler)). Following the meeting, Mr. Mengler described the "current proposal" as $40 million in total milestone funding, including $5 million upfront. In return, Endo would get the option to exclusively license the product for an additional payment of five times the projected first three years of sales or to co-promote the product to non-neurologists. (RX-387 at 0001 (June 1, 2010 Mengler internal email recapping the "current proposal"); *see also* CX1011 (June 2, 2010 Levin email to Mengler)).

RESPONSE TO FINDING NO. 296:

The first sentence of Complaint Counsel's Proposed Finding No. 296 is inaccurate and misleading in its suggestion that there was a switch in products. As Ms. Snowden testified, "Endo was interested in the Parkinson's space and wanted the deal to cover both products, the original IPX-066 and the follow-on product [IPX-203], but Impax wasn't interested in doing the deal on IPX-066. So there wasn't actually . . . a switch as much as Endo was trying to negotiate for both product rights and Impax was only interested in doing product rights on the one product." (Snowden, Tr. 405-06).

The second sentence of Proposed Finding No. 296 is incomplete and misleading in its selective description of the "current proposal" detailed in the cited evidence (RX-387). The

proposal also called for Endo to receive all profits from sales generated by non-neurologists.

(*See* RX-387 ("or they co-promote to Impax targets, *retaining 100%*") (emphasis added)).

297. On June 2, 2010, Mr. Levin clarified that Endo's offer for "066a" was for an upfront payment of $10 million and single additional milestone payment of $5 million upon successful completion of Phase II. (CX1011 (June 2, 2010 Levin email to Mengler)). If Endo elected to exclusively in-license the compound, Endo would pay Impax fives the projected first four years of sales (rather than three years) as well as give Impax a co-promote on 10% of the total promotion effort. (CX1011).

RESPONSE TO FINDING NO. 297:

Respondent has no specific response.

298. As discussed above (¶ 257), on June 3, 2010, Mr. Mengler and Mr. Levin reached an agreement in principle, which covered both the license terms and the side deal. (CX3334 at 001 (Mr. Levin reporting that Endo had "reached a handshake agreement with Impax"); CX0412 (Donatiello, IHT at 139) ("Endo and Impax reached an agreement in principal [*sic*] around midday on June 3rd."); CX0114 at 001 (June 3, 2010, email from Mr. Mengler reporting that "[i]t seems all parties internally are good to go"); Cobuzzi, Tr. 2632-33 (SLA and DCA comprised a "package of deals")). [redacted] (CX0114 at 001 (June 3, 2010 Mengler email to Nestor) (partially *in camera*); CX0407 at 001-02 (June 3, 2010 Mengler email to Hsu et al. re Status)). Mr. Mengler felt the "proposal balances the interests of the business with our FTF [first-to-file] status." (CX0407 at 001-02 (June 3, 2010 Mengler email to Hsu et al. re Status)).

RESPONSE TO FINDING NO. 298:

Respondent has no specific response.

299. The parties reached this agreement in principle even though Impax had yet to provide any information on the drug or even provide the product's actual code name. Mr. Mengler had "asked about an 066a resource" (CX1308 (June 2, 2010 Mengler email to Levin)), but had yet to provide the name of a resource or any written materials to Endo. On June 3, 2010, Mr. Mengler asked Mr. Nestor, President of Impax's Branded Division, for "a person for Endo to speak with on 066a," warning that "otherwise were [*sic*] done." (CX0114 at 002 (June 3, 2010 Mengler email to Nestor)). Mr. Mengler needed someone from Impax to provide Endo "any info so they can 'check the box.'" (CX0114 at 001 (June 3, 2010 Mengler email to Nestor); *see also* CX2948 at 001 (June 3, 2010 Nestor email to Gupta re Endo Contact Person) ("Need to give Endo a contact person for 066A (L-dope ester concept) for development aspects of drug.")).

RESPONSE TO FINDING NO. 299:

Complaint Counsel's Proposed Finding No. 299 is incorrect to the extent it claims "Impax had yet to provide any information on the drug" as of June 2, 2010. By May 27, 2010, Impax had identified the product as the next-generation version of, and follow-on product to, IPX-066, and had provided extensive information to Endo regarding that predecessor drug. (RX-318.0001). This information was relevant to understanding IPX-203, and "tremendously valuable" to Endo in assessing IPX-203. (Cobuzzi, Tr. 2625-26, 2602).

4. Endo agreed to Impax's late demand for a bigger payment

300. Despite the parties having reached an agreement in principle, Dr. Hsu, Mr. Koch, and Mr. Nestor decided they wanted a larger payment from Endo. (CX0407 at 001 (June 3, 2010 Koch email to Mengler re Status)). Though Mr. Koch understood the idea to "lower these payments 'a little' in favor of a more 'front-loaded payment structure," he felt the reduction of the total milestones to $20 million total "seems too dramatic a change." (CX0407 at 001). Mr. Mengler replied to Mr. Koch, Dr. Hsu, and Mr. Nestor: "I am done" and "Its [*sic*] fair to say I will step away from any future negotiations. Including this one." (CX0507 at 001 (June 3, 2010 Mengler emails)). He was upset that Mr. Koch and others on the executive management team wanted him to renegotiate the deal at "the 11th hour." (CX4010 (Mengler, IHT at 200-02); *see also* CX0507 at 001 (June 3, 2010 Mengler emails)). Mr. Mengler felt he had been "negotiating in good faith as best we could with Endo" and he had already "communicated to them" that they had reached an agreement in principle. (CX4010 (Mengler, IHT at 201)).

RESPONSE TO FINDING NO. 300:

Respondent has no specific response other than to clarify that Mr. Mengler actually testified that he was only "a little unhappy . . . just a little surprised, kind of the 11th hour." (CX4010 (Mengler, IHT at 200)).

301. As discussed above (¶¶ 276-78), on June 4, 2010 when Mr. Koch and Ms. Snowden took over as Impax's primary negotiators, they initially sought a "simple settlement" with a July 2011 entry date but no payment. When Endo rejected that proposal, Mr. Koch then demanded "better terms on the co-promote deal." (CX4032 (Snowden, Dep. at 102, 197-98)). In an email with the subject "It's not over till the fat lady sings," Mr. Levin informed Mr. Holveck that Impax was "looking to recut the economics on the R&D collaboration." (CX1311 (June 4, 2010 Levin email to Holveck)).

RESPONSE TO FINDING NO. 301:

The first sentence of Complaint Counsel's Proposed Finding No. 301 should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Moreover, the individual findings cited are inaccurate and not supported by the cited testimony for the reasons set out in Respondent's replies to those findings. The second sentence of Proposed Finding No. 301 is misleading and not supported by the cited evidence. Ms. Snowden testified only that Impax negotiated better terms after Endo rejected Impax's request for a 2011 license date. She did not testify that Impax demanded better terms because the 2011 license date was rejected. (CX4032 (Snowden, Dep. at 198 ("It wasn't that direct, but it was later in that conversation")). Respondent has no specific response to the third sentence of Proposed Finding No. 301.

302. On June 4, 2010, Mr. Koch proposed new terms for the IPX066a development deal with Endo paying Impax $10 million upfront, $20 million more in development milestones, and an additional $10 million if annual sales were projected to exceed $150 million within the product's first 10 years on the market. (CX0410 at 001-02 (June 4, 2010 Koch email to Donatiello and Levin)).

RESPONSE TO FINDING NO. 302:

Respondent has no specific response.

303. Internally, Endo felt the "Oinkpax" demands were "piggy" and "porcine" in nature. (CX2534 at 001 (June 6, 2010 Levin and Cobuzzi emails)). But three days later on June 7, 2010, Endo agreed to most of Impax's demands, including for the payment totals and front loading the payment to give Impax $10 million upfront and $10 million for the next milestone payment for its Phase II work. (CX2962 at 001-02 (June 6, 2010 Endo-Impax email thread); CX0416 at 001 (June 6, 2010 Endo-Impax email thread discussing $10 million payment for Phase II); RX-572 at 0001-02 (June 6, 2010 internal Impax email string); CX3349 at 001-02 (June 6, 2010 Endo-Impax email thread); CX0415 at 001 (June 6, 2010 Endo-Impax email thread); CX1405 (June 7, 2010 Levin email to Holveck); CX3183 (June 6-7, 2010 Endo-Impax email thread); CX3184 (June 7, 2010 internal Endo email string); RX-365 (CDA)).

RESPONSE TO FINDING NO. 303:

Respondent has no specific response.

5. Endo completed its review of IPX-203 within days

304. Despite Mr. Mengler notifying Endo of the switch to "066a" on May 27 (RX-565 at 0001) and Endo agreeing to the switch on June 1, 2010 (RX-387 at 0001 (June 1, 2010 Mengler internal email recapping the "current proposal"); CX1011 (June 2, 2010 Levin email to Mengler)), Mr. Levin did not immediately inform Dr. Cobuzzi or his team. On June 1, 2010, Dr. Cobuzzi sent the latest draft of the IPX-066 OEW to Mr. Holveck, Mr. Levin, and others (CX1208 at 001), and as of that date Dr. Cobuzzi believed that Endo was still discussing a deal on IPX-066 with Impax. (Cobuzzi, Tr. 2594). Also as of June 1, 2010, even though Endo was by then negotiating terms for a deal on IPX-066a, Mr. Levin was still seeking and receiving financial analyses of the potential payments based on the IPX-066 product and its expected launch in 2013. (CX2774 at 001-02 (June 1, 2010 internal email thread on IPX-066)).

RESPONSE TO FINDING NO. 304:

Complaint Counsel's Proposed Finding No. 304 is inaccurate and misleading in its suggestion that there was a switch in products. As Ms. Snowden testified, "Endo was interested in the Parkinson's space and wanted the deal to cover both products, the original IPX-066 and the follow-on product [IPX-203], but Impax wasn't interested in doing the deal on IPX-066. So there wasn't actually . . . a switch as much as Endo was trying to negotiate for both product rights and Impax was only interested in doing product rights on the one product." (Snowden, Tr. 405-06). In fact, after Endo proposed an agreement covering all of Impax's Parkinson's products on May 26, 2010, Impax responded on May 27, 2010, that any collaboration would only be "for a product I will designate as [IPX]-066a. This is our next generation of [IPX]-066." (RX-318.0001 (Impax's response to Endo's initial term sheet); RX-565.0001; CX0320-002 (Endo's initial DCA term sheet)). Finally, the Proposed Finding is misleading in its suggestion that it was unusual for Endo to seek or receive information about IPX-066. Because IPX-203 was a follow-on product to IPX-066, information regarding the predecessor drug was relevant to

understanding IPX-203, and "tremendously valuable" to Endo in assessing IPX-203. (Cobuzzi, Tr. 2625-26, 2602).

305. Even after Dr. Cobuzzi was notified of the change (CX1011 (June 2, 2010 Levin email to Mengler)), Dr. Cobuzzi's team continued to evaluate the IPX-066 opportunity. (CX3338 (June 3, 2010 Pong email and attached Project Imperial Due Diligence Reports)).

RESPONSE TO FINDING NO. 305:

Complaint Counsel's Proposed Finding No. 305 is not supported by the cited evidence to the extent it claims Dr. Cobuzzi's team continued to evaluate the IPX-066 opportunity after June 2, 2010. The June 3, 2010 email cited (CX3338) circulated a document dated June 2, 2010. The email offers no indication that Endo was still considering the broader IPX-066 franchise as of June 3, 2010. (*See* CX3338 (cover email noting only "please see the attached for your reference")).

306. [redacted] (CX3178 at 001 (June 4, 2010 Nestor email to Cobuzzi) ("Please find attached the deck on IPX-203 (the actual project code for 066A)"); *see also* CX2780 at 001 (June 5, 2010 Cobuzzi email to Levin et al.) (*in camera*)). It was also the first time Dr. Cobuzzi was put in touch with a counterpart at Impax to actually discuss the product. (CX2949 at 001 (June 4, 2010 Nestor and Cobuzzi emails re R&D Contact?); *see also* CX0410 at 001 (June 4, 2010 Levin email to Koch and Snowden) ("I recommend that we pursue a parallel track at this point in time, and ask Bob [Cobuzzi] and Suneel [Gupta] to diligence the R&D opportunity, while you, Chris [Mengler] and I address your proposed changes in economics.")).

RESPONSE TO FINDING NO. 306:

Respondent has no specific response.

307. June 4, 2010 was also the first and only time Impax sent substantive information on IPX-203—a single power point presentation— prior to entering the final agreement. (CX3178 (June 4, 2010 Nestor email to Cobuzzi re Information requested attaching IPX-203 presentation); RX-376 (June 4, 2010 Nestor email circulating IPX-203 presentation provided to Endo)). Impax did not provide Endo with any sales forecast for, or analysis of, the commercial opportunity for IPX-203; rather, they sent that information

for IPX-066. (CX3178 (June 4, 2010 Nestor email to Cobuzzi re Information requested and attached spreadsheet and presentation on IPX-066); RX-376 (June 4, 2010 Nestor email circulating IPX-066 presentation provided to Endo)).

RESPONSE TO FINDING NO. 307:

Complaint Counsel's Proposed Finding No. 307 is vague, misleading, inaccurate, and incomplete in its claim that "June 4, 2010 was also the first and only time Impax sent substantive information on IPX-203." First, it is unclear what "substantive" information refers to. To the extent "substantive" information refers to information relevant to an assessment of a collaboration regarding IPX-203, Proposed Finding No. 307 is inaccurate. On May 27, 2010, Impax had identified the product as the next-generation version of IPX-066, and had provided extensive information to Endo regarding that predecessor drug that was relevant to understanding IPX-203, and "tremendously valuable" to Endo in assessing IPX-203. (Cobuzzi, Tr. 2625-26, 2602).

308. [redacted] (CX2780 at 001 (June 5, 2010 Cobuzzi email to Levin et al.) (*in camera*)). [redacted] (CX2780 at 001 (*in camera*)). [redacted] (CX2780 at 001 (*in camera*)).

RESPONSE TO FINDING NO. 308:

Complaint Counsel's Proposed Finding No. 308 is inaccurate, incomplete, and misleading in its selective quotation from CX2780. In that document, Dr. Cobuzzi discusses ways in which information about IPX-066 is relevant to IPX-203, as well as additional information or input Endo would seek from Equinox. (CX2780-001). It therefore is unclear what group of information Dr. Cobuzzi is referring to when, immediately following that discussion, he states "this is all the information that will be available."

309. [redacted] (CX2780 at 001 (June 5, 2010 Cobuzzi email to Levin et al.) (*in camera*); *but see* CX2527 (June 4, 2010 Levin email to Bradley re Impax Update) ("Bob [Cobuzzi] will be working with external parties to get a commercial evaluation")). [redacted] (CX2780 at 001 (*in camera*)); *see also* CX3339 (June 5, 2010 email re Information Requested) (calling the mid-day Monday deadline "a very rapid turnaround")).

RESPONSE TO FINDING NO. 309:

Complaint Counsel's Proposed Finding No. 309 mischaracterizes the quoted portion of CX2780 [redacted] (CX2780-001 [redacted]).

310. Dr. Cobuzzi was relaying the short time frame to complete the review that was given to him by Mr. Levin. (Cobuzzi, Tr. 2631). Dr. Cobuzzi understood the short time frame to be due to the agreement being done in connection with the Impax settlement negotiations. (Cobuzzi, Tr. 2632-33).

RESPONSE TO FINDING NO. 310:

Respondent has no specific response.

311. [redacted] (CX2779 (June 5, 2010 valuation) (*in camera*); CX2531 (June 5, 2010 email chain); CX2777 (June 6, 2010 valuation) (*in camera*)). Late on June 6, 2010, Mr. Levin forwarded the current terms then being discussed with Impax to his finance personnel, asking for a valuation update. (CX2532 at 001 (Email chain re R&D Collaboration)).

RESPONSE TO FINDING NO. 311:

Respondent has no specific response.

312. The Endo team worked on an OEW for IPX-203 on Monday, June 7, 2010, and Dr. Cobuzzi sent a final OEW to the Endo Board of Directors on the evening of June 8, 2010. (CX1209 at 001 (June 8, 2010 Cobuzzi email to Endo BoD attaching final Imperial OEW)).

RESPONSE TO FINDING NO. 312:

Complaint Counsel's Proposed Finding No. 312 is misleading and not supported by the cited evidence to the extent it attempts to imply that the Endo team began preparing an OEW for IPX-203 on Monday June 7, 2010. The cited document (CX1209) does not reflect when the Endo team began work on the document, but rather when it was circulated to the Endo Board of Directors.

H. Endo and Impax entered the Settlement and License Agreement and the Development and Co-Promotion Agreement

1. Impax and Endo finalized the settlement

313. The patent infringement trial began on Thursday June 3, 2010. (CX2759 at 022 (*Endo v. Impax* docket sheet minute entry for bench trial held on June 3, 2010)). Once informed that the parties had reached an agreement in principle, the presiding judge adjourned the trial until the following week, stating that she would resume trial on Tuesday, June 8 unless the parties were able to reach a definitive settlement agreement by then. (CX4012 (Donatiello, IHT at 140)).

RESPONSE TO FINDING NO. 313:

Respondent has no specific response.

314. After exchanging the first drafts of the SLA and DCA on June 4, 2010, Impax and Endo continued to negotiate the language of the documents, exchanging numerous drafts and holding at least 10 teleconferences between June 4 and June 7, 2010. (CX1301 at 114-18 (Endo CID Response); *see also* CX0310 at 006-11 (Impax CID Response); CX0323 (June 4, 2010 email from Mr. Donatiello sending attached draft SLA)). Execution versions of the SLA and DCA were circulated in the late evening of June 7, 2010. (RX-312 (SLA); CX0326 (DCA)).

RESPONSE TO FINDING NO. 314:

Respondent has no specific response.

315. Early on the morning of Tuesday, June 8, 2010, Mr. Donatiello notified Ms. Snowden that the Endo signature pages for both agreements were "in place" and that he would call his counsel "in a few hours to release them." (CX3186 at 001 (June 8, 2010 Donatiello email)). Endo did not want to release the signature pages until Sandoz, another generic manufacturer seeking to market oxymorphone ER, had signed a separate settlement agreement with Endo. (CX3186 at 001).

RESPONSE TO FINDING NO. 315:

Respondent has no specific response.

316. On the morning of June 8, 2010, outside counsel for Endo sent the Endo signature pages for both the SLA and the DCA to Impax's outside counsel, but requested that Impax's counsel hold the signature pages in escrow "pending our instructions to release them." (CX3332 at 001 (June 8, 2010 Watkins email and attachments). Endo ultimately did enter a settlement agreement with Sandoz on June 8, 2010. (CX3131 at 001-02 (June 8, 2010 Manogue email announcing settlements and attaching press releases)).

RESPONSE TO FINDING NO. 316:

Respondent has no specific response.

317. Following the release of the signature pages from escrow, the SLA and DCA became final on June 8, 2010. (JX-003 at 005 (¶ 26); CX3131 at 001 (June 8, 2010 Manogue email announcing settlements and attaching press releases)). Endo issued a press release announcing the settlement the same day. (CX3131 at 006).

RESPONSE TO FINDING NO. 317:

Respondent has no specific response.

2. Endo's business partner on Opana ER contributed $8 million towards the costs of the settlement

318. In "connection with" the Impax settlement, Endo "also amended our agreement with Penwest"—its Opana ER business partner— "to provide that we pay Penwest a reduced royalty for a period of time." (CX3131 at 001 (June 8, 2010 Manogue email announcing settlements); *see also* CX3131 at 006 (June 8, 2010 press release announcing settlement with Impax and modification of agreement with Penwest)). Endo had sought

this discount from Penwest as "a way of sharing .... the costs of the settlement with a partner who benefits from the sales of the product." (CX4035 (Cuca, Dep. at 109-10)).

RESPONSE TO FINDING NO. 318:

Respondent has no specific response to the first sentence of Complaint Counsel's Proposed Finding No. 318. The second sentence of Proposed Finding No. 318 lacks foundation, is speculative, and not supported by the cited evidence. Mr. Cuca testified that he did not recall a reduction of royalties to Penwest in association with the Opana ER settlement. (CX4035 (Cuca, Dep. at 108) ("Q. Do you have any understand of why you were looking to reduce the royalty with Penwest? . . . THE WITNESS: I don't."); CX4035 (Cuca, Dep. at 109) (stating that a document regarding Penwest royalties "doesn't refresh" his recollection about reductions in Penwest royalties)). He nevertheless was asked "why would Endo be seeking a royalty reduction," to which he said it "*potentially*" was a way to share costs. (CX4035 (Cuca, Dep. at 109-10) (emphasis added)).

319. Penwest's "contribution to [Endo's] settlement agreement" with Impax was to "forego [*sic*] royalty income from expected future sales of Opana ER in amount capped at $8.75 million." (CX3133 at 001 (June 7, 2010 emails from Levin and Good re Penwest Royalties); *see also* CX3043 at 001 (June 7, 2010 Levin email re Penwest) ("Penwest have agreed to an $8 million royalty credit as part of their contribution to the settlement agreement on Opana ER litigation.")). The royalty reduction was "frontloaded to capture more than 90% of the benefit before Impax launch their generic in January 2013." (CX3043 at 001 (June 7, 2010 Levin email re Penwest)).

RESPONSE TO FINDING NO. 319:

Respondent has no specific response.

3. Endo paid Impax the $10 million upfront payment

320. Though Impax would have to wait until 2013 to receive value from either the No-AG provision or the Endo Credit, the upfront payment guaranteed Impax immediate cash in June 2010. In accordance with Section 3.1 of the DCA, Endo owed Impax $10 million within five business days of the DCA's effective date. (RX-365 at 0009 (DCA § 3.1 and preamble)). When Endo had failed to pay Impax by June 23, 2010,

Ms. Snowden alerted Mr. Donatiello that the payment was overdue. (CX1819 at 002 (June 23, 2010 Snowden email re Upfront payment)). On June 24, 2010, Endo wired the $10 million upfront payment to Impax. (CX1819 at 001 (June 24, 2010 emails from Cooper and Mollichella re Upfront payment)). The DCA had no provision that would allow Endo to recoup any of the $10 million upfront payment under any circumstances. (RX-365; *see also* Cobuzzi, Tr. 2607).

RESPONSE TO FINDING NO. 320:

The first sentence of Complaint Counsel's Proposed Finding No. 320 is not supported by any evidence and violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). The first sentence is also inaccurate and misleading in its suggestion that Impax was guaranteed any value from either the No-Authorized Generic provision or the Endo Credit. (Court, Tr. 71, 75 ("JUDGE CHAPPELL: Are you going to stand there and tell me that the lowest possible outcome was not going to be zero? You're going to stand there and tell me that because some paid expert tells you that it had to be $62 million floor that it couldn't have been zero? MR. LOUGHLIN: No, Your Honor. There was a theoretical possibility of zero."); Noll, Tr. 1654 ("Q. And that example where you get zero of both, you didn't include that on your demonstrative of scenarios, did you? A. No, I didn't.")).

Respondent has no specific response to the remainder of Proposed Finding No. 320.

VI. Endo paid Impax to eliminate the risk of competition to Opana ER until January 2013

A. Impax received two forms of payment

321. Impax received two forms of payment under the Impax-Endo Settlement Agreement. The first was the No-AG/Endo Credit payment. (*See* CCF ¶¶ 322-28, below). The second was a $10 million payment under the DCA. (*See* CCF ¶¶ 329-31, below).

RESPONSE TO FINDING NO. 321:

The proposed summary finding should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Additionally, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondent's replies to those findings.

1. The No-AG provision and the Endo Credit worked together to ensure that Impax would receive value from the settlement

322. Under § 4.1(c) of the SLA, Impax's license for generic Opana ER was exclusive during Impax's 180-day first-filer exclusivity period for five dosage strengths. (RX-364 at 0010 (SLA § 4.1(c)) (Impax's license during the Exclusivity Period for five dosages was "exclusive as to all but (i) the Opana ER® Product and any Opana ER®-branded products that are not sold as generic products and (ii) generic products covered by agreements executed by Endo and/or Penwest and a Third Party [...] prior to the Effective Date")).

RESPONSE TO FINDING NO. 322:

Complaint Counsel's Proposed Finding No. 322 is incomplete and misleading. The plain language from Section 4.1(c) indicates the license "shall be exclusive as to all *but* (i) the Opana ER® Product and any Opana ER® branded products that are not sold as generic products *and* (ii) generic products covered by agreements executed by Endo and or Penwest and a Third Party that holds an ANDA referencing the Opana® ER Product as of or prior to the Effective Date." (RX-364.0010 (emphasis added); *see* CX3164-0009-10 ("nothing in the Opana ER Settlement Agreement prohibited Endo from lowering the price of its Branded Opana ER Product to compete with Impax's Generic Oxymorphone ER Product")).

323. This provision in § 4.1(c) meant that Endo could not sell an authorized generic product of the five relevant dosages until the exclusivity period ended. (CX3164 at 009-10 (Impax Response to Request for Admission No. 15)).

RESPONSE TO FINDING NO. 323:

Respondent has no specific response.

324. During negotiations of the SLA, Impax grew concerned about the value of the deal it was negotiating if Endo reformulated its product. (Mengler, Tr. 526-27 (describing reformulation as "an effort to subvert the value of the deal that I was trying to put together")).

RESPONSE TO FINDING NO. 324:

Complaint Counsel's Proposed Finding No. 324 is incomplete, inaccurate, and misleading because it selectively quotes Mr. Mengler's answer. He testified in full that reformulation "was more an effort to subvert the value of the deal that I was trying to put together *to get my product on the market* to -- because the only way I'm in business is selling generic drugs, and so call it whatever you want. I thought it was subversion." (Mengler, Tr. 526-27 (emphasis added)). Mr. Mengler also explained that the "subversion of the benefits" was "the benefits to the American consumer for getting a generic version of what would have been an important drug and also I benefit, too, in the way I make money is by selling generic drugs, so." (Mengler, Tr. 527).

Indeed, the record is clear that Impax was concerned with reformulation because it would reduce the opportunity for oxymorphone ER. (Snowden, Tr. 434; CX4030 (Hsu, Dep. at 108); Koch, Tr. 238 (reformulation can "switch patients away from the brand product that Impax has the generic to in favor of a line extension" not covered by the ANDA)). Impax noted its concern about a "secret plan to damage *the market*"—not the settlement agreement—with the introduction of a reformulated Opana ER product. (CX0217-001 (emphasis added); *see* Snowden, Tr. 433-34; Mengler, Tr. 569-70; CX4017 (Levin, Dep. at 118); CX4035 (Cuca, Dep. at 81-82) ("Impax became concerned that the value to them of the market at that generic entry date could be different than what they had previously expected or assumed")).

325. To address this concern, Impax and Endo developed the Endo Credit, an insurance-like provision under which Endo would make Impax whole by paying for the lost profits that Impax would have made during its exclusivity period. (Mengler, Tr. 533 ("where the market was in fact destroyed, I at least wanted to be made whole for the profits that we would have otherwise achieved); Koch, Tr. 265-66 (testifying that Impax "viewed [the Endo Credit] as insurance" because Impax had a reasonable outcome almost no matter what Endo did)).

RESPONSE TO FINDING NO. 325:

Complaint Counsel's Proposed Finding No. 325 is incomplete and misleading. Mr. Mengler's actual answer was "in the absence of an acceleration trigger . . . we needed an alternative mechanism to, one, try to incentivize the product to stay on the market; and then, two, in the worst-case scenario, where the market was in fact destroyed, I at least wanted to be made whole for the profits that we would have otherwise achieved." (Mengler, Tr. 533). If "other certain sales goals were achieved, we would have even paid Endo a royalty in that scenario." (Mengler, Tr. 533). The cited evidence says nothing about the exclusivity period.

The record indicates that the Endo Credit was part of "a carrot and a stick" approach to incentivize Endo to make investments in its original Opana product and ensure Impax had a measure of control over its generic opportunity. (Koch, Tr. 236-37, 240-41; Snowden, Tr. 386). It was intended to act as "a deterrent to prevent [Endo] from switching the market." (CX4021 (Ben-Maimon, Dep. at 118, 122); *see* CX4037 (Smolenski, Dep. at 244-45) ("intended to disincentivize Endo from" introducing a reformulated product); CX4026 (Nguyen, Dep. at 163-64) (Endo Credit was used to "put [Endo] to [its] word" with respect to reformulation)). It was not intended to generate income. (Mengler, Tr. 582-83). Roberto Cuca, Endo's Vice President of Financial Planning and the author of the Endo Credit, explained that "I don't know that anyone was anticipating a change in the marketplace, but the provision was designed to insulate against a substantial decrease in sales of the innovator product." (Cuca, Tr. 615, 617).

326. Under § 4.4 of the SLA, labeled "Endo Credit," Endo agreed to pay Impax an amount determined by a mathematical formula if prescription sales of Opana ER declined by more than 50% from the quarterly peak sales during the period from July 2010 to September 2012. (RX-364 at 0003-06, 0012 (SLA §§ 1.1, 4.4) ("If the "Pre-Impax Amount is less than the Trigger Threshold, then Endo shall pay to Impax the Endo Credit"); CX3164 at 010-11 (Impax Response to Request for Admission No. 17)).

RESPONSE TO FINDING NO. 326:

Respondent has no specific response.

327. The final formula for calculating the "Endo Credit" incorporates a number of factors that relate to Impax's sales of a generic product multiplied by the market opportunity for a generic product in the quarter of peak sales. The agreement defines Impax's "Market Share Profit Value" as the product of (1) an assumed generic substitution rate for Original Opana ER (90%), (2) an assumed net realized generic price discounted from the brand-name price (75%), (3) an assumed generic profit margin (87.5%), (4) 50% (expressing the 180-day exclusivity period as half of a year) and (5) the annualized sales of Opana ER during the quarter of peak sales for Opana ER during the period from the third quarter of 2010 to the third quarter of 2012 divided by 100. (RX-364 at 0003 ("Endo Credit" definition), 0004 ("Market Share Profit Factor" definition & "Market Share Profit Value" definition), 0005 ("Pre-Impax Amount" definition), 0005–06 ("Quarterly Peak" definition), 0006 ("Trigger Threshold" definition), 0012 ("Endo Credit" provision)).

RESPONSE TO FINDING NO. 327:

Respondent has no specific response other than to clarify that the first four elements listed in Proposed Finding No. 327 make up the "Market Share Profit Factor," which is explicitly defined as a figure: 0.2953. (RX-364.0004).

328. On April 18, 2013, Endo paid Impax $102,049,199.64 under § 4.4 of the SLA. (CX0333 at 001-02 (email dated April 18, 2013 containing wire transfer)).

RESPONSE TO FINDING NO. 328:

Respondent has no specific response.

2. Impax received $10 million under the DCA

329. Under § 3.1 of the DCA, Endo agreed to pay Impax $10 million as an upfront payment within five business days of June 7, 2010. (RX-365 at 0009 (DCA § 3.1)).

RESPONSE TO FINDING NO. 329:

Respondent has no specific response other than to clarify that Endo agreed to an "upfront payment" "in consideration for the rights granted to Endo hereunder [the DCA]." (RX-365.0009).

330. On June 24, 2010, Impax received a wire transfer from Endo with the upfront payment. (CX0327 at 0001 (email entitled "RE: Upfront payment" from R. Cooper dated Jun. 24, 2010, stating that "payment has been wired to your account per your instructions"); Snowden, Tr. 400).

RESPONSE TO FINDING NO. 330:

Respondent has no specific response.

331. The $10 million upfront payment was not refunded when Endo and Impax terminated the DCA. (Snowden, Tr. 408).

RESPONSE TO FINDING NO. 331:

Respondent does not dispute that the $10 million payment was not refunded, but Proposed Finding No. 331 is inaccurate and misleading in its attempt to suggest that the payment should have been refunded. (Snowden, Tr. 409 ("JUDGE CHAPPELL: Let me go back to one of your previous questions. Is it the government's position that the agreement required Impax to refund the $10 million -- MR. WEINGARTEN: No, Your Honor. JUDGE CHAPPELL: -- that there was any term in the agreement that ever required that? MR. WEINGARTEN: No, Your Honor.")).

B. The reverse-payment settlement eliminated the risk of competition to Opana ER until January 2013

332. Under the SLA, Impax agreed not to launch generic Opana ER until January 2013. (RX-364 at 0007 (SLA § 3.2); Koch, Tr. 236)).

RESPONSE TO FINDING NO. 332:

333. Complaint Counsel's Proposed Finding No. 332 is inaccurate. Under the SLA, Impax received a license to launch its generic oxymorphone ER product no later than the date certain of January 1, 2013. However, Impax's settlement license also permitted it to launch free from patent risk earlier under certain circumstances, specified in the agreement. (See RX-364.0001-02, 09 (SLA §§ 1.1, 4.1(a)) (defining the "Commencement Date" for license granted with several alternatives)).In section 3.2 of the SLA, Impax agrees "not to, prior to the applicable Commencement Date, directly or indirectly market, offer to sell, sell, import, manufacture or have manufactured in or for the [United States] any Opana® ER Generic Product." (RX-364 at 0007 (SLA § 3.2)). For the 5mg, 10mg, 20,mg, 30mg, and 40mg dosage strengths, the Commencement Date is defined as the earliest of (i) January 1, 2013; (ii) 30 days after a final federal court decision that the Opana ER Patents are invalid or unenforceable or not infringed by an ANDA version of Original Opana ER; or (iii) the date Endo and/or Penwest withdraws patent information (RX-364 at 0001-02 (SLA § 1.1)).

RESPONSE TO FINDING NO. 333:

Respondent has no specific response.

334. The parties to the SLA agreed that, if Impax breached the provisions of section 3.2, Endo would "suffer immediate and irreparable injury not fully compensable by monetary damages and for which the other Parties may not have an adequate remedy at law" and Endo could seek injunctive or other equitable relief. (RX-364 at 0019-20) (SLA § 9.7)).

RESPONSE TO FINDING NO. 334:

Respondent has no specific response.

335. Through these provisions of the reverse-payment settlement, Impax and Endo eliminated the possibility of generic oxymorphone ER entry prior to January 1, 2013, including the possibilities that Impax would launch at risk (*see* CCF ¶¶ 336-60, below), that Impax would launch after a successful final court decision (*see* CCF ¶¶ 361-77, below), and that other generics would launch to compete against branded Opana ER (*See* CCF ¶¶ 378-87, below).

RESPONSE TO FINDING NO. 335:

The proposed summary finding should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Additionally,

the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondent's replies to those findings.

1. The reverse-payment settlement eliminated the risk that Impax would enter at-risk prior to the end of the patent litigation

336. Prior to entering the SLA, Endo faced the risk that Impax would launch at risk before final resolution of the patent infringement litigation. (*See* CCF ¶¶ 337-57, below).

RESPONSE TO FINDING NO. 336:

The proposed summary finding should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Additionally, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondent's replies to those findings.

337. While it was negotiating a possible settlement with Endo, Impax was continuing steps to be prepared to launch generic Opana ER at risk. (*See* CCF ¶¶ 148-202, above).

RESPONSE TO FINDING NO. 337:

The proposed summary finding should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Additionally, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondent's replies to those findings.

338. Indeed, whether to launch generic Opana ER at risk was under consideration by Impax in 2010. (Koch, Tr. 247).

RESPONSE TO FINDING NO. 338:

Complaint Counsel's Proposed Finding No. 338 is unsupported by the cited testimony and inconsistent with the record. In the cited testimony of Mr. Koch, Mr. Koch responded in the affirmative to Complaint Counsel's question whether an at-risk launch was "under consideration" at Impax at that time. The quotation attributed to Mr. Koch was actually a question from Complaint Counsel. This testimony, taken in context, reflects that Impax "considered" an at-risk launch only as part of a general decision-making and routine forecasting processes. Specifically, Mr. Koch testified that Impax considered an at-risk launch in the sense that it "evaluated" it. (Koch, Tr. 247). Elsewhere in Mr. Koch's testimony, he confirmed that Impax never intended to launch oxymorphone ER at-risk. (Koch, Tr. 324-25 ("JUDGE CHAPPELL: Are you a hundred percent certain you would be aware of whether or not Impax planned an at-risk launch of Opana ER? WITNESS: Absolutely. I would have a key role in that. JUDGE CHAPPELL: Do you know in fact whether Impax intended an at-risk launch of Opana ER? . . . THE WITNESS: I do know. JUDGE CHAPPELL: Did they intend to do an at-risk launch of Opana ER? THE WITNESS: No."); *see also* Koch, Tr. 310 (Impax would only consider an at-risk launch after a favorable court ruling)).

In the case of oxymorphone ER, Impax attempted to "look[] at different various scenarios" and tried "very hard to . . . describe the possible outcomes under any number of different assumptions." (Koch, Tr. 299-300; *see* Mengler, Tr. 553 (financial projections did not "imply or mean that any legal decision ha[d] been made to clear the way for a launch"); Mengler, Tr. 584 (forecasting "alert[s] the board as to the product being out there that might get to the point of an at-risk launch, so that was it")). This modelling is intended to inform and facilitate decision-making regarding possible launches and launch dates; it does not reflect any decision

regarding launch dates. (Engle, Tr. 1720 ("describing forecasting as a "tool" and a "starting point, which senior management can use to make their judgments and decisions"); Engle, Tr. 1771 (Engle not involved in launch decisions); Mengler, Tr. 553 (financial modelling based on assumed launch date does not "imply or mean that any legal decision ha[d] been made to clear the way for a launch."); Koch, Tr. 299-300 (Impax merely tried to "look[] at different various scenarios" and attempt "very hard to . . . describe the possible outcomes under any number of different assumptions.")). Indeed, in the case of oxymorphone ER, Impax modelled a set of assumptions involving a June 2010 launch date even when that date remained an "obvious[] controversial element." (CX0514-001).

Consistent with this, Larry Hsu, Impax's founder and former CEO, explained that evaluating an at-risk launch was part of a larger process that looks at all options in making a launch decision, in order to be able to defend any potential course of action to Impax's Board of Directors later on. (CX4041 (Hsu, IHT at 129-30) ("We could settle, we could launch at risk, we could do many other things, and as the job of CEO, I just have to, you know, lay out everything, get prepared so I don't get accused by the board and say, well, wait a minute, how come you didn't prepare for plan B?"); CX4041 (Hsu, IHT at 130) ("Q: So, as of May 13th, 2010, Impax was at least considering the possibility of an at-risk launch for Oxymorphone ER? A. Yes, that's one of the options, absolutely.")). Moreover, contemporaneous documents make clear that such "evaluation" of all possible "options" does not suggest an at-risk launch was likely to occur, or that Impax intended to launch oxymorphone ER at risk. To the contrary, in contemporaneous documents, Dr. Hsu noted that "it's unlikely we will launch Opana ER this year (I actually prefer not to launch this year for obvious reason[s])." (RX-297.0002; *see* CX2929-001 (Dr. Hsu further

explained that that "mostly likely we will make launch decision based on court decision on the PI.")).

With respect to at-risk launches generally, the decision-making process is especially involved, because Impax is "incredibly conservative," (CX4021 (Ben-Maimon, Dep. at 34); *see* Koch, Tr. 287), and it "is very important for [Impax] to have a . . . risk-free launch" in the vast majority of cases, (CX4014 (Hsu, IHT at 117))—as Impax's meager track record of actually launching at-risk reflects, (*see* Snowden, Tr. 424, 426 (aside from limited oxycodone launch after favorable district court decision, in a single dose, and with a cap on sales, Impax had not pursued any other at-risk launches at the time of Endo-Impax settlement)).

> 339. Had Impax seriously considered launching oxymorphone ER at-risk, it would have sought Board approval—a prerequisite at Impax for any at-risk launch (Koch, Tr. 276-77 ("every at-risk launch is a board-level decision"); Snowden, Tr. 426; CX4030 (Hsu, Dep. at 128); CX4021 (Ben-Maimon, Dep. at 160))—well before tentative FDA approval of its ANDA. (Koch, Tr. 333-34, 341). Yet Impax's senior management never even recommended an at-risk launch of oxymorphone ER to the Impax Board of Directors regarding, nor was the Impax Board of Directors ever asked to vote on such an at-risk launch. (Koch, Tr. 299; Snowden, Tr. 470-71; CX4030 (Hsu, Dep. at 85); JX-001-009 (¶ 29) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity)).An at-risk launch decision would require approval from Impax's Board of Directors. The Board had not been asked for a decision about an at-risk launch prior to signing the SLA. But a few weeks before signing, the Board was informed that Impax management had changed its outlook assumption for launching generic Opana ER in 2010 from "no launch" to assumed launch. (*See* CCF ¶¶ 340-41, below).
>
> **RESPONSE TO FINDING NO. 339:**

The proposed summary finding should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Additionally, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondent's replies to those findings.

340. The Impax Board of Directors had a meeting on May 24-25, 2010 at which the status of generic Opana ER was discussed. Mr. Mengler, the president of the generics division in 2010, told the Board that the base plan presented to the board in February 2010 did not assume a generic Opana ER launch in 2010. (Mengler, Tr. 550; CX2662 at 008 (Board of Directors Meeting, May 2010, presentation by Chris Mengler)).

RESPONSE TO FINDING NO. 340:

Complaint Counsel's Proposed Finding No. 340 is misstates Mr. Mengler's testimony. Mr. Mengler did not testify that the Board of Directors discussed "the status of generic Opana ER." Mr. Mengler testified that its "impossible to know for sure what we were thinking about a potential launch or launch timing" from the cited document. (Mengler, Tr. 550-51).

341. Mr. Mengler further explained to the Board that the revised assumption for May 2010 was "At Risk Launch" and that the company's dollar sales projections now included an at-risk launch of oxymorphone ER. (Mengler, Tr. 553; CX2662 at 012 (Board of Directors Meeting, May 2010, presentation by Chris Mengler)). At the Board meeting, Mr. Mengler "expressed the view that Oxymorphone was a good candidate for an at-risk launch." (CX2663 at 001 (May 2010 Board of Director Minutes); Koch, Tr. 258). Everyone agreed that oxymorphone was a great market opportunity for Impax. (Koch, Tr. 259).

RESPONSE TO FINDING NO. 341:

The first sentence of Complaint Counsel's Proposed Finding No. 341 is incomplete, inaccurate, and misleading. Mr. Mengler, the individual responsible for drafting the cited document (CX2662), testified that the document contained only his "assumptions" and those assumptions applied only to "just the [sales] numbers." (Mengler, Tr. 552-53; *see* Koch, Tr. 338 (document described Mr. Mengler's assumptions)). His assumptions with respect to possible sales numbers did not "imply or mean that any legal decision has been made to clear the way for a launch. It just says, when you see the slide with the numbers . . . that says 'oxymorphone' with dollars. That's all that this is saying." (Mengler, Tr. 553). Mr. Mengler testified that "it's impossible to know for sure what we were thinking about a potential launch or launch timing" based on the document. (Mengler, Tr. 551). Indeed, Impax merely tried to "look[] at different

various scenarios" and attempted "very hard to . . . describe the possible outcomes under any number of different assumptions." (Koch, Tr. 299-300).

The second sentence of Proposed Finding No. 341 is incomplete and misleading because it ignores the testimony of Arthur Koch, Impax's CFO at the time and the individual who drafted the cited document (CX2663). Mr. Koch testified that there was "no discussion of an at-risk launch by any [one]," "I regret that I used the words 'at-risk launch' [in the minutes]. It's confusing the readers. There was no discussion of an at-risk launch." (Koch, Tr. 295).

Mr. Mengler similarly testified that he mentioned oxymorphone ER at the Board meeting only to "alert the board as to the product being out there that might get to the point of an at-risk launch, so that was it." (Mengler, Tr. 584). Larry Hsu, Impax's CEO at the time, explained that senior management "want to alert the board that we are considering this is one of the scenario[s] so that if we do come up with a final recommendation to the board, there will be no surprise. . . . [T]his is very typical." (CX4030 (Hsu, Dep. at 82)). The record, moreover, is clear that Mr. Mengler did not make a recommendation for an at-risk launch, did not discuss the risk or benefits of an at-risk launch, and did not ask the Board to approve an at-risk launch at the May 2010 Board meeting. (Koch, Tr. 295; Mengler, Tr. 584-85). Finally, a passing reference to Mr. Mengler's comment is in stark contrast with documents associated with meetings where an at-risk launch actually was recommended. Those minutes reflect lengthy, in-depth discussions, and a presentation analyzing the proposed launch, and a formal resolution. (CX3223; CX2689).

The third sentence of Proposed Finding No. 341 is incomplete and misleading. Mr. Koch testified that oxymorphone "presented a great opportunity" because "Oxymorphone was a very rapidly growing product, and we had a tentative approval or we had an application that was going to be successful." (Koch, Tr. 295). There is no evidence indicating that the assessment of

oxymorphone' s opportunity had anything to do with an at-risk launch, as Proposed Finding No. 341 attempts to imply.

342. A recommendation from management to launch would have been a significant factor in the Board's decision. In fact, the Impax Board of Directors has never rejected a formal at-risk launch recommendation by Impax management. (CX3164 at 019 (Impax Response to Request for Admission No. 43)).

RESPONSE TO FINDING NO. 342:

The first sentence of Complaint Counsel's Proposed Finding No. 342 is not supported by any record evidence and should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2).

Respondent has no specific response to the second sentence of Proposed Finding No. 342 other than to clarify that the cited document states only that the Board of Directors had not rejected a formal launch-at-risk recommendation by Impax Management "prior to June 8, 2010." (CX3164-019).

343. With respect to generic Opana ER, the Impax Board of Directors never reached a decision either to launch, or not to launch, generic Opana ER at risk. (Koch, Tr. 332). The Impax Board was never asked one way or the other. (Koch, Tr. 332).

RESPONSE TO FINDING NO. 343:

Respondent has no specific response.

344. Between 2001 and 2015, there have been at least 48 generic pharmaceuticals launched at risk in the United States. (CX5004 at 092-115 (Exhibit 4) (Noll Rebuttal Report)).

RESPONSE TO FINDING NO. 344:

Complaint Counsel's Proposed Finding No. 344 is incomplete and misleading. While there have been forty-eight at-risk launches over a fifteen year period, twenty-one of those

launches were conducted by Teva, which Professor Noll explains "is by far the most likely company to do at-risk launches." (Noll, Tr. 1608-09; *see* Hoxie, Tr. 2820 (Teva has "a high willingness to take risks and "a greater appetite for risk than others")). Only four at-risk launches over the fifteen-year period were conducted by companies with less than $1 billion in revenue. (Noll, Tr. 1609). And in comparison to the forty-eight at-risk launches that occurred over a fifteen-year period, hundreds of Hatch-Waxman claims are filed every year. (Hoxie, Tr. 2824). Between 2009 and 2016, the lowest number of Hatch-Waxman cases filed in any single year was 236. (Hoxie, Tr. 2824). The highest number of Hatch-Waxman cases filed in a single year was 468. (Hoxie, Tr. 2824). All told, between 2009 and 2016 an average of 269 Hatch-Waxman cases were filed every year. (Hoxie, Tr. 2824-25).

> 345. Generic companies launch at risk often enough that branded pharmaceutical companies take at-risk launches very seriously in their planning." (CX5007 at 026 (¶ 48) (Hoxie Rebuttal Report)). Indeed, Impax had launched at risk, after approval from the Impax Board of Directors, on other products prior to the SLA and after the SLA. (Koch, Tr. 274 (generic OxyContin at-risk launch in 2005); CX5004 at 092-115 (Exhibit 4) (Noll Rebuttal Report) (at-risk generic Wellbutrin XL launch in 2006); CX4021 (Ben-Maimon, Dep. at 152-53) (at-risk azelastine launch while Ben-Maimon was at Impax).
>
> **RESPONSE TO FINDING NO. 345:**

The first sentence of Complaint Counsel's Proposed Finding No. 345 is misleading and not supported by the cited evidence. Mr. Hoxie did not cite any information regarding the frequency of at-risk launches or the manner in which brand companies assess at-risk launches based on their frequency. Indeed, Mr. Hoxie testified that he did not do any empirical work to quantify how common at-risk launches are. (Hoxie, Tr. 2822). Mr. Hoxie only has had experience with two or three at-risk launches over a thirty-year legal career. (Hoxie, Tr. 2822-23). And Mr. Hoxie agreed with industry analysts who empirically analyzed at-risk launches between 2003 and 2009 that "at-risk launches are fairly uncommon." (Hoxie, Tr. 2827-28).

The second sentence of Proposed Finding No. 345 is incomplete and misleading. The record is clear that Impax undertook at-risk launches only under unique circumstances and always with limits on its potential exposure. Impax launched a generic version of oxycodone only after it received a favorable district court decision holding the relevant patents unenforceable. (Snowden, Tr. 425-26; Koch, Tr. 275). Impax launched the product in only one dosage strength, and only after Teva, the first ANDA filer for the relevant dosage, had launched at risk six months earlier. (Snowden, Tr. 425; Noll, Tr. 1609-10). And Impax limited its risk of damages by capping its potential sales at $25 million. (Koch, Tr. 275). Impax launched an azelastine product only after its development partner notified Impax that it intended to conduct the launch and Impax limited its participation to 150,000 units. (Snowden, Tr. 462, 464-65; CX4021 (Ben-Maimon, Dep. at 37-39); CX2689 (Minutes of a Special Meeting of the Board of Directors of Impax Laboratories, Inc.)).

The second sentence of the Proposed Finding also violates this Court's Order on Post-Trial Briefs to the extent it cites "to expert testimony to support factual propositions that should be established by fact witnesses or documents."

346. With respect to Opana ER, Endo recognized the threat that an at-risk launch by Impax posed to Endo's Opana ER sales and took steps to react with an authorized generic in the event of an at-risk launch. (*See* CCF ¶¶ 347-51, below).

RESPONSE TO FINDING NO. 346:

The proposed summary finding should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Additionally, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondent's replies to those findings.

347. Contemporaneous with the SLA being negotiated in late May and early June 2010, Endo businesspeople prepared profit and loss scenario models that included multiple scenarios assuming a generic launch in July 2010. (CX3011 at 001, 004-05 (email chain entitled "Opana ER/IR P&L Scenario Model," dated May 21-25, 2010); CX3443 at 001-02 (email with revised and updated models, dated May 26, 2010); CX3009 at 003 (email chain entitled "Opana ER Combined P&L scenarios – Jul-10 generics.xlsx," dated June 1, 2010)).

RESPONSE TO FINDING NO. 347:

Complaint Counsel's Proposed Finding No. 347 is incomplete and misleading because it ignores the testimony of Demir Bingol, Endo's Senior Director of Marketing, and Roberto Cuca, Endo's Vice President of Financial Planning and Analysis. Mr. Bingol testified that the estimates were based on "many" assumptions and Endo was looking at "any possible scenario." (CX4025 (Bingol, Dep. at 59); Bingol, Tr. 1310 ("We have to consider all scenarios")). Indeed, Mr. Bingol explained that Endo forecasts were "based on scenarios that we had created, I mean, the accuracy of which are always debatable." (Bingol, Tr. 1303). And many of the assumptions were actually total unknowns. (Bingol, Tr. 1307 ("JUDGE CHAPPELL: Okay. Well, I don't want you to guess[], so according to this document, whatever those claims were you didn't know. THE WITNESS: Well, we would be -- that's correct."); Cuca, Tr. 662-63).

In the case of Opana ER, Endo's "base case" and "latest best estimate" did not assume generic entry. (CX4035 (Cuca, Dep. at 62) (discussing CX3009)). Indeed, in the spring of 2010, Endo knew "there had been ANDAs filed for generic versions of Opana ER," but believed "there was not imminently at that point going to be a generic." (Cuca, Tr. 643). But Endo still forecast different scenarios regarding the future of its Opana ER product to "analyze the full range of potential outcomes." (Cuca, Tr. 663-64).

348. Finally, all of the hypothetical scenarios at issue in these documents discuss a possible authorized generic in response to what would necessarily be an at-risk generic launch in 2010. No documents or testimony address whether, let alone suggest that, Endo would launch an authorized generic under other circumstances, such as in response

to Impax (or another generic) launching pursuant to a settlement license.Each such model that Endo created showed large declines in sales following a generic launch. (CX3011 at 005 (email chain entitled "Opana ER/IR P&L Scenario Model," dated May 21-25, 2010); CX3443 at 001-02 (email with revised and updated models, dated May 26, 2010); CX3009 at 003 (email chain entitled "Opana ER Combined P&L scenarios – Jul-10 generics.xlsx," dated June 1, 2010)).

RESPONSE TO FINDING NO. 348:

Complaint Counsel's Proposed Finding No. 348 is inaccurate. The cited documents do not "show" declines, they merely "assumed" lost sales. (CX3011-004 (discussing "key assumptions" including different scenarios, including "steep erosion of branded business"); CX3009-003 (same); CX3443 (showing what sales would be under various "erosion" scenarios)). Indeed, the record is clear that Endo created financial forecasts to look at "any possible scenario." (CX4025 (Bingol, Dep. at 59); Bingol, Tr. 1310 ("We have to consider all scenarios")). Endo did so to "analyze the full range of potential outcomes." (Cuca, Tr. 663-64).

349. One of these models was to be included in a "consolidated view" to be reviewed by the Board. (CX3009 at 001 (email chain entitled "Opana ER Combined P&L scenarios – Jul-10 generics.xlsx," dated June 1, 2010)).

RESPONSE TO FINDING NO. 349:

Respondent has no specific response.

350. On June 1, 2010, Endo projected that it would lose $71.2M in branded ER sales if Impax launched its generic version of Opana ER on July 1, 2010. (CX1314 (Levin/Cuca email chain, dated June 1, 2010)). Endo also projected that if it launched an authorized generic version of Opana ER on the same day as Impax's launch, it would gain $25 million in authorized generic sales. (CX1314 (Levin/Cuca email chain, dated June 1, 2010)). Endo planned to be ready to launch an authorized generic if Impax launched a generic version of Opana ER. (*See* CCF ¶¶ 84-92, above).

RESPONSE TO FINDING NO. 350:

Complaint Counsel's Proposed Finding No. 350 is incomplete, inaccurate, and misleading. Mr. Cuca, the author of the cited email, testified that the figures came from

"assuming some specified erosion assumption." (CX4035 (Cuca, Dep. at 66) (discussing CX1314)). Mr. Cuca also testified that under those assumptions, "the bottom-line effect"—Endo's income before taxes, which considers revenues and expenses together—would only be $2 million at the "more aggressive end of the range of cost savings" and $13.5 million if Endo was "less aggressive about cost savings." (CX4035 (Cuca, Dep. at 67) (discussing CX1314)). Mr. Cuca also testified that Endo forecast different scenarios regarding the future of its Opana ER product to "analyze the full range of potential outcomes," but did not know if any of the many different assumptions in its forecasts would come true. (Cuca, Tr. 662-64).

Finally, to the extent Proposed Finding No. 350 purports to summarize and incorporate other findings, it should be disregarded because the individual findings cited do not support the Proposed Finding and are unreliable for the reasons set out in Respondent's replies to those findings.

> 351. At the time of settlement with Impax, Endo was also preparing a reformulated version of Opana ER. Endo forecasted that if the reformulated version launched about the same time as generic Original Opana ER, peak conversion for Reformulated Opana ER would be 30-32% of the base volume. (CX1320 at 024 (email entitled "Updated Three Year Forecast 2010-2012," dated February 11, 2010 and attached "Three Year Plan Revenues"); *see also* CX1320 at 007 (assumption of generic launch date)). But if Endo launched reformulated before generic Opana ER, the market for generic Original Opana ER might disappear in favor of reformulated sales. (Mengler, Tr. 527).

RESPONSE TO FINDING NO. 351:

Respondent has no specific response to the first sentence of Complaint Counsel's Proposed Finding No. 351.

The second sentence of Proposed Finding No. 351 is not supported by the cited evidence (CX1320) and ignores the plain language of the document. Endo did not "forecast" a conversion rate, it simply assumed it for purposes of the forecast. (CX1320-024 (noting "Base assumptions" including "30-32% conversion of base volume")). It was Endo's practice to forecast different

scenarios regarding the future of its Opana ER product to "analyze the full range of potential outcomes." (Cuca, Tr. 663-64). But Endo did not know if any of the many different assumptions contained in its forecasts would come true. (Cuca, Tr. 662-63). Endo simply forecasted "a number of different potential outcomes over the course of years," the accuracy of which were "always debatable." (Bingol, Tr. 1292, 1303).

Respondent has no specific response to the third sentence of Proposed Finding No. 351 other than to clarify that Mr. Mengler did not mention any market.

352. In situations, like these, where the market opportunity for the generic product is uncertain, the generic company may be motivated to launch at risk rather than missing an opportunity to sell its product at all. In this case, Impax was concerned about the market opportunity for generic Opana ER and Endo's potential to launch a reformulated oxymorphone ER product before Impax launched its generic version of Original Opana ER. (*See* CCF ¶¶ 353-57, below).

RESPONSE TO FINDING NO. 352:

The proposed summary finding should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Additionally, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondent's replies to those findings.

353. At the time it was considering an at-risk launch of Opana ER, Impax was aware that Endo might attempt to reformulate Opana ER by introducing a crush-resistant version. (CX2696 at 020 (Impax CID Response to No. 21(A))). In April 2010, the FDA had announced its approval of a reformulation of Purdue's branded long-acting opioid pain medication, OxyContin. (CX2696 at 020 (Impax CID Response to No. 21(A))). The possibility that Endo would do a similar reformulation was on Impax's "radar." (Mengler, Tr. 568).

RESPONSE TO FINDING NO. 353:

Respondent has no specific response.

354. Endo's actions during negotiations further raised concerns at Impax about possible reformulation of Opana ER. For example, Endo rejected Impax's proposed acceleration trigger (something that was commonly seen in settlements) and insisted on keeping a 2013 entry date. Impax's lead negotiator at that time, Mr. Mengler, interpreted these positions as "troubling," adding to his concern that Endo was planning on reformulating Opana ER. (Mengler, Tr. 568). A reformulation by Endo presented a significant risk to Impax because sales of Impax's generic would be largely driven by Endo's brand sales, due to automatic substitution at pharmacies and insurance reimbursement preferences for generics. (CX5007 at 023 (¶ 43) (Hoxie Rebuttal Report)). Mr. Mengler, the president of Impax's generic division in 2010, explained that "the way generic drugs are sold is by having a substitute, and if there's no substitute, I get nothing." (Mengler, Tr. 527). Thus, if Endo successfully converted the market from Original Opana ER to Reformulated Opana ER before Impax could enter with its generic version, Impax might get "nothing" in terms of generic Opana ER sales. (Mengler, Tr. 527).

RESPONSE TO FINDING NO. 354:

Complaint Counsel's Proposed Finding No. 354 is misleading. The first and second sentences of Proposed Finding No. 354 should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). The second sentence of Proposed Finding No. 354's claim that acceleration triggers were "commonly seen in settlement agreements" is simply unsupported by any evidence in the record.

The fourth sentence of Proposed Finding No. 354 violates this Court's Order on Post-Trial Briefs to the extent it cites "to expert testimony to support factual propositions that should be established by fact witnesses or documents."

The sixth sentence of Proposed Finding No. 354 is not supported by the cited evidence. Mr. Mengler did not discuss the conversion of any market, or any conversion before Impax could enter. He simply testified that "the biggest concern that Opana ER somehow in its original form disappears or becomes so insignificant." (Mengler, Tr. 527).

355. Further, Impax could lose the opportunity to sell any generic Opana ER—with or without automatic substitution—if the Food and Drug Administration determined that

> Original Opana ER had been withdrawn because of safety reasons. (Snowden, Tr. 479-80 (a finding that Original Opana ER was withdrawn for safety reasons "would have prevented Impax' launch"); CX5007 at 023-24 (¶ 43) (Hoxie Rebuttal Report) ("there was a possibility that the FDA could rescind the Original Opana ER approval on safety grounds (as Endo in fact requested in a Citizen's Petition submitted in 2012, once it had approval for its new product).")).

RESPONSE TO FINDING NO. 355:

Respondent has no specific response other than to note that the cited evidence does not support Complaint Counsel's suggestions that (1) FDA determinations regarding withdrawal were an issue during settlement negotiations in 2009 or 2010; and (2) all forms of generic Opana ER would be impacted by an FDA determination regarding Original Opana ER, since the determination would only relate to those products which used Original Opana ER as "a reference listed drug for an ANDA applicant." (Snowden, Tr. 479-80 (discussing citizen petitions in 2012); *see* CX5007-023-24 (Hoxie Rep. ¶ 43) (same)).

> 356. Where the market opportunity is uncertain and may decline or even disappear in the near future, delaying launch may carry its own risk for generic companies. (CX5007 at 022 (¶ 41) (Hoxie Rebuttal Report)). Because of the suspected reformulation, forgoing an at-risk launch would carry risks for Impax. As a result, Impax had reasons to be motivated to launch as soon as possible. (CX5007 at 022 (¶ 42) (Hoxie Rebuttal Report)).

RESPONSE TO FINDING NO. 356:

Complaint Counsel's Proposed Finding No. 356 violates this Court's Order on Post-Trial Briefs to the extent it cites "to expert testimony to support factual propositions that should be established by fact witnesses or documents," including Impax's purported motivations and perception of risks.

Proposed Finding No. 356 is also inaccurate and misleading. Mr. Hoxie did not opine that Impax would or should have launched at risk. (Hoxie, Tr. 2760, 2769, 2910-11). Mr. Hoxie did not quantify the risks to Impax, including those from an at-risk launch, or opine that launching under the circumstances would have been a reasonable decision. (Hoxie, Tr. 2808,

2910). And Mr. Hoxie did not evaluate the magnitude of potential lost-profit damages that Impax would have faced if it launched at risk. (Hoxie, Tr. 2782-83). The record, however, is clear that those damages can be in the billions of dollars, (Hoxie, Tr. 2782), and can result in bankruptcy, (Koch, Tr. 287 (generic entry before patent expiration can be a "bet-the-company" undertaking and can "take the solvency of the company entirely"); CX4030 (Hsu, Dep. at 43) ("the risk can be huge depending on the size of the product and depending on whether we're the first to file")).

The Proposed Finding also is inaccurate and misleading in its suggestion that Impax would "delay" launch. The record is clear that Impax never intended an at-risk launch. (Koch, Tr. 324-25 ("JUDGE CHAPPELL: Are you a hundred percent certain you would be aware of whether or not Impax planned an at-risk launch of Opana ER? WITNESS: Absolutely. I would have a key role in that. JUDGE CHAPPELL: Do you know in fact whether Impax intended an at-risk launch of Opana ER? . . . THE WITNESS: I do know. JUDGE CHAPPELL: Did they intend to do an at-risk launch of Opana ER? THE WITNESS: No.")). Impax's CEO at the time of settlement, Larry Hsu, made the same point: "it's unlikely we will launch Opana ER this year (I actually prefer not to launch this year for obvious reason[s])." (RX-297.0002; *see* Hoxie, Tr. 2768, 2770 (opining Impax would not launch without a favorable court decision)).

> 357. Based on these factors, if Impax had received a favorable decision at the district court level, a launch prior to the appellate decision could be a reasonable risk from Impax's perspective, taking into account the countervailing risks of delay. (CX5007 at 024 (¶ 44) (Hoxie Rebuttal Report)).

RESPONSE TO FINDING NO. 357:

Complaint Counsel's Proposed Finding No. 357 violates this Court's Order on Post-Trial Briefs to the extent it cites "to expert testimony to support factual propositions that should be

established by fact witnesses or documents," including Impax's purported motivations and perception of risks.

Proposed Finding No. 357 is also inaccurate, misleading, and based on unreliable expert testimony. Mr. Hoxie did not opine that Impax would or should have launched at risk. (Hoxie, Tr. 2760, 2769, 2910-11). Mr. Hoxie did not quantify the risks to Impax, including those from an at-risk launch, or opine that launching under the circumstances actually *would* have been a reasonable decision. (Hoxie, Tr. 2808, 2910). And Mr. Hoxie did not evaluate the magnitude of potential lost-profit damages that Impax would have faced if it launched at risk. (Hoxie, Tr. 2782-83). The record, however, is clear that those damages can be in the billions of dollars, (Hoxie, Tr. 2782), and can result in bankruptcy, (Koch, Tr. 287 (generic entry before patent expiration can be a "bet-the-company" undertaking and can "take the solvency of the company entirely"); CX4030 (Hsu, Dep. at 43) ("the risk can be huge depending on the size of the product and depending on whether we're the first to file")).

Finally, Proposed Finding No. 356 is inconsistent with the weight of the evidence, which reflects that, in the real world, in which (1) Impax had already lost on all matters of claim construction in the patent infringement suit against Endo, which made it more likely that Endo could prevail on the merits, and (2) Endo had the stronger position on merits issues of validity and infringement. (Figg, Tr. 1870, 1884, 1904).

358. After the SLA was entered, Impax's approach changed. Impax halted launch preparations for oxymorphone ER due to the settlement with Endo. (Camargo, Tr. 991).

RESPONSE TO FINDING NO. 358:

Complaint Counsel's Proposed Finding No. 358 is incomplete and misleading. The record is clear that as early as May 7, 2010, the Supply Chain Group had stopped preparedness efforts. (RX-186.0004 ("We are then await [sic] management decision to proceed with 8-lot

launch inventory build."); Camargo, Tr. 1016-17 ("At that point, we need management decision and direction to proceed with the launch inventory build.")). Again on May 12, 2010, Mr. Camargo indicated that "we will not commence the launch inventory build until we receive direction to do so from senior [management]." (CX2898-001). This meant that the plan was to wait for directions from senior management before beginning remaining preparedness steps. (Camargo, Tr. 1017; CX2905-003 ("launch inventory build was ready to start should management give the go-ahead")).

And by May 25, 2010, the Operations group had shifted its resources to another product, noting that "I don't see the OXM happening in June." (CX2904-001; Camargo, Tr. 1017-18). Mr. Camargo explained that he had already "advised the team that it was unlikely that we would make the Oxymorphone." (CX2904-001). Mr. Camargo testified that "given the situation where it would have been an at-risk launch, and we had no history of launching products at risk due to . . . what could happen if we were to lose in the litigation, so . . . I had been given no direction at that point in time to actually execute the product launch, and it seemed unlikely to me that we would ever do that." (Camargo, Tr. 1020).

359. By 2010, Impax had removed oxymorphone ER from its 2010-2011 forecasts due to the settlement. (CX2842 at 002 (email from K. Sica entitled "July Forecast Submission" with attachment entitled "Forecast Change From Previous Forecast 0710.xls")).

RESPONSE TO FINDING NO. 359:

Respondent has no specific response.

360. As dictated by the SLA, Impax did not launch generic Opana ER until 2013. (Engle, Tr. 1703; CX2607 at 009 (Lortie Decl.) (Impax "launched its products in all dosage strengths on January 4, 2013")).

RESPONSE TO FINDING NO. 360:

Respondent has no specific response.

2. The reverse-payment settlement eliminated the risk that Impax would enter after prevailing in the patent litigation at the Federal Circuit

361. Prior to the SLA, Endo faced the risk that Impax would be able to launch generic Opana ER risk-free if Impax prevailed at the Federal Circuit. (*See* CCF ¶¶ 362-72, below).

RESPONSE TO FINDING NO. 361:

The proposed summary finding should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Additionally, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondent's replies to those findings.

362. Prior to settlement, the outcome of the patent litigation was uncertain. (RX-548 at 0030- 31 (¶ 69) (Figg Report); *see also* CCF ¶¶ 1269-308, below).

RESPONSE TO FINDING NO. 362:

Respondent has no specific response.

363. The outcome of the Endo-Impax patent litigation at the trial level was uncertain in June 2010. (Figg, Tr. 2007; CX4045 (Figg, Dep. at 131-32)).

RESPONSE TO FINDING NO. 363:

Respondent has no specific response.

364. The outcome of the Endo-Impax patent litigation on appeal, if there was one, was also uncertain. (Figg, Tr. 2007-08, 2046; CX4045 (Figg, Dep. at 132); CX5007 at 043 (¶ 79) (Hoxie Rebuttal Report)).

RESPONSE TO FINDING NO. 364:

Respondent has no specific response.

365. For example, whether Endo's patents were invalid "was going to be litigated, and the issues certainly could have come out either way." (Figg, Tr. 1904).

RESPONSE TO FINDING NO. 365:

Complaint Counsel's Proposed Finding No. 365 is incomplete and misleading because it selectively quotes Mr. Figg's testimony. Mr. Figg's full statement was that invalidity "was going to be litigated, and the issues certainly could have come out either way. But having evaluated all of the materials that I evaluated, I think it was likely that Endo was going to prevail on these validity issues." (Figg, Tr. 1904). Proposed Finding No. 365 also ignores Mr. Figg's testimony that Endo was likely to prove infringement of its patents. (Figg, Tr. 1875, 1880-81, 1883-84). And Proposed Finding No. 365 ignores Mr. Figg's testimony that the likely outcome of the Endo-Impax litigation would have been an injunction preventing Impax from marketing its product until Endo's patents expired in September 2013. (Figg, Tr. 1904-05).

366. Impax took steps to get a decision faster. For example, Impax successfully sought to move the patent litigation to a district court in New Jersey in the hopes of getting it moving faster and to get an earlier trial date. (Snowden, Tr. 358).

RESPONSE TO FINDING NO. 366:

Respondent has no specific response.

367. If Impax and Endo had not entered the SLA or another settlement agreement, the trial on the '933 and '456 patents would have continued. (Snowden, Tr. 400-01 (if the parties had not settled, trial would have continued on June 8, 2010, with cross-examination of Endo's expert)).

RESPONSE TO FINDING NO. 367:

Respondent has no specific response.

368. If litigation continued, Impax may have "obtained a favorable judgment" at the district court (CX5007 at 044 (¶ 82) (Hoxie Rebuttal Report)).

RESPONSE TO FINDING NO. 368:

Complaint Counsel's Proposed Finding No. 368 is not supported by the cited evidence and lacks foundation. Mr. Hoxie testified that he did not offer any opinion on possible outcomes of the Endo-Impax litigation. (Hoxie, Tr. 2751-52). This included no opinion on the strength of either party's litigation positions, the chances that either party would have prevailed, or whether Impax specifically would have prevailed. (Hoxie, Tr. 2693, 2751-53, 2835).

The language quoted in Proposed Finding No. 368, moreover, is selectively quoted and taken out of context. Mr. Hoxie was not opining on possible litigation outcomes. He was discussing the timing of litigation, including a scenario whereby "Impax could also have obtained a favorable judgment at the end of the trial in June of 2010 and launched right after." (CX5007-044 (Hoxie Rep. ¶ 82)).

> 369. Even if Endo won the patent litigation at the district court, it faced significant risk of loss on appeal, as there was the strong possibility that the district court's claim construction ruling could have been reversed on appeal by the Federal Circuit. (CX5007 at 041-43 (¶¶ 76, 79) (Hoxie Rebuttal Report); Figg, Tr. 2020 ("even on the appeal I probably would give Endo an edge, but – but I think it would have been an issue that was fairly litigable and it would have been a fairly close call")).

RESPONSE TO FINDING NO. 369:

Complaint Counsel's Proposed Finding No. 369 is incomplete and misleading. Mr. Hoxie explicitly testified, "I do not have an opinion one way or the other as to how the Federal Circuit would have ruled." (Hoxie, Tr. 2694). Mr. Figg did not state that there was a "strong possibility" of reversal. His testimony is explicit: "I probably would give Endo an edge." (Figg, Tr. 2020).

The record is clear, moreover, that even if Impax could have prevailed on claim construction issues in the Federal Circuit, the litigation would have needed to be remanded to the district court for proceedings under a revised claim construction. (Figg, Tr. 1911-13). And Mr.

Hoxie offered no opinion on the strength of either party's litigation positions before the claim construction issue was decided by the district court. (Hoxie, Tr. 2835).

370. Prior to the SLA, Endo estimated that the Federal Circuit decision would likely happen around June 2011. (CX2576 at 001 (Feb. 2010 internal Endo e-mail chain) ("If [Impax] wait[s] for the appeal to play out, it will likely happen around June of next year.")).

RESPONSE TO FINDING NO. 370:

Complaint Counsel's Proposed Finding No. 370 is incomplete and misleading. The estimate of a June 2011 Federal Circuit decision was in response to a question asking about "the *earliest* date" a competitor could "start shipping the generic." (CX2576-001 (emphasis added); CX4025 (Bingol, Dep. at 175-76) (discussing CX2576 and explaining there were "a lot of scenarios" and that Mr. Bingol was "simply looking at numbers of scenarios that could play out and the influencing factors in those scenarios . . . But as I point out below, there are many scenarios to play out, and we really don't know.")).

371. According to Impax's expert, the Federal Circuit could have ruled on an appeal in the Impax generic Opana ER litigation by November 2011 or possibly earlier. (Figg, Tr. 2033-34, 2044-45).

RESPONSE TO FINDING NO. 371:

Complaint Counsel's Proposed Finding No. 371 is incomplete and misleading. Mr. Figg testified that November 2011 is "a very conservative, optimistic view of the timing." (Figg, Tr. 2044-45). Indeed, the median time from docketing to final decision in the Federal Circuit was eleven months in 2010 and 2011, but that figure takes into account settlement and summary affirmances. (Figg, Tr. 1908-09). It consequently is possible that the Federal Circuit would not have issued a decision until long after 2011. (Figg, Tr. 1908-09; Hoxie, Tr. 2865).

372. Impax could have started selling generic Opana ER in 2011 free from risk if the Federal Circuit had affirmed a favorable judgment from the district court, or reversed an unfavorable district court decision and entered judgment for Impax. (Figg, Tr. 1911; (CX5007 at 044 (¶ 81) (Hoxie Rebuttal Report)).

RESPONSE TO FINDING NO. 372:

Complaint Counsel's Proposed Finding No. 372 is not supported by the cited evidence. Mr. Hoxie's report says nothing about risk-free entry in 2011. (CX5007-044 (Hoxie Rep. ¶ 81)). The cited testimony of Mr. Figg says nothing about what would happen if Impax lost at trial. Mr. Figg's testimony was limited to the earliest possible time Impax would be free from the risk of having a favorable district court decision reversed. (Figg, Tr. 1911 ("Q. If Impax had won at the trial level, what is the earliest likely date, in your opinion, that Impax could have entered free from the risk of the Federal Circuit Court of Appeals reversing the trial court's opinion? A. Well, it would be upon -- free of that risk would mean when the Federal Circuit issues its mandate affirming the district court's decision, so it would have been at some point after November 2011, using the dates that are on this chart, or it would have been after the decision, whenever that decision is issued.")). As Mr. Figg, explained, however, November 2011 is "a very conservative, optimistic view of the timing." (Figg, Tr. 2044-45). Indeed, the median time from docketing to final decision in the Federal Circuit was eleven months in 2010 and 2011, but that figure takes into account settlement and summary affirmances. (Figg, Tr. 1908-09). It consequently is possible that the Federal Circuit would not have issued a decision until long after 2011. (Figg, Tr. 1908-09; Hoxie, Tr. 2865).

373. The reverse-payment settlement terminated the Impax litigation and prevented a decision on the merits of the patent suit against Impax by either the trial court or the Federal Circuit. (*See* CCF ¶¶ 374-77, below).

RESPONSE TO FINDING NO. 373:

The proposed summary finding should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2).

374. In the SLA, Impax and Endo agreed to file a Stipulation of Dismissal and Order "pursuant to which [Endo's and Penwest's patent actions against Impax] will be dismissed with prejudice and without costs . . ." (RX-364 at 0007 (SLA § 3.1)).

RESPONSE TO FINDING NO. 374:

Respondent has no specific response.

375. The district court signed the Stipulation of Dismissal and Order and entered it on the docket on June 15, 2010. (RX-488 (stipulation of dismissal and order in *Endo v. Impax*)).

RESPONSE TO FINDING NO. 375:

Respondent has no specific response.

376. The litigation was terminated, and there was no record to go up on appeal to the Federal Circuit. (Figg, Tr. 2043).

RESPONSE TO FINDING NO. 376:

Respondent has no specific response.

377. In the SLA, Impax agreed that, on or after June 8, 2010, it would not "challenge the validity or enforceability of the Licensed Patents with respect to any product that is the subject of the Impax ANDA or the infringement of the Licensed Patents by the manufacture, use and sale of any product that is the subject of the Impax ANDA, including by . . . seeking an order or decision that any of the Licensed Patents is invalid or unenforceable with respect to any product that is the subject of the Impax ANDA or that the manufacture, use or sale of any product that is the subject of the Impax ANDA does not infringe the Licensed Patents." (RX-364 at 0007-08 (SLA § 3.3).

RESPONSE TO FINDING NO. 377:

Respondent has no specific response.

3. The reverse-payment settlement eliminated the risk of competition from any other generic company on the most important dosage strengths of Opana ER

378. Impax's first-filer exclusivity – combined with provisions in the SLA precluding Impax from selling generic Opana ER and from aiding or assisting other generic companies – eliminated the risk of competition to Endo's Opana ER from generic companies other than Impax on the five most important dosage strengths. (*See* CCF ¶¶ 379-87, below).

RESPONSE TO FINDING NO. 378:

The proposed summary finding should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Additionally, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondent's replies to those findings.

379. As of the settlement date, Impax had tentative approval for its generic Opana ER ANDA and expected to be granted 180-day first-filer exclusivity. (JX-001 at 007 (¶¶ 14, 17); Snowden, Tr. 417-18; CX3164 at 006 (Impax Response to Request for Admission No. 2)). Getting final approval for each dosage strength was a formality after the relevant 30-month stay lapsed. (Koch, Tr. 340-41 ("it's pretty routine and rubber stamp from the time of a tentative approval to final approval"); Snowden, Tr. 417-18 ("Impax was almost certain to get final approval at the conclusion of the 30-month stay")).

RESPONSE TO FINDING NO. 379:

Respondent has no specific response.

380. Impax received final approval in June 2010 for the 5mg, 10mg, 20mg, and 40mg dosage strengths and in July 2010 for the 30mg dosage strength of oxymorphone HCl extended-release tablets and was granted a 180-day exclusivity period as the first filer for each of these dosage strengths. (JX-001 at 008 (¶¶ 21, 22) (final approval dates); CX3164 at 006-07 (Impax Response to Request for Admission No. 3) (first-filer exclusivity)). These five dosage strengths comprised over 95% of Opana ER sales. (JX-001 at 007 (¶ 13)).

RESPONSE TO FINDING NO. 380:

Respondent has no specific response.

381. Under the SLA, Impax agreed not to sell generic Opana ER prior to its licensed entry date. (RX-364 at 0007 (SLA § 3.2) This agreement had the effect of blocking other generics, which could not get FDA final approval due to Impax's first-filer exclusivity. (CX5000 at 042-43 (¶ 93) (Noll Report); RX-548 at 0046 (¶ 99) (Figg Report)).

RESPONSE TO FINDING NO. 381:

The first sentence of Complaint Counsel's Proposed Finding No. 381 is inaccurate. Under the SLA, Impax received a license to launch its generic oxymorphone ER product no later than the date certain of January 1, 2013. However, Impax's settlement license also permitted it to launch free from patent risk earlier under certain circumstances, specified in the agreement. (*See* RX-364.0001-02, 09 (SLA §§ 1.1, 4.1(a)) (defining the "Commencement Date" for license granted with several alternatives)).

With respect to the second sentence of Proposed Finding No. 381, Respondent does not dispute that the FDA cannot approve other ANDA filings until after a relevant first-filer's exclusivity is used or forfeited, but the cited evidence does not support the proposition that the settlement agreement blocked anything. (CX5000-042-43 (Noll Rep. ¶ 93); RX-548.0046 (Figg, Rep. ¶ 99)). Impax, moreover, was not the first ANDA filer for all dosage strengths of Opana ER. (Snowden, Tr. 370).

382. Other generic companies had tentative approval, but did not get final approval on the 5mg, 10mg, 20mg, 30mg, and 40mg dosage strengths until after Impax's first-filer exclusivity was finished in 2013. For example, Actavis did not get final FDA approval from the FDA on Impax's first-filer dosage strengths until July 2013. (CX2594 at 002 (email from Actavis Inc. dated July 12, 2013) (containing press release about FDA approval of five dosages of generic Opana ER); CX4034 (Rogerson, Dep. at 74)).

RESPONSE TO FINDING NO. 382:

The first sentence of Complaint Counsel's Proposed Finding No. 382 is not supported by any record evidence and should be disregarded because it violates the Court's Order on Post-

Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2).

Respondent has no specific response to the second sentence of Proposed Finding No. 382 other than to clarify that none of the cited evidence supports the suggestion that Actavis had tentative approval for Impax's first-filer dosages at the time of settlement.

383. In addition to blocking other generic companies from selling oxymorphone ER, the SLA also prevented Impax from pursuing an alternate route to market, such as partnering with Actavis, which had a licensed entry date in July 2011. (*See* CCF ¶¶ 384-87, below).

RESPONSE TO FINDING NO. 383:

The proposed summary finding should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Additionally, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondent's replies to those findings.

384. [redacted] (CX3383 at 002-04, 007 (Actavis settlement with Endo §§ 1.1, 4.1(a)-(b)) (*in camera*) (admitted to prove terms of the contract, not for the truth of the matters asserted)). As of July 15, 2011, the only patents that Endo held relating to Opana ER were the '456, '933, and '250 patents. (RX-548 at 0049-50, 0054 (¶¶ 113, 125) (Figg Report) ('122 and '216 patents issued in 2012; '737 and '779 patents issued in 2014); RX-494 at 0009 (Endo 8-K) (stating that Endo acquired the '482 patent in 2012)).

RESPONSE TO FINDING NO. 384:

Respondent has no specific response.

385. During settlement negotiations with Endo, Impax knew that Endo had settled with Actavis for a licensed entry date of July 15, 2011. (Snowden, Tr. 371).

RESPONSE TO FINDING NO. 385:

Respondent has no specific response.

386. Prior to settling with Endo, an option available to Impax was partnering with Actavis by waiving or relinquishing Impax's first-filer exclusivity in favor of Actavis and allowing Actavis to sell generic Opana ER starting in July 2011, in exchange for Impax receives a share of Actavis's profits. (CX4034 (Rogerson, Dep. at 74) (agreeing that "if prior to July of 2011 Impax had waived or selectively waived first filer exclusivity in favor of Actavis and Actavis was granted final approval," then Actavis would "have been able to start selling Generic Opana ER in those five dosage strengths on July 15, 2011")).

RESPONSE TO FINDING NO. 386:

Complaint Counsel's Proposed Finding No. 386 should be disregarded because it lacks foundation, is based on a question beyond the scope of Mr. Rogerson's deposition, and is an improper hypothetical. Mr. Rogerson is a Teva employee. (CX4034 (Rogerson, Dep. at 5)). Mr. Rogerson previously worked at Actavis, but not until Actavis merged with Watson in 2012. (CX4034 (Rogerson, Dep. at 76)). Mr. Rogerson has no personal knowledge of events at Actavis prior to the Endo-Impax settlement agreement. (CX4034 (Rogerson, Dep. at 76)). As such, when Complaint Counsel asked Mr. Rogerson a hypothetical question about the theoretical possibility of a waiver of exclusivity and a partnership, he was simply speculating. (CX4034 (Rogerson, Dep. at 76)). Mr. Rogerson did not speak to anyone employed by Actavis during the relevant time to inform his speculation. (CX4034 (Rogerson, Dep. at 76-77)).

There is, moreover, no record evidence to support the proposition that "an option available to Impax was partnering with Actavis by waiving first-filer exclusivity," or that Impax and Actavis believed such an option existed, considered it, or would have pursued it. The only mention in the entire record of waiving exclusivity and partnering with another company is found in the hypothetical question by Complaint Counsel to an individual who was not employed by either Impax or Actavis at the relevant time. (CX4034 (Rogerson, Dep. at 74)).

387. Any opportunity to partner with Actavis was terminated by the SLA, which prohibited Impax from assisting or authorizing a third party, such as Actavis, from marketing or selling Opana ER. (RX-364 at 007 (SLA § 3.2) ("Impax agrees, on behalf of itself and its Affiliates, not to . . . directly or indirectly assist or authorize any Third Party to do any of the foregoing [market, offer to sell, sell, import, manufacture or have manufactured in or for the United States].")).

RESPONSE TO FINDING NO. 387:

Respondent does not dispute that the quoted language appears in the settlement agreement, but the remainder of Complaint Counsel's Proposed Finding No. 387 is not supported by record evidence and lacks foundation. There is no support for the proposition that "[a]ny opportunity to partner with Actavis was terminated by the SLA." Indeed, there is no record evidence to support the proposition that there were "opportunities" between Actavis and Impax, least of all "an option available to Impax was partnering with Actavis by waiving first-filer exclusivity," as the Proposed Finding attempts to suggest. The only mention in the entire record of a possible partnership between Actavis and Impax is found in a hypothetical question by Complaint Counsel to an individual who was not employed by either Impax or Actavis at the relevant time. (CX4034 (Rogerson, Dep. at 74, 76-77)).

VII. Impax received large payments from Endo pursuant to the terms of the Impax-Endo Settlement Agreement

A. A payment is large if it exceeds avoided litigation costs

388. A reverse payment is large if it exceeds the plausible reduction in litigation costs arising from settling the dispute before it is litigated to conclusion. (CX5000 at 162 (¶ 364) (Noll Report); Noll, Tr. 1460-61; CX5000 at 145 (¶ 332) (Noll Report) ("[T]o assist in determining whether a reverse-payment settlement harmed the competitive process, economic analysis should address whether the reverse payment was larger than saved litigation cost . . ."). Saved litigation costs are the correct benchmark for assessing whether a payment is "large" because litigation costs constitute a use "of society's resources, and so it's a benefit to society at large that [the parties] don't complete the litigation." (Noll, Tr. 1638; *see also* Noll, Tr. 1460-61). Litigation costs are a real cost to companies involved in the litigation and also to society, and saving such costs is a benefit from an economic perspective. (Noll, Tr. 1462).

RESPONSE TO FINDING NO. 388:

Complaint Counsel's Proposed Finding No. 388 is improper because it states a legal conclusion, not a fact.

389. The brand-name firm can offer a reverse payment that exceeds saved litigation costs only if the settlement terms allow the brand-name firm to recover the reverse payment in additional monopoly profits that it otherwise did not expect to earn, which means that the settlement caused anticompetitive harm. (CX5000 at 139 (¶ 318) (Noll Report)). More specifically, a brand-name firm is willing to make a reverse payment that is larger than expected litigation costs only if the present value of the additional monopoly profit from guaranteeing that generic entry is delayed exceeds the present value of the loss of monopoly profit from guaranteeing that entry will occur before patent expiration. (CX5000 at 123 (¶ 278 & fig. B5) (Noll Report)).

RESPONSE TO FINDING NO. 389:

Complaint Counsel's Proposed Finding No. 389 is improper because it states a legal conclusion, not a fact. Proposed Finding No. 389 also violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." Professor Noll was not and is not qualified as an expert with respect to the pharmaceutical industry. (Noll, Tr. 1358). The cited portions of Professor Noll's expert report, moreover, describe formulas he created, not facts based on real-world evidence. (*See* CX5000-139 (Noll Rep. ¶ 317)).

B. The size of the No-AG provision and Endo Credit payments

1. The No-AG provision was valuable to Impax

390. The term "first to file" or "first filer" refers to the first generic applicant to file a substantially complete ANDA with a Paragraph IV certification. (Snowden, Tr. 353, 355; *see also* JX-001 at 005 (¶ 27)).

RESPONSE TO FINDING NO. 390:

Respondent has no specific response.

391. A first-to-file generic company has a potential 180-day exclusivity period where no other ANDA generics would be on the market. (Reasons, Tr. 1210; *see also* JX-001-005 (¶ 27)). First-to-file exclusivity is very valuable to a generic company. (Koch, Tr. 232). First-to-file exclusivity is very valuable to a generic company because it gives the first filer "six months of runway before another entrant will be reviewed or approved." (Koch, Tr. 232). First-to-file exclusivity is very valuable to a generic company because it helps the generic company make more money. (Koch, Tr. 233).

RESPONSE TO FINDING NO. 391:

Respondent has no specific response.

392. Impax was the first company to file an ANDA with Paragraph IV certifications for the 5, 10, 20, 30, and 40 milligram dosages of Opana ER, which comprise all of the dosage forms for Opana ER except the 7.5 and 15 milligram dosages. (JX-001 at 007 (¶ 13); Koch, Tr. 231-32; Snowden, Tr. 354, 414). Impax was the first to file with respect to the five most popular dosages of Opana ER, which comprised 95% of Endo's Opana ER sales. (Mengler, Tr. 525; JX-001 at 007 (¶ 13)).

RESPONSE TO FINDING NO. 392:

Respondent has no specific response.

393. As the first filer on certain dosages of oxymorphone ER, Impax was entitled to 180 days of generic exclusivity. (Snowden, Tr. 414; JX-001 at 007 (¶ 14)). During the 180 days, no other ANDA filer could market the generic version of Opana ER because the applicable statute does not allow the FDA to give final approval to any other ANDA filer during that 180 day time period. (Snowden, Tr. 414; *see also* Mengler, Tr. 522-23).

RESPONSE TO FINDING NO. 393:

Respondent has no specific response.

394. Being the only generic version of a branded product has value for Impax. (Reasons, Tr. 1210). Impax's CFO stated on a public earnings conference call in 2013 that once Impax's exclusivity period for generic Opana ER ended, Impax expected competition and price erosion from other generic versions of Opana ER. (Reasons, Tr. 1216-17; CX2656 at 007 (Impax Q1 2013 earnings call transcript)).

RESPONSE TO FINDING NO. 394:

Respondent has no specific response.

395. The term "authorized generic" is a term of art used in the pharmaceutical industry to describe a generic that is made available for sale using the brand company's New Drug Application approval. (Mengler, Tr. 523; Koch, Tr. 233; JX-001 at005 (¶¶ 28-31)). An authorized generic is generally launched by the brand company or another company licensed by the brand company. (Mengler, Tr. 523; Reasons, Tr. 1211). Impax itself has launched authorized generics of some of Impax's own branded products in response to generic entry. (Reasons, Tr. 1211). Launching an authorized generic helps a company partially recoup sales of the branded product that are lost to generic competition. (Reasons, Tr. 1211-12).

RESPONSE TO FINDING NO. 395:

Respondent has no specific response.

396. The 180-day exclusivity period does not prevent the launching of an authorized generic. The brand, if it chooses, can launch an authorized generic during the 180-day exclusivity period and compete with the first-filing generic during that period. (Mengler, Tr. 523-24; *see also* JX-001 at 005 (¶ 28)). Endo was not legally barred from launching an authorized generic until it executed the SLA. (CX3164 at 007 (Impax Response to Request for Admission No. 4)).

RESPONSE TO FINDING NO. 396:

Respondent has no specific response other than to note that the evidence cited in the second sentence of Proposed Finding No. 396 (CX3164) does not say anything about the SLA having any particular legal effect, which is a conclusion of law, not a fact. (CX3164-007 (discussing 180-day exclusivity period)).

397. Authorized generics have a unique impact during the first six months of generic competition. (CX6052 at 003 (FTC Authorized Generics Report)). Competition from AGs during the 180-day exclusivity period has the potential to reduce both generic drug prices and generic firm revenues. (CX6052 at 003 (FTC Authorized Generics Report)).

RESPONSE TO FINDING NO. 397:

Complaint Counsel's Proposed Finding No. 397 is incomplete and misleading. The only document cited regarding purportedly "unique" impacts (CX6052) is a report from the FTC itself, which was drafted in part by members of Complaint Counsel. (CX6052-002). The

document, moreover, discusses "wholesale expenditures," not actual first-filer revenue. (CX6052-047).

398. The presence of authorized generic competition during the 180-day exclusivity period reduces the first-filer generic's revenues by 40 to 52%, on average. Moreover, revenues of the first-filer generic manufacturer in the 30 months following exclusivity are between 53% and 62% lower when facing an AG. (CX6052 at 005 (FTC Authorized Generics Report)). A first-filer's revenue will approximately double absent an authorized generic. (CX6052 at 008 (FTC Authorized Generics Report)).

RESPONSE TO FINDING NO. 398:

Complaint Counsel's Proposed Finding No. 398 is incomplete and misleading. The only document cited regarding purportedly "unique" impacts (CX6052) is a report from the FTC itself, which was drafted in part by members of Complaint Counsel. (CX6052-002). The document, moreover, discusses "wholesale expenditures," not actual first-filer revenue. (CX6052-047).

a) Endo planned to launch an AG upon generic oxymorphone ER entry

399. Endo had strong financial incentives to launch an authorized generic version of oxymorphone ER upon entry of other generic versions of oxymorphone ER. Endo expected to earn $25 million in AG sales (compared to a $71 million decline in branded Opana ER sales) during the exclusivity period (the second half of 2010) if Impax launched its generic oxymorphone ER on July 1, 2010. (CX1314 (email chain from Endo executive Roberto Cuca to then-CFO Alan Levin). Other Endo financial analyses estimated that an Impax launch in mid-2010 would cause Endo to lose $45.6 million in product contribution in 2010, but that Endo could recoup $17.7 million by launching an AG. (CX3009 at 003 (June 2010 Endo email and attachment, "Combined P&L" tab)).

RESPONSE TO FINDING NO. 399:

Proposed Finding No. 399 is incomplete, inaccurate, and misleading. Mr. Cuca, the author of the cited email (CX1314), testified that the figures came from "assuming some specified erosion assumption." (CX4035 (Cuca, Dep. at 66) (discussing CX1314)). Mr. Cuca also testified that under those assumptions, "the bottom-line effect" of a theoretical Impax

launch—Endo's income before taxes, which considers revenues and expenses together—would only be $2 million at the "more aggressive end of the range of cost savings" and $13.5 million if Endo was "less aggressive about cost savings." (CX4035 (Cuca, Dep. at 67) (discussing CX1314)). Similarly in the second cited document (CX3009), Endo did not "estimate" reductions, it merely "assumed" it for purposes of the forecast. (CX3009-003 (describing "assumptions" regarding "erosion" and "reduction in allocation")). In fact, Endo's "base case" and "latest best estimate" did not assume generic entry in 2010. (CX4035 (Cuca, Dep. at 62) (discussing CX3009)).

Mr. Cuca explained that Endo forecast different scenarios regarding the future of its Opana ER product to "analyze the full range of potential outcomes," but did not know if any of the many different assumptions in its forecasts would come true. (Cuca, Tr. 662-64; *see* CX4025 (Bingol, Dep. at 180) (an authorized generic is "another scenario that you go through, just like when you're making an assumption around potential launch dates"); Bingol, Tr. 1292, 1303 (Endo simply forecasted "a number of different potential outcomes over the course of years," the accuracy of which were "always debatable.")).

400. Endo intended to launch an authorized generic if Impax entered with generic oxymorphone ER. (CX2576 at 003 (Kelnhofer email to Kehoe) ("We will launch on word/action of first generic competitor."); CX2581 at 001 (Opana Lifecycle Management Team Meeting Minutes) ("Endo is prepared to launch an authorized generic if another generic is approved first."); CX2573 at 004 (February 2010 Endo internal presentation "EN3288 Commercial Update") (Endo planned a "Launch of authorized generic" in the event that Impax launched at risk) CX3007 at 003 (Endo oxymorphone ER pricing proposal) ("If Impax launches, Endo will launch its authorized generic . . .")).

RESPONSE TO FINDING NO. 400:

Complaint Counsel's Proposed Finding No. 400 is inaccurate, incomplete, and misleading. Brian Lortie, Endo's Senior Vice President for Pain Solutions, testified that Endo "never seriously considered taking any further steps to prepare for or to do [an authorized

generic of Opana ER] because we really didn't want to." (CX4019 (Lortie, Dep. at 118-19)). Demir Bingol, Endo's Senior Director of Marketing and the person responsible for marketing Endo's Opana ER products, testified that an authorized generic "was never . . . to my knowledge . . . fully realized as a plan or an idea." (Bingol, Tr. 1338-39; *see* Bingol, Tr. 1337 ("I don't recall specific forecasts about an authorized generic.")). And Mark Bradley, Endo's Senior Director of Corporate Finance at the time of settlement, testified, "I don't recall having any conversation with any colleagues regarding the launch of an authorized generic." (CX4031 (Bradley, Dep. at 198)).

The cited evidence does not reflect that "Endo" "intended" to do anything. The exhibits include (1) a single statement by an "account executive on our managed markets team," (CX4025 (Bingol, Dep. at 174, 179) (discussing CX2576, testifying that he did not "know what their conversation meant or why they wrote those things")); (2) a statement about authorized generics in the context of crush-resistant Opana ER, (CX2581 (discussing EN3288); CX4025 (Bingol, Dep. at 183) (discussing CX2581, explaining language meant that "mentally we have all options on the table to be commercially successful, and this is one of these levers we could pull if we had to, and at this point no steps were taken, and I don't recall that any ever were.")); (3) a draft document, (CX2573-004 ("Draft Not Approved by Management"); Bingol, Tr. 1298-99 (discussing identical "draft" language: "JUDGE CHAPPELL: . . . it says it's a draft. Why would he have presented a draft to anybody?")); and (4) a "proposal," (CX3007-003).

401. By late 2009, Endo began preparing for an authorized generic launch in the summer of 2010. (*See* CCF ¶¶ 86-90).

RESPONSE TO FINDING NO. 401:

The proposed summary finding should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported

by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Additionally, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondent's replies to those findings.

402. Endo has launched authorized generics of its branded drugs, including another branded drug called Fortesa. (CX6044 at 034, 057 (FDA listing of authorized generics); CX5001 at 026 (¶ 50) (Bazerman Report)).

RESPONSE TO FINDING NO. 402:

To the extent Complaint Counsel's Proposed Finding No. 402 purports to rely on expert testimony, it violates this Court's Order on Post-Trial Briefs by improperly citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents."

Proposed Finding No. 402 is also incomplete and misleading. The cited evidence makes clear that Endo had never launched any authorized generic at the time of its settlement with Impax. (CX6044-034, 057).

403. Endo and Impax settled the infringement case on June 8, 2010, and three days later Endo employees concluded that Endo could make arrangements to destroy its generic oxymorphone ER inventory. (CX3000 (June 11, 2010 Email)).

RESPONSE TO FINDING NO. 403:

Respondent has no specific response.

b) Impax and Endo agreed that Endo would not launch an AG during Impax's 180-day exclusivity period

404. The 180-day exclusivity period is the time when a first-filer generic makes most of its revenues and profits from selling a generic product, and the introduction of an authorized generic during that exclusivity period reduces the value of the exclusivity period by causing lower prices and fewer sales for the first-filer. (Reasons, Tr. 1213-15; Koch, Tr. 232-33). Adding a second generic will generally result in a price decrease of about 30 to 35% and generally will reduce the first generic's market share. (Reasons, Tr. 1214; Mengler, Tr. 524 (Impax president of generic division testifying about the

expectation of price erosion in a market with more than one generic product)). In addition, entry by another generic will take market share from the first generic. Rather than the first generic having 100% of generic sales, the two generic companies usually will split those sales. (Reasons, Tr. 1214; Mengler Tr. 524).

RESPONSE TO FINDING NO. 404:

The first sentence of Complaint Counsel's Proposed Finding No. 404 is incomplete, misleading, and not supported by the cited evidence. Mr. Koch testified that profits will "depend[] on market characteristics -- 'most' is hard to characterize. They can make a substantial portion of their profits. But the life of the generic and a great many other factors enter into determining whether it was most." (Koch, Tr. 232-33). Respondent has no specific response to the second, third, and fourth sentences of Proposed Finding No. 404.

405. A "no-authorized-generic" or "No-AG" provision means that the brand name company agrees not to sell a generic version of its product during a generic company's 180-day exclusivity period. (Snowden, Tr. 391-92).

RESPONSE TO FINDING NO. 405:

Respondent has no specific response.

406. Impax would generally seek a no-authorized generic provision (also called a "No-AG" provision) as an element of negotiating a settlement agreement with a brand. (Koch, Tr. 234). Along with the earliest possible entry date, a "No-AG" is among the more important things that Impax would seek as part of getting the best possible deal. (Mengler, Tr. 526). The absence of an authorized generic would mean more control for the generic company, and control can often lead to higher profits for the generic company. (Koch, Tr. 234).

RESPONSE TO FINDING NO. 406:

Respondent has no specific response to the first and third sentences of Complaint Counsel's Proposed Finding No. 406. The second sentence is incomplete and misleading because it takes Mr. Mengler's testimony out of context. Mr. Mengler testified, "I mean, most important is, you know, early entry. Then, you know, there's a few -- what's important is the

best possible deal that gets the product on the market as quickly as possible and maximizes the value to Impax shareholders, so early entry and no AG are certainly among the more important things, yes." (Mengler, Tr. 526). Mr. Mengler also explained that Impax derives value "by selling the drug [] with or without an" authorized generic. (Mengler, Tr. 528-29).

407. Mr. Mengler, Impax's primary negotiator with Endo, believed that getting a No-AG would be beneficial to Impax. (Mengler, Tr. 526). In May 2010, Impax's then-CEO asked Chris Mengler, then-President of Impax's generic drug business, "What if we can settle with Endo for January 2011 launch with No AG?" (CX0505 at 001 (Mengler/Hsu email chain) (emphasis in original)). Mr. Mengler responded: "I'd love that!!!!" (CX0505 at 001 (Mengler/Hsu email chain); *see also* CX4010 (Mengler, IHT at 113-14)).

RESPONSE TO FINDING NO. 407:

Respondent has no specific response to the first sentence of Proposed Finding No. 407. The second and third sentences of Proposed Finding No. 407 are incomplete and misleading. Mr. Mengler did not mention a No Authorized Generic provision. His full statement was, "Settlement --- different story. I'd love that !!!!" (CX0505-001).

408. The settlement agreement that Impax and Endo executed in June 2010 included a No-AG provision. (Koch, Tr. 234; Snowden, Tr. 392, 429). At time of the execution of the SLA, Impax did not know whether Endo would launch an authorized generic of the dosages as to which Impax was first-filer during Impax's 180-day exclusivity period. (CX3164 at 019-20 (Impax Response to Request for Admission No. 45)).

RESPONSE TO FINDING NO. 408:

Respondent has no specific response.

409. At the time of the execution of the SLA, Impax was concerned that Endo would launch an authorized generic of the dosages as to which Impax was first-filer during Impax's 180-day exclusivity period. (CX0514 at 004 (Email from Chris Mengler attaching 5-year forecast 2010) (showing Impax with less than 100% of the generic market share within the 180-day exclusivity period); CX2825 at 008 (Email from Ted Smolenski attaching 5-year forecast 2010) (same); CX2852 at 002 (Email from Todd Engle re: Meeting Minutes from Feb. 2, 2010 Quarterly Launch Planning Meeting) (noting that Endo "may have potential to launch AG immediately"); CX3154 at 001

(Email from Larry Hsu to Todd Engle, Chris Mengler, and Meg Snowden) ("Aren't we too optimistic to assume that we will have a 2-4 weeks head start to AG?")).

RESPONSE TO FINDING NO. 409:

Complaint Counsel's Proposed Finding No. 409 is misleading and not supported by the cited evidence. None of the cited documents express a concern that Endo would launch an authorized generic. Rather, the documents simply consider possible scenarios. (CX3154 ("The [a]ttached file has a summary tab listing Impax Profits given 3 scenarios," including an authorized generic); CX2852-002 ("potential AG"); CX0514-004 (no mention of an authorized generic); CX2825 (same)). What is more, Todd Engle, Vice President of Sales and Marketing for Impax's Generic Division, testified that such financial planning documents simply reflected Mr. Engle's "thinking walking into th[e relevant] meeting" and did not reflect Impax's thinking. (Engle, Tr. 1777).

c) The No-AG provision was a payment to Impax

410. The "No-AG provision" was worth substantial value to Impax when the SLA was executed because the "No-AG provision" ensured that Impax would face no generic competition during this exclusivity period and so would earn greater profits by not having to share generic sales with an Endo authorized generic. (CX5000 at 153-55 (¶¶ 346-48) (Noll Report); Noll, Tr. 1452-54).

RESPONSE TO FINDING NO. 410:

Complaint Counsel's Proposed Finding No. 410 violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents," including what Impax valued.

411. The "No-AG provision" means that Endo agreed not to launch or introduce an authorized generic of Opana ER in competition with Impax's generic oxymorphone ER during Impax's 180-day exclusivity period. (Koch, Tr. 235; Mengler, Tr. 525; Reasons, Tr. 1214). If there were no authorized generic and Impax maintained its exclusivity, then Impax would be the only generic product on the market during its 180 days of exclusivity. (Snowden, Tr. 392). Having a No-AG provision, Impax could charge a

> higher price for generic Opana ER than compared to a marketplace that had two companies selling generic products. (Reasons, Tr. 1215). That higher price is about 30 to 35% higher than if there were another generic in the marketplace. (Reasons, Tr. 1215).

RESPONSE TO FINDING NO. 411:

Respondent has no specific response to the first, third, and fourth sentences of Complaint Counsel's Proposed Finding No. 411. The third sentence of Proposed Finding No. 411 is incomplete and misleading. The record is replete with evidence indicating that generic oxymorphone ER would still compete with generic and branded versions of many different long-acting opioids during its 180-day exclusivity period. (Savage, Tr. 732 (when a patient seeks treatment for chronic pain in the first instance, doctors can prescribe any long-acting opioid); RX-083.0003 at 35 (highlighting real-world switching patterns between oxymorphone-based products and drugs including fentanyl, oxycodone, and morphine)). Demir Bingol, Endo's Senior Director of Marketing and the Endo employee responsible for knowing with whom oxymorphone-based products compete, testified that "all long-acting opioid formulations," including generics that are not actively marketed, are direct competitors. (Bingol, Tr. 1271, 1313).

This competition plays out through, among other things, "effective targeting of your messaging to your clinicians," "rebates that you offer payers in order to ensure that you have a competitive place on formularies," and "certain competitors coming and going that your product becomes a natural next choice." (Bingol, Tr. 1284). With respect to formularies in particular, manufacturers compete on price to secure favorable formulary placement vis-à-vis competitors. (Bingol, Tr. 1324-25). This includes rebates by brand companies in order to compete with generic products on price. (Bingol, Tr. 1327; Engle, Tr. 1718; CX4037 (Smolenski, Dep. at 155)). And it can mean that generic long-acting opioids, like oxymorphone ER, are excluded

from formulary coverage in favor of other long-acting opioids. (Noll, Tr. 1546; RX-017.0001; RX-017.0002 at 11).

412. Impax executives estimated that if Original Opana ER were still on the market and Endo launched an AG when Impax entered, Endo's AG would capture roughly half of sales and cause substantially lower generic prices during the exclusivity period than would be the case if Impax sold the only generic. (CX4037 (Smolenski, Dep. at 53-54); CX4002 (Smolenksi, IHT at 80-81); CX0202 at 001 (Smolenski email) ("worst case" is that Impax shared the market with an AG)).

RESPONSE TO FINDING NO. 412:

Complaint Counsel's Proposed Finding No. 412 is incomplete and misleading. Mr. Smolenski was responding to a question that asked "what would *the low end of our forecast* range be like?" (CX0202-001 (emphasis added)). Mr. Smolenski responded, "Think it would be about 50% share." (CX0202-001). Mr. Smolenski explained that the figure was simply "what I was assuming in this particular email." (CX4037 (Smolenski, Dep. at 53)).

413. Impax modeled the effect of an Endo AG on Impax's expected generic sales. Impax's modeling showed that the No-AG provision of the settlement was worth at least $23 million. In its ("Upside") scenario, Impax assumed that an authorized generic entered about 2 months after Impax's launch of generic Opana ER. Under this scenario, Impax's share of generic sales was estimated to fall to 60% and average price by 36% (from 55% of brand WAC to 35%). As a result, AG entry during the exclusivity period caused Impax's revenues to fall by 61.6%, amounting to $5 million per month or a reduction of about $23 million in the four and a half months after AG entry. (CX5000 at 155 (¶ 350) (Noll Report); CX4037 (Smolenski, Dep. at 147-50, 166); CX0004 at 005-19 (Impax 5-year plan "Upside" scenario sent to Mengler); CX0222 at 004-11 (Impax 5-year plan "Upside" scenario); CX2825 at 008-17 (Impax 5-year plan "Upside" scenario); CX2830 at 004-09 (Impax 5-year plan "Upside" scenario sent to Mengler); CX2831 at 003-08 (Impax 5-year plan "Upside" scenario sent to Koch)).

RESPONSE TO FINDING NO. 413:

Complaint Counsel's Proposed Finding No. 413 is not supported by the record and lacks foundation. Professor Noll did not calculate the expected value of any provision in the settlement agreement, or the overall expected value of the SLA, at the time of settlement. (Noll,

Tr. 1613, 1651-52; Addanki, Tr. 2384). None of the cited evidence, moreover, indicates that Impax ever valued the No-Authorized Generic provision in the manner or amount Professor Noll purports. In fact, Mr. Smolenski testified that the financial documents are based on various assumptions, including a decline in sales by a set percentage. (CX4037 (Smolenski, Dep. at 53, 147-49); *see* Mengler, Tr. 528-29 (Impax derives value "by selling the drug [] with or without an" authorized generic); CX4030 (Hsu, Dep. at 76-77)).

Finally, both Complaint Counsel and its economic expert admitted it was possible that both the Endo Credit and No-Authorized Generic provisions would have zero value. (Court, Tr. 71, 75 ("JUDGE CHAPPELL: Are you going to stand there and tell me that the lowest possible outcome was not going to be zero? You're going to stand there and tell me that because some paid expert tells you that it had to be $62 million floor that it couldn't have been zero? MR. LOUGHLIN: No, Your Honor. There was a theoretical possibility of zero."); Noll, Tr. 1654 ("Q. And that example where you get zero of both, you didn't include that on your demonstrative of scenarios, did you? A. No, I didn't.")).

414. In Impax's model of a "Base" scenario for launching generic Opana ER, Endo's AG enters simultaneously with Impax and captures half of the market while causing prices to fall by the same 36%. (CX5000 at 155-56 (¶ 350) (Noll Report); CX2853 at 007-15 (Impax 5-year plan "Base" scenario)). Under these assumptions, simultaneous AG entry would reduce Impax's revenues by 68% during the exclusivity period, or about $33 million for a launch on June 14, 2010. (CX5000 at 155-56 (¶ 350) (Noll Report); CX0222 at 004-11 (Impax 5-year plan)).

RESPONSE TO FINDING NO. 414:

Complaint Counsel's Proposed Finding No. 414 is not supported by the record and lacks foundation. Professor Noll did not calculate the expected value of any provision in the settlement agreement, or the overall expected value of the SLA, at the time of settlement. (Noll, Tr. 1613, 1651-52; Addanki, Tr. 2384). None of the cited evidence, moreover, indicates that

Impax ever valued the No-Authorized Generic provision in the manner or amount Professor Noll purports. In fact, Mr. Smolenski testified that the financial documents are based on various assumptions, including a decline in sales by a set percentage. (CX4037 (Smolenski, Dep. at 53, 147-49); *see* Mengler, Tr. 528-29 (Impax derives value "by selling the drug [] with or without an" authorized generic); CX4030 (Hsu, Dep. at 76-77)).

Finally, both Complaint Counsel and its economic expert admitted it was possible that both the Endo Credit and No-Authorized Generic provisions would have zero value. (Court, Tr. 71, 75 ("JUDGE CHAPPELL: Are you going to stand there and tell me that the lowest possible outcome was not going to be zero? You're going to stand there and tell me that because some paid expert tells you that it had to be $62 million floor that it couldn't have been zero? MR. LOUGHLIN: No, Your Honor. There was a theoretical possibility of zero."); Noll, Tr. 1654 ("Q. And that example where you get zero of both, you didn't include that on your demonstrative of scenarios, did you? A. No, I didn't.")).

> 415. The value of the "No-AG provision" would be higher in the future if Endo did not introduce a reformulated version of Opana ER, and the revenues from Original Opana ER continued to increase. Sales of Original Opana ER grew from $240 million in 2010 to $384 million in 2011 and, after the switch to Reformulated Opana ER in 2012, Opana ER revenues remained at $299 million. (CX3215 at 010 (Endo SEC Form 10-K Annual Report)). These data imply that the value of the "No-AG provision" for entry would have been approximately 60% greater (over $50 million) in 2011 and at least 25% greater (over $40 million) in 2012. (CX5000 at 156 (¶ 351) (Noll Report)).

RESPONSE TO FINDING NO. 415:

The first sentence of Complaint Counsel's Proposed Finding No. 415 is not supported by any record evidence and should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2).

Respondent has no specific response to the second sentence of Proposed Finding No. 415.

The third sentence of Proposed Finding No. 415 is not supported by the record and lacks foundation. Professor Noll did not calculate the expected value of any provision in the settlement agreement, or the overall expected value of the SLA, at the time of settlement. (Noll, Tr. 1613, 1651-52; Addanki, Tr. 2384). Both Complaint Counsel and its economic expert, moreover, admitted it was possible that both the Endo Credit and No-Authorized Generic provisions would have zero value. (Court, Tr. 71, 75 ("JUDGE CHAPPELL: Are you going to stand there and tell me that the lowest possible outcome was not going to be zero? You're going to stand there and tell me that because some paid expert tells you that it had to be $62 million floor that it couldn't have been zero? MR. LOUGHLIN: No, Your Honor. There was a theoretical possibility of zero."); Noll, Tr. 1654 ("Q. And that example where you get zero of both, you didn't include that on your demonstrative of scenarios, did you? A. No, I didn't.")).

416. Impax did not forfeit its 180-day exclusivity period. (Snowden, Tr. 484).

RESPONSE TO FINDING NO. 416:

Respondent has no specific response.

417. Impax launched its generic oxymorphone ER product in January 2013 and was the only generic oxymorphone ER product available for six months following its launch. (CCF ¶¶ 360, 378-82).

RESPONSE TO FINDING NO. 417:

While Respondent does not dispute that Impax launched its oxymorphone ER product in January 2013, the proposed summary finding should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2).

Additionally, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondent's replies to those findings.

2. The Endo Credit was valuable to Impax

a) Impax executives wanted to protect the value of their first-filer status in the event that Endo introduced a reformulated Opana ER product

418. Impax executives were concerned that during the period between signing the Impax-Endo Settlement Agreement and the agreed entry date of January 2013, the market for oxymorphone ER might collapse if Endo introduced a tamper-resistant reformulation of Opana ER. (Koch, Tr. 237-38; Mengler, Tr. 527-28). Impax's generic oxymoprhone ER product would not be AB-rated against Reformulated Opana ER; therefore, Impax's generic oxymorphone ER product would not be automatically substituted for prescriptions written for Reformulated Opana ER. (Mengler, Tr. 521, 528). Automatic substitution of the generic for the brand is the primary way that generics make their sales. (Mengler, Tr. 522; Engle, Tr. 1703). Impax's then-Chief Financial Officer, Art Koch, was aware that when Impax agreed not to launch generic oxymorphone ER until January 2013 that it was giving Endo time to switch the market to a reformulated version of Opana ER. (Koch, Tr. 236).

RESPONSE TO FINDING NO. 418:

Respondent has no specific response to the first, second, and third sentences of Complaint Counsel's Proposed Finding No. 418. The fourth sentence of Proposed Finding No. 418 is incomplete and misleading because it ignores Mr. Koch's full answer. He explained, "Well, it was understood when we entered into the negotiations we had developed what we called a carrot and a stick as a way to get more control than just the lost control over that period of time." (Koch, Tr. 236-37 (testifying only that it "occur[ed]" to him, not that Impax was in fact doing something)).

419. Impax did not have specific information about what Endo was planning to do, but Impax, as an industry participant, had seen a number of brand companies try to introduce a next-generation product and move the market over to the next-generation product so that the opportunity for the generic launch was much reduced. (Snowden, Tr. 433–34).

RESPONSE TO FINDING NO. 419:

Respondent has no specific response.

420. If Endo were to move to a next-generation product, then the market opportunity for Impax's generic product would be significantly reduced or even zero. (Snowden, Tr. 434). Impax's primary negotiator, Mr. Mengler, became concerned during settlement negotiations with Endo that Endo was planning to launch a reformulated version of Opana ER. (Mengler, Tr. 527). Mr. Mengler was concerned that reformulation was an effort to subvert the value of the deal he was trying to put together to get Impax's product on the market and that reformulation was potentially damaging to Impax's business. (Mengler, Tr. 526-27).

RESPONSE TO FINDING NO. 420:

Respondent has no specific response to the first and second sentences of Complaint Counsel's Proposed Finding No. 420. The third sentence of Proposed Finding No. 420 is incomplete and misleading. Mr. Mengler testified in full that reformulation "was more an effort to subvert the value of the deal that I was trying to put together to get my product on the market to -- because the only way I'm in business is selling generic drugs, and so call it whatever you want. I thought it was subversion." (Mengler, Tr. 526-27). Mr. Mengler also explained that the "subversion of the benefits" was "the benefits to the American consumer for getting a generic version of what would have been an important drug and also I benefit, too, in the way I make money is by selling generic drugs, so." (Mengler, Tr. 527).

421. Mr. Mengler's concern was that Endo would try to shift sales away from Original Opana ER to Reformulated Opana ER such that Opana ER in its original form disappears or becomes insignificant. (Mengler, Tr. 527). Impax's generic would not be AB-rated to the Reformulated Opana ER product. (Mengler, Tr. 528). This was a concern because "the way generic drugs are sold is by having a substitute, and if there's no substitute, I get nothing." (Mengler, Tr. 527). This would reduce the value of Impax's generic product including the value of Impax's 180-day exclusivity, and increase costs to consumers. (Mengler, Tr. 528).

RESPONSE TO FINDING NO. 421:

Respondent has no specific response.

422. During negotiations with Endo, Impax's primary negotiator (Mr. Mengler) told Endo that he believed that Endo was planning to launch a reformulated version of Opana ER before Impax could launch its generic. (Mengler, Tr. 531). Endo denied this. (Mengler, Tr. 531-32). Mr. Mengler did not believe Endo. (Mengler, Tr. 532).

RESPONSE TO FINDING NO. 422:

Respondent has no specific response.

423. In response, Impax negotiated for protections in case Endo moved the market away from the original formulation of Opana ER. (Snowden, Tr. 385; Mengler, Tr. 532; Snowden, Tr. 431-32; RX-318 at 0001 (Mengler email summarizing negotiations); CX0321 at 001 (Mengler email summarizing negotiations)). Protecting the market for Impax's entry date was a priority for Impax. (Snowden, Tr. 490).

RESPONSE TO FINDING NO. 423:

Respondent has no specific response.

424. Initially, Impax proposed an acceleration trigger. (Snowden, Tr. 385). Under Impax's proposed acceleration triggers, the launch date for Impax's generic version of Opana ER could become earlier than January 1, 2013, if the market for Opana ER degraded or declined to a certain level. (Mengler, Tr. 532; Snowden, Tr. 385, 432; RX-318 at 001 (Mengler email summarizing negotiations)). An acceleration trigger would have protected Impax from a decline in sales of Original Opana ER while providing consumers the benefit of generic competition at an earlier date. (CX4032 (Snowden, Dep. at 103–04) (Rule 3.33(c)(1) testimony); CX4026 (Nguyen, Dep. at 163)).

RESPONSE TO FINDING NO. 424:

Respondent has no specific response other than to note that neither Ms. Snowden nor Ms. Nguyen testified about benefits to consumers or generic competition, as Complaint Counsel attempts to suggest. Their testimony was limited to the operation of a possible acceleration trigger. (CX4032 (Snowden, Dep. at 103-04); CX4026 (Nguyen, Dep. at 163)).

425. Endo rejected the idea of an acceleration trigger. (Snowden, Tr. 385, 432; Koch, Tr. 237-39). The discussions regarding an acceleration trigger turned instead to a term called the Endo Credit. (Mengler, Tr. 532; Snowden, Tr. 385, 432).

RESPONSE TO FINDING NO. 425:

Respondent has no specific response.

b) Impax and Endo agreed to the Endo Credit provision as a means of making Impax whole if Endo launched a reformulated Opana ER product and reduced the value of the No-AG provision

426. Endo moved away from the concept of an accelerated launch date in favor of something that Impax understood as a "make-whole provision." (Koch, Tr. 238). Endo insisted on a firm entry date in 2013 but agreed to compensate Impax if the demand for Original Opana ER fell substantially before the agreed entry date. (CX4032 (Snowden, Dep. at 103-04, 113-15) (Rule 3.33(c)(1) testimony); CX4026 (Nguyen, Dep. at 163)).

RESPONSE TO FINDING NO. 426:

Respondent has no specific response to the first sentence of Complaint Counsel's Proposed Finding No. 426 other than to note that the cited evidence does not support the proposition that "Endo moved" away from or to anything. (Koch, Tr. 238 ("Q. But at some point *the negotiations with Endo* moved away from an accelerated launch date in favor of something that you understood as the make-whole provision; correct? A. Yes.") (emphasis added)). And while Respondent does not dispute that Endo refused to offer a license date earlier than 2013, the remainder of the second sentence of Proposed Finding No. 426 is not supported by the cited evidence.

427. Getting downside protection for Impax in the event Endo reformulated Opana ER was "super, super important" to Impax's primary negotiator of the Endo-Impax settlement. (Mengler, Tr. 535-36). According to Impax's primary negotiator, "something that didn't protect us from the downside was . . . a deal-breaker." (CX4010 (Mengler, IHT at 44)).

RESPONSE TO FINDING NO. 427:

Respondent has no specific response to the first sentence of Complaint Counsel's Proposed Finding No. 427. The second sentence of Proposed Finding No. 427 is incomplete,

lacks foundation, and is misleading because it selectively quotes Mr. Mengler. Mr. Mengler was asked whether "Impax would have settled its litigation with Endo without either an acceleration trigger or the Endo credit term." (CX4010 (Mengler, IHT at 44)). Mr. Mengler responded, "it is conjecture on my part," but that "as we learned more about the market, something that didn't protect us from the downside was becoming a deal-breaker. So that was something that was on our radar." (CX4010 (Mengler, IHT at 44) (noting also "deal-breaker was, I think, the term that you used")).

428. Impax's primary negotiator, Mr. Mengler, "came up with the idea of the make-good provision in the event that" Endo reformulated Opana ER. (Mengler, Tr. 581-82). With the "make-good provision," then "at least Impax would have some protection." (Mengler, Tr. 582). If Endo did reformulate and destroy the market for Original Opana ER, then Impax would at least make money though the Endo Credit payment. (Mengler, Tr. 534-35).

RESPONSE TO FINDING NO. 428:

Respondent has no specific response to the first and second sentences of Complaint Counsel's Proposed Finding No. 428. The third sentence of Proposed Finding No. 428 is incomplete and misleading because it ignores the weight of the evidence, including the admissions of Complaint Counsel and its economic expert, that the Endo Credit could have zero value, even if Endo destroyed Impax's generic opportunity. (Court, Tr. 71, 75 ("JUDGE CHAPPELL: Are you going to stand there and tell me that the lowest possible outcome was not going to be zero? You're going to stand there and tell me that because some paid expert tells you that it had to be $62 million floor that it couldn't have been zero? MR. LOUGHLIN: No, Your Honor. There was a theoretical possibility of zero."); Noll, Tr. 1654 ("Q. And that example where you get zero of both, you didn't include that on your demonstrative of scenarios, did you? A. No, I didn't."); *see also* Mengler, Tr. 582-83 (Impax did not view the Endo Credit as a means to generate income; it was instead meant to ensure Impax had a generic opportunity)).

429. The term "make-whole provision" is another phrase for what became the Endo Credit. (Mengler, Tr. 545). The Endo Credit was "intended to make [Impax] whole for what [Impax] would have otherwise achieved." (Mengler, Tr. 582). "So, [Impax's primary negotiator] didn't really care what the size of the market was" going to be. (Mengler, Tr. 582). The concept of "downside protection," or a "make-good" payment is what became the Endo Credit. (Koch, Tr. 241; Snowden, Tr. 434; Mengler, Tr. 543, 582).

RESPONSE TO FINDING NO. 429:

Respondent has no specific response to the first, second, and fourth sentences of Complaint Counsel's Proposed Finding No. 429. The third sentence of Proposed Finding No. 429 is inaccurate and misleading because it selectively quotes Mr. Mengler out of context. The relevant exchange was as follows: "Q. With respect to the Endo credit formula, did you do any analyses or forecasting as to what Impax might be paid under the Endo credit formula? A. No. Q. Why not? A. Well, because the Endo credit, make good, was not an attempt to, you know, generate income. It was intended to make us whole for what we would have otherwise achieved, so I didn't really care what the size of the market was. It was going to get in there no matter what." (Mengler, Tr. 582). The record, moreover, is clear that Mr. Mengler and Impax wanted a robust generic opportunity. (Mengler, Tr. 528-30 (Impax derives value from being able to sell its product); Snowden, Tr. 432-33 (Mr. Mengler told Endo that Impax was "happy to pay" a royalty if the generic opportunity increased); Reasons, Tr. 1226 (Impax wanted a "robust, large market and pay a royalty and have larger ongoing revenue streams than have a one-time cash payment that we would pull out of our [financial] results when we report to the investors"); Koch, Tr. 239 (royalty provision meant to incentivize Endo to support original Opana ER)).

430. The "Endo Credit" provision was designed to insulate Impax against a substantial decrease in sales of Opana ER. (Cuca, Tr. 617). At the time the parties were negotiating the terms of the "Endo Credit" provision, Endo was developing a reformulated version of Opana ER, the introduction of which could lead to such a decrease in the sales of Original Opana ER. (Cuca, Tr. 618-19; *see also* CCF ¶ 72-83, 240-48, 418-23, above)

RESPONSE TO FINDING NO. 430:

Respondent has no specific response.

431. Impax and Endo each understood that the Endo Credit might be triggered and require a significant payment. Thus, each party extensively negotiated changes to the formula that would benefit it. Impax sought revisions to the formula to maximize the magnitude of the payment. Endo sought revisions to reduce the magnitude of any Endo Credit payment. (CX0323 at 006-07, 012 (Donatiello email to Snowden attaching draft settlement); CX0324 at 045 (email from Impax counsel to Endo with draft settlement); CX2567 at 005-08, 14 (Endo email chain attaching draft settlement)).

RESPONSE TO FINDING NO. 431:

Complaint Counsel's Proposed Finding No. 431 is not supported by the cited evidence, which says nothing about the parties' understandings, why revisions were sought, or how terms impacted any party vis-à-vis another.

432. During the negotiations about the figures that became part of the Endo Credit, Impax's negotiator said to Endo that Impax would accept the alternative of a credit instead of an acceleration trigger, but all of the assumptions in the credit would be in Impax's favor. (Snowden, Tr. 386, 434-35). Impax's negotiator said to Endo that if Impax was going to agree to the Endo Credit as the structure for protection from market degradation, then Endo would have to agree to aggressive numbers for the Endo Credit. (Snowden, Tr. 386). Those assumptions were built into what eventually became known as the Endo Credit. (Snowden, Tr. 435).

RESPONSE TO FINDING NO. 432:

Respondent has no specific response.

433. At a high level, the Endo Credit called for determining the quarterly peak, which was the calendar quarter in which Opana ER sales were the highest during the relevant time period. Impax determined that the quarterly peak was the fourth quarter of 2011. That determination was based on IMS data. Impax calculated the quarterly peak. The calculation also required determining what is called the pre-Impax amount, which is the sales of Opana ER in the fourth quarter of 2012, the sales right before Impax was to launch its generic product. If the pre-Impax amount is less than 50% of the quarterly peak, which was called the trigger threshold, then the payment was triggered. The calculation of the payment consisted of multiplying the differences between those amounts by the factors set forth in the agreement to determine the final sum that was the Endo Credit. (Snowden, Tr. 437).

RESPONSE TO FINDING NO. 433:

Respondent has no specific response other than to clarify that Impax could not and did not know when the quarterly peak would occur or what the quarterly peak would be at the time of settlement, as Proposed Finding No. 433 attempts to suggest.

> 434. Impax attributed significant value to the Endo Credit provision. The downside protection for Impax that the Endo Credit provided in the event Endo reformulated Opana ER was "super, super important" to Mr. Mengler when he was negotiating. (Mengler, Tr. 535-36). According to him, "something that didn't protect us from the downside was . . . a deal-breaker." (CX4010 (Mengler, IHT at 44)). In the settlement with Endo, Impax accomplished its priority of protecting the market for its entry date for generic Opana ER. (Snowden, Tr. 490).

RESPONSE TO FINDING NO. 434:

The first sentence of Complaint Counsel's Proposed Finding No. 434 is not supported by any record evidence and should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2).

Respondent has no specific response to the second and fourth sentences of Proposed Finding No. 434.

The third sentence of Proposed Finding No. 434 is incomplete, lacks foundation, and is misleading because it selectively quotes Mr. Mengler. Mr. Mengler was asked whether "Impax would have settled its litigation with Endo without either an acceleration trigger or the Endo credit term." (CX4010 (Mengler, IHT at 44)). Mr. Mengler responded, "it is conjecture on my part," but that "as we learned more about the market, something that didn't protect us from the downside was becoming a deal-breaker. So that was something that was on our radar." (CX4010 (Mengler, IHT at 44) (noting also "deal-breaker was, I think, the term that you used")).

435. The Endo Credit and No-AG provision worked together to provide value to Impax regardless of whether Endo reformulated Opana ER. A sharp decline in the sales of branded Opana ER before Impax's generic launch would decrease the value of the No-AG provision that Impax agreed to with Endo. (Reasons, Tr. 1218). In that case, the value of the No-AG provision would decrease because the total market potential for generic Opana ER would be decreasing. (Reasons, Tr. 1218). The Endo Credit payment would "correct for the loss in the value of the market that had occurred before the generic entry date." (CX04035 (Cuca, Dep. at 69-70)).

RESPONSE TO FINDING NO. 435:

The first sentence of Complaint Counsel's Proposed Finding No. 435 is not supported by any record evidence and should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Moreover, both Complaint Counsel and its economic expert admitted it was possible that both the Endo Credit and No-Authorized Generic provisions would have zero value. (Court, Tr. 71, 75 ("JUDGE CHAPPELL: Are you going to stand there and tell me that the lowest possible outcome was not going to be zero? You're going to stand there and tell me that because some paid expert tells you that it had to be $62 million floor that it couldn't have been zero? MR. LOUGHLIN: No, Your Honor. There was a theoretical possibility of zero."); Noll, Tr. 1654 ("Q. And that example where you get zero of both, you didn't include that on your demonstrative of scenarios, did you? A. No, I didn't.")).

Respondent has no specific response to the second, third, and fourth sentences of Proposed Finding No. 435.

436. A sharp decline in branded Opana ER sales, however, would trigger Endo's obligation to make a payment under the Endo Credit provision. The "Endo Credit" provision obligated Endo to pay Impax an amount that would guarantee that Impax would earn at least as much profit as it would have earned had it launched before Endo introduced the reformulated product. (Mengler, Tr. 582; CX0506 at 001 (Mengler email to Hsu and other Impax executives) ("[I]f the product declines by more than 50%, we

would be entitled to a 'make good' payment such that our potential profits would equal to 50%.")).

RESPONSE TO FINDING NO. 436:

Complaint Counsel's Proposed Finding No. 436 is inaccurate. Actual quarterly peak sales after settlement were $185,691,457. (CX0332-003). If sales dropped just enough to trigger the Endo Credit, for instance, because sales in the last quarter of 2012 were 49 percent of their quarterly peak, this would mean the resulting liability would be roughly $2 million. If sales dropped only to 49.9 percent of their peak, the resulting liability would be roughly $200,000. (RX-364.0003-04 (any Endo Credit payment is the product of (1) 0.2953 times the annualized quarterly peak sales divided by 100, and (2) the number of percentage points under 50)). There is no evidence to suggest that such potential liabilities under the Endo Credit represented "guarantees" of Impax's profits over six months.

437. On the other hand, if Endo did not reformulate and in fact grew the market for Original Opana ER, then Impax would launch its generic and would get value from its 180-day exclusivity period and the No-AG provision. If sales of Original Opana ER reached a sufficiently high level, Impax would have paid a royalty to Endo. (Mengler, Tr. 533). Impax still would be benefited—even if it were paying a royalty to Endo—by making sales during the 180-day exclusivity period without competition from an authorized generic. (Mengler, Tr. 534; *see also* CCF ¶ 468, below).

RESPONSE TO FINDING NO. 437:

The first sentence of Complaint Counsel's Proposed Finding No. 437 is not supported by any record evidence and should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2).

Respondent has no specific response to the second or third sentences of Proposed Finding No. 437 other than to note that to the extent the Proposed Finding purports to summarize and

incorporate other findings, those findings do not support the Proposed Finding and are unreliable for the reasons set out in Respondent's replies to those findings.

> 438. Impax understood that the No-AG provision backed-up by the Endo Credit ensured that Impax would receive value from its agreement with Endo. During a November 2011 earnings call, Impax's then-CFO discounted the impact of Endo switching Opana ER to a new formulation because of Impax's agreement with Endo: "Fortunately, though, we do have [downside] protection built into the agreement so we should have a reasonable outcome almost no matter what happens." (Koch, Tr. 264-65; CX2703 at 012-13 (Transcript of Q3 2011 Impax Earnings Call)). If Endo did a "switchout" to Opana tamper-resistant, Impax would be able to realize a payment from Endo. (Koch, Tr. 265). Thus, Impax had protection that ensured that Impax had a reasonable outcome almost no matter what Endo did, and Impax executives viewed that protection as a form of insurance. (Koch, Tr. 265-66; Reasons, Tr. 1218-19; CX4020 (Reasons, Dep. at 55-56) (agreeing that "if the market for Opana ER did not decline, the value of the No-AG provision would be higher, but if the market did decline, Impax would get a payment under the Endo credit")).

RESPONSE TO FINDING NO. 438:

The first sentence of Complaint Counsel's Proposed Finding No. 438 is not supported by any record evidence and should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2).

The remainder of Proposed Finding No. 438 is incomplete and misleading. The record indicates that the Endo Credit was part of "a carrot and a stick" approach to incentivize Endo to make investments in its original Opana product, and to ensure Impax had a measure of control over its generic opportunity. (Koch, Tr. 236-37, 240-41, 265; Snowden, Tr. 386). It was intended to act as "a deterrent to prevent [Endo] form switching the market." (CX4021 (Ben-Maimon, Dep. at 118, 122); *see* CX4037 (Smolenski, Dep. at 244-45) ("intended to disincentivize Endo from" introducing a reformulated product); CX4026 (Nguyen, Dep. at 163-64) (Endo Credit was used to "put [Endo] to [its] word" with respect to reformulation)).

Numerous fact witnesses testified that, at the time of the settlement, it was uncertain whether or not the No-AG provision and the Endo Credit provided Impax with any value at all, and if so, how much. (Cuca, Tr. 629; Snowden, Tr. 437-38). Indeed, Impax knew that the Endo Credit could result in zero value. (CX4032 (Snowden, Dep. at 204-06); CX4002 (Smolenski, IHT at 128-30)). Roberto Cuca, Endo's Vice President of Financial Planning and the author of the Endo Credit, explained that "I don't know that anyone was anticipating a change in the marketplace, but the provision was designed to insulate against a substantial decrease in sales of the innovator product." (Cuca, Tr. 615, 617).

3. Endo ultimately paid Impax $102 million pursuant to the Endo Credit provision

439. In July 2010, Endo filed a supplemental New Drug Application (No. 201655) for a reformulated version of Opana ER ("Reformulated Opana ER"). The FDA approved the application in December 2011. (JX-001 at 011 (¶ 48)).

RESPONSE TO FINDING NO. 439:

Respondent has no specific response.

440. The SLA gave Endo "a clear path (until January 2013) to establish [Reformulated Opana ER] demand." (RX-007 at 001 (Endo Narrative for 3Q 2010 Earnings Call)). In 2012, Endo ceased selling Original Opana ER and began selling a "new formulation" of Opana ER (NDA No. 201655). (JX-001 at 012 (¶ 49)).

RESPONSE TO FINDING NO. 440:

Respondent has no specific response.

441. As a result, sales of Original Opana ER did decrease substantially – falling to zero – which triggered the payment of the "Endo Credit." Ultimately, Endo paid Impax $102 million under the "Endo Credit". (JX-001 at 011 (¶ 46); CX1216 (Endo Credit Invoice); CX5000 at 160-62 (¶¶ 361-62) (Noll Report)).

RESPONSE TO FINDING NO. 441:

Respondent has no specific response other than to note that to the extent Complaint Counsel's Proposed Finding No. 441 suggests that a substantial decrease in original Opana ER sales was planned or anticipated, it is inaccurate and misleading. Indeed, the first time that Endo knew its sales would be zero in the last quarter of 2012 was after the Novartis plant shutdown and resulting supply interruption in 2012. (Cuca, Tr. 615, 617, 677 ("I don't know that anyone was anticipating a change in the marketplace"); RX-094.0003-06 (supply chain disruption for original Opana ER resulted in Endo Credit liability)). Until that point, Endo expected to sell Opana ER through the fourth quarter of 2012. (CX4017 (Levin, Dep. at 131); RX-094.0006 ("Prior to March [2012], it would have been reasonable to assume that prescriptions of old formulation [Opana ER] would have occurred in Q4 2012"); RX-108.0002 at 10).

442. On January 18, 2013, Margaret Snowden, Impax's Vice President for intellectual property litigation and licensing, provided Endo with written documentation supporting its demand for payment of the Endo Credit in the amount of $102,049,199.64, pursuant to Section 4.4 of the SLA. (JX-001 at 011 (¶ 45); Snowden, Tr. 386-87, 389; CX0332 at 007-08 (Letter from Snowden to Endo notifying Endo that Endo Credit payment was due)). Ms. Snowden's letter included the backup information showing how she had calculated the value of the Endo Credit payment. (CX0332 at 010-13 (Letter from Snowden to Endo notifying Endo that Endo Credit payment was due)).

RESPONSE TO FINDING NO. 442:

Respondent has no specific response.

443. Endo did not dispute Impax's calculation of the Endo Credit. (Snowden, Tr. 491).

RESPONSE TO FINDING NO. 443:

Respondent has no specific response.

444. On April 18, 2013, pursuant to Section 4.4 of the SLA, Impax received a payment from Endo in the amount of $102,049,199.64. (JX-001 at 011 (¶ 46); Reasons, Tr. 1204; CX0333 (Email chain discussing and attaching confirmation of wire transfer from Endo

to Impax of $102,049,199.64); CX1301 at 007 (Endo response to civil investigative demand)). Endo paid to Impax the exact amount that Impax had indicated was due in Ms. Snowden's letter pursuant to the Endo Credit provision: $102,049,199.64. (JX-001 at 011 (¶¶ 45-46); Snowden, Tr. 390, 491).

RESPONSE TO FINDING NO. 444:

Respondent has no specific response.

C. The $10 million wire transfer from Endo to Impax pursuant to the Development and Co-Promote Agreement was a payment

445. The Development and Co-Promotion Agreement ("DCA") that Endo and Impax executed in June 2010 provides for certain payments to Impax by Endo. (Snowden, Tr. 399; RX-365 at 0009 (DCA)).

RESPONSE TO FINDING NO. 445:

Respondent has no specific response.

446. Endo agreed to pay Impax an "Upfront Payment" of $10 million within five days of the agreement's effective date. (JX-001 at 010 (¶ 39)). Section 3.1 of the DCA calls for an upfront payment from Endo to Impax. (RX-365 at 0009 (DCA § 3.1); Snowden, Tr. 399). That provision provides: "Endo shall pay Impax a payment of Ten Million U.S. dollars within five business days after the Effective Date" of the DCA. (RX-365 at 0009 (DCA § 3.1); Snowden, Tr. 400). The only trigger for the upfront payment was the execution of the DCA. (RX-365 at 0009 (DCA § 3.1); Snowden, Tr. 400).

RESPONSE TO FINDING NO. 446:

Respondent has no specific response other than to clarify that Complaint Counsel selectively quotes the Development and Co-Promotion Agreement's Section 3.1, which states in full, "Endo shall pay Impax a payment of Ten Million US Dollars (US$10,000,000) within five (5) business days after the Effective Date *in consideration for the rights granted to Endo hereunder*." (RX-365.0009 (emphasis added)).

447. The $10 million payment was guaranteed and non-refundable. (JX-001 at 010 (¶ 39)).

RESPONSE TO FINDING NO. 447:

Respondent has no specific response.

448. On June 24, 2010, Endo wired payment of $10 million to Impax in accordance with Section 3.1 of the DCA. (JX-001 at 011 (¶ 44); *see also* Snowden, Tr. 400)).

RESPONSE TO FINDING NO. 448:

Respondent has no specific response.

449. In 2015, Endo informed Impax that Endo had decided not to amend the DCA and that, since Impax's "existing program does not meet the definition of Product in the agreement, [Endo] will not be participating in that program." (RX-221 at 0001 (Email From Endo to Impax dated October 29, 2015); Snowden Tr. 497).

RESPONSE TO FINDING NO. 449:

While Respondent does not dispute that Endo ultimately declined to amend the DCA, Complaint Counsel's Proposed Finding No. 449 is misleading and incomplete because it ignores the fact that, in April 2015, Endo agreed to amend the DCA, noting that it "would like to maintain or even increase [its] involvement with the development program . . . as [it] remain[ed] optimistic this will be a successfully differentiated product, which Endo looks forward to the opportunity to co-promote it with Impax." (RX-218.0001; *see* Snowden, Tr. 460-61). Impax consequently prepared an amendment to the DCA and expected the parties to continue collaborating. (Snowden, Tr. 458-59; *see* CX2747-001). Endo subsequently reversed course and informed Impax that Endo had "decided not to amend the existing agreement" and would no longer "participat[e] in [the] program," but did not provide any explanation. (CX2747-001).

450. Endo and Impax agreed to terminate the DCA in 2015. (Snowden, Tr. 407; RX-221 at 0001 (Email From Endo to Impax dated October 29, 2015)).

RESPONSE TO FINDING NO. 450:

Respondent has no specific response.

451. Impax never refunded the $10 million that Endo had paid pursuant to Section 3.1 of the DCA. (Snowden, Tr. 408).

RESPONSE TO FINDING NO. 451:

Respondent does not dispute that the $10 million payment was not refunded, but Proposed Finding No. 451 is inaccurate and misleading in its attempt to suggest that the payment could or should have been refunded. (Snowden, Tr. 409 ("JUDGE CHAPPELL: Let me go back to one of your previous questions. Is it the government's position that the agreement required Impax to refund the $10 million -- MR. WEINGARTEN: No, Your Honor. JUDGE CHAPPELL: -- that there was any term in the agreement that ever required that? MR. WEINGARTEN: No, Your Honor.")).

D. The payments from Endo to Impax pursuant to the Impax-Endo Settlement Agreement were large

1. Endo and Impax saved approximately $5 to $6 million in combined litigation costs by settling their patent litigation in June 2010

452. Endo's payments to Impax exceeded any reasonable estimate of the saved litigation costs in the Endo-Impax patent litigation. (Noll, Tr. 1463, 1475-77; CX5000 at 168-69 (¶¶ 375-76) (Noll Report)).

RESPONSE TO FINDING NO. 452:

Complaint Counsel's Proposed Finding No. 452 is inaccurate, not supported by the record, and lacks foundation. Professor Noll did not calculate the expected value of any provision in the settlement agreement, or the overall expected value of the SLA, at the time of settlement. (Noll, Tr. 1613, 1651-52; Addanki, Tr. 2384). And the cited portions of Professor Noll's report and testimony do not contain any evidence or analysis supporting the declaration about how much Endo and Impax saved in litigation costs. (CX5000-168-69 (Noll Rep. ¶¶ 375-76); *see also* Noll, Tr. 1464 ("JUDGE CHAPPELL: Did you look at any recent numbers, for example, what attorneys who specialize in patent litigation charge per hour in trial? THE

WITNESS: I haven't looked at the per-hour charges, but I've looked at them all -- outside -- JUDGE CHAPPELL: Those hours matter. THE WITNESS: Huh? JUDGE CHAPPELL: Those hours matter.")).

453. Although litigation costs vary substantially among cases, a survey by the American Intellectual Property Lawyers Association estimated that litigation cost for patent cases with more than $25 million at stake averages about $5.5 million for each party. (CX5000 at 108 (¶ 247) (Noll Report)).

RESPONSE TO FINDING NO. 453:

Complaint Counsel's Proposed Finding No. 453 is improper and inadmissible. Professor Noll purports to summarize a survey that is not in evidence and, if it were, the survey itself would be the best evidence of its contents. Proposed Finding No. 453 is also irrelevant. Complaint Counsel offered no evidence to show that the sort of intellectual property cases purportedly at issue in the survey are comparable to the individual Endo-Impax litigation at issue here. Even still, Proposed Finding No. 453 misrepresents Professor Noll's purported summary, which states that the "median" cost per party when represented by firms with more than 76 attorneys is $7 million. (CX5000-108 (Noll Rep., n.278)).

454. A reasonable estimate of the combined saved litigation costs for both Endo and Impax for settling the patent litigation in June 2010 is approximately $5 million to $6 million. (Noll, Tr. 1463; CX5000 at 168 (¶ 375) (Noll Report) (estimating savings to each party from settling of "somewhere around $3 million)).

RESPONSE TO FINDING NO. 454:

Complaint Counsel's Proposed Finding No. 454 lacks foundation and is not supported by the cited evidence. The cited portion of Professor Noll's report does not contain any evidence or analysis supporting his declaration about how much Endo and Impax saved in litigation costs. (CX5000-168-69 (Noll Rep. ¶¶ 375-76); *see also* Noll, Tr. 1464 ("JUDGE CHAPPELL: Did you look at any recent numbers, for example, what attorneys who specialize in patent litigation

charge per hour in trial? THE WITNESS: I haven't looked at the per-hour charges, but I've looked at them all -- outside -- JUDGE CHAPPELL: Those hours matter. THE WITNESS: Huh? JUDGE CHAPPELL: Those hours matter.")).

455. At the time of the settlement, which occurred during trial, most of the litigation costs had been incurred. Endo had spent between $6 million and $7 million and Impax had spent about $4.7 million on litigating the infringement case. (CX2696 at 013-14 (Impax response to FTC CID); CX3212 at 009-10 (Endo response to FTC CID); CX5000 at 108 (¶ 247) (Noll Report)).

RESPONSE TO FINDING NO. 455:

The first sentence of Complaint Counsel's Proposed Finding No. 455 is not supported by any record evidence and should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2).

Respondent has no specific response to the second sentence of Proposed Finding No. 455.

456. The top end of the range that Impax uses to estimate costs for a generic patent litigation is about $3 million to $4 million per litigation. (Reasons, Tr. 1222). The $3 million to $4 million represents expenses from the start of litigation to the finish. (Reasons, Tr. 1222). As part of its budgeting process, Impax's CFO makes the best estimate he can for litigation expenses in advance. (Reasons, Tr. 1222). Impax's patent litigation expenses are largely comprised of expenses from outside counsel, such as hourly fees for attorneys. (Reasons, Tr. 1221). Impax might allocate some expenses for its internal legal department's work on patent litigation, but those allocations are minor. (Reasons, Tr. 1221).

RESPONSE TO FINDING NO. 456:

Respondent has no specific response other than to clarify that Proposed Finding No. 456 is incomplete because it ignores Mr. Reasons' testimony that the "amount that Impax spends on a specific patent litigation can vary based on a variety of factors." (Reasons, Tr. 1221 (quoting Complaint Counsel's question)).

457. For example, during a public earnings conference call in November 2011, Impax's then-CFO stated that Impax had "lowered [its] patent litigation expense guidance for the full year for 2011 from $13 million to $10 million primarily due to recent settlements." (Koch, Tr. 262; CX2703 at 004 (Transcript of Q3 2011 Impax Earnings Call)). Impax's then-CFO told the investment community that Impax was going to save $3 million in litigation expenses because of settlements, including the Endo settlement. (Koch, Tr. 263).

RESPONSE TO FINDING NO. 457:

Respondent has no specific response.

458. Impax's total budgeted patent litigation spending for 2013 was $16.5 million. (Reasons, Tr. 1222-23). Impax's $16.5 million budget for all patent litigation expenses in 2013 is far less than the $102 million Endo Credit payment that Endo paid to Impax and is far less than the $65 million net income value of the Endo Credit payment. (Reasons, Tr. 1224-25).

RESPONSE TO FINDING NO. 458:

Respondent has no specific response.

2. Endo's actual payments to Impax exceeded the possible saved litigation costs

459. The payments that were actually made from Endo to Impax pursuant to the SLA and DCA far exceeded the possible saved litigation costs. (Noll, Tr. 1463; CX5000 at 168-69 (¶¶ 375-76) (Noll Report)). Endo paid $10 million immediately under the DCA, and, 2.5 years later, another $102 million for the Endo Credit. (*See* CCF ¶¶ 320, 328-31, above). At the time of the settlement, the discounted present value of this payment, using a 15% discount rate, would have been over $65 million. (CX5000 at 169 (¶ 376) (Noll Report)).

RESPONSE TO FINDING NO. 459:

Complaint Counsel's Proposed Finding No. 459 is not supported by the record and lacks foundation. Professor Noll did not calculate the expected value of any provision in the settlement agreement, or the overall expected value of the SLA, at the time of settlement. (Noll, Tr. 1613, 1651-52; Addanki, Tr. 2384). And applying a discount rate to the actual payments made in 2013 says nothing about the expected value, if any, conveyed to Impax in June 2010,

since it excludes any scenario in which Impax would receive zero "payment" under the settlement agreement. (Court, Tr. 71, 75 ("JUDGE CHAPPELL: Are you going to stand there and tell me that the lowest possible outcome was not going to be zero? You're going to stand there and tell me that because some paid expert tells you that it had to be $62 million floor that it couldn't have been zero? MR. LOUGHLIN: No, Your Honor. There was a theoretical possibility of zero."); Noll, Tr. 1654 ("Q. And that example where you get zero of both, you didn't include that on your demonstrative of scenarios, did you? A. No, I didn't.")).

The record, however, is clear that if Endo launched reformulated Opana ER late in 2012 but continued to sell original Opana ER into the fourth quarter of that year, Endo "could have moved the market down so in the last quarter it would be down less than 50 percent and they would not have had to pay the credit." (Reasons, Tr. 1228; *see* CX4032 (Snowden, Dep. at 205-06)). If that occurred, Impax would have a much reduced opportunity for its generic version of the original Opana ER. (Mengler, Tr. 583; CX4037 (Smolenski, Dep. at 251-52)). Impax considered it "entirely plausible" that Endo could employ a late switch in products such that there was a reduced generic opportunity for Impax—and thus no benefit from a No-AG provision—while Endo still made no Endo Credit payment. (Mengler, Tr. 589-90; *see* CX4002 (Smolenski, IHT at 50-51, 129, 187-88); Bingol, Tr. 1338 (Endo had no intention of launching both an authorized generic and a reformulated version of Opana ER)). As Brian Lortie, Endo's Senior Vice President for Pain Solutions at the time of settlement, explained, Endo "intended to replace one product with the other, and that would be the only product that we had on the market," (CX4019 (Lortie, Dep. at 117-18)), but Endo still "did not expect to make a payment to Impax," (CX4017 (Levin, Dep. at 126)).

460. Even standing alone, the side-deal payment of $10 million substantially exceeds the expected saved litigation costs of $5 million to $6 million. (Noll, Tr. 1482 ("Even if

> you could assume that [all the other payments] went to zero, you still have the $10 million payment for the co-development and co-promotion agreement . . . you have to knock off at least half of that as payment for something of value to get the entire value of the agreement to go below saved litigation costs.").

RESPONSE TO FINDING NO. 460:

Complaint Counsel's Proposed Finding No. 460 lacks foundation and is not supported by the cited evidence. The cited evidence does not support the proposition that Endo and Impax saved any particular amount in litigation costs. (Noll, Tr. 1482, CX5000-168-69 (Noll Rep. ¶¶ 375-76); *see also* Noll, Tr. 1464 ("JUDGE CHAPPELL: Did you look at any recent numbers, for example, what attorneys who specialize in patent litigation charge per hour in trial? THE WITNESS: I haven't looked at the per-hour charges, but I've looked at them all -- outside -- JUDGE CHAPPELL: Those hours matter. THE WITNESS: Huh? JUDGE CHAPPELL: Those hours matter.")).

Moreover, the record contains no evidence that the $10 million payment under the Development and Co-Promotion Agreement was anything but a "payment for something of value." Indeed, the DCA states that the $10 million payment was "in consideration for the [profit-sharing] rights granted to Endo hereunder." (RX-365.0009). Dr. Geltosky, Complaint Counsel's expert in pharmaceutical business development agreements, did not conduct any valuation analysis of the DCA and offers no opinion with respect to the value of the profit-sharing rights acquired by Endo. (Geltosky, Tr. 1124-25; *see* Noll, Tr. 1456, 1581-82 (Professor Noll did not independently analyze the DCA to determine whether it had value to either party or represented an overpayment)). Endo, for its part, believed the profit-sharing rights under the DCA justified its payment. (Cobuzzi, Tr. 2564).

3. Under any reasonable scenario, the ex ante value of the No-AG/Endo Credit payment was large, even if the exact value was uncertain at the time of settlement

461. The No-AG provision of the settlement had value to Impax even if there was uncertainty about whether Endo would have launched an authorized generic. The No-AG provision provided Impax with a guarantee that there would not be an authorized generic during its 180-day exclusivity period, and that guarantee had value to Impax. (Mengler, Tr. 526; Reasons, Tr. 1210; Koch, Tr. 234; Noll, Tr. 1453-54; *see also* CX0505 at 001 (Mengler email stating of No-AG provision, "I'd love that!!!!")).

RESPONSE TO FINDING NO. 461:

The first sentence of Complaint Counsel's Proposed Finding No. 461 is not supported by record evidence and should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2).

The second sentence of Proposed Finding No. 461 is incomplete and misleading. Mr. Mengler explained that Impax derives value "by selling the drug [] with or without an" authorized generic. (Mengler, Tr. 528-29). Dr. Hsu, Impax's CEO at the time of settlement, similarly explained that getting on the market as early as possible is what matters. Impax did not value the absence of an authorized generic if it meant delaying its own product. (CX4030 (Hsu, Dep. at 76-77)). The cited evidence, moreover, does not support the proposition advanced. (Mengler, Tr. 526 ("Q. You believe that getting a no-AG would be beneficial to Impax; right? A. Yes."); Koch, Tr. 234 (generally, absence of an authorized generic would mean more control, which could lead to higher profits); Reasons, Tr. 1210 (discussing first-to-file exclusivity, no mention of authorized generic); CX0505-001 ("Settlement --- different story. I'd love that !!!!")).

462. While the No-AG provision may be of no value if Endo is no longer selling Original Opana ER, and the Endo Credit provision may be of no value if Endo still vigorously promotes and sells Original Opana ER, these two conditions are mutually

exclusive. If one provision is valueless, the other has substantial value, and the sum of the expected values of the two provisions is always not only positive, but "large" in comparison with the cost of litigating the patent infringement case to conclusion, given that at the time of the settlement the case was in trial. (CX5000 at 173 (¶ 384) (Noll Report); *see also* CX4020 (Reasons, Dep. at 55-56) (agreeing that "if the market for Opana ER did not decline, the value of the No-AG provision would be higher, but if the market did decline, Impax would get a payment under the Endo credit")).

RESPONSE TO FINDING NO. 462:

The first sentence of Complaint Counsel's Proposed Finding No. 462 is not supported by record evidence and should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2).

The second sentence of Proposed Finding No. 462 is inaccurate, lacks foundation, and is not supported by record evidence. Mr. Reasons explained that he was testifying only about his personal understanding. (CX4020 (Reasons, Dep. at 55-56)). Mr. Reasons, however, joined Impax in 2012 and had no role in the development or negotiations of the relevant settlement terms. (Reasons, Tr. 1199-1200; CX4020 (Reasons, Dep. at 16) (only connection to Endo Credit was looking at payment "calculation for mathematical accuracy and was overall in charge of collecting it and accounting for it")).

Moreover, both Complaint Counsel and its economic expert admitted it was possible that both the Endo Credit and No-Authorized Generic provisions would have zero value. (Court, Tr. 71, 75 ("JUDGE CHAPPELL: Are you going to stand there and tell me that the lowest possible outcome was not going to be zero? You're going to stand there and tell me that because some paid expert tells you that it had to be $62 million floor that it couldn't have been zero? MR. LOUGHLIN: No, Your Honor. There was a theoretical possibility of zero."); Noll, Tr. 1654 ("Q. And that example where you get zero of both, you didn't include that on your demonstrative of scenarios, did you? A. No, I didn't.")).

463. The precise magnitude of the "Endo Credit" was not known in June of 2010 when the agreement was negotiated, but it was based on a mathematical formula, the range of possible payments could be estimated on the basis of product plans and sales forecasts, and Impax executives were able to calculate the Endo Credit before the payment was actually made in 2013. (Engle, Tr. 1739-41 (testifying that Impax and Endo executives met to compare Opana ER sales numbers, that information was "straightforward," and there was no dispute between Endo and Impax about the final numbers used to calculate the actual Endo Credit payment); CX3438 at 023 (August 2012 presentation to Impax board calculating value of Endo Credit); Engle, Tr. 1746-47 (discussing calculation in CX3438)).

RESPONSE TO FINDING NO. 463:

Complaint Counsel's Proposed Finding No. 463 is inaccurate and not supported by record evidence. Whether and how much Endo would be required to pay under the Endo Credit depended on Endo's actions and external market forces beyond either party's control, including peak quarterly sales of Opana ER after settlement and sales immediately before Impax's January 2013 license date. (Cuca, Tr. 629). Those factors were unknown at the time of settlement and could not be ascertained until years later. (Snowden, Tr. 437-38). Impax and Endo both knew at the time of settlement that the Endo Credit could result in zero value to Impax. (CX4032 (Snowden, Dep. at 204-06); CX4002 (Smolenski, IHT at 128-30); Cuca, Tr. 628-29; CX4017 (Levin, Dep. at 143-44); Noll, Tr. 1611, 1649 (neither party estimated value of Endo Credit at the time of settlement); *see also* Noll, Tr. 1654 ("Q. And that example where you get zero of both, you didn't include that on your demonstrative of scenarios, did you? A. No, I didn't.")).

Only after several subsequent events—a Novartis supply disruption in early 2012, the need to launch reformulated Opana ER earlier than expected in March 2012, and the FDA's subsequent order to stop selling original Opana ER—could Endo determine whether it owed any payment under the Endo Credit. (Cuca, Tr. 665, 677; Reasons, Tr. 1203, 1229; RX-039 (Endo Credit liability discovered in April 2012)). As Roberto Cuca, Endo's Vice President of Financial Planning and Analysis, explained, "One of the components of the [Endo Credit] formula is the

sales of Opana in the last quarter immediately before Impax'[s] launch. When the Novartis supply disruption took place, we know that sales in that quarter were likely to be close to zero." (Cuca, Tr. 671). No one at Endo expected or discussed the possibility of a supply disruption at the time of settlement. (Cuca, Tr. 671). Similarly, the first time Impax learned it was likely to receive *any* payment under the Endo Credit was May 2012, when Endo publicly disclosed that it had accrued the liability. (Reasons, Tr. 1228). Impax did not even attempt to calculate the size of any payment until the third quarter of 2012. (Engle, Tr. 1765-66).

> 464. The eventual magnitude of the "Endo Credit" was determined by the rapid growth of Opana ER sales in 2010 and 2011, and then the rapid descent to zero in 2012 when Original Opana ER was withdrawn from the market. This outcome was consistent with the expectations of both Endo and Impax. (CX5000 at 170 (¶ 379) (Noll Report)).

RESPONSE TO FINDING NO. 464:

Complaint Counsel's Proposed Finding No. 464 violates this Court's Order on Post-Trial Briefs to the extent it cites "to expert testimony to support factual propositions that should be established by fact witnesses or documents." Proposed Finding No. 464 is also inaccurate. Roberto Cuca, Endo's Vice President of Financial Planning and Analysis and the author of the Endo Credit, testified that "I don't know that anyone was anticipating a change in the marketplace." (Cuca, Tr. 615, 617). Accordingly, Impax never analyzed or forecasted whether it would receive a payment under the Endo Credit at the time of settlement. (Mengler, Tr. 582; CX4038 (Engle, Dep. at 187-88)). Endo similarly had no "expectation that a payment would have to be made." (CX4017 (Levin, Dep. at 99-100) ("at the time the transaction was inked I did not expect that Endo would have to make a payment under this provision"); Cuca, Tr. 664-65 (Endo did not book a reserve because no Endo Credit payment was "probable and estimable" at settlement); *see* Noll, Tr. 1611, 1649 (neither party estimated value of Endo Credit at the time of settlement)).

Indeed, the first time that Endo knew its sales would be zero in the last quarter of 2012 was after the Novartis plant shutdown and resulting supply interruption in 2012. (Cuca, Tr. 677; RX-094.0003-06 (supply chain disruption for original Opana ER resulted in Endo Credit liability)). Until that point, Endo expected to sell Opana ER through the fourth quarter of 2012. (CX4017 (Levin, Dep. at 131); RX-094.0006 ("Prior to March [2012], it would have been reasonable to assume that prescriptions of old formulation [Opana ER] would have occurred in Q4 2012"); RX-108.0002 at 10).

Endo also did not project "rapid growth" in 2011, as the Proposed Finding asserts. Endo generated $300 million in sales of Opana products in 2010. (RX-128.0002; CX4017 (Levin, Dep. at 151)). Endo expected to generate roughly $350 million in sales of Opana products in 2011, an increase of less than 20 percent. (RX-128.0002; CX4017 (Levin, Dep. at 151)). [redacted] (RX-414). That growth resulted in $186 million in sales of Opana ER in the fourth quarter of 2011 alone. (CX4017 (Levin, Dep. at 149); RX-108.0002 at 10).

> 465. Financial projections by both firms at the time of the settlement anticipated continuation of the growth in Opana ER sales that was then in progress. (CX0222 at 003-11 (Impax forecast for Opana ER); CX2530 at 007-08 (Endo forecasts for Opana ER)). Endo used these forecasts to calculate their implications with respect to the amount that they would have to pay Impax from the "Endo Credit" formula. (CX4035 (Cuca, Dep. at 79-81, 83-84)). Impax also closely tracked and forecasted Opana ER brand sales. (CX0203 (Smolenski email to Mengler estimating Opana ER sales); Engle, Tr. 1739-40 (explaining that Impax and Endo had regular conference calls to discuss the Opana ER sales figures to be used in calculating the Endo Credit payment)).

RESPONSE TO FINDING NO. 465:

Respondent has no specific response to the first and third sentences of Complaint Counsel's Proposed Finding No. 465.

The second sentence of Proposed Finding No. 465 is inaccurate and not supported by the cited evidence. Mr. Cuca testified that he did not recall whether he calculated any kind of financial impact on Endo as a result of the Endo Credit. (CX4035 (Cuca, Tr. 84-85)). Indeed, he explained at trial that he simply "pick[ed] a number that seemed like it could be a potential outcome and run it through the formula and make sure it produced a sensible result." (Cuca, Tr. 629). But that process "would have been about five minutes of work with maybe one or two sets of numbers that I would have just to, again, make sure the provision worked, and once I was satisfied with that, that would have been the end of it." (Cuca, Tr. 630-31). Endo did not forecast any payment under the Endo Credit at the time of settlement. (Cuca, Tr. 631, 673; CX4017 (Levin, Dep. at 96-98); Noll, Tr. 1649 (neither Endo nor Impax forecast or planned for a payment under the settlement)).

466. The Endo Credit and No-AG provisions were worth tens of millions of dollars to Impax. This is true under any of the reasonable scenarios facing Impax when it signed the settlement. (CX5000 at 240 (App. F) (Noll Report); Noll, Tr. 1470-78).

RESPONSE TO FINDING NO. 466:

Complaint Counsel's Proposed Finding No. 466 is not supported by the record and lacks foundation. Professor Noll did not calculate the expected value of any provision in the settlement agreement, or the overall expected value of the SLA, at the time of settlement. (Noll, Tr. 1613, 1651-52; Addanki, Tr. 2384). Both Complaint Counsel and its economic expert admitted it was possible that both the Endo Credit and No-Authorized Generic provisions would have zero value. (Court, Tr. 71, 75 ("JUDGE CHAPPELL: Are you going to stand there and tell me that the lowest possible outcome was not going to be zero? You're going to stand there and tell me that because some paid expert tells you that it had to be $62 million floor that it couldn't have been zero? MR. LOUGHLIN: No, Your Honor. There was a theoretical possibility of

zero."); Noll, Tr. 1654 ("Q. And that example where you get zero of both, you didn't include that on your demonstrative of scenarios, did you? A. No, I didn't."); Addanki, Tr. 2355 (a rational actor like Endo "would manage that transition [to reformulated Opana ER] to minimize its patient loss and to minimize whatever payments it was going to make.")). Indeed, Mr. Cuca of Endo testified that Endo sought to reduce the payment under the Endo Credit during negotiations. (Cuca, Tr. 639-40).

467. If sales of Original Opana ER continued to increase after June 2010, then the value of the No-AG provision to Impax also would grow. If Endo did not withdraw Original Opana ER from the market, and the revenues from Original Opana ER continued to grow after the settlement was signed in June 2010 such that at the time of Impax's launch Original Opana ER sales equaled their peak sales achieved in the real world, then the value of the No-AG provision would end up being at least $53 million to Impax in 2013 (or $35 million in present value in 2010). (CX5000 at 172, 240 (¶ 382, App. F) (Noll Report); Noll, Tr. 1476-77).

RESPONSE TO FINDING NO. 467:

Complaint Counsel's Proposed Finding No. 467 is not supported by the record and lacks foundation. Professor Noll did not calculate the expected value of any provision in the settlement agreement, or the overall expected value of the SLA, at the time of settlement. (Noll, Tr. 1613, 1651-52; Addanki, Tr. 2384). All Professor Noll did was come up with "examples" of the potential value to Impax of the Endo Credit and No-AG provisions in January 2013, "under various circumstances," but he "didn't attach probabilities to those." (Noll, Tr. 1613).

Neither Impax nor Endo expected or forecast the theoretical scenario Professor Noll created. (Mengler, Tr. 582; CX4038 (Engle, Dep. at 187-88); CX4017 (Levin, Dep. at 99-100) ("at the time the transaction was inked I did not expect that Endo would have to make a payment under this provision"); Cuca, Tr. 664-65 (Endo did not book a reserve because no Endo Credit payment was "probable and estimable" at settlement); *see* Noll, Tr. 1611, 1649 (neither party estimated value of Endo Credit at the time of settlement)).

And both Complaint Counsel and Professor Noll admitted it was possible that both the Endo Credit and No-Authorized Generic provisions would have zero value. (Court, Tr. 71, 75 ("JUDGE CHAPPELL: Are you going to stand there and tell me that the lowest possible outcome was not going to be zero? You're going to stand there and tell me that because some paid expert tells you that it had to be $62 million floor that it couldn't have been zero? MR. LOUGHLIN: No, Your Honor. There was a theoretical possibility of zero."); Noll, Tr. 1653-54 ("Q. And that example where you get zero of both, you didn't include that on your demonstrative of scenarios, did you? A. No, I didn't.")).

468. The No-AG provision still had substantial value to Impax even if Original Opana ER sales grew so much that Impax ended up having to pay a royalty to Endo. (CX5001 at 026 (¶ 51) (Bazerman Report)). The SLA provided that if Endo successfully grew the market for Original Opana ER from a baseline of $46,973,081 net sales per quarter compounded at an annual rate of 10%, then Impax would pay a royalty of 28.5% of Impax's net sales to Endo. (RX-364 at 0012 (SLA § 4.3) ("Royalties")). By comparison, Impax's own forecasts show that it expected the entry of an AG to cause its revenue to decline by more than 60%. (*see* CCF ¶¶ 413-14, above, 1321, below; CX0222 at 004-08 (Impax 5-year plan)). Because the royalty percentage is lower than the expected decline in Impax's revenue attributable to competition from an AG, Impax's revenues with the No-AG provision and a royalty are always higher than revenues with competition from an AG and no royalty. (CX5000 at 155-56 (¶¶ 350-51) (Noll Report)). Any growth in the Opana ER market above the trigger for the royalty would result in even more value to Impax from the No-AG provision. In all cases, Impax would benefit more from being the only seller of a generic oxymorphone ER product, than it would be required to pay Endo in royalties. (CX5001 at 026 (¶ 51) (Bazerman Report)).

RESPONSE TO FINDING NO. 468:

Respondent has no specific response to the second sentence of Proposed Finding No. 468. The remainder of Proposed Finding No. 468 is not supported by record evidence and lacks foundation. Neither Professor Noll nor Professor Bazerman calculated the expected value of the No-Authorized Generic or Royalty provisions at the time of settlement. (Noll, Tr. 1591, 1647; Bazerman, Tr. 890, 924).

469. If sales of Opana ER did not grow at all and stayed flat from until the date of Impax's entry, then the "No AG Provision" was worth at least $33 million to Impax in 2013 (with a present value of $22 million in 2010). (CX5000 at 155, 240 (¶ 350, App. F) (Noll Report) (using Impax models to estimate value of No-AG provision); Noll, Tr. 1475-76).

RESPONSE TO FINDING NO. 469:

Complaint Counsel's Proposed Finding No. 469 is not supported by the record and lacks foundation. Professor Noll did not calculate the expected value of any provision in the settlement agreement, or the overall expected value of the SLA, at the time of settlement. (Noll, Tr. 1613, 1651-52; Addanki, Tr. 2384). All Professor Noll did was come up with "examples" of the potential value to Impax of the Endo Credit and No-AG provisions in January 2013, "under various circumstances," but he "didn't attach probabilities to those." (Noll, Tr. 1613).

Neither Impax nor Endo expected or forecast the theoretical scenario Professor Noll created. (Mengler, Tr. 582; CX4038 (Engle, Dep. at 187-88); CX4017 (Levin, Dep. at 99-100) ("at the time the transaction was inked I did not expect that Endo would have to make a payment under this provision"); Cuca, Tr. 664-65 (Endo did not book a reserve because no Endo Credit payment was "probable and estimable" at settlement); *see* Noll, Tr. 1611, 1649 (neither party estimated value of Endo Credit at the time of settlement)).

And both Complaint Counsel and Professor Noll admitted it was possible that both the Endo Credit and No-Authorized Generic provisions would have zero value. (Court, Tr. 71, 75 ("JUDGE CHAPPELL: Are you going to stand there and tell me that the lowest possible outcome was not going to be zero? You're going to stand there and tell me that because some paid expert tells you that it had to be $62 million floor that it couldn't have been zero? MR. LOUGHLIN: No, Your Honor. There was a theoretical possibility of zero."); Noll, Tr. 1653-54 ("Q. And that example where you get zero of both, you didn't include that on your demonstrative of scenarios, did you? A. No, I didn't.")).

470. If Opana ER sales peaked at the time of the settlement and dropped just enough to trigger the Endo Credit, then the Endo Credit payment to Impax would be worth approximately $62 million to Impax in 2013 ($41 million present value in 2010). (CX3013 at 003 (Endo document showing how to calculate Endo Credit); CX5000 at 171, 240 (¶ 381, App. F) (Noll Report); Noll, Tr. 1473-75). This is the smallest possible payment due to Impax under the Endo Credit if the Endo Credit were triggered. (CX3013 at 003 (Endo document showing how to calculate Endo Credit); CX5000 at 171 (¶ 381) (Noll Report); Noll, Tr. 1473-75).

RESPONSE TO FINDING NO. 470:

Complaint Counsel's Proposed Finding No. 470 is inaccurate and not supported by the cited evidence. Professor Noll's report says nothing about sales dropping "just enough to trigger the Endo Credit" and resulting in tens of millions of dollars in liability under the Endo Credit. (CX5000-171, 240). But the assertion is simply wrong. Actual sales in the third quarter of 2010 were $86,055,821. (CX0332-003). If sales peaked at the time of settlement and "dropped just enough to trigger the Endo Credit," for instance, because sales in the last quarter of 2012 were 49 percent of their quarterly peak, this would mean the resulting liability would be roughly $1 million. (*See* RX-364.0003-04 (any Endo Credit payment is the product of (1) 0.2953 times the annualized quarterly peak sales divided by 100, and (2) if original Opana ER sales in the fourth quarter of 2012 are below 50 percent of the quarterly peak, the number of percentage points under 50)). If sales dropped only to 49.9 percent of their peak (again, assuming that sales peaked in the third quarter of 2010), the resulting liability would be roughly $100,000. (*See* RX-364.0003-04 (any Endo Credit payment is the product of (1) 0.2953 times the annualized quarterly peak divided by 100, and (2) the number of percentage points under 50)).

Professor Noll came up with his $62 million figure *without* reference to the SLA's Endo Credit formula and using no apparent methodology. Estimating that Opana ER sales in the third quarter of 2010 were "approximately 62 percent of actual peak sales in 2011," Professor Noll apparently just multiplied the $102 million Endo Credit payment by 62 percent. (CX5000-171

(Noll Rep. ¶ 381) (looking at 2010 and 2011 yearly revenues)). But Opana ER sales in the third quarter of 2010 ($86,055,821) were *not* 62 percent of actual peak sales in the fourth quarter of 2011 ($185,691,457); they were *46.3 percent* of actual peak sales. (CX0332-003).

Even then, Professor Noll's so-called "estimate" assumes that Endo makes *zero* Opana ER sales in the fourth quarter of 2012, even though Endo planned to continue selling Opana ER through the fourth quarter of 2012. (CX4017 (Levin, Dep. at 131-32, 143-44, 148-49); RX-094.0006). Professor Noll's "estimate" also ignores the fact that Impax could have derived no "payment" from either the Endo Credit or the No-Authorized Generic provision. (Court, Tr. 71, 75 ("JUDGE CHAPPELL: Are you going to stand there and tell me that the lowest possible outcome was not going to be zero? You're going to stand there and tell me that because some paid expert tells you that it had to be $62 million floor that it couldn't have been zero? MR. LOUGHLIN: No, Your Honor. There was a theoretical possibility of zero."); Noll, Tr. 1653-54 ("Q. And that example where you get zero of both, you didn't include that on your demonstrative of scenarios, did you? A. No, I didn't."); Addanki, Tr. 2355 (a rational actor like Endo "would manage that transition [to reformulated Opana ER] to minimize its patient loss and to minimize whatever payments it was going to make.")).

In the end, Proposed Finding No. 470 lacks foundation. Professor Noll did not calculate the expected value of any provision in the settlement agreement, or the overall expected value of the SLA, at the time of settlement. (Noll, Tr. 1613, 1651-52; Addanki, Tr. 2384). All Professor Noll did was come up with "examples" of the potential value to Impax of the Endo Credit and No-AG provisions in January 2013, "under various circumstances," but he "didn't attach probabilities to those." (Noll, Tr. 1613). And neither Impax nor Endo expected or forecast the theoretical scenarios Professor Noll created. (Mengler, Tr. 582; CX4038 (Engle, Dep. at 187-

88); CX4017 (Levin, Dep. at 99-100) ("at the time the transaction was inked I did not expect that Endo would have to make a payment under this provision"); Cuca, Tr. 664-65 (Endo did not book a reserve because no Endo Credit payment was "probable and estimable" at settlement); *see* Noll, Tr. 1611, 1649 (neither party estimated value of Endo Credit at the time of settlement)).

> 471. If Original Opana ER sales declined after the settlement, but the Endo Credit provision was not triggered, Impax would still receive substantial value from the No-AG provision. Putting aside any Endo Credit payment, even if one assumes that the value of the No-AG provision could end up being only half of the value calculated if Original Opana ER sales stayed flat from 2010 to January 2013, the No-AG provision would still have been worth $16.5 million in 2013 ($11 million present value in 2010). (CX5000 at 172, 240 (¶ 383, App. F) (Noll Report), Noll, Tr. 1477-78).

RESPONSE TO FINDING NO. 471:

Complaint Counsel's Proposed Finding No. 471 is not supported by the record and lacks foundation. Professor Noll did not calculate the expected value of any provision in the settlement agreement, or the overall expected value of the SLA, at the time of settlement. (Noll, Tr. 1613, 1651-52; Addanki, Tr. 2384). All Professor Noll did was come up with "examples" of the potential value to Impax of the Endo Credit and No-AG provisions in January 2013, "under various circumstances," but he "didn't attach probabilities to those." (Noll, Tr. 1613).

Neither Impax nor Endo expected or forecast the theoretical scenario Professor Noll created. (Mengler, Tr. 582; CX4038 (Engle, Dep. at 187-88); CX4017 (Levin, Dep. at 99-100) ("at the time the transaction was inked I did not expect that Endo would have to make a payment under this provision"); Cuca, Tr. 664-65 (Endo did not book a reserve because no Endo Credit payment was "probable and estimable" at settlement); *see* Noll, Tr. 1611, 1649 (neither party estimated value of Endo Credit at the time of settlement)).

And both Complaint Counsel and Professor Noll admitted it was possible that both the Endo Credit and No-Authorized Generic provisions would have zero value. (Court, Tr. 71, 75

("JUDGE CHAPPELL: Are you going to stand there and tell me that the lowest possible outcome was not going to be zero? You're going to stand there and tell me that because some paid expert tells you that it had to be $62 million floor that it couldn't have been zero? MR. LOUGHLIN: No, Your Honor. There was a theoretical possibility of zero."); Noll, Tr. 1653-54 ("Q. And that example where you get zero of both, you didn't include that on your demonstrative of scenarios, did you? A. No, I didn't."); Addanki, Tr. 2355 (a rational actor like Endo "would manage that transition [to reformulated Opana ER] to minimize its patient loss and to minimize whatever payments it was going to make.")).

> 472. Under any reasonable scenario, the value of the combined No-AG and Endo Credit provisions is "large" compared to the saved cost of litigation of $5 to $6 million for both Impax and Endo (or approximately $3 million each). (CX5000 at 171-72, 240 (¶¶ 381-83, App. F) (Noll Report); Noll, Tr. 1470-78).

RESPONSE TO FINDING NO. 472:

Complaint Counsel's Proposed Finding No. 472 is not supported by the record and lacks foundation. Professor Noll did not calculate the expected value of any provision in the settlement agreement, or the overall expected value of the SLA, at the time of settlement. (Noll, Tr. 1613, 1651-52; Addanki, Tr. 2384). Moreover, both Complaint Counsel and its economic expert admitted it was possible that both the Endo Credit and No-Authorized Generic provisions would have zero value. (Court, Tr. 71, 75 ("JUDGE CHAPPELL: Are you going to stand there and tell me that the lowest possible outcome was not going to be zero? You're going to stand there and tell me that because some paid expert tells you that it had to be $62 million floor that it couldn't have been zero? MR. LOUGHLIN: No, Your Honor. There was a theoretical possibility of zero."); Noll, Tr. 1653-54 ("Q. And that example where you get zero of both, you didn't include that on your demonstrative of scenarios, did you? A. No, I didn't."); Addanki, Tr.

2355 (a rational actor like Endo "would manage that transition [to reformulated Opana ER] to minimize its patient loss and to minimize whatever payments it was going to make.")).

4. Although the No-AG/Endo Credit payment could have no value in theory, that scenario was extremely unlikely

473. An Impax businessperson, Ted Smolenski, told Impax's primary negotiator, Mr. Mengler, that he had some concerns regarding the possibility that the Endo Credit might not be worth anything. (CX4037 (Smolenski, Dep. at 253); Mengler, Tr. 589). In that scenario the No-AG credit would still be of substantial value to Impax when it launched in 2013 unless Endo also switched patients from original to Reformulated Opana ER fast enough to eliminate the value of the market for Original Opana ER by the time of Impax's licensed entry date in January 2013. (RX-547 at 0067-68 (¶ 126) (Addanki Report)).

RESPONSE TO FINDING NO. 473:

Respondent has no specific response to the first sentence of Complaint Counsel's Proposed Finding No. 473. The second sentence of Proposed Finding No. 473 is not supported by the cited evidence. Dr. Addanki's report does not state that the No-Authorized Generic clause would have "substantial value" under any circumstance. (*See* RX-547.0067-68 (Addanki, Rep. ¶ 126)).

474. For both the No-AG provision and Endo Credit provision to not be "large" payments, sales of Original Opana ER in the fourth quarter of 2012 would have to exceed 50% of peak quarterly sales, thereby avoiding the "Endo Credit," while also being low enough by January 2013 that Impax would have received no benefit from the No-AG provision. (CX5004 at 067 (¶ 142) (Noll Rebuttal Report) (discussing RX-547 at 066-70 (Addanki Report)). This hypothetical scenario requires precise timing of the entry of Endo's Reformulated Opana ER product so that there would not be enough of a decline in the fourth quarter of 2012 to trigger the Endo Credit, but that sales of Original Opana ER would be essentially zero by the end of the fourth quarter so that the No-AG provision also would be worth nothing to Impax. (Noll, Tr. 1480-81). This hypothetical is extremely implausible because it is impossible to time the entry of a reformulated product that precisely. (Noll, Tr. 1481-82).

RESPONSE TO FINDING NO. 474:

Complaint Counsel's Proposed Finding No. 474 is inaccurate and not supported by actual record evidence. Impax considered it "entirely plausible" that Endo could employ a late switch in products such that there was a reduced generic opportunity for Impax—and thus no benefit from a No-AG provision—while Endo still made no Endo Credit payment. (Mengler, Tr. 589-90; CX4002 (Smolenski, IHT at 50-51, 129, 187-88)).

Endo not only believed it was possible, but planned to implement such a late-switch strategy. Brian Lortie, Endo's Senior Vice President for Pain Solutions at the time of settlement, explained, Endo "intended to replace one product with the other, and that would be the only product that we had on the market," (CX4019 (Lortie, Dep. at 117-18)), but Endo still "did not expect to make a payment to Impax," (CX4017 (Levin, Dep. at 126)). Indeed, Endo intended to transition to a reformulated version of Opana ER at the very end of 2012. (CX4017 (Levin, Dep. at 99-100, 131) ("it was not [Endo's] expectation that a payment would have to be made"); RX-094). Endo's original budget for 2012 projected original Opana ER sales into the fourth quarter of 2012. (RX-108.0002 at 10; RX-094.0006 ("Prior to March [2012], it would have been reasonable to assume that prescriptions of old formulation [Opana ER] would have occurred in Q4 2012.")). Professor Noll admitted that such a strategy would have permitted Endo to carry out the "late switch" (and zero-payment) plan. (*See* CX4039 (Noll, Dep. at 124) (testifying that zero-payment outcome "would have required entry along about the 1st of September of 2012")).

Finally, the proposition that any Endo Credit liability under the 50 percent threshold would result in a "large" payment is not supported by record evidence. Actual quarterly peak sales after settlement were $185,691,457. (CX0332-003). If sales dropped just enough to trigger the Endo Credit, for instance, because sales in the last quarter of 2012 were 49 percent of their

quarterly peak, this would mean the resulting liability would be roughly $2 million. If sales dropped only to 49.9 percent of their peak, the resulting liability would be roughly $200,000. (RX-364.0003-04 (any Endo Credit payment is the product of (1) 0.2953 times the annualized quarterly peak sales divided by 100, and (2) the number of percentage points under 50)).

> 475. Mr. Smolenski had no evidence to support his concerns, just "speculation." (CX4037 (Smolenski, Dep. at 253-54)). Mr. Smolenski never estimated the possibility or percentage probability that the Endo Credit would be worth zero to Impax. (CX4037 (Smolenski, Dep. at 255-56)). Mr. Smolenski could not recall ever modeling an expected value of the Endo Credit. (CX4037 (Smolenski, Dep. at 254)). Mr. Smolenski did not recall conducting any kind of sensitivity analysis of the value of the Endo Credit that would model for different scenarios how Endo might switch Opana ER to a reformulated version in such a way that Endo would make no payment to Impax. (CX4037 (Smolenski, Dep. at 255-56)).

RESPONSE TO FINDING NO. 475:

Complaint Counsel's Proposed Finding No. 475 is inaccurate, incomplete, and misleading because it takes Mr. Smolenski's testimony out of context. Mr. Smolenski testified that "We hadn't -- I mean, everything on our end was speculation. We actually had no idea what Endo would do, which reinforces . . . my point about the Endo credit being uncertain. It wasn't something that in any way was guaranteed." (CX4037 (Smolenski, Dep. at 254)). Mr. Smolenski also testified that "if Endo withdrew the NDA in the fourth-quarter 2012, I didn't need to do the math to suggest that it was zero. I can simply explain why that would occur." (CX4037 (Smolenski, Dep. at 254)). And while Mr. Smolenski was not sure whether he ultimately assigned probabilities or conducted certain analyses, he explained that he did "debate in my own head and with others about how to model and probability adjust forecast. And really what you end up doing is just propagating error because you don't know what Endo's going to do. . . . So to assign a somewhat arbitrary percent to a certain scenario would probably not be any

more accurate than assigning no percent, except to know that that possibility exists." (CX4037 (Smolenski, Dep. at 255-56)).

476. Impax's hired economics expert, Dr. Addanki, also did not assess the likelihood of this hypothetical scenario coming to pass and did not offer any opinions as to the likelihood that the combination of the No-AG provision and Endo Credit was not "large" when the SLA was executed. Dr. Addanki did not assess the likelihood that both the No-AG provision and Endo Credit provisions would have provided zero value to Impax. (Addanki, Tr. 2437). Dr. Addanki simply asserts that his hypothetical scenario is "possible." (RX-547 at 067 (¶ 126) (Addanki Report) ("[I]t is possible that the 'No AG' and Endo Credit provisions would have provided zero value to Impax.")).

RESPONSE TO FINDING NO. 476:

Complaint Counsel's Proposed Finding No. 476 is inaccurate. Dr. Addanki was asked the following question: "You don't assess the likelihood in any other way; correct?" (Addanki, Tr. 2437). Dr. Addanki explained, "Well, no. I do explain that knowing the provision, the way it's written, that it would make sense for Endo to have planned its migration of patients from original to reformulated in a way that minimized patient loss and minimized whatever obligations might be payable under the Endo credit provision. And so that -- that's a statement about what I would expect to see, which is intrinsically about likelihoods." (Addanki, Tr. 2437). Dr. Addanki also explained that both his report and testimony make clear that "it would make economic sense for Endo to have done that [late-switch], and indeed, it seems like that's what Endo had in mind." (Addanki, Tr. 2439; RX-547.0067-68 (Addanki, Rep. ¶ 126 n.207)).

Finally, it is not Respondent's burden to prove that any provision was "not large when the SLA was executed." It is Complaint Counsel's burden to prove a payment was large, which it has failed by offering no evidence regarding the expected value of any provision in the settlement agreement, or the overall expected value of the SLA, at the time of settlement. (Noll, Tr. 1613, 1651-52; Addanki, Tr. 2384).

477. Dr. Addanki concedes that he did not study whether Endo would maximize its profits by launching Reformulated Opana ER earlier and paying the Endo Credit or launching later in an attempt to avoid the Endo Credit. (Addanki, Tr. 2463-64; *see also* Addanki, Tr. 2463 ("[I]f [Endo] could make profit elsewhere by incurring the Endo [C]redit, they would.")).

RESPONSE TO FINDING NO. 477:

Complaint Counsel's Proposed Finding No. 477 is incomplete and misleading. Dr. Addanki testified that "it's not a choice between those two possibilities. The point would be that I would expect Endo to launch and manage its transition in such a way as to maximize its profits. And if you hypothesize that the optimal launch might include some payment under the Endo credit, it may." (Addanki, Tr. 2463).

478. Dr. Addanki did not study how many months it would have taken Endo to switch patients from original to Reformulated Opana ER, although he acknowledged that such a switch typically takes months. (Addanki, Tr. 2459-60).

RESPONSE TO FINDING NO. 478:

Complaint Counsel's Proposed Finding No. 478 is incomplete and misleading. Dr. Addanki testified that while he hadn't studied "exactly how many months it would have taken," "these are the moving parts that Endo had under its control, was when it was going to introduce reformulated and when it was going to discontinue original. And my point is simply that knowing what obligations it had under these terms and knowing that transition takes time, I would have expected Endo to have managed that transition." (Addanki, Tr. 2460).

479. Dr. Addanki did not calculate any expected value of the payments from Endo to Impax. (Addanki, Tr. 2440). Dr. Addanki criticizes Dr. Noll for not calculating expected values for the payments to Impax at the time of the settlement, but he conceded that he does not "think it's actually in any practical sense doable." (CX4044 (Addanki, Dep. at 114); Addanki, Tr. 2444). Dr. Addanki does not offer any criticisms of the way Dr. Noll calculated the ex ante value of the No-AG and Endo Credit provisions. (Addanki, Tr. 2436). He admits that he reviewed documents suggesting that Impax thought that the settlement provisions provided "some safety net" for Impax. (Addanki, Tr. 2439). He also

admits that one potential value of the Endo Credit and No-AG provision when the settlement was executed was $102 million. (Addanki, Tr. 2463-64).

RESPONSE TO FINDING NO. 479:

Respondent has no specific response to the first sentence of Complaint Counsel's Proposed Finding No. 479. The second sentence of Proposed Finding No. 479 is inaccurate, incomplete, and misleading. Dr. Addanki was discussing only "objective expected value," and not "the expected value to Impax or the expected value to Endo." (Addanki, Tr. 2444). The third sentence of Proposed Finding No. 479 is inaccurate, incomplete, and misleading. Dr. Addanki testified that he did not criticize the specific formulas employed by Professor Noll, but that "there are absolutely reasonable scenarios in which you get calculations that are different because you have simultaneously valueless provisions, and that's what I explain in 126 and 127, and that's a criticism of his calculation." (Addanki, Tr. 2436 (Complaint Counsel stating, "I understand that you criticize part of his opinion")). Respondent has no specific response to the fourth sentence of Proposed Finding No. 479. The fifth sentence of Proposed Finding No. 479 is incomplete and misleading. Dr. Addanki actually testified, "It's certainly difficult to argue that something that actually happened was not a potential value. *As to whether it would have been a potential value for either of the parties I have no idea*." (Addanki, Tr. 2464 (emphasis added)).

480. Any concern that the payment to Impax from the combination of the No-AG and Endo Credit might be worth zero was not taken seriously within Impax and did not prevent Impax from finalizing the settlement. (CX4037 (Smolenski, Dep. at 256); Mengler, Tr. 589-90; CX0219 at 001 (Smolenski email to Hsu) (describing the "potential downside scenario which Chris [Mengler] deemed so unlikely it wasn't worth worrying about"). Impax executives, and eventually Mr. Smolenski himself, dismissed the possibility that the No-AG/Endo Credit payment could be worth little to Impax. Mr. Smolenski's concerns did not prevent Mr. Mengler from finalizing the settlement with Endo. (CX4037 (Smolenski, Dep. at 256); Mengler, Tr. 589).

RESPONSE TO FINDING NO. 480:

The first sentence of Complaint Counsel's Proposed Finding No. 480 is inaccurate and not supported by the cited evidence. Mr. Mengler testified that the possibility was "entirely plausible" and presented "a real potential," but that he didn't "think we could necessarily easily correct for it in the agreement, so it was -- I took the chance." (Mengler, Tr. 589-90). The second sentence of Proposed Finding No. 480 is not supported by any record evidence and should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Respondent has no specific response to the third sentence of Proposed Finding No. 480.

> 481. Mr. Mengler decided not to raise the issue at all beyond the conversation with Mr. Smolenski because he "didn't think it...rose to the threshold enough" to pursue the concern any further. (Mengler, Tr. 590). Mr. Mengler "deemed [it] so unlikely it wasn't worth worrying about." (CX0219 at 001 (Smolenski email to Hsu)). Indeed, Mr. Smolenski later informed the CEO and CFO that "the downside is probably unlikely." (CX0219 at 001 (Smolenski email to Hsu)).

RESPONSE TO FINDING NO. 481:

Complaint Counsel's Proposed Finding No. 481 is inaccurate, incomplete, and misleading in its use of selective quotations. Mr. Mengler testified that the possibility was "entirely plausible," the "problems it would cause internally from a debate perspective about its likelihood would not be worth the energy to do so, because while it was a real potential, I didn't -- there was no probability ascribed to it. I didn't think it was -- rose to the threshold enough nor, by the way, did I think we could necessarily easily correct for it in the agreement, so it was -- I took the chance." (Mengler, Tr. 589-90). Similarly, Mr. Smolenski's email actually states, "While the downside is probably unlikely, it is certainly not impossible and I would like you both to be aware of it." (CX0219-001).

482. Endo's actual plans are not consistent with the notion of Endo introducing Reformulated Opana ER late in 2012 so that it could reduce the value of the Endo Credit to zero. Endo's long-standing strategy was to introduce Reformulated Opana ER quickly before any generic oxymorphone ER product launched, because Endo knew that it would be harder to transition patients to Reformulated Opana ER if generic oxymorphone ER were already on the market. (CX2578 at 008-09; CX2732 at 002, CX4025 (Bingol, Dep. at 32, 63-64); CX1108 at 004 (Endo presentation showing planned launch of Reformulated Opana ER (called "Revopan") in February 2011); CX4019 (Lortie, Dep. at 11-12)).

RESPONSE TO FINDING NO. 482:

The first sentence of Proposed Finding No. 482 is not supported by any record evidence and should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2).

The second sentence of Proposed Finding No. 482 is incomplete and not supported by the cited evidence. None of the cited evidence states that Impax would introduce reformulated Opana ER "quickly." Endo "plan[ned] for different eventualities" and analyzed "different scenarios" and different "assumption[s]" about launch. (CX4025 (Bingol, Dep. at 31-32); CX2578 (a "draft" document from 2007, just after original Opana ER launched); CX2732-001-02 ("strictly in draft"; "Draft - Not for Distribution"); CX4019 (Lortie, Dep. at 11-12) (discussing CX1108 and noting that dates were "assumptions at that point," but that "[t]here was some subsequent work that needed to be done")).

483. Endo's brand manager for Opana ER testified that Endo's strategy depended on introducing Reformulated Opana ER "a reasonable amount of time" before generic oxymorphone ER launched. (CX4025 (Bingol, Dep. at 63-64). Endo's internal forecasts showed that if Endo launched Reformulated Opana ER before any generic oxymorphone ER product launched, then Endo's sales of Reformulated Opana ER would grow. (CX2724 at 006; CX2578 at 008-09; CX2732 at 002; CX4025 (Bingol, Dep. at 95-96)). But if Endo waited to launch reformulated until after generic oxymorphone ER came to market, then Endo's sales of Reformulated Opana ER would be dramatically lower. (CX2724 at 006; CX2578 at 008-09; CX2732 at 002; CX4025 (Bingol, Dep. at 95-96); CX1106 at 004 (2010 Opana Brand Strategic Plan) ("Significant erosion of oxymorphone

franchise to generics is likely if EN3288 [reformulated Opana ER] is not filed and approved in a timely manner.")).

RESPONSE TO FINDING NO. 483:

Respondent has no specific response other than to clarify that Mr. Bingol testified "for this asset it was important to try to have your follow-on formulations, products, improvements, whatever would separate this product from potential generics *or* with a reasonable amount of time to make the conversion." (CX4025 (Bingol, Dep. at 64) (emphasis added)).

484. Endo's internal documents and testimony of its executives shows it intended to launch Reformulated Opana ER as soon as possible, and long before Impax's January 2013 entry date. (CX3038 at 001 (Endo internal email stating that product launch of Reformulated Opana ER is planned for "March 2011, but could range from Dec-10 to Jun-11"); CX1108 at 004 (Endo internal presentation stating that Endo is planning for FDA approval of Reformulated Opana ER in January 2011 and commercial launch of the product in February 2011); CX1108 at 008 (Endo internal presentation stating that Endo "current planning assumption is to stop shipping all Opana ER by October 1, 2011"); CX2738 at 008 (Endo internal presentation showing scenarios for conversion of market to Reformulated Opana ER, including an "emerging view" that Endo would begin wholesaler stocking of Reformulated Opana ER by February 2012); Bingol, Tr. 1295 (agreeing that, it was "always [his] goal to launch reformulated Opana ER as soon Endo was able to"); CX2578 at 009 (Dec. 2007 Opana Brand LCM Update) ("Priority #1 – Beat Generics by 1 Year")).

RESPONSE TO FINDING NO. 484:

Complaint Counsel's Proposed Finding No. 484 is not supported by the cited evidence. None of the cited evidence states that Endo "intended" to launch Reformulated Opana ER as soon as possible or "long before" Impax's launch. Endo "plan[ned] for different eventualities" and analyzed "different scenarios" and different "assumption[s]" about launch. (CX4025 (Bingol, Dep. at 31-32); CX2578 (a "draft" document from 2007, just after original Opana ER launched); CX4019 (Lortie, Dep. at 11-12) (discussing CX1108 and noting that dates were "assumptions at that point," but that "[t]here was some subsequent work that needed to be done"); CX2738-008 ("base" assumptions was wholesaler stocking would begin August 2012)).

And while Mr. Bingol had a personal goal for the launch of reformulated Opana ER, he worked in marketing, and there is no evidence that Mr. Bingol had any role in deciding whether or when to launch a product. (Bingol, Tr. 1308 (JUDGE CHAPPELL: . . . You're a marketing person; right? THE WITNESS: Correct.")).

In fact, the evidence is clear that Endo actually intended to transition to a reformulated version of Opana ER at the very end of 2012. (CX4017 (Levin, Dep. at 131); RX-094.0003 (planned launch in roughly September 2012, with conversation by end of the year)). And Endo's original budget for 2012 projected original Opana ER sales into the fourth quarter of 2012. (RX-108.0002 at 10; RX-094.0006 ("Prior to March [2012], it would have been reasonable to assume that prescriptions of old formulation [Opana ER] would have occurred in Q4 2012.")). Professor Noll admitted that such a strategy would have permitted Endo to carry out the "late switch" (and zero-payment) plan. (*See* CX4039 (Noll, Dep. at 124) (testifying that zero-payment outcome "would have required entry along about the 1st of September of 2012")).

> 485. Endo's strategy also contradicts the idea that it would quickly switch patients from original to Reformulated Opana ER, thereby greatly reducing the value of the No-AG provision. Endo's strategy depended on having a smooth transition from original to Reformulated Opana ER that was expected to take several months. (*See* CCF ¶¶ 79-80, above, 486-87, below).

RESPONSE TO FINDING NO. 485:

The proposed summary finding should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Additionally, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondent's replies to those findings.

486. Brian Lortie, who was involved in efforts to launch Endo's Reformulated Opana ER product, testified that Endo wanted to get the reformulated product out as soon as possible and "smoothly transition from old product to new product." (CX4019 (Lortie, Dep. at 8, 32-33)). According to Mr. Lortie, Endo's goal was to make the transition "[a]s soon as we could, but also in a way that recognized that we wanted as smooth a[s] possible transition for patients that were on the old product and transitioning to the new one." (CX4019 (Lortie, Dep. at 33)).

RESPONSE TO FINDING NO. 486:

Complaint Counsel's Proposed Finding No. 486 is incomplete and misleading because it ignores Mr. Lortie's testimony, in which he explained that Endo several times changed its plans with respect to reformulated Opana ER, particularly after it failed to acquire FDA approval. (CX4019 (Lortie, Dep. at 161); *see also* CX4019 (Lortie, Dep. at 11-12) (dates were "assumptions at that point," but that "[t]here was some subsequent work that needed to be done")).

487. Endo's desire for a smooth transition was driven in part by an understanding that patients cannot be switched immediately from one long-acting opioid to another because physicians are "very careful as they adjust dosages" for patients. (CX4019 (Lortie, Dep. at 8, 39)). Endo's plan was "for an orderly and phased transition from one product to the other so we made sure we weren't leaving any current patients in a difficult situation." (CX4019 (Lortie, Dep. at 156-57)). This process could last several months. (CX4019 (Lortie, Dep. at 41-42); Mengler, Tr. 530-31 (a timeline of "six to nine months" for a branded company to shift the market from an original branded product to a reformulated product might be considered "a little fast but not unreasonable"); Addanki, Tr. 2459-60 (conceding that it takes months for a brand to switch prescriptions from an original product to a reformulated product)).

RESPONSE TO FINDING NO. 487:

Respondent has no specific response.

488. For the hypothetical scenario to have rendered the reverse payments in the SLA not "large," the expected value of the "Endo Credit" plus the "No AG" provision at the time the SLA was executed would have to been less than a few million dollars. (CX5004 at 072-73 (¶¶ 152-53) (Noll Rebuttal Report)). For that to be true, there would need to have been a 92% chance as of June 2010 that the combination of the Endo Credit and No-AG provisions would be worth $0. (CX5004 at 073 (¶ 153) (Noll Rebuttal Report); Noll, Tr. 1478-80). Dr. Addanki offers no evidence that this strategy was possible, let

> alone almost certain to occur. And the discovery record indicates that whether Endo could have achieved this outcome was highly uncertain. Yet Dr. Addanki's conclusions hinge on this outcome being by far the most likely consequence of the settlement. (CX5004 at 073-74 (¶ 154) (Noll Rebuttal Report); *see also* CCF ¶¶ 75-83, 482-87, above).

RESPONSE TO FINDING NO. 488:

Complaint Counsel's Proposed Finding No. 488 is inaccurate, is not supported by evidence, and lacks foundation. Professor Noll did not calculate the expected value of any provision in the settlement agreement, or the overall expected value of the SLA, at the time of settlement. (Noll, Tr. 1613, 1651-52; Addanki, Tr. 2384). Rather, Professor Noll simply assumed that the Endo Credit had a "present value of $65 million at the time of the settlement." (CX5004-073 (Noll Rebuttal Rep. ¶ 153)). He arrived at that value by applying a 15 percent annual discount rate to the $102 million that was actually paid in 2013. (CX5004-073 (Noll Rebuttal Rep. ¶ 153); *see* CX5000-073 (Noll Rep. ¶ 376)). From this premise, Professor Noll opined that in order to bring the "expected value" of the actual Endo Credit payment below $5 million—his estimate for saved litigation costs—the zero-payment scenario would have to be roughly 92 percent likely to occur. (CX5004-073 (Noll Rebuttal Rep. ¶ 153)).

The analysis makes no sense given that the fact and amount of any Endo Credit payment hinged on future events that neither party could entirely foresee or control. The first time that Endo knew its sales would be zero in the last quarter of 2012 was after the Novartis plant shutdown and resulting supply interruption in 2012. (Cuca, Tr. 677; RX-094.0003-06 (supply chain disruption for original Opana ER resulted in Endo Credit liability)). It also ignores the fact that Endo "intended to replace one product with the other, and that would be the only product that we had on the market," (CX4019 (Lortie, Dep. at 117-18)), but Endo still "did not expect to make a payment to Impax," (CX4017 (Levin, Dep. at 126)).

489. There is no reference in either Impax or Endo's financial planning documents to a hypothetical scenario in which both the No-AG provision and the Endo Credit provision end up being worth nothing to Impax. (Noll, Tr. 1480). Dr. Addanki merely asserts that he "would certainly expect that to be Endo's plan." (Addanki, Tr. 2447). Dr. Addanki acknowledged, however, that he did not consider several of Endo's planning documents in forming his opinions. (Addanki, Tr. 2448-56).

RESPONSE TO FINDING NO. 489:

The first sentence of Proposed Finding No. 489 violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents."

The second sentence of Proposed Finding No. 489 is inaccurate and not supported by the cited evidence. Dr. Addanki repeatedly testified that "I do know that there were at least some documents that I reviewed which were contemplating a launch later in 2012 than Endo actually ended up having to do." (Addanki, Tr. 2447-48; *see* Addanki, Tr. 2439 ("it would make economic sense for Endo to have done that [late-switch], and indeed, it seems like that's what Endo had in mind")).

Respondent has no specific response to the third sentence of Proposed Finding No. 489.

490. Endo anticipated the magnitude of the Endo Credit payment to Impax by recording a $110 million charge to its income statement in the first quarter of 2012. (RX-494 at 0007 (May 1, 2012 Endo press release reporting that Endo first quarter results "include[] the impact of a pre-tax charge in the amount of $110 million for the period to reflect a one-time payment that the company now expects to make to Impax per the terms of Endo's 2010 settlement and license agreement with Impax"); RX-117 at 0021 (Endo SEC Form 10-Q for 1Q12 showing $110 million "Accrual for payment to Impax related to sales of Opana ER"); CX5004 at 068 (¶ 144) (Noll Rebuttal Report)).

RESPONSE TO FINDING NO. 490:

While Respondent does not dispute that Endo recorded a charge to its income statement in 2012, Complaint Counsel's Proposed Finding No. 490 is inaccurate and misleading in its suggestion that Endo anticipated any payment, or the magnitude of the eventual payment, at the

time of settlement. When it was signed, the SLA did not require Endo to actually pay anything to Impax. (RX-364.0012 (SLA § 4.4) (no payment until 90 days after documentation that Endo Credit was triggered is provided)). Nor did Endo expect to make a payment at any point in the future. (CX4017 (Levin, Dep. at 99-100) ("at the time the transaction was inked I did not expect that Endo would have to make a payment under this provision")). For that reason, Endo did not book a reserve because no Endo Credit payment was "probable and estimable." (Cuca, Tr. 664-65; *see* Noll, Tr. 1611, 1649 (neither party estimated value of Endo Credit at the time of settlement)).

Indeed, the first time that Endo knew its sales would be zero was in the last quarter of 2012 after the Novartis plant shutdown and resulting supply interruption in 2012. (Cuca, Tr. 677; RX-094.0003-06 (supply chain disruption for original Opana ER resulted in Endo Credit liability)). Until that point, Endo expected to sell Opana ER through the fourth quarter of 2012. (CX4017 (Levin, Dep. at 131); RX-094.0006 ("Prior to March [2012], it would have been reasonable to assume that prescriptions of old formulation [Opana ER] would have occurred in Q4 2012"); RX-108.0002 at 10).

> 491. In the real world, Endo did not implement the hypothetical scenario for rendering both the No-AG provision and Endo Credit valueless. In the real world, Endo paid Impax approximately $102 million pursuant to the Endo Credit provision of the settlement. (JX-001 at 011 (¶¶ 45-46); Reasons, Tr. 1202, 1204; CX0333 (Email chain discussing and attaching confirmation of wire transfer from Endo to Impax of $102,049,199.64); *see also* CX5004 at 068 (¶ 144) (Noll Rebuttal Report)).

RESPONSE TO FINDING NO. 491:

The first sentence of Complaint Counsel's Proposed Finding No. 491 should be disregarded because it is not supported by any record evidence, but it is also inaccurate and misleading. Endo actually "intended to replace one product with the other, and that would be the only product that we had on the market," (CX4019 (Lortie, Dep. at 117-18)), but Endo still "did

not expect to make a payment to Impax," (CX4017 (Levin Dep. at 126)). Indeed, Endo intended to transition to a reformulated version of Opana ER at the very end of 2012. (CX4017 (Levin, Dep. at 99-100, 131) ("it was not [Endo's] expectation that a payment would have to be made"); RX-094). Endo's original budget for 2012 projected original Opana ER sales into the fourth quarter of 2012. (RX-108.0002 at 10; RX-094.0006 ("Prior to March [2012], it would have been reasonable to assume that prescriptions of old formulation [Opana ER] would have occurred in Q4 2012.")).

Endo did not undertake a late-switch strategy only because the Novartis plant at which it manufactured original Opana ER shut down and Endo was forced to rush the launch reformulated Opana ER, after which the FDA ordered it to stop selling original Opana ER. (CX4017 (Levin, Dep. at 136-39, 155) ("supply chain crisis" altered Endo's plans); RX-094.0003-04; RX-100.0001 ("Several of [Endo's] strategies envisioned [Endo] selling both [original and reformulated Opana ER] products at the same time. It was only upon [Endo's] discussions with the FDA in February [2012] that they told [Endo] not to do this in order to avoid patient confusion.")). Professor Bazerman, one of Complaint Counsel's own experts, admits that the FDA's actions shutting down Novartis' plant "took matters out of [Endo's] hands." (Bazerman, Tr. 923-24).

Respondent has no specific response to the second sentence of Proposed Finding No. 491.

5. The size of the payments was sufficient to induce Impax to abandon its patent challenge of the Opana ER patents

492. The size of the payments from Endo to Impax were sufficient to induce Impax to abandon its patent claim. (CX5001 at 014-19 (¶¶ 29, 32-37) (Bazerman Report); Bazerman, Tr. 845-46, 873-74, 877).

RESPONSE TO FINDING NO. 492:

Complaint Counsel's Proposed Finding No. 492 violates this Court's Order on Post-Trial Briefs by improperly citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents," including what led Impax to settle the patent litigation.

> 493. The payments that Impax received from Endo exceeded the stakes that Impax had in actually entering the market with a generic oxymorphone ER product. (Noll, Tr. 1467-68; CX5000 at 169 (¶ 377) (Noll Report)). At the time of the settlement, Impax analysts estimated that Impax could expect to earn approximately $57 million of oxymorphone ER revenue until the expiration of all patent claims at issue in the infringement litigation on September 9, 2013 if it entered at risk on the earliest date that was possible for all five doses for which it was the first filer. The amount that Impax received from the "Endo Credit" was approximately double those revenues. (CX0222 at 004-11 (Impax financial models) (summing "Impax Net Sales" by month for all five doses from the earliest date of final FDA approval (June 14, 2010 for four doses and December 21, 2010, for the 30 mg dose) through September 9, 2013); *see also* CX5000 at 169 (¶ 377 n.425) (Noll Report) (explaining calculations and concluding that Impax expected profits of about $50 million)).

RESPONSE TO FINDING NO. 493:

Complaint Counsel's Proposed Finding No. 493 is inaccurate and not supported by the cited evidence. The cited document (CX0222) says nothing about an at-risk launch. There is, moreover, no suggestion that Impax analyzed or forecasted whether it would receive a payment under the Endo Credit at the time of settlement, or how any estimated revenue would compare to a payment under the Endo Credit. (Mengler, Tr. 582; CX4038 (Engle, Dep. at 187-88); *see* Noll, Tr. 1611, 1649 (neither party estimated value of Endo Credit at the time of settlement)). Finally, the cited document (CX0222) was never shown to any fact witness and there is no explanation regarding the meaning of the document, despite Complaint Counsel's efforts to use their economic expert to testify about the purpose and nature of figures within the document.

494. Impax estimated the value of its expected net sales of oxymorphone ER during its six months of exclusivity as equal to approximately $27 million, assuming Impax launched in July 2010. (CX0203 (Smolenski email to Mengler)). In May 2010, Impax's then-president of generic drugs told Impax's board of directors that Impax's estimated sales in 2010 from being first-to-file on oxymorphone ER would be approximately $28.8 million, assuming Impax launched in June 2010. (CX2662 at 015 (Board presentation)). The actual $102 million payment was about four times as large as Impax's expected revenues during its exclusivity period.

RESPONSE TO FINDING NO. 494:

Respondent has no specific response to the first and second sentences of Proposed Finding No. 494. The third sentence of Proposed Finding No. 494 is incomplete and misleading in its suggestion that any payment under the Endo Credit was expected or known at the time of settlement. The record is clear that Impax never analyzed or forecasted whether it would receive a payment under the Endo Credit at the time of settlement. (Mengler, Tr. 582; CX4038 (Engle, Dep. at 187-88); *see* Noll, Tr. 1611, 1649 (neither party estimated value of Endo Credit at the time of settlement)).

495. The magnitude of the "Endo Credit" was also large in relation to total annual revenues and profits for Impax. Before Impax received the Endo Credit payment, Impax told investors that it may receive $110 million from Endo. (Reasons, Tr. 1204-05). Impax informed investors of the potential Endo Credit payment because a potential payment of $110 million would be material to Impax's cash flows. (Reasons, Tr. 1205). According to Impax's current CFO, when Impax received the Endo Credit payment in 2013, the payment had a substantial impact on Impax's net income. (Reasons, Tr. 1205).

RESPONSE TO FINDING NO. 495:

Respondent has no specific response other than to note that there is no evidence that Impax was informing investors about a potential payment under the Endo Credit at the time of settlement, as Proposed Finding No. 495 attempts to suggest.

496. Impax stated in its SEC Form 10-K for 2013 that the increase in profits over the prior year was primarily due to the payment from Endo, as well as a much smaller settlement payment from another company. (CX0425 at 018, 069, 074 (Impax 2013 SEC Form 10-K); CX5000 at 170-71 (¶ 378) (Noll Report)). The Endo Credit payment

increased Impax's 2013 net income by about $65 million, which is the amount of the $102 million payment minus taxes. (Reasons, Tr. 1205). Impax's net income for 2013, the year that the Endo Credit was paid to Impax, was approximately $101.3 million. (Reasons, Tr. 1207; CX0425 at 069 (Impax 2013 10-K securities filing)). The Endo Credit payment represented almost two-thirds of Impax's net income for 2013. (Reasons, Tr. 1208). Impax stated that its increase in net income between 2012 and 2013 was primarily attributable to two things, the first of which was the $102 million Endo Credit payment. The second was a $48 million payment that Impax received from another litigation settlement. (Reasons, Tr. 1208-09; CX0425 at 069 (Impax 2013 10-K securities filing)).

RESPONSE TO FINDING NO. 496:

Respondent has no specific response.

497. Impax's net income in 2012 was about $55.9 million. (Reasons, Tr. 1209; CX0425 at 069 (Impax 2013 10-K securities filing)). The $65 million net income from the Endo Credit payment was about $10 million more than the total net income from all of Impax in 2012. (Reasons, Tr. 1209).

RESPONSE TO FINDING NO. 497:

Respondent has no specific response.

VIII. The relevant market is the sale of oxymorphone ER products in the United States

498. The evidence supports the following conclusions with regard to market definition. First, Opana ER and generic oxymorphone ER are close economic substitutes and so are in the same relevant market. Second, neither oxymorphone IR nor other LAOs are close economic substitutes for oxymorphone ER, and hence none of these drugs are in the same relevant market as Opana ER for purposes of assessing the conduct at issue in this case. (CX5000 at 082 (¶ 180) (Noll Report)).

RESPONSE TO FINDING NO. 498:

Complaint Counsel's Proposed Finding No. 498 is inaccurate and contrary to the weight of the record evidence. It is "very clear that the evidence . . . points to the relevant market being no smaller than the market for long-acting opioids in the United States." (Addanki, Tr. 2328). That market includes, at a minimum, extended-release oxycodone, morphine, hydromorphone, tapentadol, hydrocodone, oxymorphone, and fentanyl. (RX-547.0047 (Addanki, Rep. ¶ 85)).

Indeed, the evidence at trial demonstrated that all long-acting opioids are interchangeable for the vast majority of patients, and that long-acting opioids compete vigorously on price. (*See, e.g.*, Michna, Tr. 2107; Bingol, Tr. 1324-25; Addanki, Tr. 2291 (*in camera*)).

> 499. In the two years after entry of its generic, Impax captured about half of Opana ER's sales at prices that were substantially lower than the prices for Opana ER. The success of Impax's generic entry could not have occurred if other LAOs already were imposing the same competitive restraints that generic oxymorphone ER imposed on Opana ER. (CX5000 at 082 (¶ 182) (Noll Report)).

RESPONSE TO FINDING NO. 499:

Complaint Counsel's Proposed Finding No. 499 violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents," including Impax's sales. Proposed Finding No. 499 is also inaccurate and contrary to the weight of the record evidence. The cited portions of Professor Noll's report do not contain any evidence or analysis to support the asserted proposition. It is, moreover, "very clear that the evidence . . . points to the relevant market being no smaller than the market for long-acting opioids in the United States." (Addanki, Tr. 2328). That market includes, at a minimum, extended-release oxycodone, morphine, hydromorphone, tapentadol, hydrocodone, oxymorphone, and fentanyl. (RX-547.0047 (Addanki, Rep. ¶ 85)). Indeed, the evidence at trial demonstrated that all long-acting opioids are interchangeable for the vast majority of patients, and that long-acting opioids compete vigorously on price. (*See, e.g.*, Michna, Tr. 2107; Bingol, Tr. 1324-25; Addanki, Tr. 2291 (*in camera*)).

> 500. Review of the sales histories of other LAOs do not reveal the pattern of substitution that would be expected if each of these LAOs were in the same relevant product market as oxymorphone ER. The abrupt rise and fall in sales of Opana ER in 2010-2012 do not reflect a parallel fall and rise in the sales of any of the other single-API LAOs. The presence of high generic market shares in two LAOs, fentanyl ER and morphine ER, with much greater sales than oxymorphone ER, did not prevent Opana ER

from rapidly expanding its sales from its introduction in 2006 until Reformulated Opana ER was introduced in 2012. (CX5000 at 082-83 (¶ 183) (Noll Report)).

RESPONSE TO FINDING NO. 500:

Complaint Counsel's Proposed Finding No. 500 is inaccurate and contrary to the weight of the record evidence. It is "very clear that the evidence . . . points to the relevant market being no smaller than the market for long-acting opioids in the United States." (Addanki, Tr. 2328). That market includes, at a minimum, extended-release oxycodone, morphine, hydromorphone, tapentadol, hydrocodone, oxymorphone, and fentanyl. (RX-547.0047 (Addanki, Rep. ¶ 85)). Indeed, the evidence at trial demonstrated that all long-acting opioids are interchangeable for the vast majority of patients, and that long-acting opioids compete vigorously on price. (*See, e.g.*, Michna, Tr. 2107; Bingol, Tr. 1324-25; Addanki, Tr. 2291 (*in camera*)).

This includes evidence of actual substitution among long-acting opioids. (RX-449.0007 ([redacted]); CX2732-003 ("Withdrawal of Embeda by Pfizer/King had led to another unexpected inflexion point in Opana ER TRx demand as clinicians seek alternative therapies for their Embeda patients. . . . Of all branded LAOs, Opana ER and Kadian have benefited the most from the removal of Embeda."); RX-073.0002 at 13, 16 (Endo document tracking switching among various long-acting opioids and noting Endo "must accelerate the gain of switches from Oxycontin"); RX-060.0002 at 25 (thousands of patients switched between Opana ER and other long-acting opioids every month)).

501. Thus, oxymorphone ER is the relevant product market for purposes of assessing the conduct at issue in this case. Generic oxymorphone ER is a close economic substitute for Original Opana ER. Moreover, generic oxymorphone ER, despite not being therapeutically equivalent, has taken half of the prescriptions from Reformulated Opana

ER at substantially lower prices, and is the only substantial competitive restraint on sales of Reformulated Opana ER. (CX5000 at 083 (¶ 183) (Noll Report)).

RESPONSE TO FINDING NO. 501:

Complaint Counsel's Proposed Finding No. 501 is inaccurate and contrary to the weight of the record evidence. It is "very clear that the evidence . . . points to the relevant market being no smaller than the market for long-acting opioids in the United States." (Addanki, Tr. 2328). That market includes, at a minimum, extended-release oxycodone, morphine, hydromorphone, tapentadol, hydrocodone, oxymorphone, and fentanyl. (RX-547.0047 (Addanki, Rep. ¶ 85)). Indeed, the evidence at trial demonstrated that all long-acting opioids are interchangeable for the vast majority of patients, and that long-acting opioids compete vigorously on price. (*See, e.g.*, Michna, Tr. 2107; Bingol, Tr. 1324-25; Addanki, Tr. 2291 (*in camera*)).

A. Oxymorphone ER and other long-acting opioids differ in important ways

502. Opioids are among the oldest medicinal substances known, and they remain the most potent analgesic (pain-relieving) medications available. (CX5002 at 009 (¶ 18) (Savage Report)).

RESPONSE TO FINDING NO. 502:

Respondent has no specific response.

503. Opioids are generally indicated when other interventions are not effective in treating pain or when opioids present less risk than other interventions. (Savage, Tr. 697; RX-549 at 0020 (¶ 49 n.28) (Michna Report)).

RESPONSE TO FINDING NO. 503:

Respondent has no specific response.

504. Given the complex nature of opioids – their potent efficacy in relieving pain and other symptoms when used well, and their potential for serious harm when misused – it is critical that physicians have a diverse selection of different opioids available, and understand the differences between these opioids, in order to carefully tailor their use to

meet the individualized needs and responses of difference patients. (CX5002 at 010 (¶ 21) (Savage Report)).

RESPONSE TO FINDING NO. 504:

Respondent has no specific response.

505. Opioid medications exert their effects when the opioid molecules bind to opioid receptors on nerve cells. (CX5002 at 020 (¶ 53) (Savage Report)).

RESPONSE TO FINDING NO. 505:

Respondent has no specific response.

506. Most commonly-used opioid pain medications, including oxymorphone, act primarily on mu opioid receptors, though some, such as oxycodone, have kappa receptor effects as well. (CX5002 at 021 (¶ 55) (Savage Report)).

RESPONSE TO FINDING NO. 506:

Respondent has no specific response.

507. It has long been observed that different people respond somewhat differently to different opioid medications in term of analgesic response and side effects. At least two mechanisms are likely responsible for the variable responses to different opioids: variability in individual expression of opioid receptors, and metabolic differences between individuals. (CX5002 at 22 (¶ 58) (Savage Report); Michna, Tr. 2186, 2191-92).

RESPONSE TO FINDING NO. 507:

Respondent has no specific response.

508. There is significant variability in the molecular expression of mu opioid receptors from person to person with multiple variants (called polymorphisms). It is believed that observed clinically different responses to different opioid drugs are, at least in part, a result of how a particular mu opioid drug matches the mu opioid sub-receptor profile of the individual being treated. (CX5002 at 022 (¶ 59) (Savage Report); (Michna, Tr. 2185-86)).

RESPONSE TO FINDING NO. 508:

Respondent has no specific response.

509. As a result, opioid treatment often requires trial and error to find the best drug to treat a given individual. Differences in mu receptors may mean that a patient who responds well to one opioid may not respond as well to another. (CX5002 at 023 (¶ 61) (Savage Report); Michna, Tr. 2168-69 (agreeing that there is no reliable way of identifying which delivery system or opioid is most compatible with an individual patient beyond trial and error)).

RESPONSE TO FINDING NO. 509:

Respondent has no specific response.

510. Opana ER is an extended release formulation of the opioid oxymorphone. Oxymorphone is a semisynthetic opioid and a full mu agonist. (CX5002 at 037 (¶ 104) (Savage Report); Bingol, Tr. 1261-62)).

RESPONSE TO FINDING NO. 510:

Respondent has no specific response.

B. Relevant market definition is based on economic substitutability

511. Market definition focuses solely on demand substitution factors, i.e. on customers' ability and willingness to substitute away from one product to another in response to a price increase or corresponding non-price change such as a reduction in product quality or service. (CX6054 at 010 (§ 4) (Merger Guidelines)).

RESPONSE TO FINDING NO. 511:

Complaint Counsel's Proposed Finding No. 511 is improper because it states a legal conclusion, not a fact.

512. In antitrust economics, market definition is not an end in itself, but is a tool that is valuable only to the extent that it helps shed light on whether the conduct at issue caused anticompetitive harm by increasing or maintaining market concentration or by enabling a group of independent sellers to engage in effective collusion. (CX5000 at 016 (¶ 36) (Noll Report)).

RESPONSE TO FINDING NO. 512:

Respondent has no specific response.

513. A relevant antitrust market is a group of products that, hypothetically, could be monopolized profitably by a common owner, but in which sellers acting independently

would effectively complete, thereby causing prices to be lower. (CX5000 at 016 (¶ 36) (Noll Report); Noll, Tr. 1368-69 (describing a relevant antitrust market as the products that are at issue in the antitrust litigation "plus the smallest number of other products that, if they were all sold by the same entity . . . they could successfully implement a profit-enhancing price increase . . .")).

RESPONSE TO FINDING NO. 513:

Complaint Counsel's Proposed Finding No. 513 is improper because it states a legal conclusion, not a fact.

514. The starting place for defining a relevant market is a reference product – a product or a set of products that is offered by the entities that engaged in the anticompetitive conduct. (Noll, Tr. 1368-69; CX5000 at 016 (¶ 37) (Noll Report)).

RESPONSE TO FINDING NO. 514:

Complaint Counsel's Proposed Finding No. 514 is improper because it states a legal conclusion, not a fact.

515. Because the anticompetitive conduct in this case is the agreement between Endo and Imapx to settle their patent infringement litigation, the reference products in this case are the oxymorphone ER products that are sold by Endo (Opana ER) and Impax (generic oxymorphone ER). (CX5000 at 016-17 (¶ 37) (Noll Report)).

RESPONSE TO FINDING NO. 515:

Complaint Counsel's Proposed Finding No. 515 is improper because it states a legal conclusion, not a fact.

516. The process of defining a relevant antitrust market consists of identifying the products that collectively impose a competitive constraint on the prices of the reference products. The concept that underpins market definition is economic substitution. (CX5000 at 017 (¶ 38) (Noll Report)).

RESPONSE TO FINDING NO. 516:

Complaint Counsel's Proposed Finding No. 516 is improper because it states a legal conclusion, not a fact.

517. A product is a close economic substitute for a reference product if a "small but significant non-transitory increase in price" (SSNIP) of the reference product would cause a sufficient amount of sales to shift to the other product to make the price increase unprofitable. (CX5000 at 017 (¶ 38) (Noll Report); Noll, Tr. 1374 ("That is, if we think about our SSNIP test, we ask the question, if one product's price goes up relative to the other, does that cause a large enough switch from one category to another that it wasn't profit-enhancing to increase the price.")).

RESPONSE TO FINDING NO. 517:

Respondent has no specific response.

518. A relevant market for purposes of antitrust analysis is a reference product plus the smallest group of other products for which a SSNIP would be profitable if a hypothetical monopolist sold all the products. (CX5000 at 017 (¶ 38) (Noll Report)).

RESPONSE TO FINDING NO. 518:

Complaint Counsel's Proposed Finding No. 518 is improper because it states a legal conclusion, not a fact.

519. The "smallest market principle" implies that not all substitutes for the reference product necessarily must be included in the relevant market. Instead, the market includes the reference product plus the minimum number of other products that, if sold by a single firm (hypothetical monopolist) would command prices above the competitive level. (CX5000 at 017 (¶ 38) (Noll Report)).

RESPONSE TO FINDING NO. 519:

Complaint Counsel's Proposed Finding No. 519 is improper because it states a legal conclusion, not a fact.

520. Although market definition is based solely on identifying products that are substitutes on the demand side of the market, the principle of substitution applies to both demand and supply responses to a change in relative prices. (CX5000 at 017 (¶ 39) (Noll Report)).

RESPONSE TO FINDING NO. 520:

Respondent has no specific response.

521. *Demand substitution* refers to actions by consumers to switch purchases among a given group of products. *Supply substitution* refers to the entry of new products from new sellers in the relevant market, either by shifting sales efforts from another geographic area to the relevant geographic area or by initiating production of a new product that is a demand-side substitute for the reference products. (CX5000 at 017 (¶ 39) (Noll Report)).

RESPONSE TO FINDING NO. 521:

Respondent has no specific response.

522. A new product (e.g., generic oxymorphone ER) is part of the relevant antitrust market for an incumbent product (e.g., Opana ER) if and when the new product is among the smallest group of products that effectively competes against the incumbent product by undercutting its price. (CX5000 at 017-18 (¶ 39) (Noll Report)).

RESPONSE TO FINDING NO. 522:

Complaint Counsel's Proposed Finding No. 522 is improper because it states a legal conclusion, not a fact.

523. In identifying a relevant product market, economists use several types of evidence. The normal starting place is to identify products that have functions and technical descriptions that are the same as, or very similar to, the reference product. This step is useful for identifying the set of products that plausibly are close competitive substitutes for the reference product. (CX5000 at 018 (¶ 40) (Noll Report)).

RESPONSE TO FINDING NO. 523:

Respondent has no specific response.

524. In most circumstances, competition arises among so-called "differentiated products," i.e. products with different qualities and technical characteristics and that buyers perceive as not having identical functionality. The fact that products are differentiated does not imply that they cannot be competitive substitutes in a relevant antitrust market. (CX5000 at 018 (¶ 40) (Noll Report)).

RESPONSE TO FINDING NO. 524:

Respondent has no specific response other than to note that cited expert report (CX5000) offers no evidence or analysis to support the claim regarding how competition occurs in "most circumstances."

525. In the end, whether products are in the same market is not simply a matter of functional definition and technical description, but whether customers regard the products as sufficiently close substitutes that a small change in the price of one product would cause buyers to switch their purchases to the other. (CX5000 at 018 (¶ 40) (Noll Report); Noll, Tr. 1369 ("The key issue in this case is the degree to which there is price competition . . . that is to say, for the prices charged by producers of long-acting opioids to be competitive.")).

RESPONSE TO FINDING NO. 525:

Respondent has no specific response.

526. The core underlying fact that economists seek to uncover in defining a relevant market is the cross-elasticity of demand between a reference product and each product that is a plausible close substitute. The cross-elasticity of demand is the percentage change in sales of one product arising from a one percent change in the price of another product. (CX5000 at 018 (¶ 41, 41 n.12) (Noll Report)).

RESPONSE TO FINDING NO. 526:

Respondent has no specific response.

527. If the cross-elasticity of demand between two products is high, an attempt by the producer of one product to increase price will cause a large loss of sales to the other product, assuming that the prices of the other products remain unchanged. (CX5000 at 018 (¶ 41) (Noll Report)).

RESPONSE TO FINDING NO. 527:

Respondent has no specific response.

528. In some cases econometric models can be used to estimate the cross-elasticity of demand between a reference product and each candidate for inclusion in the relevant market. The basic idea is to estimate the relationship between the price of the reference product and variables that capture the supply and demand conditions that determine its price, such as its technical features, its marginal cost of production, and the prices of its most plausible substitutes. Unfortunately, an econometric analysis of price behavior rarely is feasible because estimating each cross-elasticity of demand can be very difficult, and sometimes is impossible. (CX5000 at 019 (¶ 42) (Noll Report)).

RESPONSE TO FINDING NO. 528:

Respondent has no specific response other than to note that the cited expert report (CX5000) contains no evidence or analysis to support the proposition that certain types of analysis are "rarely" feasible.

529. Economists use other types of evidence besides econometric models of price formulation as indicators of the degree of competition between two products to determine whether they are in the same markets. The *Merger Guidelines* list these other kinds of evidence that bear on defining a relevant market. (CX5000 at 019 (¶ 43) (Noll Report)).

RESPONSE TO FINDING NO. 529:

Respondent has no specific response other than to note that the *Merger Guidelines* speak for themselves.

530. This evidence includes documents from buyers, sellers, and informed third parties that contain information about which products are regarded as competitive substitutes, the nature and extent of downstream competition in the buyers' output markets, and the costs of switching products. (CX5000 at 019 (¶ 43) (Noll Report)).

RESPONSE TO FINDING NO. 530:

Respondent has no specific response other than to note that to the extent Proposed Finding No. 530 purports to summarize the *Merger Guidelines*, the *Merger Guidelines* speak for themselves.

531. One potentially useful indicator is the understanding of experienced observers of the industry. The kind of information that is useful is a supplier's or a buyer's sense of principal competitors and a buyer's sense of which products are reasonably close substitutes. (CX5000 at 020 (¶ 44) (Noll Report)).

RESPONSE TO FINDING NO. 531:

Respondent has no specific response.

532. Another useful source of information for identifying drugs that potentially are close therapeutic substitutes and, hence, candidates to be economic substitutes for a given

brand-name drug, is clinical researchers. This group writes scholarly articles reporting the results of clinical trials, review articles summarizing many clinical trials, clinical practice guidelines to assist physicians, and the labels that drug companies must include with a prescription drug and that must be approved by the FDA. (CX5000 at 020 (¶ 45) (Noll Report)).

RESPONSE TO FINDING NO. 532:

Respondent has no specific response.

533. Additional evidence about market definition is the actual extent to which buyers switch among sellers. Two products are close economic competitors only if buyers regard them as sufficiently close substitutes that, in response to small changes in relative prices or other market conditions, they switch the product that they purchase. (CX5000 at 020 (¶ 46) (Noll Report)).

RESPONSE TO FINDING NO. 533:

Complaint Counsel's Proposed Finding No. 533 is improper because it states a legal conclusion, not a fact.

534. If products are sold in the same location and have identical attributes, buyers are likely to make their purchase decisions on the basis of price. If products differ in their attributes and where they are sold, buyers may have strong preferences among them and so give little weight to price in making purchase decisions. (CX5000 at 020 (¶ 46) (Noll Report)).

RESPONSE TO FINDING NO. 534:

Respondent has no specific response other than to note that the cited expert report (CX5000) contains no evidence or analysis to support the contention about what buyers are "likely" to do.

535. In economics, "horizontal differentiation," refers to qualitative attributes for which buyers have different preferences. For example, consumers differ in the amount of salt that they prefer in their soup or sugar in their tea. (CX5000 at 020-21 (¶ 47) (Noll Report)).

RESPONSE TO FINDING NO. 535:

Respondent has no specific response.

536. Another type of differences is product quality, where buyers agree on the rank ordering of products. These differences are called "vertical differentiation." For example, all consumers probably agree that a Porsche is a better automobile than a Chevrolet and that automobile tires that last for 75,000 miles are better than tires that last for 40,000 miles. (CX5000 at 021 (¶ 47) (Noll Report)).

RESPONSE TO FINDING NO. 536:

Respondent has no specific response.

537. Given differences in relative prices between high and low quality goods, some prefer the cheaper option, while others prefer the more expensive product. For both types of differences, whether goods of different quality are part of the same relevant market depends on whether enough buyers would switch to a product of different quality in response to a change in relative prices. (CX5000 at 021 (¶ 47) (Noll Report)).

RESPONSE TO FINDING NO. 537:

Complaint Counsel's Proposed Finding No. 537 is improper because it states a legal conclusion, not a fact.

538. Another useful indicator for identifying whether a reference product faces close competitive substitutes is the presence of market power. Antitrust economics separates market definition from market power; however, evidence that a firm has substantial market power is pertinent to market definition. (CX5000 at 021 (¶ 48) (Noll Report)).

RESPONSE TO FINDING NO. 538:

Complaint Counsel's Proposed Finding No. 538 is improper because it states a legal conclusion, not a fact.

539. If products from many independent suppliers are close substitutes, competition among them will drive prices to the competitive level. Hence, if products are broadly similar but the supplier of one product is able to sustain its price substantially above its average total cost of production and thereby to earn profits in excess of the competitive level, the highly profitable product must be sold in a relevant market that contains few competitive substitutes. (CX5000 at 021 (¶ 48) (Noll Report)).

RESPONSE TO FINDING NO. 539:

Complaint Counsel's Proposed Finding No. 539 is improper because it states a legal conclusion, not a fact.

C. Distinct features of prescription pharmaceutical markets may enhance market power

540. The standard procedures of medical practice, the nature of technological progress and entry in the drug industry, and the regulation of drugs by the FDA and generic substitution laws together have produced a system for classifying drugs that is useful for identifying the most plausible functional substitutes for a reference pharmaceutical product. (CX5000 at 022 (¶ 49) (Noll Report)).

RESPONSE TO FINDING NO. 540:

Respondent has no specific response.

541. In the pharmaceutical industry, products are differentiated according to the active ingredient in each drug within a therapeutic class. (CX5000 at 022 (¶ 50) (Noll Report)).

RESPONSE TO FINDING NO. 541:

Complaint Counsel's Proposed Finding No. 541 violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." Professor Noll was not and is not qualified as an expert with respect to the pharmaceutical industry. (Noll, Tr. 1358).

542. Because of safety and efficacy regulation, including the requirement to monitor the effects of a drug on patients after it has been approved, product differentiation among drugs tends to be horizontal in that the FDA allows a drug to remain on the market only if, for some patients, it is a valuable treatment option. (CX5000 at 022 (¶ 50) (Noll Report)).

RESPONSE TO FINDING NO. 542:

Complaint Counsel's Proposed Finding No. 542 violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by

fact witnesses or documents." Professor Noll was not and is not qualified as an expert with respect to the pharmaceutical industry. (Noll, Tr. 1358).

543. Empirical examination of product choice within a group of drugs that are used to treat the same conditions can be used to investigate whether buyers switch among products in the group (e.g., among opioid analgesics) in response to changes in relative price, the entry and exit of a product in the group, or other features of the market. (CX5000 at 022 (¶ 51) (Noll Report)).

RESPONSE TO FINDING NO. 543:

Respondent has no specific response.

544. Two drugs are not close economic substitutes if an event that changes the relative price attractiveness of one does not significantly affect the distribution of sales between them. (CX5000 at 022 (¶ 51) (Noll Report)).

RESPONSE TO FINDING NO. 544:

Respondent has no specific response.

545. The first step in determining which drugs are likely to be economic substitutes for a brand-name drug is to identify other drugs that are used to treat the same medical conditions. (CX5000 at 024 (¶ 54) (Noll Report)).

RESPONSE TO FINDING NO. 545:

Respondent has no specific response.

546. The drugs that are most similar to a brand-name drug are generic versions of the same drug. (CX5000 at 024 (¶ 54) (Noll Report)).

RESPONSE TO FINDING NO. 546:

Complaint Counsel's Proposed Finding No. 546 violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." Professor Noll was not and is not qualified as an expert with respect to the pharmaceutical industry. (Noll, Tr. 1358).

547. The FDA categorizes generic drugs according to whether they are a "therapeutic equivalent" to the associated brand-name drug. The term "therapeutic equivalent" is potentially confusing because it is a much narrower concept than a "therapeutic class" of drugs, which refers to all drugs that are used to treat the same broad medical condition, or a "pharmacologic class," which includes drugs that treat the same condition in a similar way. (CX5000 at 025 (¶ 56) (Noll Report)).

RESPONSE TO FINDING NO. 547:

Complaint Counsel's Proposed Finding No. 547 violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." Professor Noll was not and is not qualified as an expert with respect to the pharmaceutical industry. (Noll, Tr. 1358).

548. To be classified as therapeutically equivalent requires that the generic and brand-name drugs have essentially the same formulation and uses, and so are essentially perfect functional substitutes. Thus, the only source of product differentiation between a brand-name drug and a therapeutically equivalent generic is brand loyalty arising from the reputation and familiarity with the brand name. (CX5000 at 025-26 (¶ 57) (Noll Report)).

RESPONSE TO FINDING NO. 548:

Complaint Counsel's Proposed Finding No. 548 violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." Professor Noll was not and is not qualified as an expert with respect to the pharmaceutical industry. (Noll, Tr. 1358).

549. A generic drug can be bioequivalent to a brand-name drug without being classified as a therapeutic equivalent if it delivers the same API in the same dose at the same rate to the patient, but its formulation differs in other ways that the FDA regards as potentially important to some patient but that do not significantly affect the direct effect of the drug. (CX5000 at 026 (¶ 57) (Noll Report)).

RESPONSE TO FINDING NO. 549:

Complaint Counsel's Proposed Finding No. 549 violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by

fact witnesses or documents." Professor Noll was not and is not qualified as an expert with respect to the pharmaceutical industry. (Noll, Tr. 1358).

550. The closest functional substitute for a brand-name drug is a generic that is designated as therapeutically equivalent. (Noll, Tr. 1370-71; CX5000 at 026 (¶ 59) (Noll Report)).

RESPONSE TO FINDING NO. 550:

Complaint Counsel's Proposed Finding No. 550 violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." Professor Noll was not and is not qualified as an expert with respect to the pharmaceutical industry. (Noll, Tr. 1358).

551. Other drugs may be sufficiently similar that they are reasonably close functional substitutes and, therefore, candidates to be economic substitutes and so part of the same relevant market. (CX5000 at 024 (¶ 54) (Noll Report)).

RESPONSE TO FINDING NO. 551:

Respondent has no specific response.

552. The next closest functional substitute for a brand-name drug is a bioequivalent drug that is not categorized as therapeutically equivalent, which includes bioequivalent generic drugs that are not therapeutically equivalent. (Noll, Tr. 1371; CX5000 at 027 (¶ 59) (Noll Report)).

RESPONSE TO FINDING NO. 552:

Complaint Counsel's Proposed Finding No. 552 violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." Professor Noll was not and is not qualified as an expert with respect to the pharmaceutical industry. (Noll, Tr. 1358).

553. While drugs that are therapeutically equivalent constitute the narrowest category of drugs that plausibly are in the relevant market for a drug that is a reference product, the

broadest possible market includes all drugs that are in the same therapeutic class. The broad therapeutic class that contains oxymorphone is analgesics (pain killers). (CX5000 at 027 (¶ 60) (Noll Report)).

RESPONSE TO FINDING NO. 553:

Complaint Counsel's Proposed Finding No. 553 is improper because it states a legal conclusion, not a fact.

554. Within a therapeutic class, drugs are further divided into pharmacologic classes, which are drugs that treat a given medical condition in a similar way. The pharmacologic class that includes oxymorphone is called opioid analgesics. (CX5000 at 028 (¶ 61) (Noll Report)).

RESPONSE TO FINDING NO. 554:

Complaint Counsel's Proposed Finding No. 554 violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." Professor Noll was not and is not qualified as an expert with respect to the pharmaceutical industry. (Noll, Tr. 1358).

555. A still narrower potential market eliminates drugs within the same pharmacologic class that are prescribed for different variations of the same medical conditions. For example, within the class of opioids, immediate release (IR) opioids are prescribed for acute (short-term) pain relief, extended release long-acting (ER/LA) opioids are prescribed for chronic pain, and some low-dose opioids are prescribed for facilitating withdrawal from opioid addiction. (CX5000 at 028 (¶ 61) (Noll Report)).

RESPONSE TO FINDING NO. 555:

The first sentence of Complaint Counsel's Proposed Finding No. 555 is improper because it states a legal conclusion, not a fact.

The second sentence of Proposed Finding No. 555 violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." Professor Noll was not and is not qualified as an expert with respect to the pharmaceutical industry. (Noll, Tr. 1358).

556. Often different drugs in a pharmacologic class are not close economic substitutes because they are prescribed for different conditions (e.g., mild versus severe pain) and/or different types of patients (e.g., children versus adults, women versus men, opioid experienced versus opioid inexperienced). (CX5000 at 028 (¶ 62) (Noll Report)).

RESPONSE TO FINDING NO. 556:

Complaint Counsel's Proposed Finding No. 556 violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." Professor Noll was not and is not qualified as an expert with respect to the pharmaceutical industry. (Noll, Tr. 1358).

557. In addition, drugs in the same pharmacologic class may not be close therapeutic substitutes because they have different adverse side effects and/or interactions with other drugs. (CX5000 at 028 (¶ 62) (Noll Report)).

RESPONSE TO FINDING NO. 557:

Complaint Counsel's Proposed Finding No. 557 violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." Professor Noll was not and is not qualified as an expert with respect to the pharmaceutical industry. (Noll, Tr. 1358).

558. Thus, in defining a relevant drug market, the appropriate starting place is drugs containing the same API. The next step is to consider other drugs in the same pharmacologic class that are used to treat the same symptoms and have the same or similar therapeutic benefits and risks. (CX5000 at 028-29 (¶ 62) (Noll Report)).

RESPONSE TO FINDING NO. 558:

Complaint Counsel's Proposed Finding No. 558 is improper because it states a legal conclusion, not a fact.

559. Drugs can be functional substitutes but not necessarily close economic substitutes because functionality is not the only thing that matters. In most markets, products are differentiated, and consumers will differ in the values they place upon those attributes.

Moreover, the act of switching from one product to another may be costly. (Noll, Tr. 1373).

RESPONSE TO FINDING NO. 559:

To the extent Complaint Counsel's Proposed Finding No. 559 relates to purported characteristics of unidentified pharmaceutical markets, it violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." Professor Noll was not and is not qualified as an expert with respect to the pharmaceutical industry. (Noll, Tr. 1358).

560. Thus, identifying functional and technical similarity is only a beginning to identifying products that potentially are economic substitutes and so part of the same relevant market. The nature and intensity of competition among pharmaceuticals is heavily influenced by the unique institutional environment in which the industry operates. (CX5000 at 029 (¶ 63) (Noll Report)).

RESPONSE TO FINDING NO. 560:

The first sentence of Complaint Counsel's Proposed Finding No. 560 is improper because it states a legal conclusion, not a fact. Respondent has no specific response to the second sentence of Proposed Finding No. 560.

561. This environment includes laws and policies regarding drug patents, regulation of drug manufacturing and marketing by the FDA, separation of the decisions by doctors/patients about drug consumption from payments for drugs by insurance companies, federal procurement rules that govern the purchase of drugs for military and veterans hospitals and Medicaid patients, and, in the case of opioids, rules about controlled substances (opioids are Schedule II substances, the use of which is regulated by the DEA). (CX5000 at 029 (¶ 63) (Noll Report)).

RESPONSE TO FINDING NO. 561:

Respondent has no specific response.

562. For drugs that require a prescription, such as oxymorphone, the central figure in decisions about which drug a patient takes is the patient's physician. (CX5000 at 029 (¶ 64) (Noll Report)).

RESPONSE TO FINDING NO. 562:

Complaint Counsel's Proposed Finding No. 562 violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." Professor Noll was not and is not qualified as an expert with respect to the pharmaceutical industry. (Noll, Tr. 1358).

563. The primary concern of a physician in writing a prescription is to select a drug that will deliver the greatest therapeutic benefit, taking into account the patient's overall condition, including use of other drugs and reliability in following the prescription. (CX5000 at 029 (¶ 64) (Noll Report); *see also* Savage, Tr. 771; Michna, Tr. 2177)).

RESPONSE TO FINDING NO. 563:

Complaint Counsel's Proposed Finding No. 563 violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." Professor Noll was not and is not qualified as an expert with respect to the pharmaceutical industry. (Noll, Tr. 1358).

The cited testimony of Dr. Savage and Dr. Michna speaks for itself. (Savage, Tr. 771 ("Q. Now, why wouldn't minor changes in prices change your prescribing habits? A. First, because I'm generally not aware of the minor changes in price. Second, because . . . my concerns here are for the clinical well-being of the patient, and those would take priority over more abstract financial concerns."); Michna, Tr. 2177 ("Q. Okay. But you prescribe the product that you feel is the best for your patient in his or her clinical situation? A. Yes. Q. And your priority is the safety and health of your patient? A. Ultimately, yes.")).

Finally, the Proposed Finding is misleading to the extent it ignores that, in some instances—including the treatment of chronic pain with long-acting opioids—there are multiple prescription drug options that deliver the same therapeutic benefit. (*See* Michna, Tr. 2107; Noll, Tr. 1504-05; *see also* Savage, Tr. 782-83 ("[M]ost [opioids] are interchangeable if attention is

paid to relative potencies and onset and duration of action.")). Under such circumstances, physician prescribing behavior may be driven by other factors, such as relative cost to the patient, including insurance coverage, and physician habit. (RX-549.0006-07, 20-23 (Michna Rep. ¶¶ 21, 49-51); Michna, Tr. 2148; CX4046 (Michna, Dep. at 115-16); CX4044 (Addanki, Dep. at 148)). In fact, Complaint Counsel's economic expert, Professor Noll, admitted that doctors make prescribing decisions based on price and formulary tiering, among other issues. (Noll, Tr. 1505-06). Dr. Savage, Complaint Counsel's medical expert, similarly admitted that "the copay is one variable that may be considered" when making prescription choices—"clinical determinations are usually the first consideration and then copays." (CX4041 (Savage, Dep. at 138); *see* Savage, Tr. 772 (availability of insurance coverage for a medication would affect Dr. Savage's clinical decision-making)).

> 564. Physicians do not have a strong incentive to take into account the relative prices of drugs in selecting among them, especially if a substantial fraction of a patient's drug expenditures are covered by insurance or a government health program. (CX5000 at 029 (¶ 64) (Noll Report)).

RESPONSE TO FINDING NO. 564:

Complaint Counsel's Proposed Finding No. 564 violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." Professor Noll was not and is not qualified as an expert with respect to the pharmaceutical industry. (Noll, Tr. 1358).

Proposed Finding No. 564 is also inaccurate. Doctors seek to avoid high out-of-pocket costs for patients, and they regularly do so by making prescribing decisions based on price and where a medication is located on an insurance company's formulary. (CX4046 (Michna, Dep. at 115-16); CX4044 (Addanki, Dep. at 148)). In fact, Complaint Counsel's economic expert, Professor Noll, admitted that doctors make prescribing decisions based on price and formulary

tiering, among other issues. (Noll, Tr. 1505-06). Dr. Savage, Complaint Counsel's medical expert, similarly admitted that "the copay is one variable that may be considered" when making prescription choices—"clinical determinations are usually the first consideration and then copays." (CX4041 (Savage, Dep. at 138); *see* CX5002-063 (Savage Rep. ¶ 177) (noting that clinicians will "consciously consider costs" when they are "aware that the patient will need to pay out of pocket")). Indeed, where there are multiple equally safe and effective treatment options—for example, when treating severe pain with long-acting opioids—cost to the patient (which is a function of insurance coverage and formulary placement for insured patients) is a "main driver" of prescribing decisions. (RX-549.0007 (Michna Rep. ¶ 21); Michna, Tr. 2129)).

> 565. Indeed, clinicians are generally unaware of the prices of different long-acting opioid medications. As a result, clinicians are unlikely to change prescribing habits or switch a patient that is being successfully treated with Opana ER to another long-acting opioid based on minor fluctuations or differences in price. (CX5002 at 064 (¶ 180) (Savage Report); Michna, Tr. 2187 (stating he would only be aware of dramatic changes in price); CX4046 (Michna, Dep. at 149) ("Q. So are you ever aware of fluctuations in price for a specific brand of product? A. From day to day, no. I mean, I – it's the dramatic events that I mentioned to you.")).

RESPONSE TO FINDING NO. 565:

Complaint Counsel's Proposed Finding No. 565 is inaccurate. Doctors seek to avoid high out-of-pocket costs for patients, and they regularly do so by making prescribing decisions based on price and where a medication is located on an insurance company's formulary. (CX4046 (Michna, Dep. at 115-16); CX4044 (Addanki, Dep. at 148)). In fact, Complaint Counsel's economic expert, Professor Noll, admitted that doctors make prescribing decisions based on price and formulary tiering, among other issues. (Noll, Tr. 1505-06). Dr. Savage, Complaint Counsel's medical expert, similarly admitted that "the copay is one variable that may be considered" when making prescription choices—"clinical determinations are usually the first consideration and then copays." (CX4041 (Savage, Dep. at 138); *see* CX5002-063 (Savage Rep.

¶ 177) (noting that clinicians will "consciously consider costs" when they are "aware that the patient will need to pay out of pocket")).

Indeed, doctors are aware of drug prices when prescribing medications. When they enter a "drug order in the system, as [they are] ready to print it or electronically send the prescription to the pharmacy, [they] will get an immediate feedback as to whether that's a covered medication for that insurance company, also what level of additional pay that the patient has to pay at the pharmacy." (Michna, Tr. 2122). Doctors also receive feedback directly from patients, pharmacists, and drug manufacturers regarding drug costs and formulary tiering. (Michna, Tr. 2123; CX4046 (Michna, Dep. at 115-16)). Dr. Savage personally is not aware of drug prices because formulary tiering and what patients pay in copays "truly is outside [her] experience" since she is "a consultant in [her] practice area" and "the staff physicians who do the direct management of the patients deal with insurance companies." (CX4041 (Savage, Dep. at 117-18)). Finally, the citations to Dr. Michna's testimony are inaccurate and misleading. Dr. Michna did not testify that he is unaware of prices when prescribing medications; just the opposite. (Michna, Tr. 2122-23; CX4046 (Michna, Dep. at 115-16)). Indeed, in the testimony cited in the proposed finding, Dr. Michna discussed the ways and the extent to which he was aware of prices, and how they affected his prescribing behavior. (Michna, Tr. 2187-88 (discussing fluctuations in price and explaining "I'd be aware of it if there's dramatic changes"); CX4046 (Michna, Dep. at 148-49) ("I don't trawl the daily cost of all the pharmaceutical products, but I have a general idea.")).

> 566. As a result, pharmaceutical companies devote substantial resources to providing physicians with information about the therapeutic benefits of their drugs. (CX5000 at 029-30 (¶ 64) (Noll Report); Bingol, Tr. 1265 ("So, I mean, you take all this together and you create different strategies or promotional tactics in order to be able to effectively communicate why your product is different and why it would be needed by certain patient groups.")).

RESPONSE TO FINDING NO. 566:

Respondent has no specific response.

567. Average drug prices are strongly affected by state "generic substitution" law. All states have laws that allow or even require, under some circumstances, pharmacists to substitute a generic drug for a brand-name drug as long as the generic and the brand-name drug use the same active ingredient in the same dosage, form and method of delivery. (CX5000 at 030 (¶ 66) (Noll Report)).

RESPONSE TO FINDING NO. 567:

The first sentence of Complaint Counsel's Proposed Finding No. 567 violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." Professor Noll was not and is not qualified as an expert with respect to the pharmaceutical industry. (Noll, Tr. 1358). Moreover, the cited portion of Professor Noll's report contains no evidence or analysis to support the proposition.

Respondent has no specific response to the second sentence of Proposed Finding No. 567.

568. Most states allow pharmacists to engage in generic substitution only for generic drugs that the FDA has classified as therapeutically equivalent. Because generic oxymorphone ER is not therapeutically equivalent to the reformulated version of Opana ER, in most states' pharmacists cannot substitute the generic version for the brand-name version without first obtaining the written permission of the physician. (CX5000 at 030 (¶ 66) (Noll Report)).

RESPONSE TO FINDING NO. 568:

Complaint Counsel's Proposed Finding No. 568 is inaccurate and misleading. A pharmacist may substitute a non-AB-rated generic for a branded drug if the physician writes the chemical name of the drug, rather than the brand name, on the prescription. (JX-003-011 (¶ 72) (Second Set of Joint Stipulations)).

569. A common practice among third-party payers is to create a formulary that lists the drugs that qualify for some reimbursement and to classify these drugs into tiers on the basis of the perceived cost-effectiveness of the drug. The highest tier includes drugs that are most preferred within a therapeutic class. These drugs usually have lower co-payments and/or co-insurance rates to encourage their use. (CX5000 at 031 (¶ 68) (Noll Report)).

RESPONSE TO FINDING NO. 569:

Respondent has no specific response.

570. Normally the highest (most preferred) tier contains only the generic version of a drug if a generic is available. (CX5000 at 031 (¶ 68) (Noll Report); Bingol, Tr. 1319 ("But in general, the first tier is usually reserved for, let's say, generic products.")).

RESPONSE TO FINDING NO. 570:

Respondent has no specific response.

571. The existence of a generic drug is, by far, the most important competitive factor affecting drug prices. (Noll, Tr. 1524).

RESPONSE TO FINDING NO. 571:

Complaint Counsel's Proposed Finding No. 571 violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." Professor Noll was not and is not qualified as an expert with respect to the pharmaceutical industry. (Noll, Tr. 1358).

Proposed Finding No. 571 is also incomplete and misleading. Professor Noll testified that drug prices are "an interaction among buyers and sellers, and insurance companies are an important component, patients themselves are an important component, and the federal government is an important component." (Noll, Tr. 1523).

572. Economists have extensively studied the nature and extent of competition among different drugs. A great deal of this research has focused on the effect of generic entry on prices and sales of brand-name drugs because generic entry is, by far, the most important

source of price competition in the pharmaceutical industry. (CX5000 at 035 (¶ 76) (Noll Report)).

RESPONSE TO FINDING NO. 572:

Complaint Counsel's Proposed Finding No. 572 is improper and inadmissible. The Proposed Finding purports to summarize academic literature that is not in evidence and, if it were, that literature would be the best evidence of its contents.

573. Drugs within the same therapeutic class usually exhibit sufficiently extensive product differentiation that a brand-name drug usually faces, at best, weak price competition from other drugs in the same therapeutic class. (CX5000 at 035 (¶ 77) (Noll Report)).

RESPONSE TO FINDING NO. 573:

Complaint Counsel's Proposed Finding No. 573 violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." Professor Noll was not and is not qualified as an expert with respect to the pharmaceutical industry. (Noll, Tr. 1358).

574. Prior to the entry of a bioequivalent generic, the price of a drug typically is far above the competitive level. (CX5000 at 035 (¶ 77) (Noll Report)).

RESPONSE TO FINDING NO. 574:

Complaint Counsel's Proposed Finding No. 574 violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." Professor Noll was not and is not qualified as an expert with respect to the pharmaceutical industry. (Noll, Tr. 1358).

575. By comparison, the price of generic drugs after entry by a handful of generic firms typically is ten percent or less of the price of the brand-name drug, making generics far more important in reducing prices than the presence of other brand-name drugs in the same pharmacologic class. (CX5000 at 035 (¶ 77) (Noll Report)).

RESPONSE TO FINDING NO. 575:

Complaint Counsel's Proposed Finding No. 575 violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." Professor Noll was not and is not qualified as an expert with respect to the pharmaceutical industry. (Noll, Tr. 1358).

576. Within a few months after entry, generics take away most sales from the brand-name drug. The price of the first generic entrant typically is substantially below the price of the brand-name equivalent, and as more generic drugs enter, generic prices continue to fall. (CX5000 at 035-36 (¶ 78) (Noll Report)).

RESPONSE TO FINDING NO. 576:

Complaint Counsel's Proposed Finding No. 576 violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." Professor Noll was not and is not qualified as an expert with respect to the pharmaceutical industry. (Noll, Tr. 1358).

577. Thus generic entry can be used as a reasonable indicator or proxy of substantially lowered price for the product. (CX5000 at 072 (¶ 158 n.214) (Noll Report)).

RESPONSE TO FINDING NO. 577:

Complaint Counsel's Proposed Finding No. 577 is improper because it states a legal conclusion. The Proposed Finding is also unsupported and wrong. The cited portion of Professor Noll's report contains no evidence or analysis to support the proposition. Professor Noll's analysis is based on his scanning for any "visible effect" on Opana ER sales, a metric he never defined. (Noll, Tr. 1384). Professor Noll recognizes that a SSNIP test is the normal test used to determine close economic substitutes. (CX5000 at 017 (Noll Rep. ¶ 38)). But Professor Noll admits he did not conduct a SSNIP test. (Noll, Tr. 1514).

578. The smallest price difference between generic and brand-name drugs arise during the 180-day exclusivity period when a single generic firm is in the market as a first-filer. If a single independently-sold generic drug is available during the exclusivity period, its price averages about thirty percent less than the brand-name price. When generic entry occurs with no exclusivity period, generic prices are about fifty percent below the brand-name price during the first six months after generic entry. (CX5000 at 036 (¶ 78) (Noll Report)).

RESPONSE TO FINDING NO. 578:

Complaint Counsel's Proposed Finding No. 578 violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." Professor Noll was not and is not qualified as an expert with respect to the pharmaceutical industry. (Noll, Tr. 1358).

D. Generic versions of oxymorphone ER are uniquely close substitutes for Opana ER

579. Reformulated Opana ER is bioequivalent to Original Opana ER. Impax's oxymorphone ER is bioequivalent and therapeutically equivalent to Original Opana ER, but only bioequivalent to the reformulated version. (CX5000 at 038 (¶ 86) (Noll Report); Engle, Tr. 1703 (agreeing that Impax's generic was not AB-rated to the reformulated version of Opana ER)).

RESPONSE TO FINDING NO. 579:

While Respondent does not dispute that Impax's oxymorphone ER product was not AB-rated to the reformulated version of Opana ER, the remainder of Complaint Counsel's Proposed Finding No. 579 violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." Professor Noll was not and is not qualified as an expert with respect to the pharmaceutical industry. (Noll, Tr. 1358).

580. The most plausible candidates to be close economic substitutes for a brand-name drug are other drugs that contain the same API and are bioequivalent. (CX5000 at 038 (¶ 86) (Noll Report)).

RESPONSE TO FINDING NO. 580:

Complaint Counsel's Proposed Finding No. 580 violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." Professor Noll was not and is not qualified as an expert with respect to the pharmaceutical industry. (Noll, Tr. 1358).

581. When analyzing pharmaceutical product markets, one technique to determine whether drugs are close substitutes is to observe what happens to the price and sales volume of one drug when a generic version of another, functionally substitutable, drug is introduced. (Noll, Tr. 1374-1375).

RESPONSE TO FINDING NO. 581:

Complaint Counsel's Proposed Finding No. 581 violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." Professor Noll was not and is not qualified as an expert with respect to the pharmaceutical industry. (Noll, Tr. 1358).

582. Generic entry significantly erodes the market share of a therapeutically equivalent branded pharmaceutical product within a very rapid period of time. (CX4025 (Bingol, Dep. at 43)).

RESPONSE TO FINDING NO. 582:

Complaint Counsel's Proposed Finding No. 582 is not supported by the cited evidence. Mr. Bingol did not say anything about "therapeutically equivalent" products. He spoke only of generic products generally, and explained "[w]e monitored all matter. Competitive intelligence and generics are one component that you have to monitor as a course of normal due diligence in your business." (CX4025 (Bingol, Dep. at 43)).

583. Numerous documents show that both Endo and Impax anticipated that entry of Impax's generic oxymorphone ER would reduce the sale of Opana ER, and that this loss

would be far greater if generics were rated as therapeutically equivalent. (CX5000 at 043 (¶ 94) (Noll Report); *see also* CCF ¶¶ 590-98, 603-27, below).

RESPONSE TO FINDING NO. 583:

Complaint Counsel's Proposed Finding No. 583 violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." Moreover, to the extent Proposed Finding No. 583 purports to summarize and incorporate other findings, the individual findings cited do not support the Proposed Finding and are unreliable for the reasons set out in Respondent's replies to those findings.

584. These documents show that both Endo and Impax believed that a therapeutically equivalent generic version of Opana ER would quickly take nearly all of the branded drug's market share, even if Opana ER was reformulated and the generic entrant was not, and that the price of the generic would be much lower. These documents also show that Endo believed that entry by generic versions of Opana ER that were not therapeutically equivalent, while capturing a lower share of the market, still would have had a substantial competitive effect on Opana ER. These expectations imply that Opana ER and generic oxymorphone ER are close economic substitutes even if the generic is not therapeutically equivalent and, therefore, are sold in the same relevant product market. (CX5000 at 053-54 (¶ 115) (Noll Report)).

RESPONSE TO FINDING NO. 584:

Complaint Counsel's Proposed Finding No. 584 violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." Moreover, Proposed Finding No. 584 is improper because it states a legal conclusion.

1. Impax forecasted that entry of generic oxymorphone ER would have a unique impact on Opana ER sales and prices

585. When forecasting the average net selling price of its generic, and assuming that Impax would be the first and only generic on the market, Impax would assume that the average net price would be approximately 55% of the brand's WAC price. (Engle, Tr. 1716-17).

RESPONSE TO FINDING NO. 585:

Respondent has no specific response.

586. When there are more generics on the market, Impax expects that the additional generic competition will compete down the price. (Engle, Tr. 1717).

RESPONSE TO FINDING NO. 586:

Respondent has no specific response, except to clarify that, in the cited testimony, Mr. Engle was not speaking to Impax's general expectations, but rather to the assumptions he applied when forecasting, and the reasoning behind them. (Engle, Tr. 1717).

587. Impax's forecasts were based on the best information available to it at the time, and were an input into Impax's corporate plans. (Koch, Tr. 223-224).

RESPONSE TO FINDING NO. 587:

Respondent does not dispute that Mr. Koch would try to use the best information available to the company at the time he prepared a forecast, but the cited evidence does not support the remainder Complaint Counsel's Proposed Finding No. 587.

588. Impax relied on the forecasts its employees produced to inform both production planning and make management decisions. (Engle, Tr. 1710; Camargo, Tr. 958-960, 964).

RESPONSE TO FINDING NO. 588:

Respondent has no specific response.

589. In the ordinary course of its business, Impax consistently projected that therapeutically equivalent generic oxymorphone ER would quickly gain substantial market share. (CX5000 at 052 (¶ 113) (Noll Report); *see also* CCF ¶¶ 590-98).

RESPONSE TO FINDING NO. 589:

Complaint Counsel's Proposed Finding No. 589 violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by

fact witnesses or documents." Moreover, to the extent Proposed Finding No. 589 purports to summarize and incorporate other findings, the individual findings cited do not support the Proposed Finding and are unreliable for the reasons set out in Respondent's replies to those findings.

590. In February 2010, the "Upside" or more optimistic case of Impax's Five Year Plan showed that Impax expected that its generic oxymorphone ER would capture 50% of the brand's prescriptions in the first month it was on the market, June 2010. (CX0004 at 014 (Updated Five Year Plan); Engle, Tr. 1722, 1725).

RESPONSE TO FINDING NO. 590:

Complaint Counsel's Proposed Finding No. 590 is incomplete and misleading. Mr. Engle testified that his forecasts "assumed" things like launch dates and the amount of sales Impax could capture for purposes of modelling possible outcomes based on those assumptions. (Engle, Tr. 1710-11, 1719 (five-year plans are "draft[s] with many, many assumptions")). With respect to the amount of sales, he explained that he used the figure as a "milestone or marker that I generally default to *as a first step*" for purposes of a forecast. (Engle, Tr. 1711 (emphasis added)). With respect to the cited document in particular (CX0004), the document was not part of any normal planning process. (Engle, Tr. 1767). Mr. Engle did not testify that Impax "expected" anything as a result of the forecast, but rather that assumptions were used to understand possible outcomes, and that the forecast would not contain all relevant information. (Engle, Tr. 1720, 1766-67).

591. In February 2010, the "Upside" case of Impax's Five Year Plan showed that Impax expected that its generic oxymorphone ER would have a net price that was 55% of the brand WAC price. (CX0004 at 014 (Updated Five Year Plan); Engle, Tr. 1724).

RESPONSE TO FINDING NO. 591:

Complaint Counsel's Proposed Finding No. 591 is incomplete and misleading. Mr. Engle testified that his forecasts "assumed" things like launch dates and the amount of sales Impax could capture for purposes of modelling possible outcomes based on those assumptions. (Engle, Tr. 1710-11, 1719 (five-year plans are "draft[s] with many, many assumptions")). With respect to the cited document in particular (CX0004), the document was not part of any normal planning process. (Engle, Tr. 1767). Mr. Engle did not testify that Impax "expected" anything as a result of the forecast, but rather that assumptions were used to understand possible outcomes, and that the forecast would not contain all relevant information. (Engle, Tr. 1720, 1766-67).

592. Likewise, in the February 2010 Five Year Plan, Impax's "Base" or more conservative case indicated that Impax expected generic oxymorphone ER to capture 50% of the brand's prescriptions in the first month it was on the market, July 2011. (CX0004 at 015 (Updated Five Year Plan); Engle, Tr. 1726).

RESPONSE TO FINDING NO. 592:

Complaint Counsel's Proposed Finding No. 592 is incomplete and misleading. Mr. Engle testified that his forecasts "assumed" things like launch dates and the amount of sales Impax could capture for purposes of modelling possible outcomes based on those assumptions. (Engle, Tr. 1710-11, 1719 (five-year plans are "draft[s] with many, many assumptions")). With respect to the amount of sales, he explained that he used the figure as a "milestone or marker that I generally default to *as a first step*" for purposes of a forecast. (Engle, Tr. 1711 (emphasis added)). With respect to the cited document in particular (CX0004), the document was not part of any normal planning process. (Engle, Tr. 1767). Mr. Engle did not testify that Impax "expected" anything as a result of the forecast, but rather that assumptions were used to

understand possible outcomes, and that the forecast would not contain all relevant information. (Engle, Tr. 1720, 1766-67).

593. In the February 2010 Five Year Plan, Impax's "Base" case indicated that Impax expected generic oxymorphone ER would have a net price that was 35% of the brand WAC price. (CX0004 at 015 (Updated Five Year Plan); Engle, Tr. 1727-28).

RESPONSE TO FINDING NO. 593:

Complaint Counsel's Proposed Finding No. 593 is incomplete and misleading. Mr. Engle testified that his forecasts "assumed" things like launch date and the amount of sales Impax could capture for purposes of forecasting possible results. (Engle, Tr. 1710-11, 1719 (five-year plans are "draft[s] with many, many assumptions")). With respect to the cited document in particular (CX0004), the document was not part of any normal planning process. (Engle, Tr. 1767). Mr. Engle did not testify that Impax "expected" anything as a result of the forecast, but rather that assumptions were used to drive and understand possible outcomes, and that the forecast would not contain all relevant information. (Engle, Tr. 1720, 1766-67).

594. Impax's February 2010 Five Year Plan also showed that it expected additional generic competition to result in further price decreases relative to brand WAC price in August 2010 for the "Upside" case. (CX0004 at 014 (Updated Five Year Plan); Engle, Tr. 1732).

RESPONSE TO FINDING NO. 594:

Complaint Counsel's Proposed Finding No. 594 is incomplete and misleading. Mr. Engle testified that his forecasts "assumed" things like launch dates and the amount of sales Impax could capture for purposes of modelling possible outcomes based on those assumptions. (Engle, Tr. 1710-11, 1719 (five-year plans are "draft[s] with many, many assumptions")). With respect to the cited document in particular (CX0004), the document was not part of any normal planning process. (Engle, Tr. 1767). Mr. Engle did not testify that Impax "expected" anything

as a result of the forecast, but rather that assumptions were used to understand possible outcomes, and that the forecast would not contain all relevant information. (Engle, Tr. 1720, 1766-67).

595. In May 2010, the head of Impax's generics subsidiary, Chris Mengler, circulated a five-year plan that included Impax's expected net sales, market shares and substitution rates for generic oxymorphone ER. (CX0514 at 001, 004 (Impax Five Year Plan)).

RESPONSE TO FINDING NO. 595:

Respondent has no specific response other than to clarify that the cited evidence does not indicate that Impax expected each of the results. Five year plans instead utilize "many, many assumptions" to understand possible outcomes based on those assumptions. (Engle, Tr. 1710, 1719-20 (they "give a good range of possibilities")). Among those assumptions are substitution rates and market shares. (Engle, Tr. 1711, 1713-14). Moreover, these forecast would not contain all relevant information. (Engle, Tr. 1766-67).

596. In the May 2010 Five Year Plan "Upside" case, generic substitution was estimated to be 50% in June 2010, and 90% by October 2010. (CX0514 at 004 (Impax Five Year Plan)).

RESPONSE TO FINDING NO. 596:

Complaint Counsel's Proposed Finding No. 596 is incomplete and misleading because it omits the plain language of the document, which notes that the launch-date assumption in the forecast was an "obvious[] controversial element." (CX0514-001; *see* Engle, Tr. 1710-11, 1719 (five year plans are "draft[s] with many, many assumptions")).

597. In the May 2010 Five Year Plan "Base" case, which assumed that generic launch occurred in July 2011 and others followed immediately, generic penetration was 50% of prescriptions initially and 80% by October 2011. (CX0514 at 004 (Impax Five Year Plan)).

RESPONSE TO FINDING NO. 597:

Respondent has no specific response.

598. In the May 2010 Five Year Plan, Impax also projected that its generic launch would have a dramatic impact on the average price of oxymorphone ER. The "Upside" case anticipates that Impax's price for generic oxymorphone ER would be 55% of the price of Opana ER on launch and would fall to 5% of the price of Opana ER after the first year. In the "Base" case, Impax's estimated launch price was 35% of the price of Opana ER and steadily declined to 5% by the eleventh month. (CX0514 at 004 (Impax Five Year Plan)).

RESPONSE TO FINDING NO. 598:

Complaint Counsel's Proposed Finding No. 598 is incomplete and misleading. The cited evidence does not indicate that Impax "anticipated" anything. Rather, Impax used assumptions of sales price as a "milestone or marker that I generally default to *as a first step*" for purposes of forecasting possible outcomes. (Engle, Tr. 1711 (emphasis added)). Five year plans utilize "many, many assumptions" to understand possible outcomes. (Engle, Tr. 1710, 1719-20 (they "give a good range of possibilities")).

2. Endo recognized that entry of generic oxymorphone ER would have a unique impact on Opana ER sales and prices

599. For Endo, the entry of generic oxymorphone ER was a "worst-case scenario" for the Opana ER brand. (CX4025 (Bingol, Dep. at 74-75) (testifying that Endo's forecasts for Opana ER considered the entry of generic oxymorphone because "it was a worst-case scenario"); (CX4025 (Bingol, Dep. at 75-76) ("[A]n entry of a generic is – we would consider that to be a fairly negative impact to the overall business and somewhat of a worst-case scenario.")).

RESPONSE TO FINDING NO. 599:

Complaint Counsel's Proposed Finding No. 599 is incomplete and misleading. Mr. Bingol testified that when conducting projections in order to estimate the future performance of Opana ER, "an entry of a generic is -- we would consider that to be a fairly negative impact to the overall business and somewhat of a worst-cast scenario. So you want to plan for that and

show that potential impact. Whether or not it comes to pass is another question. . . . [F]orecasts, especially these types of assumptions, aren't always probability based. You can't really know." (CX4025 (Bingol, Dep. at 74-76)).

600. Endo ordinary business documents support the conclusion that Opana ER and generic oxymorphone ER are close economic substitutes and, therefore, in the same relevant market. (CX5000 at 043 (¶ 95) (Noll Report); *see also* CCF ¶¶ 603-27, below)).

RESPONSE TO FINDING NO. 600:

Complaint Counsel's Proposed Finding No. 600 violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." Moreover, to the extent Proposed Finding No. 600 purports to summarize and incorporate other findings, the individual findings cited do not support the Proposed Finding and are unreliable for the reasons set out in Respondent's replies to those findings.

601. Endo regularly produced and obtained forecasts of future sales volume and net sales, and Endo relied on these forecasts for business planning purposes and to inform investors. As such, Endo took great pains in establishing the most reliable methodology possible for its forecasts. (CX2607 at 013 (¶ 30) (Lortie Decl.)).

RESPONSE TO FINDING NO. 601:

Respondent has no specific response other than to clarify that Mr. Lortie's declaration was written in August 2013, and says nothing about Endo's behavior at the time of the Endo-Impax settlement. (CX2607-024).

602. Endo's forecasts are reliable evidence of its expectations because Endo prepared such forecasts in order to make budgeting decisions and set its goals. (Cuca, Tr. 604-605, 606-607).

RESPONSE TO FINDING NO. 602:

While Respondent does not dispute that Endo used forecasts to set goals and that forecasts of revenues were part of the budgeting process, (Cuca, Tr. 604-05), Mr. Cuca did not testify that Endo's forecasts were reliable evidence of Endo's expectations. In fact, the record makes clear that Endo's forecasts were based on "many" assumptions and Endo was looking at "any possible scenario." (CX4025 (Bingol, Dep. at 59); Bingol, Tr. 1310 ("We have to consider all scenarios")). The forecasts were "based on scenarios that we had created, I mean, the accuracy of which are always debatable." (Bingol, Tr. 1303). And many of the assumptions were actually total unknowns. (Bingol, Tr. 1307 ("JUDGE CHAPPELL: Okay. Well, I don't want you to guess[], so according to this document, whatever those claims were you didn't know. THE WITNESS: Well, we would be -- that's correct."); Cuca, Tr. 662-63). But Endo still forecast different scenarios to "analyze the full range of potential outcomes." (Cuca, Tr. 663-64).

603. In December 2007, Endo estimated that the present value of sales of Opana ER could vary by $844 million, depending on whether Reformulated Opana ER was introduced before generic entry and whether it could successfully keep generics off the market through a citizen petition. (CX2578 at 008 (Opana Brand LCM Update) (showing sales NPV ranging from $18 million, if Endo did not beat generics or succeed with a citizen petition, to $862 million if Endo beat generics and was successful with a citizen petition)).

RESPONSE TO FINDING NO. 603:

Complaint Counsel's Proposed Finding No. 603 is incomplete and misleading in its suggestion that "Endo" "estimated" anything. The cited document is a draft from 2007, just after original Opana ER launched. (CX2578-009 ("draft"); *see* Bingol, Tr. 1298-99 (discussing "draft" language: "JUDGE CHAPPELL: . . . it says it's a draft. Why would he have presented a draft to anybody?")).

604. In its 2007 "OPANA Brand LCM Update," Endo estimated that if it beat generics to market with Reformulated, but was unable to force generics off the market with a citizen petition, generics would capture about 50% of the market. (CX2578 at 009 (Opana Brand LCM Update)). [redacted] (CX5000 at 177-83 (Exhibits 2A1 through 2A7) (*in camera*)).

RESPONSE TO FINDING NO. 604:

The first sentence of Complaint Counsel's Proposed Finding No. 604 is incomplete and misleading in its suggestion that "Endo" "estimated" anything. The cited document is a draft from 2007, just after original Opana ER launched. (CX2578-009 ("draft"); *see* Bingol, Tr. 1298-99 (discussing "draft" language: "JUDGE CHAPPELL: . . . it says it's a draft. Why would he have presented a draft to anybody?")).

The second sentence of Proposed Finding No. 604 violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents."

605. In January 2010, Endo forecasted a substantial decline in Opana ER sales if it was unable to launch its reformulated product ahead of generic entry. (CX2724 at 006 (Endo Commercial Strategy Scenarios); Bingol, Tr. 1309-10 (stating that the blue/green line is "a scenario in which we have Opana ER only, the current formulation, with generics."); CX4025 (Bingol, Dep. at 59-60) (agreeing that the dashed blue line showed a substantial decrease in value following entry of generic Opana ER)).

RESPONSE TO FINDING NO. 605:

Complaint Counsel's Proposed Finding No. 605 is incomplete and misleading because it ignores the testimony of Mr. Bingol, the author of the cited document (CX2724). Mr. Bingol explained that the forecast was based on "many" assumptions and Endo was looking at "any possible scenario." (CX4025 (Bingol, Dep. at 59); Bingol, Tr. 1310 ("We have to consider all scenarios")). It was "based on scenarios that we had created, I mean, the accuracy of which are always debatable." (Bingol, Tr. 1303). And many of the assumptions were actually total

unknowns. (Bingol, Tr. 1307 ("JUDGE CHAPPELL: Okay. Well, I don't want you to guess[], so according to this document [CX2724], whatever those claims were you didn't know. THE WITNESS: Well, we would be -- that's correct."); Cuca, Tr. 662-63). But Endo still forecast different scenarios regarding the future of its Opana ER product to "analyze the full range of potential outcomes." (Cuca, Tr. 663-64).

> 606. In February 2010, Endo prepared a projection of Opana ER sales after generic entry that was based on the assumption that generic entry would occur in July 2011. For the second quarter of 2011, the last quarter before launch, Endo forecast that 200,500 prescriptions would be written for Opana ER. In the third quarter, after generic launch, Opana ER prescriptions would fall to 117,900. By the fourth quarter of 2011, the number of prescriptions for Opana ER would drop to 29,100, where roughly they would remain through the rest of the forecast (the last quarter of 2012). (CX1320 at 007 (Endo 2010 Three Year Plan)).

RESPONSE TO FINDING NO. 606:

Complaint Counsel's Proposed Finding No. 606 is incomplete and misleading. Endo did not "project" a loss in sales, it simply assumed lost sales for purposes of the particular forecast. (CX1320-007 (describing "assumptions")). It was Endo's practice to forecast different scenarios regarding the future of its Opana ER product to "analyze the full range of potential outcomes." (Cuca, Tr. 663-64). Endo did not know if any of the many different assumptions contained in its forecasts would come true. (Cuca, Tr. 662-63). Endo simply forecasted "a number of different potential outcomes over the course of years," the accuracy of which were "always debatable." (Bingol, Tr. 1292, 1303).

> 607. As of March 2010, Endo's 10 Year Outlook, assuming generic Opana ER launch in June of 2010, projected that Opana ER's revenues would peak in 2010 at $215 million, fall to $137 million in 2011, and then decrease to $34.8 million in 2012. (CX2564 at 013, 099 (Endo 10 Year Forcast)).

RESPONSE TO FINDING NO. 607:

Complaint Counsel's Proposed Finding No. 607 is incomplete and misleading. Endo did not "project" a loss in sales, it simply assumed lost sales at a set rate for purposes of the particular forecast. (CX2564-094 (describing "assumptions")). It was Endo's practice to forecast different scenarios regarding the future of its Opana ER product to "analyze the full range of potential outcomes." (Cuca, Tr. 663-64). Endo did not know if any of the many different assumptions contained in its forecasts would come true. (Cuca, Tr. 662-63). Endo simply forecasted "a number of different potential outcomes over the course of years," the accuracy of which were "always debatable." (Bingol, Tr. 1292, 1303).

608. In May 21, 2010, as part of the patent litigation against Impax, Endo's Senior Director for the Opana brand submitted a declaration in support of Endo's motion for a preliminary injunction against Impax. (CX3273 at 001 (¶ 1) (Bingol Decl.)).

RESPONSE TO FINDING NO. 608:

Respondent has no specific response.

609. In Mr. Bingol's May 2010 declaration, he stated under oath that "in the absence of a generic substitute for Opana ER, Endo forecasts continued growth of the Opana franchise until expiration of the patents-in-suit." (CX3273 at 005 (¶ 11) (Bingol Decl.)).

RESPONSE TO FINDING NO. 609:

Respondent has no specific response.

610. However, Endo recognized the unique and disastrous effects a generic launch would have on its Opana ER sales, projecting that it would lose at least 70-80% market share within three months of generic entry. (CX3273 at 007 (¶ 17) (Bingol Decl.) ("In the ordinary course of business, Endo has projected that it will lose at least 70-80% of its market share within three months of the launch of a generic substitute for Opana ER in the commercially significant tablet strengths . . ."); CX3273 at 008 (¶ 18) (Bingol Decl.) ("Endo anticipates that upon launch of generic OPANA ER by Impax, Impax will set the price 15-20 percent lower than the price of Endo's branded price during Impax's 180-day period of exclusivity.")).

RESPONSE TO FINDING NO. 610:

Respondent has no specific response other than to note that Mr. Bingol did not state that generic entry would be "unique and disastrous," or that a launch was imminent: "Endo has been planning that the launch of a generic substitute for Opana ER in these higher tablet strengths will not occur until at least September 2013." (CX3273-007-08).

611. In January 2011, Endo was estimating that Reformulated Opana ER would suffer 85% erosion in 2013 upon entry of AB rated generics, and 40-50% erosion if generic formulations were not AB rated. (CX2520 at 172 (Long-Term Opana ER Forecast Impact); *see also* CX2791 at 005 (2010 Opana Three Year Plan) (assuming 15% brand volume remains three months after generic entry)). [redacted] (CX5000 at 177-83 (Exhibits 2A1 through 2A7) (*in camera*)).

RESPONSE TO FINDING NO. 611:

The first sentence of Complaint Counsel's Proposed Finding No. 611 is incomplete and misleading. Endo did not "estimate" that it would lose 85 percent of sales, it simply assumed it for purposes of the forecast. (CX2520-172; CX2791-005). Endo did not know if any of the many different assumptions contained in its forecasts would come true. (Cuca, Tr. 662-63). The Proposed Finding also ignores the testimony of Mr. Bingol, who testified that Endo always forecast "a number of different potential outcomes over the course of years," but that the accuracy of such forecasts were "debatable." (Bingol, Tr. 1292, 1303).

The second sentence of Proposed Finding No. 611 violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents."

612. In May 2011, Endo's Senior Director of Oral Pain Solutions, Demir Bingol emailed a chart illustrating the significance of eliminating the risk of generic entry for Opana ER. It showed that the estimated demand for Opana ER prior to generic settlement was substantially lower than the estimated demand following the settlement with Impax. Moreover, the estimated demand was substantially lower before the settlement because

there was a risk of generic entry before the settlement. (CX2732 at 002 (Opana ER Demand Justification); CX4025 (Bingol, Dep. at 95)).

RESPONSE TO FINDING NO. 612:

Complaint Counsel's Proposed Finding No. 612 is incomplete, misleading, and not supported by the cited evidence. The cited evidence does not discuss "eliminating the risk of generic entry." Moreover, the document states it is "[s]trictly in draft" and "Draft- Not for Distribution." (CX2732-001-02). Finally, Endo "plan[ned] for different eventualities" and analyzed "different scenarios" and different "assumption[s]" about launch. (CX4025 (Bingol, Dep. at 31-32, 95-96) ("I don't know that I'm qualified to answer what the level of risk was for other products, but certainly there was a settlement here.")).

613. In December 2011, Endo's 10 Year Outlook compared a "Base" case and more conservative "Downside" case. The "Base" case assumed Reformulated Opana ER launch in 2012, and generic entry in 2017. (CX2579 at 009 (Endo 10 Year Revenue Outlook)). The "Downside" case assumed Reformulated Opana ER launch in 2012, and AB rated generic entry in 2013. (CX2579 at 011 (Endo 10 Year Revenue Outlook)). In the "Base" projection, Reformulated Opana ER revenues grew from $262.5 million in 2012 to $744.2 million in 2016, followed by a decline to $455.4 million in 2017. (CX2579 at 003 (Endo 10 Year Revenue Outlook)). In the "Downside" case, revenues of Reformulated Opana ER would peak at $233.4 million in 2012, then fall to $142.1 million in 2013. (CX2579 at 007 (Endo 10 Year Revenue Outlook)).

RESPONSE TO FINDING NO. 613:

While Respondent does not dispute that the cited figures appear in the cited document, Complaint Counsel's Proposed Finding No. 613 is incomplete and misleading. The cited document contained additional scenarios, and other forecasting assumptions, including sales erosion. (CX2579-009-11). Indeed, it was Endo's practice to forecast different scenarios regarding the future of its Opana ER product to "analyze the full range of potential outcomes." (Cuca, Tr. 663-64). Endo did not know if any of the many different assumptions contained in its forecasts would come true. (Cuca, Tr. 662-63). Endo simply forecasted "a number of different

potential outcomes over the course of years," the accuracy of which were "always debatable." (Bingol, Tr. 1292, 1303).

614. In August 2012, Endo submitted a "Citizen Petition" requesting that the FDA determine that Original Opana ER was withdrawn from the market for safety reasons. (CX3203 at 030 (Endo's Citizen Petition)).

RESPONSE TO FINDING NO. 614:

Respondent has no specific response.

615. In November 2012, Endo sued the FDA to obtain a court order to require that the FDA rule on its citizen petition, which would have the effect of prohibiting ANDA filers from selling generic oxymorphone ER. (CX1223 at 002 (Endo Complaint Against FDA)).

RESPONSE TO FINDING NO. 615:

Respondent has no specific response.

616. In its 2012 lawsuit against the FDA, Endo submitted a sworn declaration from Chief Operating Officer Julie H. McHugh asserting that, if the FDA waited until May 10, 2013 to make its withdrawn-for-safety determination, and Impax entered the market with its generic oxymorphone ER on January 1, 2013, Endo projected that Reformulated Opana ER annualized net sales would decrease by an amount up to $135 million based on standard generic erosion rates and marketplace dynamics. (CX3204 at 037 (Endo's opposition to motions to dismiss filed by the FDA and Impax)).

RESPONSE TO FINDING NO. 616:

While Respondent does not dispute that the cited language appears in the cited document, Complaint Counsel's Proposed Finding No. 616 is incomplete and misleading. Endo subsequently admitted that Impax's actual "generic sales have had a relatively small effect on Opana ER." (CX2607-010-11 ("Endo has not had to significantly discount its branded Opana ER CRF beyond previous discount rates and loss of market share has been relatively mild")).

617. In her 2012 declaration, Endo's COO further stated under oath that Endo projected – based on standard generic erosion models – that Impax would garner a

significant share of Endo's Reformulated Opana ER market share if it entered the market with its generic oxymorphone ER in January 1, 2013. (CX3204 at 038 (Endo's opposition to motions to dismiss filed by the FDA and Impax)).

RESPONSE TO FINDING NO. 617:

While Respondent does not dispute that the cited language appears in the cited document, Complaint Counsel's Proposed Finding No. 617 is incomplete and misleading. Endo subsequently admitted that Impax's actual "generic sales have had a relatively small effect on Opana ER." (CX2607-010-11 ("Endo has not had to significantly discount its branded Opana ER CRF beyond previous discount rates and loss of market share has been relatively mild")).

618. In December 2012, Endo projected revenues of Reformulated Opana ER for 2013. At that time Endo knew that Impax could launch in January 2013, that other generics potentially could launch six months later, and that these generics would not be therapeutically equivalent. Endo projected that if the FDA ruled in its favor on the citizen petition, Reformulated Opana ER would regain 95% of the sales lost to Impax and achieve sales in 2013 of $236 million. If the FDA did not order generics off the market, Endo estimated that 2013 Opana ER sales would be $154 million. (CX2555 at 003 (Opana ER: Protect and Grow Strategy)).

RESPONSE TO FINDING NO. 618:

While Respondent does not dispute that the cited figures appear in the cited document, Complaint Counsel's Proposed Finding No. 618 is incomplete and misleading. Endo subsequently admitted that Impax's actual "generic sales have had a relatively small effect on Opana ER." (CX2607-010-11 ("Endo has not had to significantly discount its branded Opana ER CRF beyond previous discount rates and loss of market share has been relatively mild")).

619. In April 2013, Endo personnel circulated a document entitled "Opana ER Financial Scenario Overview." This document states that if generics were removed from the market in mid-2013, the erosion of Endo's market share in oxymorphone ER market would be reversed and Endo would earn $235 to $243 million in net sales in 2013. (CX2519 at 006 (Opana ER Financial Scenario Overview)).

RESPONSE TO FINDING NO. 619:

Complaint Counsel's Proposed Finding No. 619 is incomplete and misleading. The Proposed Finding cites only a document marked "DRAFT Not Approved by Management." (CX2519-001; *see* Bingol, Tr. 1298-99 (discussing identical "draft" language: "JUDGE CHAPPELL: . . . it says it's a draft. Why would he have presented a draft to anybody?")). The document, moreover, states that even if one or two generics stayed on the market, Endo could earn $230 million in sales. (CX2519-006). Finally, Endo subsequently admitted that Impax's actual "generic sales have had a relatively small effect on Opana ER." (CX2607-010-11 ("Endo has not had to significantly discount its branded Opana ER CRF beyond previous discount rates and loss of market share has been relatively mild")).

620. Endo's 2013 Financial Scenario Overview also stated that, if generics remained on the market for the full year, as many as four generics might enter by mid-2013, Endo's share of oxymorphone ER sales volume would erode by 85% by December, and Endo would earn only $130 million in net sales in 2013. (CX2519 at 006 (Opana ER Financial Scenario Overview)).

RESPONSE TO FINDING NO. 620:

Complaint Counsel's Proposed Finding No. 620 is incomplete and misleading. The Proposed Finding cites only a document marked "DRAFT Not Approved by Management." (CX2519-001; *see* Bingol, Tr. 1298-99 (discussing identical "draft" language: "JUDGE CHAPPELL: . . . it says it's a draft. Why would he have presented a draft to anybody?")). The document, moreover, states that even if one or two generics stayed on the market, Endo could earn $230 million in sales with only 10 percent erosion. (CX2519-006). Finally, Endo subsequently admitted that Impax's actual "generic sales have had a relatively small effect on Opana ER." (CX2607-010-11 ("Endo has not had to significantly discount its branded Opana ER CRF beyond previous discount rates and loss of market share has been relatively mild")).

621. In May 2013, after Impax had entered, another Endo document set forth further estimates of the consequences of limiting generic competition. Three market conditions were examined: (1) the FDA removal of generics from the market, (2) no new generic launches, and (3) at least three generics on the market by the end of 2013. Estimated 2014 revenues for Reformulated Opana ER under these three scenarios are $315 million, $226 million, and $35 million, respectively. (CX3202 (Opana ER Scenario Request)).

RESPONSE TO FINDING NO. 621:

Respondent has no specific response.

622. On August 5, 2013, in support of a request for a preliminary injunction against Actavis and Roxane, Endo's Senior VP and Head of Branded Pharmaceuticals, Brian Lortie, submitted a declaration stating that "If additional Opana ER Original Formulation generic products are approved and marketed, the market for Endo's branded product will be rapidly and irreversibly devastated." (CX2607 at 012 (¶ 29) (Lortie Decl.)).

RESPONSE TO FINDING NO. 622:

While Respondent does not dispute that the quoted language appears in the cited document, Complaint Counsel's Proposed Finding No. 622 is incomplete and misleading. Mr. Lortie's declaration has nothing to do with Impax and admits that Impax's actual "generic sales have had a relatively small effect on Opana ER." (CX2607-010-11 ("Endo has not had to significantly discount its branded Opana ER CRF beyond previous discount rates and loss of market share has been relatively mild")).

623. Absent an injunction Mr. Lortie predicted Endo's market share would shrink, the price of Opana ER would be driven down, and that "the more competitors, the faster and more profound will be Endo's loss of market share and revenue." (CX2607 at 012 (¶ 29) (Lortie Decl.)).

RESPONSE TO FINDING NO. 623:

While Respondent does not dispute that the quoted language appears in the cited document, Complaint Counsel's Proposed Finding No. 623 is incomplete and misleading. Mr. Lortie's declaration has nothing to do with Impax and admits that Impax's actual "generic sales have had a relatively small effect on Opana ER." (CX2607-010-11 ("Endo has not had to

significantly discount its branded Opana ER CRF beyond previous discount rates and loss of market share has been relatively mild")).

624. In its 2013 Litigation against Actavis and Roxane, Endo also submitted a declaration from Henry G. Grabowski, Professor Emeritus of Economics at Duke University. Professor Grabowski concluded that the launch of generic oxymorphone ER by Actavis and Roxane was likely to "result in substantial price erosion" and that "Endo should expect the magnitude and pace of price erosion to increase as additional generic versions of Opana ER enter the marketplace." (CX2609 at 015 (¶¶ 35, 36) (Grabowski Decl.)).

RESPONSE TO FINDING NO. 624:

Respondent has no specific response other than to clarify that the document has nothing to do with Impax or the Endo-Impax settlement in 2010.

625. Endo predicted, in multiple forecasts, the substantial impact of additional generic entry on its sales of Opana ER. (CX2607 at 013 (¶ 31) (Lortie Decl.) ("Each of our forecasts have demonstrated the enormous impact the introduction of additional generic products will have on the market for Endo's branded product")).

RESPONSE TO FINDING NO. 625:

While Respondent does not dispute that the quoted language appears in the cited document, Complaint Counsel's Proposed Finding No. 625 is incomplete and misleading. Mr. Lortie's declaration has nothing to do with Impax and admits that Impax's actual "generic sales have had a relatively small effect on Opana ER." (CX2607-010-11 ("Endo has not had to significantly discount its branded Opana ER CRF beyond previous discount rates and loss of market share has been relatively mild")).

626. In August 2013, Endo predicted the dramatic effect of additional generic competition, estimating that its net sales in 2014 would be about $118 million lower, and 2015 net sales would be about $135 million lower if multiple generics were allowed on the market. (CX2607 at 015 (¶ 35) (Lortie Decl.)).

RESPONSE TO FINDING NO. 626:

While Respondent does not dispute that the language appears in the cited document, Complaint Counsel's Proposed Finding No. 626 is incomplete and misleading. Mr. Lortie's declaration has nothing to do with Impax and admits that Impax's actual "generic sales have had a relatively small effect on Opana ER." (CX2607-010-11 ("Endo has not had to significantly discount its branded Opana ER CRF beyond previous discount rates and loss of market share has been relatively mild")).

627. In September 2013, as part of its appeal of a District Court ruling denying an injunction against Actavis, Endo argued that further generic entry by Actavis in the oxymorphone ER market would irreparably harm Endo by causing the prices and sales of Opana ER to fall. (CX2608 at 013 (Endo's reply in support of motion for an injunction pending appeal)).

RESPONSE TO FINDING NO. 627:

Respondent has no specific response other than to clarify that the cited document has nothing to do with Impax or the Endo-Impax settlement.

3. Data available since the entry of generic oxymorphone ER confirms the unique impact of such generic entry on Opana ER sales and prices

628. The proposition that generic oxymorphone ER is a close economic substitute for Opana ER can be tested by examining the effect of generic entry on the sales and prices of Opana ER and the total sales and average prices of all forms of oxymorphone ER. These data are shown in Exhibits 2A and 2B of the Noll Report. (CX5000 at 053-54 (¶ 116) (Noll Report)).

RESPONSE TO FINDING NO. 628:

Complaint Counsel's Proposed Finding No. 628 is both unsupported and wrong. Professor Noll's analysis is based on his scanning for any "visible effect" on Opana ER sales, a metric he never defined. (Noll, Tr. 1384). Professor Noll recognizes that a SSNIP test is the

normal method used to determine close economic substitutes. (CX5000 at 017 (¶ 38)). But Professor Noll admits he did not conduct a SSNIP test. (Noll, Tr. 1514).

629. Exhibits 2A1 through 2A7 of the Noll Report show the total number of prescriptions of Opana ER and generic oxymorphone ER by quarter for each available dose. (CX5000 at 054 (¶ 117) (Noll Report); CX5000 at 177-83 (Exhibits 2A1-7) (Noll Report)).

RESPONSE TO FINDING NO. 629:

Respondent has no specific response.

630. The 5 mg 10 mg, 20 mg, 30 mg, and 40 mg doses, all of which were launched after Reformulated Opana ER was introduced, exhibit a general pattern. [redacted] (CX5000 at 055 (¶ 119) (Noll Report); CX5000 at 177, 179, 181-183 (Exhibits 2A1, 2A3, 2A5, 2A6 and 2A7) (Noll Report) (*in camera*)).

RESPONSE TO FINDING NO. 630:

Complaint Counsel's Proposed Finding No. 630 violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." Any data speaks for itself.

631. With respect to the 7.5 mg and 15 mg doses, Endo did not attempt to compete with Actavis when it first entered, curtailing sales before entry and losing all sales within months thereafter. Endo restarted selling these doses when Reformulated Opana ER was introduced. [redacted] (CX5000 at 054-55 (¶ 118) (Noll Report); CX5000 at 178, 180 (Exhibits 2A2, 2A4) (Noll Report) (*in camera*)).

RESPONSE TO FINDING NO. 631:

Complaint Counsel's Proposed Finding No. 631 violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." Any data speaks for itself.

632. [redacted] (CX5000 at 054-55 (¶ 118) (Noll Report); CX5000 at 178, 180 (Exhibits 2A2, 2A4) (Noll Report) (*in camera*)).

RESPONSE TO FINDING NO. 632:

Complaint Counsel's Proposed Finding No. 632 violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." Any data speaks for itself.

633. Exhibits 2B1 through 2B7 of the Noll Report show the average net realized price per tablet of prescriptions for each of the seven doses of Opana ER, generic oxymorphone ER, and all formulations of oxymorphone ER. These data are actual average realized prices as derived from the financial records of Endo, Actavis and Impax. Data have not been produced by Endo and Actavis for the entire period that each was selling oxymorphone ER. (CX5000 at 055 (¶ 120, ¶ 120 n.139) (Noll Report); CX5000 at 184-190 (Exhibits 2B1-7) (Noll Report)).

RESPONSE TO FINDING NO. 633:

Respondent has no specific response other than to note that the data speaks for itself, but is incomplete and does not consider other long-acting opioid products.

634. [redacted] (CX5000 at 055 (¶ 120) (Noll Report); CX5000 at 184 (Exhibits 2B1) (Noll Report) (*in camera*)).

RESPONSE TO FINDING NO. 634:

Complaint Counsel's Proposed Finding No. 634 violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." Any data speaks for itself, but is incomplete and does not consider other long-acting opioid products. Finally, Respondent objects to the use of the phrase [redacted] as vague and ambiguous.

635. [redacted] (CX5000 at 055 (¶ 120) (Noll Report); CX5000 at 185, 187 (Exhibits 2B2, 2B4) (Noll Report) (*in camera*)).

RESPONSE TO FINDING NO. 635:

Complaint Counsel's Proposed Finding No. 635 violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." Any data speaks for itself, but is incomplete and does not consider other long-acting opioid products.

636. [redacted] (CX5000 at 055-56 (¶ 120) (Noll Report); CX5000 at 186, 188-190 (Exhibits 2B3, 2B5-7) (Noll Report) (*in camera*)).

RESPONSE TO FINDING NO. 636:

Complaint Counsel's Proposed Finding No. 636 violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." Any data speaks for itself, but is incomplete and does not consider other long-acting opioid products. Professor Noll, moreover, was not and is not qualified as an

expert regarding issues with respect to the pharmaceutical industry. (Noll, Tr. 1358). Finally, Respondent objects to the use of the phrase [redacted] as vague and ambiguous.

637. The price data show that generic entry captured market share by offering a substantially lower price. (CX5000 at 056 (¶ 120) (Noll Report)).

RESPONSE TO FINDING NO. 637:

Complaint Counsel's Proposed Finding No. 637 violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." Any data speaks for itself, but is incomplete and does not consider other long-acting opioid products.

638. The beneficial competitive effects of a second generic entrant are confirmed by the subsequent entrance of Actavis. In September 2013, eight months after Impax's launch, Actavis launched generic versions of the five major dosages of oxymorphone ER. This entry caused Impax to lower its price of oxymorphone ER. (CX5000 at 054 (¶ 121) (Noll Report)).

RESPONSE TO FINDING NO. 638:

Complaint Counsel's Proposed Finding No. 638 violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." Respondent also objects to the use of the phrase "beneficial competitive effects" as vague and ambiguous.

639. Impax's Vice President for Sales and Marketing of Generics testified in his deposition that Impax had to lower its price to meet competition from Actavis. (CX4038 (Engle, Dep. at 116-17, 118-19)). Similarly, Impax's former President of Global (Impax's generics division) testified that Impax defended its generics business from Actavis by dropping its price. (CX4021 (Ben-Maimon, Dep. at 131-32)).

RESPONSE TO FINDING NO. 639:

Complaint Counsel's Proposed Finding No. 639 is incomplete, inaccurate, and misleading because it misrepresents the testimony of Mr. Engle and Dr. Ben-Maimon. Mr.

Engle testified that Impax would "periodically" lower prices. (CX4038 (Engle, Dep. at 119)). Dr. Ben-Maimon said that she did not recall whether Impax's prices were ever lowered. (CX4021 (Ben-Maimon, Dep. at 132)).

640. Impax's February 2014 generics division board presentation noted "Actavis launched in Sept 2013 – Defended vigorously except for a few small accounts." (CX2537 at 013 (Impax Board Meeting Presentation)). Similarly, the December 2014 generics division board presentation noted "Oxymorphone ER sales continued to experience pricing pressure from Actavis with Global defending all price challenges." (CX3140 at 015 (Impax Board Meeting Presentation)).

RESPONSE TO FINDING NO. 640:

Respondent has no specific response.

641. The sales and price data for oxymorphone ER reveal that generic entry caused Opana ER to lose market share and the average price of oxymorphone ER to fall, although these outcomes were more protracted than would have been expected had the generics been rated therapeutically equivalent substitutes for Opana ER. (CX5000 at 056 (¶ 122) (Noll Report)).

RESPONSE TO FINDING NO. 641:

Complaint Counsel's Proposed Finding No. 641 violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." Any data speaks for itself, but is incomplete and does not consider other long-acting opioid products.

642. The evidence shows that nearly half of the sales of branded Opana ER diverted to sales of generic oxymorphone. At the time generics entered, the market for Opana ER could not have been competitive, or else the price would not have fallen as dramatically as it did and the shift to generics would not have been as great. (Noll, Tr. 1380-81).

RESPONSE TO FINDING NO. 642:

Complaint Counsel's Proposed Finding No. 642 violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by

fact witnesses or documents." Proposed Finding No. 642 is also improper because it states a legal conclusion.

643. These results support the conclusion that generic oxymorphone ER imposes a competitive constraint on Opana ER, which implies that generic and brand-name oxymorphone ER are in the same relevant product market. (CX5000 at 056-57 (¶ 122) (Noll Report)).

RESPONSE TO FINDING NO. 643:

Complaint Counsel's Proposed Finding No. 643 is improper because it states a legal conclusion, not a fact.

644. Under the "smallest market principle" the relevant market inquiry can end with inclusion of generic versions of oxymorphone ER. Opana ER and oxymorphone ER are the minimum number of products that, if sold by a single firm (hypothetical monopolist) would command prices above the competitive level. (CX5000 at 017 (¶ 38) (Noll Report); Noll, Tr. 1368-69 (defining a relevant antitrust market)).

RESPONSE TO FINDING NO. 644:

Complaint Counsel's Proposed Finding No. 644 is improper because it states a legal conclusion, not a fact.

4. Impax considered only the market for Opana ER when evaluating the market opportunity for its generic oxymorphone ER product

645. The primary way that Impax makes sales of an AB-rated generic drug is through substitution for the branded product. (Engle, Tr. 1703).

RESPONSE TO FINDING NO. 645:

Respondent has no specific response.

646. When Impax assesses the potential market opportunity for a new generic drug, it looks at the size of the corresponding brand's sales. (Reasons, Tr. 1219).

RESPONSE TO FINDING NO. 646:

Respondent has no specific response, except to clarify that this approach must be understood in the larger context that generic companies like Impax achieve generic sales primarily through substitution of generic products for the corresponding brand-name product. (Mengler, Tr. 522; Engle, Tr. 1703).

647. The best way to estimate the size of a generic market opportunity is to look at the size of the brand plus the existing generic products. (Reasons, Tr. 1219-20; CX4020 (Reasons, Dep. at 74) ("In the generic industry, generally . . . the size of the brand and existing generics is used to estimate the potential opportunity of your own generics."); CX4037 (Smolenski, Dep. at 48) ("[G]enerally speaking, doing generic forecasting, you would focus specifically on the reference listed product.")).

RESPONSE TO FINDING NO. 647:

Respondent has no specific response, except to clarify that this approach must be understood in the larger context that generic companies like Impax achieve generic sales primarily through substitution of generic products for the corresponding brand-name product. (Mengler, Tr. 522; Engle, Tr. 1703).

648. In a December 2012 Board of Directors presentation, Impax indicated that the market value of the oxymorphone ER dosage strengths on which Impax was first to file was $450 million. Consistent with Impax's general practice, this market value included only Opana ER, and did not include any other products. (CX3119 at 020 (December 4, 2012 Board of Directors Presentation); CX4020 (Reasons, Dep. at 75-76)).

RESPONSE TO FINDING NO. 648:

Respondent has no specific response to the first sentence of Proposed Finding No. 648. The second sentence of Proposed Finding No. 648 is not supported by the cited evidence and lacks foundation. The cited evidence says nothing about Impax's general practice. Mr. Reasons also testified that he was not sure what was included in the market value. (CX4020 (Reasons, Dep. at 73-74) ("Q. Is anything else included in that market value? A. I don't know.")).

649. In other contemporaneous business documents, Impax considered only other oxymorphone ER products as competitors to its generic oxymorphone ER. It did not consider any other long-acting opioids as competitors. (CX3102 at 017 (October Rating Agency Presentation) (identifying Endo's branded Opana as the only competitor); CX3107 at 007 (November 2014 Executive Committee Review) (identifying "no competitors" for oxymorphone)).

RESPONSE TO FINDING NO. 649:

Complaint Counsel's Proposed Finding No. 649 is incomplete and misleading. The first cited document (CX3102) lists Endo as a competitor but says nothing about whether other long-acting opioids are competitors. The second cited document (CX3107) does not conclude there are "no competitors" for oxymorphone ER, it simply assumed it for purposes of the specific forecast. (CX3107-007). Proposed Finding No. 649 also ignores the testimony of Todd Engle, Impax's Vice President of Sales and Marketing for the Generics Division, who explained that Impax specifically targeted OxyContin/oxycodone prescribers with its promotional efforts after it launched its oxymorphone ER product. (CX4004 (Engle, IHT at 210-11); RX-394.0001). Mr. Engle's testimony is consistent with contemporaneous Impax documents as well. (*See* RX-394; RX-304).

5. Impax considered only the price of other oxymorphone ER products in setting the price of its generic oxymorphone ER product

650. In forecasting generic prices, Impax assumes a discount off the reference brand's list price and not the prices of other branded products. (Engle, Tr. 1715).

RESPONSE TO FINDING NO. 650:

Complaint Counsel's Proposed Finding No. 650 is not supported by the cited evidence and is misleading. Mr. Engle did not testify about forecasting generic prices. He was asked about "forecasting sales of a generic product." (Engle, Tr. 1715). In order to do that, Mr. Engle makes an "assumption" about "the average net selling price," for which he will use a discount off the brand's list price. (Engle, Tr. 1715). Such general testimony should be viewed in the larger

context that generic companies like Impax achieve generic sales primarily through substitution of generic products for the corresponding brand-name product. (Mengler, Tr. 522; Engle, Tr. 1703).

651. In doing forecasts for oxymorphone ER, Impax used a discount off the list price of Opana ER and not other branded long-acting opioid products. (Engle, Tr. 1715-16).

RESPONSE TO FINDING NO. 651:

Respondent has no specific response.

652. In initially setting the price for oxymorphone ER in 2013, Impax did not take into account the prices of any products other than branded Opana ER. (CX4038 (Engle, Dep. at 112-113) ("Q. And for setting prices to individual customers for oxymorphone ER in 2013, did you refer to any prices other than brand Opana ER price? A. No.")).

RESPONSE TO FINDING NO. 652:

Respondent has no specific response.

653. Impax did not face price competition for its generic oxymorphone ER product from any other long-acting opioids. Rather, Impax's price competition was limited to other generic oxymorphone ER products. (CX4038 (Engle, Dep. at 120) ("Q. So did anyone ever come to Impax seeking a price adjustment because they had a price challenge for a product other than another generic oxymorphone ER? A. I don't recall that ever happening."); CX4038 (Engle, Dep. at 116-17, 118-19); CX4021 (Ben-Maimon, Dep. at 131-32)).

RESPONSE TO FINDING NO. 653:

Complaint Counsel's Proposed Finding No. 653 is not supported by the cited evidence. Neither Mr. Engle nor Dr. Ben-Maimon testified that Impax was free of price competition from other products. The quoted language from Mr. Engle speaks for itself and is limited to his lack of recollection regarding "anyone ever com[ing] to Impax seeking a price adjustment." (CX4038 (Engle, Dep. at 120)).

E. Other long-acting opioids did not sufficiently constrain Opana ER sales and prices

654. Complaint Counsel's economic expert, Roger Noll, was able to infer the lack of demand cross elasticity between different long-acting opioids based on facts about market events. (Noll, Tr. 1509-10; CX4039 (Noll, Dep. at 188) ("And if we observe that there's little interaction between events in – that occur in the sales of one opioid on the sales of another opioid, then that's indirect evidence that the cross-elasticities of demand are relatively low, and so there's relatively little competition.")).

RESPONSE TO FINDING NO. 654:

Complaint Counsel's Proposed Finding No. 654 is not supported by the record. Professor Noll "did not attempt to estimate the elasticity of the demand curve for any drug." (Noll, Tr. 1509-10). In fact, Professor Noll did not conduct any econometric or statistical analysis regarding switching among products. (Addanki, Tr. 2331). Professor Noll merely scanned for any "visible effect" on Opana ER sales, a metric he never defined. (Noll, Tr. 1384).

The record is clear, however, that market events regularly lead to switching between Opana ER and other long-acting opioid products. [redacted] (RX-449.0007). [redacted] (Addanki, Tr. 2266-67). Formulary changes and changes in price also led to switches. When UPMC instituted formulary changes that preferenced Opana ER and several generic long-acting opioids over OxyContin—thereby lowering the prices that patients paid for those drugs—roughly 70 percent of OxyContin patients switched to alternative long-acting opioids, including Opana ER, generic Morphine Sulfate ER (MS ER), and generic Fentanyl patches. (RX-087).

Endo regularly was impacted by such market events. (RX-087 (significant increase in usage for Opana ER following formulary change in which it was preferenced over OxyContin); CX2732-003 ("Withdrawal of Embeda by Pfizer/King had led to another unexpected inflexion point in Opana ER TRx demand as clinicians seek alternative therapies for their Embeda patients. . . . Of all branded LAOs, Opana ER and Kadian have benefited the most from the removal of Embeda."); RX-26.0005-08 ([redacted]); RX-073.0002 at 13, 16 (Endo document tracking switching among various long-acting opioids and noting Endo "must accelerate the gain of switches from Oxycontin"); RX-060.0002 at 25 (thousands of patients switched between Opana ER and other long-acting opioids every month)).

655. The use of indirect evidence regarding the lack of cross-elasticity of demand between Opana ER and other long-acting opioids is required because both economists agree that it was not possible to reliably calculate cross-elasticity based on the available data. (Noll, Tr. 1517; Addanki, Tr. 2476 ("I think your economist and I agree that calculating cross-elasticities is actually in practice very hard to do in pharmaceuticals for a bunch of reasons I think we all agree on.")).

RESPONSE TO FINDING NO. 655:

While Respondent does not dispute that both economists agreed that that calculating cross-elasticities of demand can be very hard in practice in the pharmaceutical industry, this does not support the proposition that it is "not possible" or that the so-called "indirect evidence" relied on by Professor Noll was proper or sufficient to make an "inference" about cross-elasticities of demand.

656. The pharmacologic class of long-acting opioids (LAOs) includes various opioids that are available in extended release formulations, many of which are used for the treatment of moderate to severe pain. (CX5000 at 059 (¶ 129, ¶ 129 n.148) (Noll Report);

CX5000 at 194-195 (Exhibit 4) (Noll Report); CX5002 at 106 (Appendix C) (Savage Report)).

RESPONSE TO FINDING NO. 656:

Respondent has no specific response.

657. Many LAOs (although not oxymorphone) are available as compound products, combining an LAO with another drug, but single-API LAOs are the natural starting place to try to find economic substitutes for oxymorphone ER since a drug that combines an LAO with some other drug is unlikely to be a close competitive substitute for oxymorphone ER if the single-API version of the same drug is not a close competitive substitute. (CX5000 at 060-61 (¶ 130) (Noll Report)).

RESPONSE TO FINDING NO. 657:

Complaint Counsel's Proposed Finding No. 657 is based on unreliable expert testimony and should be disregarded. Professor Noll was not and is not qualified as an expert with respect to the pharmaceutical industry. (Noll, Tr. 1358).

Respondent also objects to Proposed Finding No. 657 because the term "natural starting place" is vague and ambiguous. Further, if there is any "natural starting place" to try to find economic substitutes for oxymorphone ER, it is by evaluating price competition among long-acting opioids at three levels: the payor, prescriber, and patient levels. (*See* Addanki, Tr. 2218-34; RX-547.0028-31 (Addanki Rep. ¶¶ 52-59)).

658. Whether two LAOs that use different APIs are economic substitutes depends on the extent of product differentiation between them. If two LAOs differ substantially in their therapeutic effects, then one LAO is not likely to be an economic substitute for the other. Opioids differ according to their biological receptors, pharmacokinetic profiles, and adverse side effects, including adverse interactions with other drugs. Consequently, an opioid that works well for one patient may be inappropriate or ineffective for another. (CX5000 at 061 (¶ 132) (Noll Report); CX5002 at 020, 041-042 (¶¶ 51, 115-116) (Savage Report); Michna, Tr. 2193 (agreeing that individual patients may respond differently to different drugs); RX-549 at 0006, 0016 (¶¶ 18, 40) (Michna Report) (acknowledging that individuals may tolerate one opioid better than another or may not be able to take a specific opioid)).

RESPONSE TO FINDING NO. 658:

Complaint Counsel's Proposed Finding No. 658 is incomplete, inaccurate, and misstates the facts in the record. Whether two long-acting opioids that use different APIs are economic substitutes depends on actual substitution in the face of price changes. Product differentiation is only one part of that calculus. As Professor Noll notes, "two products are close economic substitutes if a buyer will switch from one to the other in response to a small change in relative prices." (CX5000-061-62 (Noll Rep. ¶ 133)). And the record is replete with evidence that long-acting opioid prescriptions switched between products as a result of changes in price. (RX-087 (UPMC formulary change led 70 percent of patients on OxyContin to switch to a different, lower-priced long-acting opioid, including Opana ER, generic Morphine Sulfate ER (MS ER), and generic Fentanyl patches); RX-021.0005, 07 ([redacted]); RX-022.0004 (same); RX-448.0020 ([redacted]); Addanki, Tr. 2500 (describing formulary price competition and noting that rebates are on the order of magnitude of a small but significant non-transitory increase in price, indicating that "even small price changes were competitively potentially significant")).

Further, the record shows that all long-acting opioids are equally safe and effective in relieving pain in the vast majority of patients. (Michna, Tr. 2107; Noll, Tr. 1504-05). "[M]ost [opioids] are interchangeable if attention is paid to relative potencies and onset and duration of action." (Savage, Tr. 782-83). Accordingly, no one long-acting opioid is superior to any other long-acting opioid across broad populations of patients. (Savage, Tr. 790-91). The only differences in long-acting opioid treatments occur among "*individual* patients with *specific* types

of pain in *specific* contexts" that render particular opioid treatments "superior choices for individuals in particular contexts." (Savage, Tr. 743-44, 788-89 (emphasis added)). To the extent any patients exist for whom oxymorphone ER or any other long-acting opioid is the most effective option, such patients cannot be identified in advance of treatment. (Michna, Tr. 2148-49).

> 659. Even if a patient can obtain the same long-term pain relief from more than one LAO, these LAOs still are not close economic substitutes if the patient already is taking a particular LAO. Two products are close economic substitutes if a buyer will switch from one to the other in response to a small change in relative prices. (CX5000 at 061-62 (¶ 133) (Noll Report)).

RESPONSE TO FINDING NO. 659:

Complaint Counsel's Proposed Finding No. 659 is inaccurate. The record indicates that even if a patient is taking one long-acting opioid, other long-acting opioids remain close economic substitutes. Indeed, switching among long-acting opioids occurs frequently. (Michna, Tr. 2124, 2126 (switching is "probably done thousands of times each day"); Savage, Tr. 693-94, 762, 782-83; RX-073.0002 at 45 ("Opioid rotation/switching is common in this therapeutic category.")). And switching among long-acting opioids frequently occurs for economic reasons. Dr. Savage, Complaint Counsel's medical expert, testified that she would rotate a patient to another long-acting opioid based on a minor increase in price "depend[ing] upon the patient and what the increase in price meant to them." (Savage, Tr. 770; Michna, Tr. 2125, 2148 (switch because of changes in insurance coverage and patient out-of-pocket expenses)). Similarly, when UPMC instituted formulary changes that preferenced Opana ER and several generic long-acting opioids over OxyContin—thereby lowering the prices that patients paid for those drugs—roughly 70 percent of OxyContin patients switched to alternative long-acting opioids, including Opana ER, generic Morphine Sulfate ER (MS ER), and generic Fentanyl patches. (RX-087; *see*

also RX-073.0002 at 13, 16 (Endo document tracking switching among various long-acting opioids and noting Endo "must accelerate the gain of switches from Oxycontin"); RX-060.0002 at 25 (thousands of patients switched between Opana ER and other long-acting opioids every month)).

> 660. In the case of LAOs, patients cannot easily switch in response to a change in relative prices for two reasons. First, even if two opioids are equally safe and effective for a given patient, switching between them is risky. Second, opioids differ in medically important ways so that they are not all equally safe and effective for all patients, regardless of the patient's physiology and health status. (CX5000 at 061 (¶ 133) (Noll Report); CX5002 at 041-42, 061-062 (¶¶ 115-116, 172) (Savage Report); Savage, Tr. 770 ("If they're tolerating [Opana ER] well and it's meeting their needs, I'd prefer to keep them on the drug that they're using."); Michna, Tr. 2126 ("[A]s humans we're afraid of the unknown, so you could understand, if a patient has been on a medication for months or years and getting good pain relief, that there would be some anxiety about switching to a medication that . . . may not have that same effect.")).

RESPONSE TO FINDING NO. 660:

Complaint Counsel's Proposed Finding No. 660 is inaccurate and not supported by the evidence in the record. Dr. Savage, Complaint Counsel's own medical expert, explained that switching a patient between long-acting opioids can be "simple." (Savage, Tr. 762). If "you're taking two Percocet a day and you want to switch to a couple of hydrocodone, that's not going to be a complicated switch." (Savage, Tr. 765-66, 768-69). Even for patients on high doses of multiple opioids, it is only "a bit more complicated" to switch. (Savage, Tr. 762). In fact, Dr. Savage has never been unable to switch a patient between long-acting opioids. (Savage, Tr. 793-94; Michna, Tr. 2126 (never heard of any instance when a switch was not accomplished safely and effectively)). Dr. Savage also testified that she would rotate a patient based on a minor increase in price "depend[ing] upon the patient and what the increase in price meant to them." (Savage, Tr. 770).

For these reasons, rotating from one long-acting opioid to another does not involve significant risks when conducted by a doctor who knows the medications, and it occurs frequently. (Michna, Tr. 2124, 2126 (switching is "probably done thousands of times each day"); Savage, Tr. 693-94, 762, 782-83; RX-073.0002 at 45 ("Opioid rotation/switching is common in this therapeutic category.")). Indeed, patients are almost always switched between opioids when they leave the hospital, even if they are tolerating a specific opioid. (Savage, Tr. 798-801; Noll, Tr. 1530 ("physicians very often switch which molecule is used when the patient leaves the hospital")). The most commonly used opioids in emergency rooms and other inpatient settings are hydromorphone, fentanyl, and morphine. (Savage, Tr. 787). The most commonly prescribed opioids in outpatient settings are oxycodone, hydrocodone, and morphine. (Savage, Tr. 786). More generally, thousands of patients are switched from Opana ER to other long-acting opioids—and from other long-acting opioids to Opana ER—every month. (RX-073.0002 at 16).

Finally, the Proposed Finding's use of Dr. Michna's testimony is misleading because it selectively quotes his answer, in which he explained that the "fear of the unknown" does not change the fact that long-acting opioids are therapeutically equivalent, and that switching is not a complex process. (Michna, Tr. 2126-27).

661. In markets with high switching costs firms are likely to possess sufficient market power to set price above the competitive level even if products are perfect functional substitutes and the market contains many sellers. (CX5000 at 061-62 (¶ 134) (Noll Report)).

RESPONSE TO FINDING NO. 661:

Complaint Counsel's Proposed Finding No. 661 is improper because it states a legal conclusion. Proposed Finding No. 661 is also irrelevant and misleading because the evidence indicates that the market for long-acting opioids is not characterized by high switching costs.

(*See* Michna, Tr. 2127-29). Instead, switching costs are insignificant and characterized only by follow-up visits with the doctor to assess whether the patient is getting adequate pain relief. (Michna, Tr. 2127). These visits can be completed over the phone in some instances. (Michna, Tr. 2127). Because switching between long-acting opioids is often driven by insurance companies and their formulary changes, insurance companies calculate the savings achieved by their formulary changes and believe that "savings they have on the medication front more than make[] up for the additional cost of the follow-up visit." (Michna, Tr. 2127-29). Patients, for their part, generally do not mind extra doctor visits in order to treat their pain effectively. (Michna, Tr. 2128). In fact, there are some indications that the more often patients suffering from pain see doctors, the less pain they experience overall. (Michna, Tr. 2128-29).

662. Switching costs go beyond any price difference between drugs, to other costs one might experience because of the switch. Here, the price differences in the drugs are small compared to the costs of switching from one drug to another. (Noll, Tr. 1388).

RESPONSE TO FINDING NO. 662:

Complaint Counsel's Proposed Finding No. 662 is inaccurate, lacks foundation, and is not supported by record evidence. Professor Noll has not done any empirical analysis of the switching costs in the long-acting opioid market and cannot quantify whether the cost of switching between long-acting opioids is high. (Noll, Tr. 1552-53). Still, Dr. Addanki identified three reasons why the unsubstantiated claim of high switching costs is wrong: *first*, the expert clinicians testified that "switching can and does occur" and that it "does occur in response to economic forces, such as formularies"; *second*, there is no switching cost at all for new patients starting an opioid therapy; and *third*, the UPMC study showed a natural experiment in which a large number of switches were made because of a change in price. (Addanki, Tr. 2330-31; RX-

087 (UPMC formulary change led to 70 percent of patients on one long-acting opioid switching to a different long-acting opioids, both branded and generic, with no adverse increase in cost)).

As Dr. Addanki explained, if switching costs actually were high, "you wouldn't see the efforts by managed care and by manufactures responding to managed care to be getting the best terms possible for the most favorable position on the formulary because . . . when you see that happening, that underscores that economic substitution is in fact taking place, so whatever the switching costs were, they were not an impediment to economic substitution." (Addanki, Tr. 2330-31).

663. When a patient initiates treatment on a new opioid when switching from one to another, treatment begins with a low dose that is then gradually increased until pain relief is achieved. This dosage titration process must be monitored by a medical professional to ensure that patients are not overdosed before achieving pain relief. (CX5000 at 061-62 (¶ 134) (Noll Report); CX5002 at 061-062 (¶¶ 172-173) (Savage Report); Noll, Tr. 1389-90 ("The first part of the switching cost is that you can't just go from the final dose of the first drug to the final dose of the second drug instantaneously. . . . And then the second part is that the whole process of tapering off and tapering in has to be supervised by a physician . . ."); Michna, Tr. 2127 (testifying that switching a patient from one ER opioid to another involves monitoring by the physicians)).

RESPONSE TO FINDING NO. 663:

Complaint Counsel's Proposed Finding No. 663 is incomplete. While switches between opioids are monitored by a medical professional, this monitoring is a relatively straight-forward and non-burdensome process. (Michna, Tr. 2127). In fact, the record indicates that insurance companies calculate the savings achieved by their formulary changes and believe that "savings they have on the medication front more than make[] up for the additional cost of the follow-up visit." (Michna, Tr. 2129). Patients, for their part, generally do not mind extra doctor visits in order to treat their pain effectively. (Michna, Tr. 2128).

664. Thus, while patients can be switched from one opioid to another, the process is risky, time-consuming, and expensive because of the need for medical supervision. For

this reason, it is implausible that patients who are taking one LAO would switch to another just because the former experienced a "small but significant, non-transitory increase in price." (CX5000 at 063 (¶ 136) (Noll Report); Noll, Tr. 1390 ("And so those are the switching costs. It's that you have to invest a significant fraction of your own time and you have to have the supervision of a physician in order to switch from one to the other.")).

RESPONSE TO FINDING NO. 664:

The first sentence of Complaint Counsel's Proposed Finding No. 664 is not supported by any evidence and should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Complaint Counsel cites *no* evidence to support the claim that the process of switching from one opioid to another is "risky, time-consuming, and expensive."

Moreover, Proposed Finding No. 664 is inaccurate. As Professor Noll admitted under cross-examination, he made no attempt to quantify or estimate the alleged "switching" costs; he merely "identified" the supposed costs. (Noll, Tr. 1553-54). Nor did he analyze how frequently patients are switched from one long-acting opioid to another. (Noll, Tr. 1525). Dr. Savage, Complaint Counsel's own medical expert, confirmed that switching between long-acting opioids is not prohibitively risky, expensive, or time-consuming. For example, she testified that switching a patient between long-acting opioids can be "simple." (Savage, Tr. 762). If "you're taking two Percocet a day and you want to switch to a couple of hydrocodone, that's not going to be a complicated switch." (Savage, Tr. 765-66, 768-69). Even for patients on high doses of multiple opioids, it is only "a bit more complicated" to switch. (Savage, Tr. 762). In fact, Dr. Savage has *never* been unable to switch a patient between long-acting opioids. (Savage, Tr. 793-94; Michna, Tr. 2126 (never heard of any instance when a switch was not accomplished safely and effectively)). For these reasons, rotating from one long-acting opioid to another does not

involve significant risks when conducted by a doctor who knows the medications, and, in fact, it occurs frequently. (Michna, Tr. 2124, 2126 (switching is "probably done thousands of times each day"); Savage, Tr. 693-94, 762, 782-83; RX-073.0002 at 45 ("Opioid rotation/switching is common in this therapeutic category.")). As Dr. Michna confirmed, the doctor's supervision may be limited to a simple follow-up phone call or office visit. (Michna, Tr. 2127-28).

Complaint Counsel's suggestion that it is "implausible" that patients would switch between long-acting opioids in response to small but significant and non-transitory price changes is unfounded, since Professor Noll did not calculate cross-elasticities or conduct a SSNIP test. (Noll, Tr. 1514, 1517). More to the point, the record evidence reflects that patients *do* switch between long-acting opioids in response to changes in relative price. (RX-087 (UPMC formulary change led 70 percent of patients on one long-acting opioid to switch to different long-acting opioids, both branded and generic); RX-021.0005, 07 ([redacted]); RX-022.0004 [redacted]; RX-448.0020 ([redacted]); Addanki, Tr. 2500 (describing formulary price competition and noting that rebates are on the order of magnitude of a small but significant non-transitory increase in price, indicating that "even small price changes were competitively potentially significant")). Dr. Michna has switched *hundreds* of patients in response to formulary changes in recent years. (RX-549.0007 (Michna Rep. ¶ 23)). And Dr. Savage testified that she would rotate a patient among long-acting opioids based on a minor increase in price "depend[ing] upon the patient and what the increase in price meant to them." (Savage, Tr. 770).

Finally, Proposed Finding No. 664 violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." Professor Noll was not and is not qualified as an expert regarding medical risks. (Noll, Tr. 1358).

665. This is consistent with the testimony of Dr. Savage, who stated that minor changes in price would not change her prescribing habits because she is generally not aware of them and because her concerns are for the clinical well-being of the patient. (Savage, Tr. 771).

RESPONSE TO FINDING NO. 665:

Complaint Counsel's Proposed Finding No. 665 is inaccurate, incomplete, and misleading. Dr. Savage personally is not aware of drug prices because formulary tiering and what patients pay in copays "truly is outside [her] experience" since she is "a consultant in [her] practice area" and "the staff physicians who do the direct management of the patients deal with insurance companies." (CX4041 (Savage, Dep. at 117)). Even still, Dr. Savage noted that she does take economic considerations into account in her "clinical decision-making" when the patient raises the issue with her, especially if the patient does not have insurance. (Savage, Tr. 772-73; CX4041 (Savage, Dep. at 138) ("the copay is one variable that may be considered" when making prescription choices—"clinical determinations are usually the first consideration and then copays")). Dr. Savage also testified that she would rotate a patient between long-acting opioids based on a minor increase in price "depend[ing] upon the patient and what the increase in price meant to them." (Savage, Tr. 770; *see* CX5002-063 (Savage Rep. ¶ 177) (noting that clinicians will "consciously consider costs" when they are "aware that the patient will need to pay out of pocket")). Dr. Michna reiterated this point, noting that the patient's insurance coverage "plays a major role" in the choice of a long-acting opioid. (Michna, Tr. 2129).

666. Impax's expert, Dr. Michna likewise agreed that his ultimately priority is the safety and health of his patients, and that he prescribes the product that he feels is best for the patient in his or her clinical situation. (Michna, Tr. 2177).

RESPONSE TO FINDING NO. 666:

Complaint Counsel's Proposed Finding No. 666 is incomplete and misleading. While Dr. Michna testified that he prescribes the product he feels is best for the patient, he also testified that he takes economic considerations, like formulary placement and out-of-pocket expenses, into account when making clinical decisions. (Michna, Tr. 2121-22). Where there are multiple equally-safe and effective options to address a patient's needs, physicians take into account the patient's out-of-pocket costs in selecting from among those treatment options. (RX-549.0006-07, 20-23 (Michna Rep. ¶¶ 21, 49-51)). Accordingly, even though a physician's priority is the health and safety or her patients, cost and insurance coverage still play a key role in her prescribing decisions when choosing between equally-safe and effective long-acting opioids. (Michna, Tr. 2148; CX4046 (Michna, Dep. at 115-16); CX4044 (Addanki, Dep. at 148); RX-549.0006-07, 21 (Michna Rep. ¶¶ 21, 51)).

In fact, Complaint Counsel's economic expert, Professor Noll, admitted that doctors make prescribing decisions based on price and formulary tiering, among other issues. (Noll, Tr. 1505-06). Dr. Savage, Complaint Counsel's medical expert, similarly admitted that "the copay is one variable that may be considered" when making prescription choices—"clinical determinations are usually the first consideration and then copays." (CX4041 (Savage, Dep. at 138); *see* Savage, Tr. 772 (availability of insurance coverage for a medication would affect Dr. Savage's clinical decision-making)).

667. Dr. Michna also agreed that he does not keep track of the prices of long-acting opioids on a daily basis, and would only be aware of dramatic changes in price or availability. (Michna, Tr. 2187-88 ("I'd be aware of it if there's dramatic changes . . ."); CX4046 (Michna, Dep. at 149) ("Q. So are you ever aware of fluctuations in price for a

specific brand of product? A. From day to day, no. I mean, I – it's the dramatic events that I mentioned to you.")).

RESPONSE TO FINDING NO. 667:

Complaint Counsel's Proposed Finding No. 667 is incomplete and misleading. While Dr. Michna does not keep track of prices "on a daily basis," doctors have access to electronic systems through which they "get an immediate feedback as to whether that's a covered medication for that insurance company, [and] also what level of additional pay that the patient has to pay at the pharmacy." (Michna, Tr. 2122). Dr. Michna also testified that patients will often raise cost concerns during visits, and pharmacists will call to inform the physician of cost concerns. (Michna, Tr. 2123; *see* CX4046 (Michna, Dep. at 148-49) ("I don't trawl the daily cost of all the pharmaceutical products, but I have a general idea.")). He further testified that drug manufacturers inform him regarding changes in cost and insurance coverage as well. (Michna, Tr. 2123). Dr. Michna further explained, he is aware of formulary changes, and has switched hundreds of patients among LAOs in recent years due to such changes. (CX4046 (Michna, Dep. at 149); RX-549.0007 (Michna Rep. ¶ 23)).

668. The fact that consumers cannot easily switch LAOs in response to a change in relative prices does not preclude the possibility that, at the time that treatment is initiated, some LAOs may be close economic substitutes for a first prescription. Whether competition for first prescriptions is sufficiently intense to cause substantial price competition between two LAOs depends in part on the fraction of prescriptions that are written for new patients and on the extent to which the two drugs are close therapeutic substitutes. For many reasons, patients and their physicians are not likely to regard different LAOs as close economic substitutes – that is, to choose among them on the basis of relative prices. (CX5000 at 063-64 (¶ 138) (Noll Report)).

RESPONSE TO FINDING NO. 668:

Complaint Counsel's Proposed Finding No. 668 violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." Professor Noll was not and is not qualified as an expert regarding

the "likely" views of patients and physicians. (Noll, Tr. 1358). The cited portion of Professor Noll's expert report, moreover, does not include any citations to evidence or analysis in support of his assertions. The first two sentences of Proposed Finding No. 668 should also be disregarded because they violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2).

Proposed Finding No. 668 is also inaccurate and not supported by the record. First, patients and doctors can and do choose among long-acting opioids on the basis of price. (CX5002-063 (Savage Rep. ¶ 177) (noting that clinicians will "consciously consider costs" when they are "aware that the patient will need to pay out of pocket"); Michna, Tr. 2148; RX-087 (UPMC formulary change led 70 percent of patients on one long-acting opioid to switch to different long-acting opioids, both branded and generic); RX-448.0020 ([redacted])).

Second, patients and their physicians do regard different long-acting opioids as close substitutes. Complaint Counsel's own expert physician conceded that "most" people can get equally effective and safe pain relief from numerous long-acting opioids, and that individual responses to any particular opioid cannot be identified in advance of treatment. (CX4041 (Savage, Dep. at 60, 66-67)). Accordingly, no one long-acting opioid is superior to any other long-acting opioid across populations of patients. (Savage, Tr. 790-91; Michna, Tr. 2149).

Third, first-time opioid prescriptions are "the biggest opportunity in the market." (RX-060.0002 at 29). [redacted]

[redacted] (RX-073.0002 at 7). [redacted]

[redacted] (RX-073.0002 at 7; Addanki, Tr. 2262-63).

669. Ultimately, there is no evidence of significant price competition between brand name opioids with different APIs. (CX4039 (Noll, Dep. at 188-89)).

RESPONSE TO FINDING NO. 669:

Complaint Counsel's Proposed Finding No. 669 is inaccurate and not supported by the record. Demir Bingol, Endo's Senior Director of Marketing and the Endo employee responsible for knowing with whom oxymorphone-based products compete, testified that "all long-acting opioid formulations," directly compete. (Bingol, Tr. 1271, 1313). This competition plays out through, among other things, "effective targeting of your messaging to your clinicians," "rebates that you offer payers in order to ensure that you have a competitive place on formularies," and "certain competitors coming and going that your product becomes a natural next choice." (Bingol, Tr. 1284).

Manufacturers compete on price at the insurer level to secure favorable formulary placement vis-à-vis competitors. (Bingol, Tr. 1324-25). This includes rebates by brand companies in order to compete with generic products on price. (Bingol, Tr. 1327; Engle, Tr. 1718; CX4037 (Smolenski, Dep. at 155)). And it can mean that generic long-acting opioids, like oxymorphone ER, are excluded from formulary coverage in favor of other long-acting opioids. (Noll, Tr. 1546; RX-017.0001; RX-017.0002 at 11). That price competition results in frequent changes in insurance coverage and switching between long-acting opioids. (RX-087 (UPMC formulary change led to 70 percent of patients on OxyContin switching to different long-acting opioids, including Opana ER, generic Morphine Sulfate ER (MS ER), and generic Fentanyl patches); RX-021.0005, 07 ([redacted]

[redacted]); RX-022.0004 (same); Addanki, Tr. 2500 (describing formulary price competition and noting that rebates are on the order of magnitude of a small but significant non-transitory increase in price, indicating that "even small price changes were competitively potentially significant")).

Manufacturers also compete on price at the consumer level in order to secure additional sales. (*See, e.g.*, RX-448.0020 [redacted]); Addanki, Tr. 2236-37 ("JUDGE CHAPPELL: Let me ask another way. Have you ever seen a rebate being used like this when there's only one brand on the market with no competition? THE WITNESS: No. No. It is the hallmark of when there's actually competition.")).

1. Data confirms that the introduction of new long-acting opioids or generic versions of existing LAOs had no discernible impact on Opana ER sales

670. The conclusion that other long-acting opioids are not close economic substitutes that lead to price competition for Opana ER can be tested by examining whether changes in the market environment for other LAOs affected output and prices for oxymorphone ER. (CX5000 at 072 (¶ 158) (Noll Report)).

RESPONSE TO FINDING NO. 670:

Complaint Counsel's Proposed Finding No. 670 is based on unreliable expert testimony and wrong. Professor Noll's analysis is based on his scanning for any "visible effect" on Opana ER sales, a metric he never defined. (Noll, Tr. 1384). Professor Noll recognizes that a SSNIP test is the normal method used to determine close economic substitutes. (CX5000-017 (Noll Rep. ¶ 38)). But Professor Noll admits he did not conduct a SSNIP test. (Noll, Tr. 1514).

Further, the test described by Professor Noll deliberately ignores the multitude of evidence of economic substitution between long-acting opioids, including switching after

changes on insurance formularies. (*See* Addanki, Tr. 2232). Indeed, Professor Noll dismisses as irrelevant evidence that demand for oxymorphone ER increased after Impax's generic entry, with patients switching from other long-acting opioids to oxymorphone ER. (Noll, Tr. 1525). Professor Noll similarly dismisses evidence that Opana ER experienced its highest loss rates in 2012 when physicians switched their patients to other long-acting opioids. Professor Noll claims instead that patients leaving Opana ER switched to heroin or other illegal drugs instead. (Noll, Tr. 1525-26).

> 671. Generic entry is a price phenomenon as well as a product phenomenon. In other words, one can look at generic entry in one drug market – for example ER morphine – and see what happens to brand name ER morphine and what happens to another other long-acting opioid. If those effects are different, the other long-acting opioid is not in the same market. (Noll, Tr. 1374-75).

RESPONSE TO FINDING NO. 671:

Complaint Counsel's Proposed Finding No. 671 is improper because it states a legal conclusion, not a fact. Respondent nevertheless objects to the terms "price phenomenon" and "product phenomenon" as vague and ambiguous. What happens to one long-acting opioid after the generic entry of another long-acting opioid is not dispositive of whether each is in the same market. The key marker of a relevant market is whether there are output effects.

> 672. Because the introduction of a generic version of another LAO is a reasonable indicator of a substantial fall in the price of that LAO, a reliable test of whether other LAOs are in the same relevant market as oxymorphone ER is whether the launch of a generic of the other LAO causes reduced sales of oxymorphone ER. (CX5000 at 072 (¶ 158 n.214) (Noll Report)).

RESPONSE TO FINDING NO. 672:

Complaint Counsel's Proposed Finding No. 672 is improper because it states a legal conclusion, not a fact. Complaint Counsel's Proposed Finding No. 672 is also unsupported and wrong. The cited portion of Professor Noll's report contains no evidence or analysis to support

the proposition. Professor Noll's analysis is based on his scanning for any "visible effect" on Opana ER sales, a metric he never defined. (Noll, Tr. 1384). Professor Noll recognizes that a SSNIP test is the normal method used to determine close economic substitutes. (CX5000-017 (Noll Rep. ¶ 38)). But Professor Noll admits he did not conduct a SSNIP test. (Noll, Tr. 1514).

Further, the test described by Professor Noll deliberately ignores the multitude of evidence of economic substitution between long-acting opioids, including switching after changes on insurance formularies. (*See* Addanki, Tr. 2232). Indeed, Professor Noll dismisses as irrelevant evidence that demand for oxymorphone ER increased after Impax's generic entry, with patients switching from other long-acting opioids to oxymorphone ER. (Noll, Tr. 1525). Professor Noll similarly dismisses evidence that Opana ER experienced its highest loss rates in 2012 when physicians switched their patients to other long-acting opioids. Professor Noll claims instead that patients leaving Opana ER switched to heroin or other illegal drugs instead. (Noll, Tr. 1525-26).

> 673. No pattern of substitution is exhibited between oxymorphone ER sales and the introduction or exit of other brand-name LAOs or the entry or exit of generics against these other brand-name LAOs. (CX5000 at 073 (¶ 158) (Noll Report); Noll, Tr. 1394 ("[T]here is no spillover effect from state of competition for one long-acting opioid into prices and sales of another long-acting opioid.")).

RESPONSE TO FINDING NO. 673:

Complaint Counsel's Proposed Finding No. 673 is inaccurate and is not supported by the record. Professor Noll did not calculate cross-elasticity of demand between Opana ER and any other long-acting opioid, nor did he conduct a SSNIP test. (Noll, Tr. 1514, 1517). In fact, he did not conduct any empirical analysis of the effects of generic entry; Professor Noll merely scanned for any "visible effect" on Opana ER sales, a metric he did not define. (Noll, Tr. 1384). Importantly, Professor Noll did not undertake any empirical or econometric analysis to

determine whether there was substitution between oxymorphone ER and other long-acting opioids. (Addanki, Tr. 2331). The proper test is whether output expanded when generic Opana ER entered the long-acting opioid market. If Endo had been exercising monopoly power to restrict output, then there should have been an expansion of overall output when Impax launched generic Opana ER in January 2013. (Addanki, Tr. 2348-50; RX-547 (Addanki Rep. ¶ 96, Ex. 12)). When Impax entered the market, however, there was no increase in output. (Addanki, Tr. 2350; RX-547 (Addanki Rep. ¶ 96)). Proposed Finding No. 673 also ignores numerous other forms of price competition, including at the payor, prescriber, and patient level. (*See* Addanki, Tr. 2253-2300 (*in camera*)).

674. Sales of oxymorphone ER and oxycodone ER are compared in Exhibits 5A1, 5A2 and 5A3 of the Noll Report. Exhibit 5A1 shows the quarterly number of prescriptions (brand-name and generics) for oxycodone ER and oxymorphone ER. Exhibit 5A2 shows the quarterly quantity of each drug sold per unit of the same dose strength, which conventionally is measured in mg of morphine equivalent (MME). Exhibit 5A3 shows sales revenues of both drugs. (CX5000 at 074 (¶ 161) (Noll Report); CX5000 at 196-198 (Exhibits 5A1-5A3) (Noll Report)).

RESPONSE TO FINDING NO. 674:

Respondent has no specific response. The data and associated charts speak for themselves.

675. OxyContin sales are much greater than sales of oxymorphone ER and, except for 2010 and 2011, sales of OxyContin and oxymorphone ER do not exhibit a strong negative correlation that would be present if they were substitutes. In other words, there is no evidence that decreased sales of one product correspond to increased sales of the other, or vice versa. (CX5000 at 074-75 (¶ 162) (Noll Report); CX5000 at 196-198 (Exhibits 5A1-5A3) (Noll Report)).

RESPONSE TO FINDING NO. 675:

Complaint Counsel's Proposed Finding No. 675 is inaccurate. Professor Noll's comparison of OxyContin sales with oxymorphone ER sales fails to take into account the rest of

the opioids in the long-acting opioid market. Therefore, even if there was a lack of a "strong negative correlation" of sales between OxyContin and oxymorphone ER, it would not be indicative of whether OxyContin and oxymorphone ER are substitutes.

But Professor Noll's analysis is wrong and ignores real-world evidence that shows Endo competed to "accelerate the gain of switches from OxyContin." (RX-073.0002 at 13, 16; *see* RX-060.0002 at 29). The results were tangible. [redacted] (RX-449.0007). [redacted] (Addanki, Tr. 2266-67). [redacted] (RX-26.0005-08).

And when UPMC changed its formulary such that OxyContin was no longer preferred, and therefore more expensive than other long-acting opioids, 70 percent of patients switched to an alternative long-acting opioid, with roughly 30 percent of those who switched choosing Opana ER. (RX-087; Noll, Tr. 1562; Michna, Tr. 2148). Prior to the formulary change, Opana ER received only 1.62 percent of UPMC's long-acting opioid prescriptions. (RX-087; Addanki, Tr. 2307). The UPMC formulary change also led to an uptick in generic Morphine Sulfate ER and generic Fentanyl patch prescriptions. (RX-087).

> 676. Before the introduction of Opana ER, sales of OxyContin fell precipitously due to generic competition in 2004, but recovered after 2006. This recovery occurred despite the introduction of Opana ER as both drugs experienced sales growth from the introduction of Opana ER in 2006 until the end of 2009, when sales of OxyContin reached their peak.

(CX5000 at 074-75 (¶ 162) (Noll Report); CX5000 at 196-198 (Exhibits 5A1-5A3) (Noll Report)).

RESPONSE TO FINDING NO. 676:

Complaint Counsel's Proposed Finding No. 676 violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." Any data speaks for itself.

677. Sales of OxyContin then began a long decline that continued into 2017, but most of this decline occurred after the sales of oxymorphone peaked. [redacted] (CX5000 at 074-75 (¶ 162) (Noll Report); CX5000 at 196-198 (Exhibits 5A1-5A3) (Noll Report) (*in camera*)).

RESPONSE TO FINDING NO. 677:

Complaint Counsel's Proposed Finding No. 677 violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." Any data speaks for itself.

678. Thus, except for 2010-11, sales of OxyContin and Opana ER rose and fell in parallel, with no substitution between them apparent in the data. (CX5000 at 074-75 (¶ 162) (Noll Report); CX5000 at 196-198 (Exhibits 5A1-5A3) (Noll Report)).

RESPONSE TO FINDING NO. 678:

Complaint Counsel's Proposed Finding No. 678 is not supported by the record and is misleading. Professor Noll did not actually conduct any econometric or statistical analysis regarding switching among products. (Addanki, Tr. 2331). Professor Noll merely scanned for any "visible effect" on Opana ER sales, a metric he never defined. (Noll, Tr. 1384). Respondent, moreover, objects to the term "parallel" as vague and ambiguous. Whether or not Professor Noll believes substitution between OxyContin and Opana ER is "apparent in the data"

he used to create the exhibits in his report, its irrelevant in the face of significant real-world evidence of substitution and switching. (*See, e.g.,* Addanki, Tr. 2266-67, 2309; Savage, Tr. 762; RX-073.0002 at 13, 16; RX-449.0007 (*in camera*); RX-26.0005-08 (partially *in camera*); RX-087).

679. Between the third quarter of 2010 and the third quarter of 2011, sales of OxyContin fell while sales of Opana ER increased, but the magnitudes were very different. (CX5000 at 075 (¶ 163) (Noll Report); CX5000 at 196-198 (Exhibits 5A1-5A3) (Noll Report)).

RESPONSE TO FINDING NO. 679:

Respondent objects to the phrase "very different" in this Proposed Finding as vague and ambiguous. Complaint Counsel's Proposed Finding No. 679 also violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." Any data speaks for itself.

680. [redacted] (CX5000 at 075 (¶ 163) (Noll Report); CX5000 at 196-198 (Exhibits 5A1-5A3) (Noll Report) (*in camera*)).

RESPONSE TO FINDING NO. 680:

Complaint Counsel's Proposed Finding No. 680 violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." Any data speaks for itself.

681. When Reformulated Opana ER was introduced in 2012, Opana ER sales fell, but sales of OxyContin did not increase. (CX5000 at 075 (¶ 163) (Noll Report); CX5000 at 196-198 (Exhibits 5A1-5A3) (Noll Report)).

RESPONSE TO FINDING NO. 681:

Complaint Counsel's Proposed Finding No. 681 violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." Any data speaks for itself.

682. These data show that both drugs experienced a significant loss of sales when reformulated versions were introduced, but neither drug benefitted appreciably from the lost sales of the other. (CX5000 at 075 (¶ 163) (Noll Report); CX5000 at 196-198 (Exhibits 5A1-5A3) (Noll Report)).

RESPONSE TO FINDING NO. 682:

Complaint Counsel's Proposed Finding of Fact No. 682 is incomplete and misleading. The statement that "neither drug benefitted appreciably from the lost sales of the other" does not follow from the fact that "both drugs experienced a significant loss of sales when reformulated versions were introduced." The cited paragraphs of Professor Noll's report do not include any citations to sources or analysis of the data to support this conclusory statement. The data and associated charts speak for themselves. Finally, Proposed Finding No. 682 ignores numerous other forms of price competition, including at the payor, prescriber, and patient level. (*See* Addanki, Tr. 2253-2300 (*in camera*)).

683. OxyContin sales also were not materially affected by the introduction of generic oxymorphone ER in all doses in January 2013. (CX5000 at 075-76 (¶ 164) (Noll Report); CX5000 at 196-198 (Exhibits 5A1-5A3) (Noll Report)).

RESPONSE TO FINDING NO. 683:

Respondent objects to the phrase "materially affected" in this Proposed Finding as vague and ambiguous. Complaint Counsel's Proposed Finding No. 683 also violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." Any data speaks for itself.

684. If oxycodone ER and oxymorphone ER were close economic substitutes, then the introduction of a generic version with a much lower price of one of these drugs should cause a reduction in sales of the other. Specifically, if these products were close substitutes, one would expect to see a shift in sales from oxycodone ER to oxymorphone ER, which experienced a price decrease with generic entry. However, the entry of generic oxymorphone ER could not have had more than a trivial effect on total sales of OxyContin because the fall in the quantity of Opana ER sales roughly equaled the increase in generic sales, leaving no additional sales to be accounted for by substitution for OxyContin or any other LAO. (CX5000 at 076 (¶ 164) (Noll Report); CX5000 at 196-198 (Exhibits 5A1-5A3) (Noll Report)).

RESPONSE TO FINDING NO. 684:

Complaint Counsel's Proposed Finding No. 684 is incomplete, misleading, and based on unreliable expert testimony. The Proposed Finding is not probative of whether oxymorphone ER and oxycodone ER are "close economic substitutes" for a number of reasons: First, the Proposed Finding is not based on any quantitative or statistical analysis; Professor Noll simply relied on a scan for a "visible effect" on Opana ER sales, a metric he never defined. (Noll, Tr. 1384). Indeed, Professor Noll did not conduct any econometric or statistical analysis regarding switching among products. (Addanki, Tr. 2331). Second, even if we assume Professor Noll has shown that a generic LAO took more sales from the corresponding branded LAO than from other LAOs, this is to be expected because of the unique setup of the pharmaceutical market, including automatic substitution. (Addanki, Tr. 2313-15). Third, Professor Noll's analysis ignores significant price competition at the payor, prescriber, and patient levels. (*See* also RX-547.0035-43 (Addanki Rep. ¶¶ 67-79)). Fourth, Professor Noll ignores evidence offered by Dr. Michna that physicians working with patients will respond to price changes among LAOs. (RX-549.0007 (Michna Rep. ¶ 23); Michna, Tr. 2125). Finally, Professor Noll's analysis says nothing about whether the entrance of generic LAOs increased output and thereby diminished monopoly power. (Addanki, Tr. 2203; RX-547.0019, 51 (Addanki Rep. ¶¶ 32, 96)).

Accordingly, the graphical, non-econometric analysis described in Proposed Finding No. 684 should be disregarded.

> 685. Thus, these data support the conclusion that oxymorphone ER and oxycodone ER are not close economic substitutes and so are not sold in the same relevant product market for purposes of assessing the conduct at issue in this case. (CX5000 at 076 (¶ 164) (Noll Report); CX5000 at 196-198 (Exhibits 5A1-5A3) (Noll Report)).

RESPONSE TO FINDING NO. 685:

Complaint Counsel's Proposed Finding No. 685 is incomplete, misleading, and based on unreliable expert testimony. The Proposed Finding is not probative of whether oxymorphone ER and oxycodone ER are "close economic substitutes" for a number of reasons: First, the Proposed Finding is not based on any quantitative or statistical analysis; Professor Noll simply relied on a scan for a "visible effect" on Opana ER sales, a metric he never defined. (Noll, Tr. 1384). Indeed, Professor Noll did not conduct any econometric or statistical analysis regarding switching among products. (Addanki, Tr. 2331). Second, even if we assume Professor Noll has shown that a generic LAO took more sales from the corresponding branded LAO than from other LAOs, this is to be expected because of the unique setup of the pharmaceutical market, including automatic substitution (Addanki, Tr. 2313-15). Third, Professor Noll's analysis ignores significant price competition at the payor, prescriber, and patient levels. (*See* also RX-547.0035-43 (Addanki Rep. ¶¶ 67-79)). Fourth, Professor Noll ignores evidence offered by Dr. Michna that physicians working with patients will respond to price changes among LAOs. (RX-549.0007 (Michna Rep. ¶ 23); Michna, Tr. 2125). Finally, Professor Noll's analysis says nothing about whether the entrance of generic LAOs increased output and thereby diminished monopoly power. (Addanki, Tr. 2203; RX-547.0019, 51 (Addanki Rep. (¶¶ 32, 96)). Accordingly, the graphical, non-econometric analysis described in Proposed Finding No. 685 should be disregarded.

686. Exhibits 5B1, 5B2 and 5B3 of the Noll Report compare prescriptions, MME sales quantities, and total sales revenues between oxymorphone ER and morphine ER. (CX5000 at 076 (¶ 166) (Noll Report); CX5000 at 199-201 (Exhibits 5B1-5B3) (Noll Report)).

RESPONSE TO FINDING NO. 686:

Respondent has no specific response. The data and associated charts speak for themselves.

687. These exhibits show that morphine ER accounts for substantially greater sales than oxymorphone ER. In addition, generic sales dwarf brand-name sales for morphine ER. (CX5000 at 077 (¶ 166) (Noll Report); CX5000 at 199-201 (Exhibits 5B1-5B3) (Noll Report)).

RESPONSE TO FINDING NO. 687:

Complaint Counsel's Proposed Finding No. 687 violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." Any data speaks for itself.

688. Generics already dominated sales of morphine ER at the time that Opana ER entered the market, and brand-name sales shares by all three measures continued to decline until the end of the data period. (CX5000 at 076 (¶ 166) (Noll Report); CX5000 at 199-201 (Exhibits 5B1-5B3) (Noll Report)).

RESPONSE TO FINDING NO. 688:

Respondent objects to the phrase "dominated sales" in this Proposed Finding as vague and ambiguous. Complaint Counsel's Proposed Finding No. 688 also violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." Any data speaks for itself.

689. By comparison, the growth in sales of Opana ER from its introduction in 2006 to its peak at the end of 2011 shows that generic morphine ER was not a close economic substitute for Opana ER as it was for brand-name morphine ER. (CX5000 at 076-7 (¶ 166) (Noll Report); CX5000 at 199-201 (Exhibits 5B1-5B3) (Noll Report); Noll, Tr. 1382 ("[I]f generic morphine is a close economic substitute for brand name Opana ER,

> and that generic entry occurred several years earlier . . . the generic entry in morphine would have had the same effect as the generic entry in oxymorphone, and it didn't. . . . [T]he price [of Opana ER] didn't actually fall and the sales decline until generic oxymorphone entered.")).

RESPONSE TO FINDING NO. 689:

Complaint Counsel's Proposed Finding No. 689 is incomplete, misleading, and based on unreliable expert testimony. The Proposed Finding is not probative of whether morphine ER is a "close economic substitute for Opana ER" for a number of reasons: First, the Proposed Finding is not based on any quantitative or statistical analysis; Professor Noll simply relied on a scan for a "visible effect" on Opana ER sales, a metric he never defined. (Noll, Tr. 1384). Indeed, Professor Noll did not conduct any econometric or statistical analysis regarding switching among products. (Addanki, Tr. 2331). Second, even if we assume Professor Noll has shown that a generic LAO took more sales from the corresponding branded LAO than from other LAOs, this is to be expected because of the unique setup of the pharmaceutical market, including automatic substitution. (Addanki, Tr. 2313-15). Third, Professor Noll's analysis ignores significant price competition at the payor, prescriber, and patient levels. (*See* also RX-547.0035-43 (Addanki Rep. ¶¶ 67-79)). Fourth, Professor Noll ignores evidence offered by Dr. Michna that physicians working with patients will respond to price changes among LAOs. (RX-549.0007 (Michna Rep. ¶ 23); Michna, Tr. 2125). Finally, Professor Noll's analysis says nothing about whether the entrance of generic LAOs increased output and thereby diminished monopoly power. (Addanki, Tr. 2203; RX-547.0019, 51 (Addanki Rep. ¶¶ 32, 96)). Accordingly, the graphical, non-econometric analysis described in Proposed Finding No. 689 should be disregarded.

> 690. The output measures for morphine ER diverge from the patterns for oxymorphone ER. The MME measure shows a gradual decline in output for morphine ER since the end of 2011, while the number of prescriptions has continued to rise. Revenues for generic morphine ER also rose dramatically, especially after mid-2013. (CX5000 at 077 (¶ 167) (Noll Report); CX5000 at 199-201 (Exhibits 5B1-5B3) (Noll Report)).

RESPONSE TO FINDING NO. 690:

Complaint Counsel's Proposed Finding No. 690 violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." Any data speaks for itself.

> 691. These data imply substantial increases in realized prices for morphine ER that did not result in a decline in prescriptions, much less a shift in sales to oxymorphone, which in turn implies that oxymorphone ER and morphine ER are not close economic substitutes. (CX5000 at 077 (¶ 167) (Noll Report); CX5000 at 199-201 (Exhibits 5B1-5B3) (Noll Report)).

RESPONSE TO FINDING NO. 691:

Complaint Counsel's Proposed Finding No. 691 is incomplete, misleading, and based on unreliable expert testimony. The Proposed Finding is not probative of whether oxymorphone ER and morphine ER are "close economic substitutes" for a number of reasons: First, the Proposed Finding is not based on any quantitative or statistical analysis; Professor Noll simply relied on a scan for a "visible effect" on Opana ER sales, a metric he never defined. (Noll, Tr. 1384). Indeed, Professor Noll did not conduct any econometric or statistical analysis regarding switching among products. (Addanki, Tr. 2331). Second, even if we assume Professor Noll has shown that a generic LAO took more sales from the corresponding branded LAO than from other LAOs, this is to be expected because of the unique setup of the pharmaceutical market, including automatic substitution. (Addanki, Tr. 2313-15). Third, Professor Noll's analysis ignores significant price competition at the payor, prescriber, and patient levels. (*See* also RX-547.0035-43 (Addanki Rep. ¶¶ 67-79)). Fourth, Professor Noll ignores evidence offered by Dr. Michna that physicians working with patients will respond to price changes among LAOs. (RX-549.0007 (Michna Rep. ¶ 23); Michna, Tr. 2125). Finally, Professor Noll's analysis says nothing about whether the entrance of generic LAOs increased output and thereby diminished

monopoly power. (Addanki, Tr. 2203; RX-547.0019, 51 (Addanki Rep. ¶¶ 32, 96)). Accordingly, the graphical, non-econometric analysis described in Proposed Finding No. 684 should be disregarded.

692. Exhibits 5C1, 5C2 and 5C3 of the Noll Report show the sales of hydromorphone ER (Exalgo) and oxymorphone ER as measured by prescriptions, MME and sales revenue. (CX5000 at 077-078 (¶¶ 168-69) (Noll Report); CX5000 at 202-204 (Exhibits 5C1-5C3) (Noll Report)).

RESPONSE TO FINDING NO. 692:

Respondent has no specific response. The data and associated charts speak for themselves.

693. The introduction of Exalgo in 2010 occurred during the period of rapid growth in Opana ER sales, with no apparent effect of the former on the latter. (CX5000 at 077 (¶ 169) (Noll Report); CX5000 at 202-204 (Exhibits 5C1-5C3) (Noll Report)).

RESPONSE TO FINDING NO. 693:

Respondent objects to the phrases "apparent affect" in Complaint Counsel's Proposed Finding No. 693 as vague and ambiguous. The Proposed Finding also violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." Any data speaks for itself. Moreover, the use of the term "apparent" in Proposed Finding No. 693 demonstrates that Professor Noll failed to conduct any empirical or econometric analysis to determine any actual effects, and that the Proposed Finding is based on unreliable expert testimony. (Noll, Tr. 1384 (noting he scanned for "visible effect[s]"); Addanki, Tr. 2331 (noting Professor Noll conducted no econometric or statistical analysis)). Finally, the cited portion of Professor Noll's report (CX5000-077-78 (Noll Rep. ¶ 169)) contains no external citations for the proposition that generic oxymorphone ER had no apparent effect on the growth in sales of Exalgo.

694. Moreover, the introduction of generic oxymorphone ER, while taking substantial sales away from Opana ER, had no apparent effect on the growth in sales of Exalgo. (CX5000 at 078 (¶ 169) (Noll Report); CX5000 at 202-204 (Exhibits 5C1-5C3) (Noll Report)).

RESPONSE TO FINDING NO. 694:

Respondent objects to the phrases "substantial sales" and "apparent affect" in Complaint Counsel's Proposed Finding No. 694 as vague and ambiguous. The Proposed Finding also violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." Any data speaks for itself. But the use of the term "apparent" in Proposed Finding No. 694 demonstrates that Professor Noll failed to conduct any empirical or econometric analysis to determine any actual effects, and that the Proposed Finding is based on unreliable expert testimony. (Noll, Tr. 1384 (noting he scanned for "visible effect[s]"); Addanki, Tr. 2331 (noting Profess Noll conducted no econometric or statistical analysis)). Finally, the cited portion of Professor Noll's report (CX5000-077-78 (Noll Rep. ¶ 169)) contains no external citations for the proposition that generic oxymorphone ER had no apparent effect on the growth in sales of Exalgo.

695. The entry of generic hydromorphone ER occurred only near the end of the data period, in 2014, but for the limited period in the exhibits the only apparent effect of generic entry is on sales of Exalgo. There was no apparent effect on total sales of oxymorphone ER, which rose slightly after generic hydromorphone ER was introduced. (CX5000 at 078 (¶ 169) (Noll Report); CX5000 at 202-204 (Exhibits 5C1-5C3) (Noll Report)).

RESPONSE TO FINDING NO. 695:

Respondent objects to the phrase "apparent affect" in Complaint Counsel's Proposed Finding No. 695 as vague and ambiguous. Proposed Finding No. 695 also violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." Any data speaks for itself. Moreover,

the use of the term "apparent" in Proposed Finding No. 695 demonstrates that Professor Noll failed to conduct any empirical or econometric analysis to determine any actual effects, and that the Proposed Finding is based on unreliable expert testimony. (Noll, Tr. 1384 (noting he scanned for "visible effect[s]"); Addanki, Tr. 2331 (noting Professor Noll conducted no econometric or statistical analysis)).

696. These data support the conclusion that hydromorphone ER is not a close economic substitute for oxymorphone ER. (CX5000 at 078 (¶ 169) (Noll Report); CX5000 at 202204 (Exhibits 5C1-5C3) (Noll Report)).

RESPONSE TO FINDING NO. 696:

Complaint Counsel's Proposed Finding No. 696 is incomplete, misleading, and based on unreliable expert testimony. The Proposed Finding is not probative of whether oxymorphone ER and hydromorphone ER are "close economic substitutes" for a number of reasons: First, the Proposed Finding is not based on any quantitative or statistical analysis; Professor Noll simply relied on a scan for a "visible effect" on Opana ER sales, a metric he never defined. (Noll, Tr. 1384). Indeed, Professor Noll did not conduct any econometric or statistical analysis regarding switching among products. (Addanki, Tr. 2331). Second, even if we assume Professor Noll has shown that a generic LAO took more sales from the corresponding branded LAO than from other LAOs, this is to be expected because of the unique setup of the pharmaceutical market, including automatic substitution. (Addanki, Tr. 2313-15). Third, Professor Noll's analysis ignores significant price competition at the payor, prescriber, and patient levels. (*See* also RX-547.0035-43 (Addanki Rep. ¶¶ 67-79)). Fourth, Professor Noll ignores evidence offered by Dr. Michna that physicians working with patients will respond to price changes among LAOs. (RX-549.0007 (Michna Rep. ¶ 23); Michna, Tr. 2125). Finally, Professor Noll's analysis says nothing about whether the entrance of generic LAOs increased output and thereby diminished

monopoly power. (Addanki, Tr. 2203; RX-547.0019, 51 (Addanki Rep. ¶¶ 32, 96)). Accordingly, the graphical, non-econometric analysis described in Proposed Finding No. 696 should be disregarded.

697. Butrans (buprenorphine patch) was introduced in 2010 during the period when Opana ER sales were growing rapidly. (CX5000 at 078-79 (¶¶ 170-72) (Noll Report); CX5000 at 205-207 (Exhibits 5D1-5D3) (Noll Report)).

RESPONSE TO FINDING NO. 697:

Complaint Counsel's Proposed Finding No. 697 violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents."

698. [redacted] (CX5000 at 078-79 (¶¶ 170, 172) (Noll Report); CX5000 at 205207 (Exhibits 5D1-5D3) (Noll Report) (*in camera*)).

RESPONSE TO FINDING NO. 698:

Complaint Counsel's Proposed Finding No. 698 violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." Any data speaks for itself. Further, Respondent objects to the phrase [redacted] in Complaint Counsel's Proposed Finding No. 698 as vague and ambiguous.

699. The rapid decline in Opana ER sales in 2012, when Reformulated Opana ER replaced the old Opana ER, did not cause a change in sales growth for Butrans. (CX5000 at 079 (¶ 172) (Noll Report); CX5000 at 205-207 (Exhibits 5D1-5D3) (Noll Report)).

RESPONSE TO FINDING NO. 699:

Complaint Counsel's Proposed Finding No. 699 violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by

fact witnesses or documents." Any data speaks for itself. Moreover, the cited portion of Professor Noll's report (CX5000-079 (Noll Rep. ¶ 172)) contains no external citations for the proposition that the decline in Opana ER sales in 2012 did not cause a change in sales growth for Butrans. Further, Respondent objects to the phrase "rapid decline" in Complaint Counsel's Proposed Finding No. 699 as vague and ambiguous.

> 700. The introduction of generic oxymorphone in all dose sizes did not lead to a fall in Butrans sales as it did in sales of Opana ER. (CX5000 at 079 (¶ 172) (Noll Report); CX5000 at 205-207 (Exhibits 5D1-5D3) (Noll Report)).

RESPONSE TO FINDING NO. 700:

Complaint Counsel's Proposed Finding No. 700 is misleading, not supported by the cited evidence, and based on unreliable expert testimony. The cited portion of Professor Noll's report (CX5000-079 (Noll Rep. ¶ 172)) contains no external citations for the proposition that the introduction of generic oxymorphone did not lead to a fall in Butrans sales.

> 701. Thus, Butrans' sales data are not consistent with Butrans and oxymorphone ER being close economic substitutes. (CX5000 at 079 (¶ 172) (Noll Report); CX5000 at 205-207 (Exhibits 5D1-5D3) (Noll Report)).

RESPONSE TO FINDING NO. 701:

Complaint Counsel's Proposed Finding No. 701 is incomplete, misleading, and based on unreliable expert testimony. The Proposed Finding is not probative of whether oxymorphone ER and Butrans are "close economic substitutes" for a number of reasons: First, the Proposed Finding is not based on any quantitative or statistical analysis; Professor Noll simply relied on a scan for a "visible effect" on Opana ER sales, a metric he never defined. (Noll, Tr. 1384). Indeed, Professor Noll did not conduct any econometric or statistical analysis regarding switching among products. (Addanki, Tr. 2331). Second, even if we assume Professor Noll has shown that a generic LAO took more sales from the corresponding branded LAO than from other

LAOs, this is to be expected because of the unique setup of the pharmaceutical market, including automatic substitution. (Addanki, Tr. 2313-15). Third, Professor Noll's analysis ignores significant price competition at the payor, prescriber, and patient levels. (*See* also RX-547.0035-43 (Addanki Rep. ¶¶ 67-79)). Fourth, Professor Noll ignores evidence offered by Dr. Michna that physicians working with patients will respond to price changes among LAOs. (RX-549.0007 (Michna Rep. ¶ 23); Michna, Tr. 2125). Finally, Professor Noll's analysis says nothing about whether the entrance of generic LAOs increased output and thereby diminished monopoly power. (Addanki, Tr. 2203; RX-547.0019, 51 (Addanki Rep. ¶¶ 32, 96)). Accordingly, the graphical, non-econometric analysis described in Proposed Finding No. 701 should be disregarded.

> 702. Exhibits 5E1, 5E2 and 5E3 of the Noll Report compare sales of oxymorphone ER and fentanyl ER (the brand name for which is Duragesic) in terms of total prescriptions, MME, and revenues. (CX5000 at 080 (¶¶ 173-75) (Noll Report); CX5000 at 208-210 (Exhibits 5E1-5E3) (Noll Report)).

RESPONSE TO FINDING NO. 702:

Respondent has no specific response. The data and associated charts speak for themselves.

> 703. Two noticeable features about fentanyl are that fentanyl vastly outsells oxymorphone and that generic fentanyl vastly outsells Duragesic. (CX5000 at 080 (¶ 175) (Noll Report); CX5000 at 208-210 (Exhibits 5E1-5E3) (Noll Report)).

RESPONSE TO FINDING NO. 703:

Respondent objects to the phrase "vastly outsells" in Complaint Counsel's Proposed Finding No. 703 as vague and ambiguous. Complaint Counsel's Proposed Finding No. 703 also violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual

propositions that should be established by fact witnesses or documents." Any data speaks for itself.

704. Generic fentanyl ER has dominated the sales of fentanyl ER throughout the data period, but the availability of generic fentanyl did not inhibit the rapid growth of Opana ER sales through the end of 2011. (CX5000 at 081 (¶ 175) (Noll Report); CX5000 at 208-210 (Exhibits 5E1-5E3) (Noll Report)).

RESPONSE TO FINDING NO. 704:

Respondent objects to the phrases "dominated the sales" and "inhibit the rapid growth" in Complaint Counsel's Proposed Finding No. 704 as vague and ambiguous. Proposed Finding No. 704 also violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." The cited portion of Professor Noll's report (CX5000-080 (Noll Rep. ¶ 175)) cites no sources for the proposition that generic fentanyl did not inhibit the rapid growth of Opana ER sales through the end of 2011. Any data speaks for itself.

705. The rise and fall of sales of oxymorphone ER through the end of 2012 (before the entry of Impax) is in contrast to the stable quantity of sales and steady decline in revenues of fentanyl ER. (CX5000 at 081 (¶ 175) (Noll Report); CX5000 at 208-210 (Exhibits 5E1-5E3) (Noll Report)).

RESPONSE TO FINDING NO. 705:

Complaint Counsel's Proposed Finding No. 705 violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." Any data speaks for itself.

706. Finally, the introduction of generic oxymorphone ER did not have a substantial effect on sales of fentanyl ER. (CX5000 at 081 (¶ 175) (Noll Report); CX5000 at 208-210 (Exhibits 5E1-5E3) (Noll Report)).

RESPONSE TO FINDING NO. 706:

Respondent objects to the phrase "substantial effect" in Complaint Counsel's Proposed Finding No. 706 as vague and ambiguous. Proposed Finding No. 706 also violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." The cited portion of Professor Noll's report (CX5000-080 (Noll Rep. ¶ 175)) cites no sources for the proposition that oxymorphone ER did not have a substantial effect on sales of fentanyl ER. Professor Noll merely surmises this by looking for a "visible effect." (Noll, Tr. 1384). But Exhibit 5E3 [redacted] (CX5000-210 (Noll Rep., Ex. 5E3)).

707. Thus, the patterns of sales of fentanyl ER and oxymorphone ER are not consistent with the hypothesis that these drugs are close economic substitutes. (CX5000 at 081 (¶ 175) (Noll Report); CX5000 at 208-210 (Exhibits 5E1-5E3) (Noll Report)).

RESPONSE TO FINDING NO. 707:

Complaint Counsel's Proposed Finding No. 707 is incomplete, misleading, and based on unreliable expert testimony. The Proposed Finding is not probative of whether oxymorphone ER and fentanyl ER are "close economic substitutes" for a number of reasons: First, the Proposed Finding is not based on any quantitative or statistical analysis; Professor Noll simply relied on a scan for a "visible effect" on Opana ER sales, a metric he never defined. (Noll, Tr. 1384). Indeed, Professor Noll did not conduct any econometric or statistical analysis regarding switching among products. (Addanki, Tr. 2331). Second, even if we assume Professor Noll has shown that a generic LAO took more sales from the corresponding branded LAO than from other LAOs, this is to be expected because of the unique setup of the pharmaceutical market, including automatic substitution. (Addanki, Tr. 2313-15). Third, Professor Noll's analysis ignores

significant price competition at the payor, prescriber, and patient levels. (*See* also RX-547.0035-43 (Addanki Rep. ¶¶ 67-79)). Fourth, Professor Noll ignores evidence offered by Dr. Michna that physicians working with patients will respond to price changes among LAOs. (RX-549.0007 (Michna Rep. ¶ 23); Michna, Tr. 2125). Finally, Professor Noll's analysis says nothing about whether the entrance of generic LAOs increased output and thereby diminished monopoly power. (Addanki, Tr. 2203; RX-547.0019, 51 (Addanki Rep. ¶¶ 32, 96)). Accordingly, the graphical, non-econometric analysis described in Proposed Finding No. 707 should be disregarded.

708. Exhibits 5F1, 5F2 and 5F3 of the Noll Report show sales as measured by prescriptions, MME and revenues for Zohydro (hydrocodone ER) and oxymorphone ER. (CX5000 at 081 (¶¶ 176-77) (Noll Report); CX5000 at 211-213 (Exhibits 5F1-5F3) (Noll Report)).

RESPONSE TO FINDING NO. 708:

Respondent has no specific response other than to note that Exhibits 5F1-5F3 purport to show only three quarters of sales for Zohydro, which is insufficient data from which to draw any reliable conclusions.

709. These exhibits show that Zohydro's sales are much smaller than sales of oxymorphone ER. The early sales of Zohydro occurred when total sales of oxymorphone ER also were rising, so the entry of Zohydro did not substitute for sales of oxymorphone ER. (CX5000 at 081 (¶ 177) (Noll Report); CX5000 at 211-213 (Exhibits 5F1-5F3) (Noll Report)).

RESPONSE TO FINDING NO. 709:

Complaint Counsel's Proposed Finding No. 709 violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." Any data speaks for itself. Nevertheless, even if Zohydro's "early sales" occurred when "total sales of oxymorphone ER were also rising," that does not indicate

that the sales of Zohydro did not substitute for sales of oxymorphone ER. The Proposed Finding fails to acknowledge that Zohydro's sales may have come at the expense of additional oxymorphone ER sales. The cited portion of Professor Noll's report (CX5000-081 (Noll Rep. ¶ 177)) contains no external citations for the proposition that Zohydro did not substitute for sales of oxymorphone ER. Finally, no conclusions related to Zohydro can be reliably drawn from Professor Noll's analysis since it only looks at three quarters' of sales of Zohydro across a ten-year period.

> 710. Zohydro's sales also were achieved despite the presence of a generic form of oxymorphone ER. (CX5000 at 081 (¶ 177) (Noll Report); CX5000 at 211-213 (Exhibits 5F1-5F3) (Noll Report)).

RESPONSE TO FINDING NO. 710:

The data and associated charts cited in Complaint Counsel's Proposed Finding No. 710 speak for themselves. Nonetheless, the fact Zohydro had sales while there were simultaneous sales of generic oxymorphone ER does not mean that potential sales of oxymorphone ER were not lost to Zohydro, or vice versa. Finally, no conclusions related to Zohydro can be reliably drawn because Professor Noll's analysis only looks at three quarters' of sales of Zohydro across a ten-year period.

> 711. Thus, the data support the conclusion that hydrocodone ER is not a close economic substitute for oxymorphone ER and so not part of the same relevant product market for purposes of assessing the conduct at issue in this case. (CX5000 at 081 (¶ 177) (Noll Report); CX5000 at 211-213 (Exhibits 5F1-5F3) (Noll Report)).

RESPONSE TO FINDING NO. 711:

Complaint Counsel's Proposed Finding No. 711 is incomplete, misleading, and based on unreliable expert testimony. The Proposed Finding is not probative of whether oxymorphone ER and hydrocodone ER are "close economic substitutes" for a number of reasons: First, the

Proposed Finding is not based on any quantitative or statistical analysis; Professor Noll simply relied on a scan for a "visible effect" on Opana ER sales, a metric he never defined. (Noll, Tr. 1384). Indeed, Professor Noll did not conduct any econometric or statistical analysis regarding switching among products. (Addanki, Tr. 2331). Second, even if we assume Professor Noll has shown that a generic LAO took more sales from the corresponding branded LAO than from other LAOs, this is to be expected because of the unique setup of the pharmaceutical market, including automatic substitution. (Addanki, Tr. 2313-15). Third, Professor Noll's analysis ignores significant price competition at the payor, prescriber, and patient levels. (*See* also RX-547.0035-43 (Addanki Rep. ¶¶ 67-79)). Fourth, Professor Noll ignores evidence offered by Dr. Michna that physicians working with patients will respond to price changes among LAOs. (RX-549.0007 (Michna Rep. ¶ 23); Michna, Tr. 2125). Finally, Professor Noll's analysis says nothing about whether the entrance of generic LAOs increased output and thereby diminished monopoly power. (Addanki, Tr. 2203; RX-547.0019, 51 (Addanki Rep. ¶¶ 32, 96)). Accordingly, the graphical, non-econometric analysis described in Proposed Finding No. 711 should be disregarded.

712. Exhibits 5G1, 5G2 and 5G3 of the Noll Report compare sales of tapentadol ER (Nucynta ER) and oxymorphone ER by prescriptions, MME and revenues. (CX5000 at 081 (¶¶ 178-79) (Noll Report); CX5000 at 214-216 (Exhibits 5G1-5G3) (Noll Report)).

RESPONSE TO FINDING NO. 712:

Respondent has no specific response. The data and associated charts speak for themselves.

713. [redacted] (CX5000 at

081 (¶ 179) (Noll Report); CX5000 at 214-216 (Exhibits 5G1-5G3) (Noll Report) (*in camera*)).

RESPONSE TO FINDING NO. 713:

Respondent objects to the phrase "increasing rapidly" in Complaint Counsel's Proposed Finding No. 713 as vague and ambiguous. Proposed Finding No. 713 also violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." The cited portion of Professor Noll's report (CX5000-081 (Noll Rep. ¶ 179)) contains no external citations for the proposition that [redacted] Nevertheless, [redacted]

714. During 2012, sales of Nucynta ER continued to grow while Opana ER sales fell, but the former was much smaller than the latter. (CX5000 at 081 (¶ 179) (Noll Report); CX5000 at 214-216 (Exhibits 5G1-5G3) (Noll Report)).

RESPONSE TO FINDING NO. 714:

Respondent objects to the phrase "much smaller" in Complaint Counsel's Proposed Finding No. 714 as vague and ambiguous. Proposed Finding No. 714 also violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." Any data speaks for itself.

715. Later, the entry of generic oxymorphone ER had no effect on sales of Nucynta ER. (CX5000 at 081 (¶ 179) (Noll Report); CX5000 at 214-216 (Exhibits 5G1-5G3) (Noll Report)).

RESPONSE TO FINDING NO. 715:

Complaint Counsel's Proposed Finding No. 715 is not supported by the cited evidence and is misleading because Professor Noll did not actually conduct any empirical or econometric analysis of the effect generic oxymorphone ER had on sales of Nucynta ER. (Addanki, Tr. 2331). The cited portion of Professor Noll's report (CX5000-081 (Noll Rep. ¶ 179)) contains no external citations for the proposition that oxymorphone ER had no effect on sales of Nucynta ER.

716. These data indicate that tapentadol is not a close economic substitute for oxymorphone ER. (CX5000 at 081 (¶ 179) (Noll Report); CX5000 at 214-216 (Exhibits 5G1-5G3) (Noll Report)).

RESPONSE TO FINDING NO. 716:

Complaint Counsel's Proposed Finding No. 716 is incomplete, misleading, and based on unreliable expert testimony. The Proposed Finding is not probative of whether oxymorphone ER and tapentadol ER are "close economic substitutes" for a number of reasons: First, the Proposed Finding is not based on any quantitative or statistical analysis; Professor Noll simply relied on a scan for a "visible effect" on Opana ER sales, a metric he never defined. (Noll, Tr. 1384). Indeed, Professor Noll did not conduct any econometric or statistical analysis regarding switching among products. (Addanki, Tr. 2331). Second, even if we assume Professor Noll has shown that a generic LAO took more sales from the corresponding branded LAO than from other LAOs, this is to be expected because of the unique setup of the pharmaceutical market, including automatic substitution. (Addanki, Tr. 2313-15). Third, Professor Noll's analysis ignores significant price competition at the payor, prescriber, and patient levels. (*See* also RX-547.0035-43 (Addanki Rep. ¶¶ 67-79)). Fourth, Professor Noll ignores evidence offered by Dr. Michna that physicians working with patients will respond to price changes among LAOs. (RX-

549.0007 (Michna Rep. ¶ 23); Michna, Tr. 2125). Finally, Professor Noll's analysis says nothing about whether the entrance of generic LAOs increased output and thereby diminished monopoly power. (Addanki, Tr. 2203; RX-547.0019, 51 (Addanki Rep. ¶¶ 32, 96)). Accordingly, the graphical, non-econometric analysis described in Proposed Finding No. 716 should be disregarded.

2. Endo's internal documents confirm that other long-acting opioids did not meaningfully constrain Opana ER

717. The information in the Endo discovery record supports the conclusion that other LAOs, while offering some competition against Opana ER, are not close economic substitutes that lead to price competition between Opana ER and any of them. (CX5000 at 72 (¶ 158) (Noll Report); Noll, Tr. 1394 ("These support the idea that . . . other long-acting opioids are not close economic substitutes. They don't force competitive pricing on Endo."); *see also* CCF ¶¶ 718-90, below).

RESPONSE TO FINDING NO. 717:

Complaint Counsel's Proposed Finding No. 717 is inaccurate and misstates the record. Endo's documents indicate substantial price competition. (RX-087 (UPMC formulary change led to 70 percent of patients on OxyContin switching to different long-acting opioids with lower prices, including Opana ER, generic Morphine Sulfate ER (MS ER), and generic Fentanyl patches); RX-021.0005, 07 ([redacted]); RX-022.0004 (same); RX-448.0020 ([redacted]); Addanki, Tr. 2500 (describing formulary price competition and noting that rebates are on the order of magnitude of a small but significant non-transitory increase in price, indicating that "even small price changes were competitively potentially significant")).

The documents also indicate how this price competition led to switching and economic substitution among long-acting opioids. (*See, e.g.*, RX-083.0003 at 35 (highlighting real-world switching patterns between Opana ER and other long-acting opioid products, including drugs containing fentanyl, oxycodone, and morphine); RX-073.0002 at 13, 16 (tracking switching prescriptions for various long-acting opioids and noting Endo "must accelerate the gain of switches from Oxycontin"); RX-060.0002 at 28; CX2610-024 (2010 Endo document listing oxycodone, morphine, tapentadol, hydromorphone, fentanyl, buprenorphine, and duloxetine as competitors to oxymorphone ER); RX-014.0002; RX-021.0005; RX-022.0004; RX-087).

> 718. In June of 2009, increased availability of generic versions of OxyContin did not cause any change to Endo's marketing strategy for Opana ER. (CX2731 at 001 (Endo email to sales leadership) ("This will no doubt increase the amount of generic OxyContin in the market, but it does not change our strategy."); Bingol, Tr. 1278-79 ("Our molecule was still the better fit for different types of patients. Whether there's generic OxyContin or not didn't necessarily change that dynamic.")).

RESPONSE TO FINDING NO. 718:

Complaint Counsel's Proposed Finding No. 718 is incomplete and misleading. While Mr. Bingol testified that the increased availability of generic versions of OxyContin did not cause any change to Endo's marketing strategy, Mr. Bingol explained that the increased availability of generic OxyContin ER would affect Endo's market share in the long-acting opioid market. (Bingol, Tr. 1278 ("JUDGE CHAPPELL: Did I understand you to say basically OxyContin was already on the market and adding a generic wouldn't change the market share? A. No, Sir.")). Mr. Bingol testified that "all long-acting opioid formulations," including generics that are not actively marketed, are direct competitors. (Bingol, Tr. 1271, 1313). Whether Endo changed its marketing strategy in response to increased availability of generic OxyContin is irrelevant to the market definition analysis.

719. Opana ER had continued to grow in 2009 despite generic versions of OxyContin coming back on the market. (CX2731 at 001 (Endo email to sales leadership)).

RESPONSE TO FINDING NO. 719:

Complaint Counsel's Proposed Finding No. 719 is incomplete and misleading. The cited document (CX2731) states that "Opana ER has continued to grow in 2009 even though generic OxyContin *has been back in the market on a limited basis*." (CX2731-001 (emphasis added) (noting further that there "will no doubt [be an] increase [in] the amount of generic OxyContin in the market")).

720. In Mr. Bingol's May 2010 declaration from the patent litigation against Impax, he stated that "despite the presence of new entrants in the market who are actively promoting their new products (EMBEDA and EXALGO), and despite the fact that Endo's promotion spend has declined, Endo's share of the market with OPANA ER continues to grow at a steady rate." (CX3273 at 004 (¶ 8) (Bingol Decl.)).

RESPONSE TO FINDING NO. 720:

Complaint Counsel's Proposed Finding No. 720 is incomplete and misleading. In both his trial testimony and his written declaration, Mr. Bingol explained that there is a long-acting opioid market. (CX3273-004 (¶ 8) (referring to the "share breakdown in the LAO market"); *see also* Court, Tr. 1284 ("JUDGE CHAPPELL: The first sentence in that paragraph you were just telling us about starts out by talking about the LAO market. For the record, tell us what you mean by 'LAO.' WITNESS: Long-acting opioid.")). Mr. Bingol emphasized in his declaration that "OPANA ER is sold into a market segment referred to as the long-acting opioid (LAO) market, which comprises controlled release opioid products." (CX3273-003 (¶6)). That market "was a well-established and competitive market that consisted of many products that had been on the market for years." (CX3273-003 (¶ 6)).

721. Endo's internal documents rarely mention relative prices as an important factor in determining sales of Opana ER. (CX5000 at 67 (¶ 146) (Noll Report)).

RESPONSE TO FINDING NO. 721:

Complaint Counsel's Proposed Finding No. 721 violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." Further, the cited portion of Professor Noll's report actually references a document in which Endo compared the prices of OxyContin and Opana ER for high dose patients. (*See* CX3158). In any event, Endo tracked its competitors' "[a]ggressive couponing" when formulating its own patient copay program. (RX-028.0011; *see* Addanki, Tr. 2280-82). [redacted] (RX-445.0015). Professor Noll also discusses an email in which Endo noted that Purdue had offered Group Purchasing Organizations ("GPOs") discounts on OxyContin ranging from 15 percent to 20 percent. (CX5000-068 (Noll Rep. ¶ 149) (citing CX3206)). In order to "achieve pricing parity to Oxycontin," Endo proposed "an additional 11% discount on Opana ER" in response. (CX3206-002). Finally, Respondent objects to the word "rarely" in the Proposed Finding as vague and ambiguous.

> 722. Rather, the importance of differentiation between Opana ER and other opioids was discussed in Endo's internal business documents. For example, the Opana ER strategic plan for 2010 notes the importance of sales efforts to high-prescribing physicians that emphasize differentiating factors of Opana ER, stating: "Failure to adequately differentiate Opana ER will limit the brand's growth . . . ." (CX1106 at 004 (2010 Opana Brand Strategic Plan)).

RESPONSE TO FINDING NO. 722:

Complaint Counsel's Proposed Finding No. 722 is inaccurate and misleading in its suggestion that marketing efforts focused on product differentiation require a narrow market definition. Professor Noll fails to appreciate that long-acting opioid manufacturers attempt to differentiate their products precisely *because* they are close substitutes and competing vigorously. Demir Bingol, Endo's Senior Director of Marketing, testified that the differences between Opana ER and other long-acting opioids were used as a marketing tactic because they

represented Endo's "best opportunity to compete against those [other long-acting opioid] products based on their profile and what they brought to the market." (Bingol, Tr. 1314); *see* CX4025 (Bingol, Dep. at 104) (Opana ER is "the same as everything else. Differentiation is always your mission in marketing.")). And Mr. Bingol explained that Opana ER competed with all other branded and generic long-acting opioids, including on price. (Bingol, Tr. 1326-27). Finally, the quoted language in the Proposed Finding is incomplete and misleading. The statement in CX1106 is "Failure to adequately differentiate Opana ER will limit the brand's growth in 2010 *vs. existing competitors*." (CX1106-004 (emphasis added)).

> 723. It was important for Endo to differentiate Opana ER from other long-acting opioids because otherwise there was no basis for creating value or having a prescriber want to prescribe it for a patient. (CX4025 (Bingol, Dep. at 104) ("Differentiation is always your mission in marketing.")).

RESPONSE TO FINDING NO. 723:

Complaint Counsel's Proposed Finding No. 723 is misleading and not supported by the cited evidence. Mr. Bingol testified that Opana ER is "*the same as everything else*. Differentiation is always your mission in marketing." (CX4025 (Bingol, Dep. at 104) (emphasis added)). Mr. Bingol testified at trial that any differences between Opana ER and other long-acting opioids were used as a marketing tactic because they represented Endo's "best opportunity to compete against those [other long-acting opioid] products based on their profile and what they brought to the market." (Bingol, Tr. 1314).

> 724. A promotional strategy that focuses on product differentiation reduces the intensity of price competition, it doesn't increase it. (Noll, Tr. 1402-03).

RESPONSE TO FINDING NO. 724:

Complaint Counsel's Proposed Finding No. 724 violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by

fact witnesses or documents." Professor Noll fails to appreciate that long-acting opioid manufacturers attempt to differentiate their products precisely *because* they are close substitutes and competing vigorously. Demir Bingol, Endo's Senior Director of Marketing, testified that the differences between Opana ER and other long-acting opioids were used as a marketing tactic because they represented Endo's "best opportunity to compete against those [other long-acting opioid] products based on their profile and what they brought to the market." (Bingol, Tr. 1314); *see* CX4025 (Bingol, Dep. at 104) (Opana ER is "the same as everything else. Differentiation is always your mission in marketing.")). And Mr. Bingol explained that Opana ER competed with all other branded and generic long-acting opioids, including on price. (Bingol, Tr. 1326-27).

725. Product differentiation provides an explanation for why one wouldn't expect two different long-acting opioids to be close economic substitutes. (Noll, Tr. 1403).

RESPONSE TO FINDING NO. 725:

Complaint Counsel's Proposed Finding No. 725 is inaccurate. Dr. Addanki explained that "Pharmaceutical firms often engage in efforts to differentiate their branded product from therapeutic alternatives. Those efforts are often particularly pronounced where the firm's product is therapeutically very similar to the available alternatives, so that prescribing decisions are more likely to be influenced, at the margin, by the promotional activities undertaken by the firm and its therapeutic competitors; indeed, it is often the case that the more therapeutically similar the products at issue, the more vigorous the competition via detailing, promotion and other brand-building activities." (RX-547.0026 (Addanki Rep. ¶ 49)).

What is more, Demir Bingol, Endo's Senior Director of Marketing, testified that Opana ER is "*the same as everything else*. Differentiation is always your mission in marketing." (CX4025 (Bingol, Dep. at 104) (emphasis added)). Mr. Bingol testified at trial that any differences between Opana ER and other long-acting opioids were used as a marketing tactic

because they represented Endo's "best opportunity to compete against those [other long-acting opioid] products based on their profile and what they brought to the market." (Bingol, Tr. 1314).

726. Oxymorphone as a molecule has intrinsic qualities that might have meaningful importance to clinicians or patients. (Bingol, Tr. 1270; CX4025 (Bingol, Dep. at 99-100); CX2529 at 050 (Opana ER "is the only long-acting opioid that contains oxymorphone, a molecule with distinct pharmacologic properties compared with most other opioids...") (Opana ER Strategic Platform presentation).

RESPONSE TO FINDING NO. 726:

While Respondent does not dispute that oxymorphone may be preferred by individual patients in particular contexts, the record does not support the proposition that oxymorphone has any inherent qualities that make it superior to any other long-acting opioid across any population of patients. (Savage, Tr. 790-91; Michna, Tr. 2149). Complaint Counsel's own medical expert, Dr. Savage, admits that "most" people can get equally effective and safe pain relief from numerous long-acting opioids. (CX4041 (Savage, Dep. at 60, 66-67)). Doctors Savage and Michna agree that no medical conditions produce pain for which oxymorphone ER or any other opioid medication is the only long-acting opioid option. (Savage, Tr. 791; Michna, Tr. 2149). "[M]ost [opioids] are interchangeable if attention is paid to relative potencies and onset and duration of action." (Savage, Tr. 782-83). Indeed, doctors use every long-acting opioid to treat the same medical conditions, including post-operation pain, lumbago, and chronic pain syndrome. (RX-547.0105 (Addanki Rep., Ex. 4); Addanki, Tr. 2245-47).

727. As early as 2007, in an attempt to highlight one such intrinsic quality, Endo sent letters to health care professionals touting the advantages of Opana ER. (CX2722 at 001 (Letter from Demir Bingol to Healthcare Professionals) ("Opana ER has no known CYP450 drug-drug interactions at clinically relevant doses. Please see the enclosed information for further details and talk to your Endo sales representative today about the benefits of Opana ER for your patients . . .")).

RESPONSE TO FINDING NO. 727:

Complaint Counsel's Proposed Finding No. 727 is incomplete and misleading. Opana ER was not (and is not) the only long-acting opioid that did not raise CYP 450 issues, as the Proposed Finding attempts to suggest. Neither morphine nor hydromorphone utilize the CYP 450 pathway. (Savage, Tr. 795-96). Endo nevertheless used metabolic differences between Opana ER and some other long-acting opioids as a marketing tactic because it represented Endo's "best opportunity to compete against those [other long-acting opioid] products based on their profile and what they brought to the market." (Bingol, Tr. 1314). Still, such metabolic differences are "not clinically relevant." (Michna, Tr. 2154-55; *see also* RX-549.0018-19 (Michna Rep. ¶ 46) ("I have never seen a case in which CYP 450 metabolism had any real clinical relevance in my decision to prescribe an opioid.")).

728. Likewise, Demir Bingol, who was responsible for marketing Opana ER, testified that Endo marketed Opana ER by "creat[ing] different strategies or promotional tactics in order to be able to effectively communicate why your product is different and why it would be needed by certain patient types." (Bingol, Tr. 1265).

RESPONSE TO FINDING NO. 728:

Respondent has no specific response other than to note that fact that Endo used "promotional tactics" to compete against other long-acting opioids is consistent with a long-acting opioids market. (CX4025 (Bingol, Dep. at 104) (Opana ER is "the same as everything else. Differentiation is always your mission in marketing."); Bingol, Tr. 1314 (marketing tactics highlighting any differences represented Endo's "best opportunity to compete against those [other long-acting opioid] products based on their profile and what they brought to the market.")).

729. Another Endo document summarizes a strategy for convincing physicians to prescribe Opana ER rather than OxyContin, but the document emphasizes qualitative

attributes of Opana ER, such as "12 hour pain reliever" and "No CYP450 PK drug-drug interactions" that make it a better choice for patients. (CX3198 at 044 (Branded Pharmaceuticals Business Review)).

RESPONSE TO FINDING NO. 729:

Complaint Counsel's Proposed Finding No. 729 is incomplete and misleading. Opana ER was not (and is not) the only long-acting opioid that did not raise CYP 450 issues, as the Proposed Finding attempts to suggest. Neither morphine nor hydromorphone utilize the CYP 450 pathway. (Savage, Tr. 795-96). Endo nevertheless used differences between Opana ER and other long-acting opioids as a marketing tactic because it represented Endo's "best opportunity to compete against those [other long-acting opioid] products based on their profile and what they brought to the market." (Bingol, Tr. 1314; CX4025 (Bingol, Dep. at 104) (Opana ER is "the same as everything else. Differentiation is always your mission in marketing.")).

730. Endo executives stated publicly that Opana ER has distinct features that differentiate it from other LAOs. For example, in Endo's Q2 2011 investor call, then-COO, Julie McHugh, noted that Opana ER was a "rapidly growing brand . . . due to the inherent characteristics of the compound . . . ." (CX3219 at 017 (Endo's Q2 2011 Earnings Call Transcript)).

RESPONSE TO FINDING NO. 730:

Complaint Counsel's Proposed Finding No. 730 is incomplete and misleading because it ignores the testimony of Demir Bingol, Endo's Senior Director of Marketing, who explained that Opana ER is "the same as everything else. Differentiation is always your mission in marketing." (CX4025 (Bingol, Dep. at 104); *see* Bingol, Tr. 1314). That an Endo executive—charged with touting Endo's future success for investors—cited "inherent characteristics" of the Opana ER for its "rapid growth" is hardly probative of market definition. The record, moreover, does not support the proposition that oxymorphone has any inherent qualities that make it superior to any other long-acting opioid across any population of patients. (Savage, Tr. 790-91; Michna, Tr.

2149). Complaint Counsel's own medical expert, Dr. Savage, admits that "most" people can get equally effective and safe pain relief from numerous long-acting opioids. (CX4041 (Savage, Dep. at 60, 66-67)). Doctors Savage and Michna agree that no medical conditions produce pain for which oxymorphone ER or any other opioid medication is the only long-acting opioid option. (Savage, Tr. 791; Michna, Tr. 2149). "[M]ost [opioids] are interchangeable if attention is paid to relative potencies and onset and duration of action." (Savage, Tr. 782-83). Indeed, doctors use every long-acting opioid to treat the same medical conditions, including post-operation pain, lumbago, and chronic pain syndrome. (RX-547.0105 (Addanki Rep., Ex. 4); Addanki, Tr. 2245-47).

731. Again in Endo's Q4 2011 investor call, Ms. McHugh noted that "Opana ER is a product that has inherent characteristics that make it a product that physicians and patients both want to use." (CX3221 at 019 (Endo's Q4 2011 Earnings Call Transcript) (citing cytochrome P450 drug-drug interactions and true BID dosing regimen)).

RESPONSE TO FINDING NO. 731:

Complaint Counsel's Proposed Finding No. 731 is incomplete and misleading because it ignores the testimony of Demir Bingol, Endo's Senior Director of Marketing, who explained that Opana ER is "the same as everything else. Differentiation is always your mission in marketing." (CX4025 (Bingol, Dep. at 104); *see* Bingol, Tr. 1314). That an Endo executive—charged with touting Endo's future success for investors—cited "inherent characteristics" of the Opana ER for its "rapid growth" is hardly probative of market definition. The record, moreover, does not support the proposition that oxymorphone has any inherent qualities that make it superior to any other long-acting opioid across any population of patients. (Savage, Tr. 790-91; Michna, Tr. 2149). Complaint Counsel's own medical expert, Dr. Savage, admits that "most" people can get equally effective and safe pain relief from numerous long-acting opioids. (CX4041 (Savage, Dep. at 60, 66-67)). Doctors Savage and Michna agree that no medical conditions produce pain

for which oxymorphone ER or any other opioid medication is the only long-acting opioid option. (Savage, Tr. 791; Michna, Tr. 2149). "[M]ost [opioids] are interchangeable if attention is paid to relative potencies and onset and duration of action." (Savage, Tr. 782-83). Indeed, doctors use every long-acting opioid to treat the same medical conditions, including post-operation pain, lumbago, and chronic pain syndrome. (RX-547.0105 (Addanki Rep., Ex. 4); Addanki, Tr. 2245-47).

> 732. Likewise, in Endo's Q2 2012 earnings call, Ms. McHugh emphasized that "what we really focus on in terms of positioning Opana ER in the marketplace is the inherent advantages of the compound itself." (CX3220 at 023 (Endo's Q2 2012 Earnings Call Transcript)).

RESPONSE TO FINDING NO. 732:

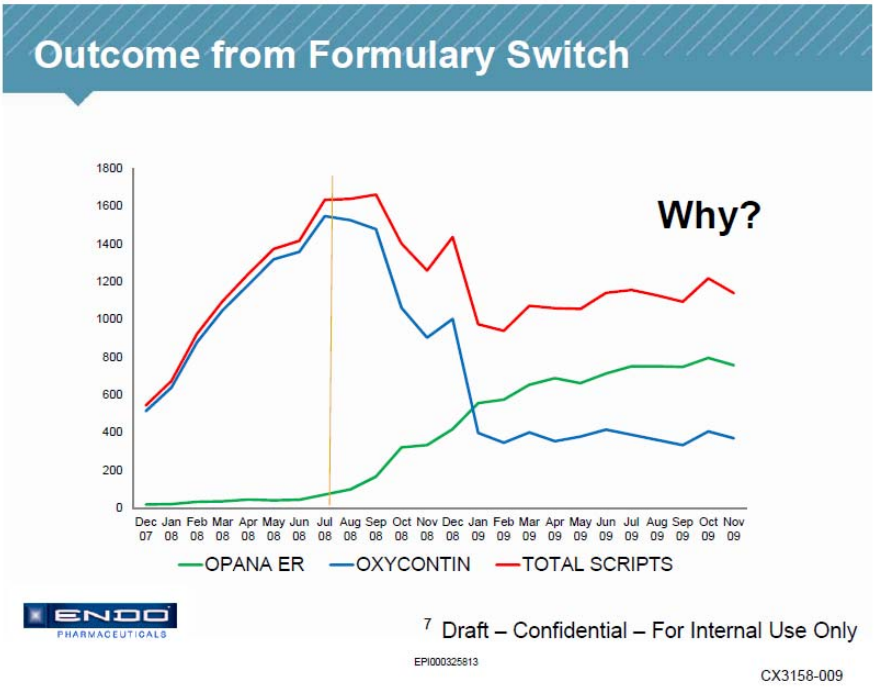
Complaint Counsel's Proposed Finding No. 732 is incomplete and misleading because it ignores the testimony of Demir Bingol, Endo's Senior Director of Marketing, who explained that Opana ER is "the same as everything else. Differentiation is always your mission in marketing." (CX4025 (Bingol, Dep. at 104); *see* Bingol, Tr. 1314). That an Endo executive—charged with touting Endo's future success for investors—cited "inherent characteristics" of the Opana ER for its "rapid growth" is hardly probative of market definition. The record, moreover, does not support the proposition that oxymorphone has any inherent qualities that make it superior to any other long-acting opioid across any population of patients. (Savage, Tr. 790-91; Michna, Tr. 2149). Complaint Counsel's own medical expert, Dr. Savage, admits that "most" people can get equally effective and safe pain relief from numerous long-acting opioids. (CX4041 (Savage, Dep. at 60, 66-67)). Doctors Savage and Michna agree that no medical conditions produce pain for which oxymorphone ER or any other opioid medication is the only long-acting opioid option. (Savage, Tr. 791; Michna, Tr. 2149). "[M]ost [opioids] are interchangeable if attention is paid to relative potencies and onset and duration of action." (Savage, Tr. 782-83). Indeed, doctors use

every long-acting opioid to treat the same medical conditions, including post-operation pain, lumbago, and chronic pain syndrome. (RX-547.0105 (Addanki Rep., Ex. 4); Addanki, Tr. 2245-47).

> 733. One document entitled "Value Strategy Review" does contain a comparison of the prices of OxyContin and Opana ER, but the document primarily examines the cost advantages from differentiating therapeutic features of Opana ER compared to OxyContin, such as lower daily consumption and lack of CYP 450 drug-drug interactions. (CX3158 at 011, 014) (EN3288 [Reformulated Opana ER] Value Strategy Review)).

RESPONSE TO FINDING NO. 733:

Complaint Counsel's Proposed Finding No. 733 is incomplete and misleading. The cited document (CX3158) is a good example of *price competition*: The presentation's goal is to "demonstrate to payers that EN3288 confers additional value over existing long-acting opioids *and reduces costs* by bringing together the attributes of oxymorphone." (CX3158-006 (emphasis added)). While the document discusses "differentiating therapeutic features," it does so in an attempt to show how these features represent cost savings compared to OxyContin and other long-acting opioids. Indeed, the document shows dramatic substitution between OxyContin and Opana ER in response to a "Formulary Switch," pictured below. (CX3158-009).



734. In 2012, Novartis Consumer Health, Endo's manufacturer of Opana ER, contemplated a recall. Endo requested a meeting with FDA to discuss the situation. In requesting the meeting, Endo noted that, although patients can be switched among opioids, differences in potency, dosing schedule and patient responsiveness of different opioids can result in serious overdosing or under-dosing if the transition is not carefully managed by a medical professional, and that in the case of a recall of a widely prescribed drug like Opana ER, the availability of trained supervisory personnel is likely to be insufficient to manage the transition of all patients to another opioid. (CX1101 at 002-003 (Endo Letter to FDA re: Possible Recall)).

RESPONSE TO FINDING NO. 734:

Complaint Counsel's Proposed Finding No. 734 is incomplete and misleading because it ignores the testimony of Dr. Savage, Complaint Counsel's medical expert. Dr. Savage testified that if oxymorphone ER were no longer available in any form, doctors could rotate patients to other opioids. (Savage, Tr. 817). Indeed, doctors can "do our best with whatever opioids are available," even after significant changes eliminate the availability of a particular medicine. (Savage, Tr. 761-62).

735. As Endo stated, "the process of switching from one opioid to another is difficult, fraught with dangers, and requires careful follow-up with the medical provider, which

> may be difficult in the current healthcare system. . . . The process of switching a patient to a different opioid requires skill, trial-and-error, and intense medical supervision, and will be costly and time-consuming for the patient." (CX1101 at 005 (Medical Assessment of a Recall)).

RESPONSE TO FINDING NO. 735:

Complaint Counsel's Proposed Finding No. 735 is incomplete and misleading. The cited quotation omits the following sentence in the ellipse: "Although there are conversion tables to try to reach equivalent doses, this is based on pharmacologic properties and is not a precise science as dosing must be tailored to the individual patient's response." (CX1101-005). The conversion tables are proof of regular switching among long-acting opioids. Dr. Michna testified to the frequent use of conversion tables in switching patients to a new opioid. (*See* Michna, Tr. 2126-27). Further, despite the statements by Endo in an effort to forestall a recall of its product, neither Dr. Savage nor Dr. Michna could identify a single instance when they were unable to switch a patient from one long-acting opioid to another. (*See* Savage, Tr. 762; Michna, Tr. 2126). All told, thousands of patients switch from Opana ER to other long-acting opioids—and from other long-acting opioids to Opana ER—every month. (RX-073.0002 at 16, 45 ("Opioid rotation/switching is common in this therapeutic category"); Michna, Tr. 2124, 2126 (switching is "probably done thousands of times each day"); Savage, Tr. 693-94, 762, 782-83).

> 736. In 2012, when Endo was switching to the reformulated version of Opana ER, the possibility of a disruption in supply caused Endo to advise health care professionals that a supply shortage might occur and advised that they should "temporarily refrain from starting new patients as there is no therapeutically equivalent or pharmaceutically alternative substitute product available." (RX-057 at 0001 (Letter Regarding Potential Endo Product Supply Disruption); CX1102 at 003 (Endo Field Communication Letter)).

RESPONSE TO FINDING NO. 736:

Complaint Counsel's Proposed Finding No. 736 is incomplete and misleading. The record is replete with evidence that there are numerous long-acting opioids that are therapeutic

equivalents for Opana ER. Dr. Savage admits that "most" people can get equally effective and safe pain relief from numerous long-acting opioids, and that any individuals who react better to a particular opioid cannot be identified in advance of treatment. (CX4041 (Savage, Dep. at 60, 66-67)). Accordingly, no one long-acting opioid is superior to any other long-acting opioid. (Savage, Tr. 790-91; Michna, Tr. 2149). In fact, there is no medical condition for which oxymorphone ER or any other long-acting opioid is the only safe and effective option to treat pain. (Michna, Tr. 2149; RX-547.0105 (Addanki Rep., Ex. 4); Addanki, Tr. 2248 ("there's no indication for which oxymorphone had any significant use for which there isn't at least one other long-acting opioid available that was also used for the same indication")). All told, thousands of patients switch from Opana ER to other long-acting opioids—and from other long-acting opioids to Opana ER—every month. (RX-073.0002 at 16, 45 ("Opioid rotation/switching is common in this therapeutic category"); Michna, Tr. 2124, 2126 (switching is "probably done thousands of times each day"); Savage, Tr. 693-94, 762, 782-83).

> 737. Most Endo documents that deal with Opana ER pricing do not refer to any other drugs, and make no mention of the prices of any competing product. (CX5000 at 69-70 (¶ 152) (Noll Report); *see also* CX2678 at 019-022 (January 2009 Opana ER Price Proposal) (recommending a 4.5% price increase); CX2665 (February 2011 Oxymorphone Franchise Pricing Proposal); CX4025 (Bingol, Dep. at 162-63) (testifying that CX2665 did not reference any other products); CX2670 (February 2010 Price Increase Proposal for Opana ER); CX4025 (Bingol, Dep. at 169-70) (testifying that CX2670 does not include a reference to any opioid product other than Opana ER)).

RESPONSE TO FINDING NO. 737:

Complaint Counsel's Proposed Finding No. 737 is inaccurate and misstates the evidence in the record. First, the Proposed Finding's claim that "most" Endo documents do not refer to the prices of competing products is vague and ambiguous, particularly because it only cites expert testimony and three Endo documents. Second, comparisons of list prices are not relevant.

[redacted]

[redacted] (Noll, Tr. 1684-85). [redacted] (Noll, Tr. 1681).

Third, the evidence indicates that Endo tracked relative prices of competing long-acting opioids. For example, [redacted] (CX3206-002). Endo also compared the prices of OxyContin and Opana ER for high dose patients. (CX3158). And Endo tracked its competitors' "[a]ggressive competitive couponing" when formulating its own patient copay program. (RX-028.0011; *see* Addanki, Tr. 2280-82). Endo also tracked switching between various long-acting opioids. (RX-083.0003 at 35; *see* RX-073.0002 at 13, 16; RX-060.0002 at 25).

Finally, there is significant evidence that Endo compared formulary placement, and actively worked to exclude competing long-acting opioids from formularies by offering price discounts to insurance companies. (*See* Addanki, Tr. 2293). For example, [redacted] (RX-021.0005; Addanki, Tr. 2296). [redacted] (RX-021.0005).

738. By contrast, a proposed 4.5% price increase for another Endo product, Frova, compares the price of Frova to the prices of six other brand-name drugs and recommends "a 'value' pricing strategy for the brand within the triptan market." (CX2678 at 003 (January 2009 Frova Price Proposal)).

RESPONSE TO FINDING NO. 738:

Respondent has no specific response.

739. This comparison indicates that the extent of price competition varies among pharmacologic classes and that Opana ER, unlike Frova, is in a pharmacologic class for which the prices of competitors are not sufficiently important to include them in making a business justification for a price increase. (CX5000 at 70 (¶ 152) (Noll Report)).

RESPONSE TO FINDING NO. 739:

Complaint Counsel's Proposed Finding No. 739 is inaccurate and not supported by the record. The purported comparison—based on a single document—between Frova and Opana ER is not sufficient to conclude competitor prices are "not sufficiently important" to justify a broad long-acting opioid market. This comparison ignores the record, which shows price-based competition at the payor level (*i.e.,* competing for superior formulary placement); prescriber level; and patient level. (*See, e.g.*, CX3206-002; CX3158; RX-028.0011; RX-021.0005; Addanki, Tr. 2217-25 (describing competition at the payor level); Addanki, Tr. 2233-34, 2280, 2284 (describing competition at the patient level); Addanki, Tr. 2215-16, 2269 (describing competition at the prescriber level)).

740. A pricing proposal for Reformulated Opana ER (at the time called Revopan) recommends charging the same prices for original and Reformulated Opana ER because doing so "allows payers to advocate for the benefits of the new Revopan formulation without incurring an additional cost . . . ." This oxymorphone franchise pricing proposal reflects the expectation by the Endo employees who were involved in pricing that the success of Reformulated Opana ER depended on the relationship between its price and the price of Opana ER if both drugs were on the market simultaneously, but the document contains no mention of how the prices of other LAOs would affect the success of Revopan's launch. (CX2664 at 004 (January 2011 Oxymorphone Franchise Pricing Proposal); (CX5000 at 71 (¶ 154) (Noll Report)).

RESPONSE TO FINDING NO. 740:

Complaint Counsel's Proposed Finding No. 740 is inaccurate and not supported by the cited evidence. The cited document (CX2664) makes direct reference to price competition with other long-acting opioids, nothing that "[d]uring the first 6-8 months post approval, Revopan will be most vulnerable to payers' desire to negotiate new terms. This may delay managed care

access for the product *and could require higher discounts than currently offered on OPANA ER*." (CX2664-004 (emphasis added)). The document also notes that "significant increases in the price of OPANA and/or OPANA ER may negatively impact overall profitability of Revopan." (CX2664-005). The document even leaves a placeholder for the "impact on net sales" from a potential price increase. (CX2664-005).

F. The significant clinical differences between Opana ER and other long-acting opioids explain why long-acting opioids do not sufficiently constrain Opana ER sales and prices

741. Complaint Counsel's medical expert, Dr. Seddon Savage, is a physician in pain medicine and addiction medicine. (Savage, Tr. 678).

RESPONSE TO FINDING NO. 741:

Respondent has no specific response.

742. Dr. Savage has been the medical director of the Chronic Pain Recovery Center at Silver Hill Hospital in New Canaan, Connecticut since 2012, and an adviser to the Dartmouth Hitchcock Medical Center in New Hampshire on issues of pain and addiction since 2016. (Savage, Tr. 679; CX5002 at 069 (Appendix A) (Savage Report)).

RESPONSE TO FINDING NO. 742:

Respondent has no specific response.

743. Dr. Savage was the Director of the Dartmouth Center on Addiction Recovery and Education from 2004 to 2016, and a pain consultant for the United States Veterans Administration Medical Center in Manchester, New Hampshire from 1998 to 2012. (CX5002 at 069 (Appendix A) (Savage Report)).

RESPONSE TO FINDING NO. 743:

Respondent has no specific response.

744. Dr. Savage has over thirty years of experience with the use of opioids to treat pain. (Savage, Tr. 684-85).

RESPONSE TO FINDING NO. 744:

Respondent has no specific response.

745. Dr. Savage offered testimony about the important differences between Opana ER and other long-acting opioids and how they relate to the treatment of pain. (Savage, Tr. 67879, 709).

RESPONSE TO FINDING NO. 745:

Respondent does not dispute that Dr. Savage testified about purported differences between Opana ER and other opioid products, but the record does not support the proposition that any such differences are "important" either clinically or with respect to market definition. Dr. Savage testified that no opioid is superior to any other opioid. (Savage, Tr. 743-44, 791-92; *see* Noll, Tr. 1504-05 (same)). Nor are there any medical conditions that produce pain for which oxymorphone ER or any other opioid is the only treatment option. (Savage, Tr. 791; Michna, Tr. 2149). The only differences in long-acting opioid treatments occur among "*individual* patients with *specific* types of pain in *specific* contexts" that render particular opioid treatments "superior choices for individuals in particular contexts." (Savage, Tr. 743-44, 788-89 (emphasis added)).

Yet even for patients with unique medical conditions that prevent the use of certain long-acting opioids, there are always multiple opioid options available that would be equally safe and effective for the treatment of chronic pain. (Michna, Tr. 2148-49; Noll, Tr. 1548). This means that there is no identifiable group of patients for whom oxymorphone ER or any other long-acting opioid is the only treatment option. (Michna, Tr. 2148-49; Noll, Tr. 1508-09; CX4041 (Savage, Dep. at 60)). This inability to identify individuals or patient groups for whom oxymorphone ER may be the best treatment also means that Endo and any other drug manufacturer has no means to price discriminate against patients. (CX4039 (Noll, Dep. at 171-72)).

What is more, Demir Bingol, Endo's Senior Director of Marketing, testified that the differences between Opana ER and other long-acting opioids were used as a marketing tactic because they represented Endo's "best opportunity to compete against those [other long-acting opioid] products based on their profile and what they brought to the market." (Bingol, Tr. 1314). When Endo attempted to market such differences, clinicians "universally . . . said no because it's really not clinically relevant." (Michna, Tr. 2154-55). As Dr. Savage admitted, the differences among long-acting opioids are no different than those found in over-the-counter pain relievers like Advil, Tylenol, Aleve, and aspirin, which nevertheless are used for the same treatments and compete for the same customers. (Savage, Tr. 812-16).

> 746. Even within the category of opioids, there are significant differences in opioids and in individual responses to different medications. These differences can be very important to the treatment of individual patients. (CX5002 at 020 (¶ 51) (Savage Report); Savage, Tr. 692 ("[T]here are differences in the way different opioids bind to different opioid receptors . . . [and] there's variability in the way human beings express opioid receptors, so we may or may not respond the same to a different opioid . . ."); Michna, Tr. 2109 ("Well, we're all different physiologically in the way we tolerate medications. Some people have very high tolerance. Some people have side effects. There's a lot of variability.")).

RESPONSE TO FINDING NO. 746:

While Respondent does not dispute that there are differences among opioids and that individuals may respond differently to individual medications, the record does not support the proposition that such differences are "significant" in terms of market definition or across groups of patients. Dr. Savage testified that no opioid is superior to any other opioid. (Savage, Tr. 743-44, 791-92; *see* Noll, Tr. 1504-05 (same)). Nor are there any medical conditions that produce pain for which oxymorphone ER or any other opioid is the only treatment option. (Savage, Tr. 791; Michna, Tr. 2149). The only differences in long-acting opioid treatments occur among "*individual* patients with *specific* types of pain in *specific* contexts" that render particular opioid

treatments "superior choices for individuals in particular contexts." (Savage, Tr. 743-44, 788-89 (emphasis added)).

Yet even for patients with unique medical conditions that prevent the use of certain long-acting opioids, there are always multiple opioid options available that would be equally safe and effective for the treatment of chronic pain. (Michna, Tr. 2148; Noll, Tr. 1548). This means that there is no identifiable group of patients for whom oxymorphone ER or any other long-acting opioid is the only treatment option. (Michna, Tr. 2148-49; Noll, Tr. 1508-09; CX4041 (Savage, Dep. at 60)). This inability to identify individuals or patient groups for whom oxymorphone ER may be the best treatment also means that Endo and any other drug manufacturer has no means to price discriminate against patients. (CX4039 (Noll, Dep. at 171-72)).

> 747. With respect to Opana ER "there were a number of different potential differences in the drug . . . and these differences [can be] meaningful for certain patient types. And the trick, of course, is to match up the right patient type with the right difference so that the patient gets the appropriate therapy." (Bingol, Tr. 1267).

RESPONSE TO FINDING NO. 747:

Complaint Counsel's Proposed Finding No. 747 is incomplete and misleading because it selectively quotes Mr. Bingol's testimony. Mr. Bingol was explaining how Endo sought to market Opana ER in order to differentiate it in the minds of potential customers. (Bingol, Tr. 1266-67). As Mr. Bingol explained, such differences between Opana ER and other long-acting opioids were used as a marketing tactic because they represented Endo's "best opportunity to compete against those [other long-acting opioid] products based on their profile and what they brought to the market." (Bingol, Tr. 1314). When Endo attempted to market such differences, however, clinicians "universally . . . said no because it's really not clinically relevant." (Michna, Tr. 2154-55). As Dr. Savage admitted, the differences among long-acting opioids are no different than those found in over-the-counter pain relievers like Advil, Tylenol, Aleve, and

aspirin, which nevertheless are used for the same treatments and compete for the same customers. (Savage, Tr. 812-16).

748. Opana ER contains a different opioid molecule (oxymorphone) than other long-acting opioids, therefore individuals may experience different levels of analgesia, different side effect profiles, and different tolerances. (Savage, Tr. 709; Michna, Tr. 2167 ("We never know how a patient is going to respond. . . . they may have adverse events.")).

RESPONSE TO FINDING NO. 748:

Respondent has no specific response.

749. The practical significance of two drugs having different active ingredients is that different patients may respond differently to the medications. (Savage, Tr. 729; Michna, Tr. 2167 ("Q. And there is variability from person to person in terms of the way they respond to drugs? A. We never know how a patient is going to respond. As I think I testified earlier, they may have adverse events. It's un – you know, it's impossible to predict that, yes."); CX4025 (Bingol, Dep. at 99-100) ("And patient variability is such that patients respond differently to different opioids . . . So this becomes another option where other pain medicines might not be effective.")).

RESPONSE TO FINDING NO. 749:

Respondent has no specific response.

750. It is useful to have a variety of opioids available for the treatment of pain because people respond very differently to different opioids. (Savage, Tr. 712-13).

RESPONSE TO FINDING NO. 750:

Respondent has no specific response.

751. Indeed, approximately fifty percent of patients don't tolerate the first opioid they try. (Michna, Tr. 2169).

RESPONSE TO FINDING NO. 751:

Respondent has no specific response.

752. Opioid rotation is the substitution of one opioid medication for another. It may be done due to inadequate analgesia, the development of tolerance to analgesic effects, or persistent side effects. (CX5002 at 060 (¶ 170) (Savage Report)).

RESPONSE TO FINDING NO. 752:

Respondent has no specific response other than to clarify that substitution among opioids is not limited to the listed reasons. It can and often does occur because of changes in price or availability as well. (*See, e.g.*, RX-087 (UPMC formulary change led to 70 percent of patients on OxyContin switching to different long-acting opioids, including Opana ER, generic Morphine Sulfate ER (MS ER), and generic Fentanyl patches); Michna, Tr. 2125, 2148; Noll, Tr. 1561; Addanki, Tr. 2305). For these various reasons, switches are frequent. (Savage, Tr. 693-94; Michna, Tr. 2124 (switching is "probably done thousands of times each day"); RX-073.0002 at 45 ("Opioid rotation/switching is common in this therapeutic category.")). Substitution among opioids may also occur as a result of hospitalization or surgery, when an intravenous opioid must be administered. (RX-549.0019 (Michna Rep. ¶ 47) ("What I have seen countless times—what is indeed very common—is that a patient switched from one IV opioid to a totally different oral medication without incident. It is telling that the most common oral opioid in a post-operative setting is oxycodone, which does not have an injectable form.")).

753. Because of individual variability in responses to opioids, it is impossible to reliably predict an individual patient's response to a new opioid. Therefore, patients going through opioid rotation must be closely monitored because the transition period is fraught with potential risks: too much opioid can lead to sedation or overdose; too little can lead to unrelieved pain. (CX5002 at 061-62 (¶ 172) (Savage Report); RX-549 at 0025 (¶ 57) (Michna Report) ("[P]atients can be switched to a new ER Opioid without negative clinical implications, assuming the switch is performed slowly and with the proper understanding of these medications.")).

RESPONSE TO FINDING NO. 753:

Complaint Counsel's Proposed Finding No. 753 is incomplete and misleading because it ignores the testimony of Dr. Savage, who explained that switching a patient between long-acting

opioids can be "simple." (Savage, Tr. 762). If "you're taking two Percocet today and you want to switch to a couple of hydrocodone, that's not going to be a complicated switch." (Savage, Tr. 765-66, 768-69). Even for patients on high doses of multiple opioids, it is only "a bit more complicated" to switch. (Savage, Tr. 762). In fact, Dr. Savage has never been unable to switch a patient between long-acting opioids. (Savage, Tr. 793-94). For these reasons, rotating from one long-acting opioid to another does not involve significant risks when conducted by a doctor who knows the medications, and it occurs frequently. (Michna, Tr. 2124, 2126 (switching is "probably done thousands of times each day"); Savage, Tr. 693-94, 762, 782-83; RX-073.0002 at 45 ("Opioid rotation/switching is common in this therapeutic category.")).

754. The complexity and risks inherent in opioid rotation means that it is not advised unless there is a clear clinical indication for a change and the clinician is prepared to provide adequate supervision of the rotation. (CX5002 at 063 (¶ 176) (Savage Report); Savage, Tr. 770).

RESPONSE TO FINDING NO. 754:

Complaint Counsel's Proposed Finding No. 754 is inaccurate. Dr. Savage explained that switching a patient between long-acting opioids can be "simple." (Savage, Tr. 762). If "you're taking two Percocet today and you want to switch to a couple of hydrocodone, that's not going to be a complicated switch." (Savage, Tr. 765-66, 768-69). Even for patients on high doses of multiple opioids, it is only "a bit more complicated" to switch. (Savage, Tr. 762). For this reason, switching occurs frequently. (Savage, Tr. 693-94, 762; Michna, Tr. 2124 (switching is "probably done thousands of times each day"); RX-073.0002 at 45 ("Opioid rotation/switching is common in this therapeutic category.")).

Dr. Savage also testified that she would rotate a patient based on a minor increase in price "depend[ing] upon the patient and what the increase in price meant to them." (Savage, Tr. 770). Indeed, the record is clear that switching regularly occurs in practice because of changes in price

or availability. (*See, e.g.*, RX-087 (UPMC formulary change led to 70 percent of patients on OxyContin switching to different long-acting opioids, including Opana ER, generic Morphine Sulfate ER (MS ER), and generic Fentanyl patches); Michna, Tr. 2125, 2148; Noll, Tr. 1561; Addanki, Tr. 2305). What is more, patients are almost always switched between opioids when they leave the hospital, even if they are already tolerating a specific opioid. (Savage, Tr. 798-801; Noll, Tr. 1530 (physicians "very often switch which molecule is used when the patient leaves the hospital")). The most commonly used opioids in emergency rooms and other inpatient settings are hydromorphone, fentanyl, and morphine. (Savage, Tr. 787). The most commonly prescribed opioids in outpatient settings are oxycodone, hydrocodone, and morphine. (Savage, Tr. 786).

755. Switching a patient from Opana ER to generic oxymorphone ER is more predictable than switching to another opioids like oxycodone because it is the same molecule. (Savage, Tr. 715; Michna, Tr. 2186-87 (testifying that for such a switch he would start by doing a one-to-one conversion rather than down-titrating the dose)).

RESPONSE TO FINDING NO. 755:

Complaint Counsel's Proposed Finding No. 755 is incomplete and misleading because it ignores Dr. Michna's actual testimony, in which he explained that even when switching between branded and generic versions of the same opioid, "there's variability in generics in terms of patients' responses, so, you know, they might get less pain relief or they might get slightly more, depending on the product." (Michna, Tr. 2187).

756. And in fact, some patients that try to rotate from Opana ER to a different opioid end up switching back to Opana ER because it was the opioid that worked best for them. (Savage, Tr. 822).

RESPONSE TO FINDING NO. 756:

Respondent has no specific response.

757. The numerous differences between Opana ER and other long-acting opioids are identified in Appendix C to Dr. Savage's expert report. (CX5002 at 106 (Appendix C) (Savage Report)).

RESPONSE TO FINDING NO. 757:

Respondent has no specific response.

758. Key differences between Opana ER and other long-acting opioids are also identified in Figures 4 through 12 of Dr. Savage's report. (CX5002 at 045, 047, 049, 050, 052, 054, 056, 058, 060 (Figures 4-12) (Savage Report)).

RESPONSE TO FINDING NO. 758:

Respondent objects to the characterization that the differences are "key" with respect to clinical decision-making or market definition, or across groups of patients, but otherwise has no specific response.

759. Opioid prescribers should be knowledgeable about specific characteristics of the different long-acting opioids they prescribe, including the drug substance, formulation, strength, dosing interval, key instructions, specific information about conversion between products, specific drug interactions, use in opioid-tolerant patients, product-specific safety concerns, and relative potency to morphine. (CX3355 at 006-07 (FDA Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioid Analgesics); Michna, Tr. 2173-76 (testifying that he agreed with the FDA statements to this effect)).

RESPONSE TO FINDING NO. 759:

While Respondent does not dispute that the relevant language appears in the cited document, Complaint Counsel's Proposed Finding No. 759 is incomplete and misleading because it ignores the fact that the cited FDA document (CX3355) relates to the long-acting opioid Risk Evaluation Mitigation System (REMS). REMS programs ensure that the benefits of a medication outweigh the medication's risks. (Michna, Tr. 2110). In the case of long-acting and long-acting opioids, the FDA utilizes a single REMS program, which means that the FDA assesses the risks and benefits of these opioids collectively across the entire class of such

products, even though individual patients may react differently to individual opioids. (Michna, Tr. 2111).

760. Consistent with Dr. Savage's testimony, the FDA Blueprint for Prescriber Education identifies numerous clinically significant differences between the various available long-acting opioids. (CX3355 at 010-21 (FDA Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioid Analgesics); Savage, Tr. 750 (identifying the characteristics shown in this table as clinically significant to the prescription of opioids); Michna, Tr. 2174 (agreeing that prescribers should be knowledgeable about specific characteristics of the long-acting opioids they prescribe)).

RESPONSE TO FINDING NO. 760:

Complaint Counsel's Proposed Finding No. 760 is misleading and not supported by the cited evidence. The cited FDA document (CX3355) does not state that differences among long-acting opioids are "clinically significant." In fact, the cited document relates to the long-acting opioid Risk Evaluation Mitigation System (REMS). REMS programs ensure that the benefits of a medication outweigh the medication's risks. (Michna, Tr. 2110). In the case of long-acting opioids, the FDA utilizes a single REMS program, which means that the FDA assesses the risks and benefits of long-acting and extended release opioids collectively across the entire class of such products, even though individual patients may react differently to individual opioids. (Michna, Tr. 2111).

And while there are differences among long-acting opioids, there are no medical conditions that produce pain for which oxymorphone ER or any other opioid medication is the only long-acting opioid option. (Savage, Tr. 791; Michna, Tr. 2149). Even for patients with unique medical conditions that prevent the use of certain long-acting opioids, there are always multiple opioid options available that would be equally safe and effective for the treatment of chronic pain. (Michna, Tr. 2148; Noll, Tr. 1548). This means that there is no identifiable group

of patients for which oxymorphone ER or any other long-acting opioid is the only treatment option. (Michna, Tr. 2148-49; Noll, Tr. 1508-09; CX4041 (Savage, Dep. at 60)).

761. In contemporaneous documents and promotional materials, Endo highlighted certain intrinsic qualities of oxymorphone that might have meaningful importance to clinicians or patients, including "No CYP450 PK DDIs," "True 12-hour dosing," and "Low euphoria." (CX2610 at 014 (Revopan [reformulated Opana ER] Playbook); Bingol, Tr. 1270; *see also* CCF ¶¶ 769, 781, 787).

RESPONSE TO FINDING NO. 761:

Complaint Counsel's Proposed Finding No. 761 is incomplete and misleading because it ignores Mr. Bingol's testimony in which he explained that the differences between Opana ER and other long-acting opioids were used as a marketing tactic because they represented Endo's "best opportunity to compete against those [other long-acting opioid] products based on their profile and what they brought to the market." (Bingol, Tr. 1314). When Endo attempted to market such differences, clinicians "universally . . . said no because it's really not clinically relevant." (Michna, Tr. 2154-55). As Dr. Savage admitted, the differences among long-acting opioids are no different than those found in over-the-counter pain relievers like Advil, Tylenol, Aleve, and aspirin, which nevertheless are used for the same treatments and compete for the same customers. (Savage, Tr. 812-16).

1. Lack of CPY 450 drug-drug interactions

762. Most opioids, although significantly not oxymorphone, are primarily metabolized in the liver via the Cytochrome P 450 (CYP 450) system. The human body contains numerous different CYP 450 enzymes that are responsible for the metabolism of diverse drugs, toxins, and other substances. (CX5002 at 026 (¶ 72) (Savage Report); Savage, Tr. 716).

RESPONSE TO FINDING NO. 762:

Respondent has no specific response other than to clarify that oxymorphone is not the only opioid that is metabolized outside the CYP 450 pathway, as Complaint Counsel's Proposed

Finding No. 762 attempts to suggest. Neither morphine nor hydromorphone utilize the CYP 450 system. (Savage, Tr. 795-96).

763. There can be considerable variability between different individuals in the CYP 450 system that can affect opioid metabolism in clinically important ways. (CX5002 at 026 (¶ 74) (Savage Report)).

RESPONSE TO FINDING NO. 763:

Respondent has no specific response.

764. In addition, the use of some drugs can alter activity of certain CYP 450 enzymes. Many drugs commonly used by pain patients, such as antidepressants, anti-seizure medications, and antibiotics, can inhibit or induce CYP 450 enzymes. (CX5002 at 027 (¶ 75) (Savage Report); CX2558 at 030 (Opana ER Presentation); Savage, Tr. 716 ("Yes. Many drugs use those metabolic pathways."); Michna, Tr. 2151 ("[S]ince a lot of the medications we prescribe, you know, concurrent meds for depression and other diseases, are metabolized through that system, there can be effects on the other drugs when they're coprescribed.")).

RESPONSE TO FINDING NO. 764:

Respondent has no specific response.

765. Variations in metabolic activity, particularly in the CYP 450 system can have meaningful clinical consequences. Higher enzyme activity may result in rapid metabolism of an active drug, rendering usual doses ineffective. On the other hand, lower enzyme activity can result in higher blood levels of a drug, potentially leading to side effects or toxicity. (CX5002 at 027 (¶ 78) (Savage Report); CX2558 at 030 (Opana ER Presentation); Bingol, Tr. 1273-74 ("[T]he patients may be fast metabolizers or slow metabolizers through this pathway, and if you're avoiding it, then you're potentially able to avoid certain types of interactions, potentially making a safer choice for a patient.")).

RESPONSE TO FINDING NO. 765:

While Respondent does not dispute that there are variations in metabolic activity among individuals and that those variations can lead to differences in metabolism of a medication, the record does not support the proposition that CYP 450 metabolism is a clinically relevant factor when physicians are prescribing long-acting opioids. (Michna, Tr. 2151-52). When doctors

prescribe a long-acting opioid, they start at low doses and then build up to assess reaction and side effects. (Michna, Tr. 2151-52). Accordingly, even if a patient has trouble metabolizing via the CYP 450 pathway, it would simply mean that the patient would achieve pain relief "at a much earlier point" in the buildup of dosing than if the patient had more rapid metabolism. (Michna, Tr. 2152). Even Dr. Savage concedes that individual patients who do not respond well to CYP 450 metabolism can still take opioids that utilize that pathway as long as the medication is used with proper care and attention to dosing. (Savage, Tr. 796). And while there is a test to assess how a patient will metabolize drugs though the CYP 450 pathway, Dr. Savage did not testify that she has ever used it and Dr. Michna has never seen any other doctor use it when prescribing long-acting opioids. (Michna, Tr. 2152). The CYP 450 pathway, finally, is utilized by the majority of all medications prescribed generally. (Michna, Tr. 2151).

766. As such, physicians must take care when prescribing opioids that are metabolized via the CYP 450 system to consider possible drug interactions or biogenetic variations. (CX5002 at 028 (¶ 79) (Savage Report); Savage, Tr. 716-17 (testifying that drug interactions may cause higher blood levels, and thus more side effects, or lower blood levels, thus a reoccurrence of pain)).

RESPONSE TO FINDING NO. 766:

While Respondent does not dispute that doctors must take care when prescribing any medication, the record does not support the proposition that CYP 450 is a clinically relevant factor when physicians are prescribing long-acting opioids. (Michna, Tr. 2151-52). When doctors prescribe a long-acting opioid, they start at low doses and then build up to assess reaction and side effects. (Michna, Tr. 2151-52). Accordingly, even if a patient has trouble metabolizing via the CYP 450 pathway, it would simply mean that the patient would achieve pain relief "at a much earlier point" in the buildup of dosing than if the patient had more rapid metabolism. (Michna, Tr. 2152). Even Dr. Savage concedes that individual patients who do not respond well

to CYP 450 metabolism can still take opioids that utilize that pathway as long as the medication is used with proper care and attention to dosing. (Savage, Tr. 796). And while there is a test to assess how a patient will metabolize drugs though the CYP 450 pathway, Dr. Savage did not testify that she has ever used it and Dr. Michna has never seen any other doctor use it when prescribing long-acting opioids. (Michna, Tr. 2152). The CYP 450 pathway, finally, is utilized by the majority of all medications prescribed generally. (Michna, Tr. 2151).

767. Oxymorphone is metabolized through glucuronidation and does not significantly engage the CYP 450 system. (CX5002 at 039 (¶ 107) (Savage Report); CX2558 at 030 (Opana ER Presentation); Savage, Tr. 715-16; Michna, Tr. 2151).

RESPONSE TO FINDING NO. 767:

Respondent has no specific response.

768. Drug interactions and genetic variability involving the CYP 450 system do not appear to affect drugs, such as oxymorphone, that are exclusively metabolized through glucuronidation and do not rely on the CYP 450 system. Thus, oxymorphone is not subject to increased or decreased effects due to drug interactions or genetic variability in CYP 450 metabolic pathways. As a result, patients at risk for CYP 450 drug interactions or genetic variability may be better candidates for an opioid like oxymorphone. (CX5002 at 028 (¶ 80) (Savage Report); Bingol, Tr. 1273 ("Oxymorphone is metabolized through the liver through glucuronidation, not through the CYP450 enzymatic pathway, thereby potentially being safer in some regards.")).

RESPONSE TO FINDING NO. 768:

Complaint Counsel's Proposed Finding No. 768 is incomplete and misleading. Oxymorphone is not the only opioid that is metabolized outside the CYP 450 pathway. Neither morphine nor hydromorphone utilize the CYP 450 system. (Savage, Tr. 795-96). And the record is clear that CYP 450 metabolism is not a clinically relevant factor when physicians are prescribing long-acting opioids. (Michna, Tr. 2151-52). When doctors prescribe a long-acting opioid, they start at low doses and then build up to assess reaction and side effects. (Michna, Tr. 2151-52). Accordingly, even if a patient has trouble metabolizing via the CYP 450 pathway, it

would simply mean that the patient would achieve pain relief "at a much earlier point" in the buildup of dosing than if the patient had more rapid metabolism. (Michna, Tr. 2152). Even Dr. Savage concedes that individual patients who do not respond well to CYP 450 metabolism can still take opioids that utilize that pathway as long as the medication is used with proper care and attention to dosing. (Savage, Tr. 796). And while there is a test to assess how a patient will metabolize drugs though the CYP 450 pathway, Dr. Savage did not testify that she has ever used it and Dr. Michna has never seen any other doctor use it when prescribing long-acting opioids. (Michna, Tr. 2152). The CYP 450 pathway, finally, is utilized by the majority of all medications prescribed generally. (Michna, Tr. 2151).

769. Endo's documents show that it touted the lack of CYP 450 drug-drug interactions, among other characteristics, in its marketing materials and internal documents related to Opana ER. (CX2717 at 008 (Opana ER Advisory Board Executive Summary) (identifying lack of CYP450 interactions as a key benefit of Opana ER); CX2610 at 014 (Revopan [reformulated Opana ER] Playbook) (identifying "No CYP450 PK DDIs" as part of the heritage of oxymorphone); CX2716 at 022 (Opana Marketing Presentation) (listing "No known CYP450 PK drug-drug interactions" as a key message); CX3220 at 023 (Endo Q2 2012 Earnings Call Transcript) ("Oxymorphone is not metabolized by the cytochrome P450 system, unlike other opioids . . .")).

RESPONSE TO FINDING NO. 769:

Complaint Counsel's Proposed Finding No. 769 is incomplete and misleading because it ignores the testimony of Demir Bingol, Endo's Senior Director of Marketing, who explained that the metabolic differences between Opana ER and other long-acting opioids were used as a marketing tactic because they represented Endo's "best opportunity to compete against those [other long-acting opioid] products based on their profile and what they brought to the market." (Bingol, Tr. 1314). When Endo attempted to market such differences, clinicians "universally . . . said no because it's really not clinically relevant." (Michna, Tr. 2154-55). As Dr. Savage admitted, the differences among long-acting opioids are no different than those found in over-

the-counter pain relievers like Advil, Tylenol, Aleve, and aspirin, which nevertheless are used for the same treatments and compete for the same customers. (Savage, Tr. 812-16).

> 770. The risks of CYP 450 drug-drug interactions are significant. (CX2549 at 005 (EN3288 [reformulated Opana ER] HOPE Launch Readiness Plans) ("The risk of exposing chronic pain patients to potentially serious drug-drug interactions when using opioids metabolized through CYP 450 is ~25%."); Savage, Tr. 725-26 (testifying that one study suggested that up to 30% of patients may be at risk for CYP450 drug interactions)).

RESPONSE TO FINDING NO. 770:

Complaint Counsel's Proposed Finding No. 770 is inaccurate and misleading. The cited document (CX2549) explicitly states that the language quoted by Complaint Counsel "only focused on observed economic events. *There are no claims of therapeutic superiority among the products whose utilization patterns were observed*." (CX2549-005 (emphasis added) (discussing only oxycodone and oxymorphone and the possibility that patients who do not respond well to CYP 450 may have "higher medical and pharmacy costs (~$100-200/month)")).

Demir Bingol, Endo's Senior Director of Marketing, similarly explained that the metabolic differences between Opana ER and other long-acting opioids were used as a marketing tactic because they represented Endo's "best opportunity to compete against those [other long-acting opioid] products based on their profile and what they brought to the market." (Bingol, Tr. 1314). When Endo attempted to market such differences, clinicians "universally . . . said no because it's really not clinically relevant." (Michna, Tr. 2154-55). Indeed, the CYP 450 pathway is utilized by the majority of all medications prescribed generally. (Michna, Tr. 2151).

Even Dr. Savage concedes that individual patients who do not respond well to CYP 450 metabolism can still take opioids that utilize that pathway as long as the medication is used with proper care and attention to dosing. (Savage, Tr. 796). And while there is a test to assess how a patient will metabolize drugs though the CYP 450 pathway, Dr. Savage did not testify that she

has ever used it and Dr. Michna has never seen any other doctor use it when prescribing long-acting opioids. (Michna, Tr. 2152).

Finally, to the extent Proposed Finding No. 770 attempts to summarize academic literature, the Proposed Finding is improper and inadmissible. The relevant literature is not in evidence and, if it were, that literature would be the best evidence of its contents.

> 771. For example, a patient in Dr. Savage's practice who had been stable on methadone treatment suddenly became sedated when prescribed an antidepressant, likely because of a CYP450 drug interaction. (Savage, Tr. at 718-19).

RESPONSE TO FINDING NO. 771:

Complaint Counsel's Proposed Finding No. 771 is improper and inadmissible. The Proposed Finding consists entirely of speculation, even though there is a test to assess how a patient metabolizes drugs though the CYP 450 pathway. (Michna, Tr. 2152).

> 772. Likewise, there are examples of CYP450 interactions from the medical literature, for example where a patient on oxycodone was prescribed an antifungal agent and subsequently experienced sedation due to inhibition of the breakdown of oxycodone. (Savage, Tr. at 719).

RESPONSE TO FINDING NO. 772:

Complaint Counsel's Proposed Finding No. 772 is improper and inadmissible. The Proposed Finding purports to summarize academic literature that is not in evidence and, if it were, that literature would be the best evidence of its contents.

> 773. The risk of CYP 450 drug-drug interactions carries economic consequences in terms of significantly higher medical and pharmacy costs. (CX2549 at 005 (EN3288 [reformulated Opana ER] HOPE Launch Readiness Plans) ("Exposure of patients to these potential drug-drug interactions is associated with significantly higher medical and pharmacy costs . . .")).

RESPONSE TO FINDING NO. 773:

Complaint Counsel's Proposed Finding No. 773 is inaccurate and misleading. The cited document (CX2549) explicitly states that the language quoted by Complaint Counsel "only focused on observed economic events. *There are no claims of therapeutic superiority among the products whose utilization patterns were observed*." (CX2549-005 (emphasis added) (discussing only oxycodone and oxymorphone and the possibility that patients who do not respond well to CYP 450 may have "higher medical and pharmacy costs (~$100-200/month)")). Such claims were advanced by Endo in hopes of crafting a "value platform message." (CX2549-004).

Demir Bingol, Endo's Senior Director of Marketing, explained that any metabolic differences between Opana ER and other long-acting opioids were used as a marketing tactic because they represented Endo's "best opportunity to compete against those [other long-acting opioid] products based on their profile and what they brought to the market." (Bingol, Tr. 1314). When Endo attempted to market such differences, clinicians "universally . . . said no because it's really not clinically relevant." (Michna, Tr. 2154-55). Indeed, the CYP 450 pathway is utilized by the majority of all medications prescribed generally. (Michna, Tr. 2151).

Even Dr. Savage concedes that individual patients who do not respond well to CYP 450 metabolism can still take opioids that utilize that pathway as long as the medication is used with proper care and attention to dosing. (Savage, Tr. 796). And while there is a test to assess how a patient will metabolize drugs though the CYP 450 pathway, Dr. Savage did not testify that she has ever used it and Dr. Michna has never seen any other doctor use it when prescribing long-acting opioids. (Michna, Tr. 2152).

774. Thus, among these patients, opioids that are metabolized by CYP450 are not close therapeutic substitutes for oxymorphone. (CX5000 at 066 (¶ 143) (Noll Report)).

RESPONSE TO FINDING NO. 774:

Complaint Counsel's Proposed Finding No. 774 is inaccurate and not supported by the record. The CYP 450 pathway is utilized by the majority of all medications prescribed generally. (Michna, Tr. 2151). With respect to long-acting opioids, the CYP 450 system is not a clinically relevant factor when physicians are writing prescriptions. (Michna, Tr. 2151-52). Indeed, when doctors prescribe a long-acting opioid, they start at low doses and then build up to assess reaction and side effects. (Michna, Tr. 2151-52). Accordingly, even if a patient has trouble metabolizing via the CYP 450 pathway, it would simply mean that the patient would achieve pain relief "at a much earlier point" in the buildup of dosing than if the patient had more rapid metabolism. (Michna, Tr. 2152). Even Dr. Savage concedes that individual patients who do not respond well to CYP 450 metabolism can still take opioids that utilize that pathway as long as the medication is used with proper care and attention to dosing. (Savage, Tr. 796). And while there is a test to assess how a patient will metabolize drugs though the CYP 450 pathway, Dr. Savage did not testify that she has ever used it and Dr. Michna has never seen any other doctor use it when prescribing long-acting opioids. (Michna, Tr. 2152).

Demir Bingol, Endo's Senior Director of Marketing, explained that any metabolic differences between Opana ER and other long-acting opioids were used as a marketing tactic because they represented Endo's "best opportunity to compete against those [other long-acting opioid] products based on their profile and what they brought to the market." (Bingol, Tr. 1314). When Endo attempted to market such differences, clinicians "universally . . . said no because it's really not clinically relevant." (Michna, Tr. 2154-55).

At bottom, Dr. Savage admitted that the differences among long-acting opioids are no different than those found in over-the-counter pain relievers like Advil, Tylenol, Aleve, and

aspirin, which are used for the same treatments and compete for the same customers despite their differences. (Savage, Tr. 812-16).

2. True 12-hour dosing

775. The concept of drug half-life is important to understanding the duration of effects of different drugs. Half-life is defined as the amount of time it takes the plasma concentration of a drug to decline by one half. (CX5002 at 029 (¶ 82) (Savage Report)).

RESPONSE TO FINDING NO. 775:

Respondent has no specific response.

776. Different drugs have different typical half-lives or ranges of half-lives based on inherent pharmacologic factors. A longer plasma half-life of a drug is usually associated with a longer duration of action – in the case of opioids, longer duration of pain relief. (CX5002 at 029 (¶ 83) (Savage Report)).

RESPONSE TO FINDING NO. 776:

Respondent has no specific response.

777. When considering the half-life of extended release opioids, one must also consider the duration of release of the medication, since uptake of the full dose is delayed. (CX5002 at 029 (¶ 84) (Savage Report)).

RESPONSE TO FINDING NO. 777:

Respondent has no specific response.

778. The half-life of oxymorphone is ~7-9 hours. Opana ER is formulated to provide sustained release of oxymorphone over a 12-hour period and is to be taken every 12 hours. The half-life of Opana ER is ~9-11 hours. (CX5002 at 038 (¶ 106) (Savage Report)).

RESPONSE TO FINDING NO. 778:

Respondent has no specific response.

779. The relatively long half-life of oxymorphone, per se, combined with its sustained release formulation, results in sustained effects over 12 hours. (CX5002 at 038 (¶ 106) (Savage Report); Savage, Tr. 720 ("Q. What is the practical significance of the relatively

long half-life of oxymorphone compared to other opioids? A. We would expect it to have a longer duration of action.")).

RESPONSE TO FINDING NO. 779:

Respondent has no specific response.

780. This long half-life may result in more sustained analgesia at end of dose when given at 12-hour intervals than some other controlled release opioids. For example, OxyContin is also approved for 12 hour dosing, but patients sometimes experience decreased analgesia towards the end of the dosing period, resulting in breakthrough pain. As a result OxyContin is often prescribed for use at 8-hour intervals. (CX5002 at 038-39 (¶ 106) (Savage Report)).

RESPONSE TO FINDING NO. 780:

Respondent has no specific response.

781. The longer half-life of oxymorphone was promoted by Endo and treated as significant in its internal documents. (CX2717 at 008 (Opana ER Advisory Board Executive Summary) (identifying no end of dose failure as a key benefit of Opana ER); CX2610 at 014 (Revopan [reformulated Opana ER] Playbook) (identifying "True 12-hour dosing" as part of the heritage of oxymorphone); CX2716 at 022 (Opana Marketing Presentation) (listing "Stable, steady-state plasma levels for true 12-hour dosing that lasts" as a key message); CX3220 at 023 (Endo Q2 2012 Earnings Call Transcript) (stating that Opana ER is "a compound that given its PK profile lends itself to twice daily dosing whereas with a lot of other product [sic] including oxycodone doses tend to get migrated to 3 sometimes even greater frequency of dosages per day.")).

RESPONSE TO FINDING NO. 781:

Complaint Counsel's Proposed Finding No. 781 is incomplete and misleading because it ignores the testimony of Demir Bingol, Endo's Senior Director of Marketing, who explained that frequency of dosage differences between Opana ER and other long-acting opioids were used as a marketing tactic because they represented Endo's "best opportunity to compete against those [other long-acting opioid] products based on their profile and what they brought to the market." (Bingol, Tr. 1314). But as Dr. Savage admitted, the differences among long-acting opioids are no different than those found in over-the-counter pain relievers like Advil, Tylenol, Aleve, and

aspirin, which nevertheless are used for the same treatments and compete for the same customers. (Savage, Tr. 812-16). Dr. Savage also explained that frequency of dosing is mostly about patient preferences. She explained that patients may want to take a certain long-acting opioids that require more pills more frequently so that they have a sense of control over their treatment; others patients do not. (Savage, Tr. 742).

> 782. Patients using oxymorphone on average use fewer tablets per day than those on oxycodone. (CX2549 at 005 (EN3288 [reformulated Opana ER] HOPE Launch Readiness Plans) ("In chronic use, patients using oxycodone are dispensed more tablets per day than those receiving oxymorphone . . ."); CX3158 at 006 (EN3288 [reformulated Opana ER] Value Strategy Review) ("Lower Daily Average Consumption with OpanaER compared to OxyContin.")).

RESPONSE TO FINDING NO. 782:

Complaint Counsel's Proposed Finding No. 782 is inaccurate and misleading. The cited document (CX2549) explicitly states that the language quoted by Complaint Counsel "only focused on observed economic events. *There are no claims of therapeutic superiority among the products whose utilization patterns were observed*." (CX2549-005 (emphasis added) (discussing only oxycodone and oxymorphone)). Such claims were advanced by Endo in hopes of crafting a "value platform message." (CX2549-004; *see also* CX3158-006 ("draft" document attempting to convince payors that crush-resistant Opana ER "confers additional value over existing extended-release opioids")).

Demir Bingol, Endo's Senior Director of Marketing, explained that frequency of dosage differences between Opana ER and other long-acting opioids were used as a marketing tactic because they represented Endo's "best opportunity to compete against those [other long-acting opioid] products based on their profile and what they brought to the market." (Bingol, Tr. 1314). But as Dr. Savage admitted, the differences among long-acting opioids are no different than those found in over-the-counter pain relievers like Advil, Tylenol, Aleve, and aspirin, which

nevertheless are used for the same treatments and compete for the same customers. (Savage, Tr. 812-16). Dr. Savage also explained that frequency of dosing is mostly about patient preferences. She explained that some patients may want to take a certain long-acting opioid that requires more pills more frequently so that they have a sense of control over their treatment; other patients do not. (Savage, Tr. 742).

> 783. The relatively long half-life of Opana ER carried economic and clinical significance. (Bingol, Tr. 1272 ("[F]rom a payer perspective, it was reassuring perhaps to know that [Opana ER] wouldn't be used more frequently than as prescribed, from a cost perspective."); Bingol, Tr. 1272 ("From a clinician or a patient perspective, it had more of a clinical message to know that their pain could be controlled with a reliable dosing scheme of . . . every twelve hours rather than having to maybe rely on breakthrough medications . . .")).

RESPONSE TO FINDING NO. 783:

Complaint Counsel's Proposed Finding No. 783 is incomplete and misleading because it ignores the testimony of Demir Bingol, Endo's Senior Director of Marketing, who explained that frequency of dosage differences between Opana ER and other long-acting opioids were used as a marketing tactic because they represented Endo's "best opportunity to compete against those [other long-acting opioid] products based on their profile and what they brought to the market." (Bingol, Tr. 1314). As Dr. Savage admitted, the differences among long-acting opioids are no different than those found in over-the-counter pain relievers like Advil, Tylenol, Aleve, and aspirin, which nevertheless are used for the same treatments and compete for the same customers. (Savage, Tr. 812-16). Dr. Savage also explained that frequency of dosing is mostly about patient preferences. She explained that some patients may want to take a certain long-acting opioid that requires more pills more frequently so that they have a sense of control over their treatment; other patients do not. (Savage, Tr. 742).

3. Flexible dosing

784. Oxymorphone, unlike some other long-acting opioids used for oral analgesia, is available in an injectable or IV formulation. This is significant because a patient using Opana ER that requires IV opioids can continue to use oxymorphone without the need to transition to a new opioid with the inherent uncertainty in terms of analgesic response and potential side effects. (CX5002 at 039-40 (¶ 108) (Savage Report)).

RESPONSE TO FINDING NO. 784:

While Respondent does not dispute that oxymorphone is available in both injectable and tablet formulations, there is no support in the record for the proposition that the availability of both formulations is "significant" for purposes of pain treatment or market definition. Dr. Savage admitted the point is only a "theoretical consideration," and keeping patients on a tablet version of an injectable opioid is "not often done." (Savage, Tr. 802). In fact, the most commonly used opioids in emergency rooms and other inpatient settings are hydromorphone, fentanyl, and morphine. (Savage, Tr. 787). The most commonly prescribed opioids in outpatient settings are oxycodone, hydrocodone, and morphine. (Savage, Tr. 786; Michna, Tr. 2150). When patients are released from the hospital they are almost always switched from one opioid to an entirely different opioid for outpatient purposes. (Savage, Tr. 798, 799-800; Michna, Tr. 2149-50; Noll, Tr. 1530 (physicians "very often switch which molecule is used when the patient leaves the hospital")). For this reason, the availability of oxymorphone in both injectable and tablet form is not a clinically relevant factor. (Michna, Tr. 2149-50).

785. Because oxymorphone is available as an IV formulation, it is possible to switch a patient from that to an oral form of oxymorphone when they leave the hospital and know that the patient will tolerate it. (Savage, Tr. 802).

RESPONSE TO FINDING NO. 785:

While Respondent does not dispute that oxymorphone is available in both injectable and tablet formulations, Dr. Savage admitted the point is only a "theoretical consideration," and

keeping patients on a tablet version of an injectable opioid is "not often done." (Savage, Tr. 802). In fact, the most commonly used opioids in emergency rooms and other inpatient settings are hydromorphone, fentanyl, and morphine. (Savage, Tr. 787). The most commonly prescribed opioids in outpatient settings are oxycodone, hydrocodone, and morphine. (Savage, Tr. 786; Michna, Tr. 2150). When patients are released from the hospital they are almost always switched from one opioid to an entirely different opioid for outpatient purposes. (Savage, Tr. 798, 799-800; Michna, Tr. 2149-50; Noll, Tr. 1530 (physicians "very often switch which molecule is used when the patient leaves the hospital")). For this reason, the availability of oxymorphone in both injectable and tablet form is not a clinically relevant factor. (Michna, Tr. 2149-50).

> 786. In addition to the ER and IV formulations, oxymorphone is also available in an immediate release (IR) formulation, meaning that the molecule can be dosed in a variety of ways as needed for an individual patient. (CX2529 at 059 (Opana ER Strategic Platform) ("Opana has an advantage over other opioids in that it is available in both parenteral [injectable] and oral (IR and ER) formulations, which leads to easy titration and conversion when patients need to transition from IV to oral dosage forms.")).

RESPONSE TO FINDING NO. 786:

While Respondent does not dispute that oxymorphone is also available in an immediate release formulation, Complaint Counsel's Proposed Finding No. 786 is incomplete and misleading in its claim that Opana had any therapeutic advantage as a result. Demir Bingol, Endo's Senior Director of Marketing, explained that differences between Opana ER and other long-acting opioids were used as a marketing tactic because they represented Endo's "best opportunity to compete against those [other long-acting opioid] products based on their profile and what they brought to the market." (Bingol, Tr. 1314). As Dr. Savage admitted, the differences among long-acting opioids are no different than those found in over-the-counter pain

relievers like Advil, Tylenol, Aleve, and aspirin, which nevertheless are used for the same treatments and compete for the same customers. (Savage, Tr. 812-16).

4. Less euphoria/cognitive impairment

787. Endo's clinical data indicated that Opana ER was less euphorigenic and caused less cognitive impairment than some other long-acting opioids. (CX4025 (Bingol, Dep. at 128-129) (stating that "cognitive ability was less impaired on Opana ER on some of the parameters versus OxyContin"); CX2610 at 014 (Revopan [reformulated Opana ER] Playbook) (identifying "Low euphoria" as part of the heritage of oxymorphone); CX2553 at 018 (Oxymorphone Franchise Business Plan) ("Opana ER demonstrated less cognition, psychomotor impairment and liking than equi-analgesic doses of OxyContin . . .")).

RESPONSE TO FINDING NO. 787:

Respondent has no specific response other than to clarify that the cited evidence does not support the proposition with respect to any long-acting opioid other than OxyContin.

788. In particular, Endo had a study indicating that there was less euphoria associated with patients taking Opana ER versus OxyContin demonstrating that on every-twelve hour dosing patients were able to function better. (Bingol, Tr. 1274).

RESPONSE TO FINDING NO. 788:

Respondent has no specific response other than to clarify that Mr. Bingol testified that "at that point in time" the study indicated that there "was *perhaps* less euphoria." (Bingol, Tr. 1274 (emphasis added) (patients could be "a little bit more clearheaded")).

5. Lack of particular side effects

789. Some data show fewer side effects with Opana ER as compared to other long-acting opioids. (CX2717 at 008 (Opana ER Advisory Board Executive Summary) (identifying lack of side effects as a key benefit of Opana ER)).

RESPONSE TO FINDING NO. 789:

Complaint Counsel's Proposed Finding No. 789 is inaccurate, misleading, and not supported by the cited evidence. The so-called "data" referenced in Proposed Finding No. 789 comes from twenty-eight Endo "advisors" who attended Endo meetings and were asked "to

provide 1 top key benefit of Opana ER." (CX2717-003-04, 08). Among the "[c]ommon themes" was that Opana ER was "well tolerated/lack of side effects." (CX2717-008). The cited document says nothing about Opana ER side effects in relation to any other long-acting opioid.

790. Endo identified an incidence of adverse events (AEs) similar to that of a placebo in its internal documents. (CX2610 at 024 (Revopan [reformulated Opana ER] Playbook) (identifying "AEs similar to placebo post titration" as a key advantage of Revopan); CX2528 at 023 (Revopan [reformulated Opana ER] Launch Readiness Review) (same)).

RESPONSE TO FINDING NO. 790:

Respondent has no specific response other than to clarify that the cited documents indicate that the placebo issue was promoted as an Opana ER advantage only in relation to morphine, which is one of the several long-acting opioids in a "Competitive Market" that includes oxycodone, tapentadol, hydromorphone, fentanyl, buprenorphine, and duloxetine as well. (CX2610-024).

791. Some other opioids, like methadone, may result in QTc elongation, which puts patients at risk for potentially lethal cardiac arrhythmias. (Savage, Tr. 754; CX3355 at 012-13 (FDA Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioid Analgesics)). Opana ER does not present a similar safety concern associated with QTc prolongation. (Savage, Tr. 756).

RESPONSE TO FINDING NO. 791:

Respondent has no specific response other than to clarify that Dr. Savage testified that to the extent patients develop side effects, those side effects can be treated with additional medications and that there is no way to tell which opioid will work best or result in minimal side effects in advance of treatment. (Savage, Tr. 711, 785, 794).

792. Similarly, opioids other than Opana ER, like morphine and hydromorphone, pose a risk of neuroexcitatory effects, which means they can cause irritability and hyperreflexia. (Savage, Tr. 738).

RESPONSE TO FINDING NO. 792:

Respondent has no specific response other than to clarify that Dr. Savage testified that to the extent patients develop side effects, those side effects can be treated with additional medications and that there is no way to tell which opioid will work best or result in minimal side effects in advance of treatment. (Savage, Tr. 711, 785, 794).

G. Immediate release forms of oxymorphone did not sufficiently constrain Opana ER sales and prices

793. Another potential candidate to be a close economic substitute for oxymorphone ER is immediate release (IR) oxymorphone. Oxymorphone IR is used to treat acute pain and is available in two formulations: tablet (Opana, also approved in 2006, with six approved generics, the first of which entered at the end of 2010) and injectable solution (Opana Injection, approved in 1959 as Numorphan, no generics). (CX5000 at 057 (¶ 123) (Noll Report)).

RESPONSE TO FINDING NO. 793:

Proposed Finding No. 793 violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." Professor Noll was not and is not qualified as an expert with respect to the pharmaceutical industry. (Noll, Tr. 1358).

794. Immediate release and extended release oxymorphone differ sufficiently in their therapeutic uses that they are unlikely to be therapeutic substitutes, and hence unlikely to be in the same relevant market. (CX5000 at 057 (¶ 125) (Noll Report); Noll, Tr. 1383-84 (explaining why one wouldn't expect ER and IR oxymorphone to be perfect substitutes)).

RESPONSE TO FINDING NO. 794:

Proposed Finding No. 794 violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." Professor Noll was not and is not qualified as an expert with respect to the

pharmaceutical industry. (Noll, Tr. 1358). Proposed Finding No. 794 also is improper because it states a legal conclusion.

795. ER opioids have advantages over IR opioids. First, ER drugs reduce pill burden (the number and frequency of doses), which is beneficial to the extent that a lower pill burden improves adherence to the prescription and reduces the likelihood of misuse, such as accidental overdose. Second, an ER formulation allows the drug to be put into the system continuously "around the clock," even when the patient is sleeping. (CX5000 at 057 (¶ 125) (Noll Report); Savage, Tr. 705 ("Extended-release opioids are indicated for people who have sustained pain usually that goes on longer than 12 to 24 hours or of a chronic nature that requires relief 24 hours a day.")).

RESPONSE TO FINDING NO. 795:

Proposed Finding No. 795 violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." Professor Noll was not and is not qualified as an expert with respect to the pharmaceutical industry. (Noll, Tr. 1358). The quoted portion of Dr. Savage's testimony speaks for itself and does not support the propositions advanced in the Proposed Finding.

796. From a clinical care perspective, ER formulations are valuable because they provide more sustained relief of pain. If taken as prescribed, ER medications more easily provide stable blood levels of opioid than most IR medications, so they are also expected to have fewer CNS impairing side effects due to peaking of blood levels. (CX5002 at 034 (¶ 97) (Savage Report); Savage, Tr. 706-07; Michna, Tr. 2114 ("In those situations, consideration may be given to using a long-acting opioid, which maintains the blood level of the medication more constant over a long period of time . . .")).

RESPONSE TO FINDING NO. 796:

Complaint Counsel's Proposed Finding No. 796 is incomplete and misleading because it ignores the testimony of both Dr. Savage and Dr. Michna. Dr. Michna explained that even for "chronic conditions, [patients] might be very doing very well on the short-acting opioid and we would continue them on it." (Michna, Tr. 2113 (quoted language about blood level considerations noted when talking about "breakthrough pain")). Dr. Savage testified that "it is

possible to overlap doses of short-acting medications in a way that provides a steady state." (Savage, Tr. 707). Indeed, there is no difference in the efficacy of immediate-release and long-acting opioids. (Michna, Tr. 2117).

797. ER Opioids also have disadvantages compared with IR opioids that make them unlikely to be close substitutes. For example, IR opioids are more amenable to use "as needed" (based on the presence of pain), which can lead to a lower daily dosage. (CX5000 at 0558 (¶ 126) (Noll Report); Savage, Tr. 705 ("If somebody has short-lived, quick onset pain that goes away fairly quickly, a shorter-acting opioid would be indicated.")).

RESPONSE TO FINDING NO. 797:

Proposed Finding No. 797 violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." Professor Noll was not and is not qualified as an expert with respect to the pharmaceutical industry. (Noll, Tr. 1358). The quoted portion of Dr. Savage's testimony speaks for itself and does not support the propositions advanced in the Proposed Finding.

798. Thus, short acting opioids are not routinely or reliably interchangeable with a long-acting opioid with like Opana ER. (Savage, Tr. 708).

RESPONSE TO FINDING NO. 798:

Complaint Counsel's Proposed Finding No. 798 is not supported by the record. Dr. Michna explained that even for "chronic conditions, [patients] might be very doing very well on the short-acting opioid and we would continue them on it." (Michna, Tr. 2113). Dr. Savage testified that "it is possible to overlap doses of short-acting medications in a way that provides a steady state." (Savage, Tr. 707). Indeed, there is no difference in the efficacy of immediate-release and long-acting opioids. (Michna, Tr. 2117).

799. Exhibits 3A, 3B and 3C of the Noll Report test whether oxymorphone IR is a close economic substitute for oxymorphone ER by examining whether generic entry in

oxymorphone IR affected sales of Opana ER. Exhibit 3A counts total prescriptions, Exhibit 3B shows total mg for each formulation of oxymorphone, and Exhibit 3C shows gross revenues from sales of the two products. (CX5000 at 058-59 (¶ 127) (Noll Report)).

RESPONSE TO FINDING NO. 799:

While Respondent does not dispute that the cited exhibits in Professor Noll's expert report purport to test the asserted propositions, Professor Noll's analysis is based on his scanning for any "visible effect" on Opana ER sales, a metric he never defined. (Noll, Tr. 1384). Professor Noll recognizes that a SSNIP test is the normal method used to determine close economic substitutes. (CX5000 at 017 (Noll Rep. ¶ 38)). But Professor Noll admits he did not conduct a SSNIP test. (Noll, Tr. 1514).

800. Generic entry for a product is a reasonable indicator of a substantial fall in its price. Thus, for purposes of defining the relevant market that contains oxymorphone ER, the key issue is whether generic entry for the IR formulation affected sales of the ER formulation. (CX5000 at 058-59; 072 (¶ 128, ¶ 158 n.214) (Noll Report)).

RESPONSE TO FINDING NO. 800:

Complaint Counsel's Proposed Finding No. 800 is improper because it states a legal conclusion. The Proposed Finding is also unsupported and wrong. The cited portion of Professor Noll's report contains no evidence or analysis to support the proposition. Professor Noll's analysis is based on his scanning for any "visible effect" on Opana ER sales, a metric he never defined. (Noll, Tr. 1384). Professor Noll recognizes that a SSNIP test is the normal method used to determine close economic substitutes. (CX5000-017 (Noll Rep. ¶ 38)). But Professor Noll admits he did not conduct a SSNIP test. (Noll, Tr. 1514).

801. One independent generic version of oxymorphone IR and one authorized generic entered in 2010. For all three output measures, sales of oxymorphone IR exhibit the normal pattern after entry by therapeutically equivalent generics in that the generics quickly took substantial sales away from Opana IR. [redacted]

[redacted]
(CX5000 at 059 (¶ 128) (Noll Report) (*in camera*)).

RESPONSE TO FINDING NO. 801:

Complaint Counsel's Proposed Finding No. 801 violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." Any data speaks for itself.

802. Essentially, brand name Opana IR was driven from the market, and that market was taken over by the generic oxymorphone IR at a much lower price. But, while that was going on, there was no visible effect at all on sales of Opana ER – its sales continued to go up. (Noll, Tr. 1384-85).

RESPONSE TO FINDING NO. 802:

Complaint Counsel's Proposed Finding No. 802 violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." Any data speaks for itself.

803. These data show that generic oxymorphone IR did not significantly substitute for sales of Opana ER and that, therefore, oxymorphone IR and Opana ER are not in the same relevant product market for purposes of assessing the conduct at issue in this case. (CX5000 at 059 (¶ 128) (Noll Report); Noll, Tr. 1385 ("That tells you that IR is not a close economic substitute for ER . . . ")).

RESPONSE TO FINDING NO. 803:

Complaint Counsel's Proposed Finding No. 803 violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." Proposed Finding No. 803 also is improper because it states a legal conclusion.

H. Other pain relief products did not meaningfully constrain Opana ER sales and prices

804. Individuals have highly variable responses to many classes of medications that are used to treat pain, including nonsteroidal anti-inflammatory drugs, anticonvulsant drugs, certain antidepressants that are used for pain, and to opioids. (Savage, Tr. 689-90).

RESPONSE TO FINDING NO. 804:

Respondent has no specific response.

805. Nonsteroidal anti-inflammatory drugs are generally indicated for mild to moderate pain, whereas opioids are indicated for greater pain severity. Anti-inflamatory drugs also have a different mechanism of action from opioids. (Savage, Tr. 699; CX5002 at 015 (¶¶ 3336) (Savage Report)).

RESPONSE TO FINDING NO. 805:

Respondent has no specific response.

806. Acetaminophen is also indicated for only mild to moderate pain, and also has a different mechanism of action than opioids. (Savage, Tr. 699; CX5002 at 016 (¶¶ 37-40) (Savage Report)).

RESPONSE TO FINDING NO. 806:

Respondent has no specific response.

807. Anticonvulsants are not as potent as opioids in relieving pain, and their efficacy appears to be greater for nerve-related pain, unlike opioids. (Savage, Tr. 700-701).

RESPONSE TO FINDING NO. 807:

Respondent has no specific response.

808. Similarly, anti-depressants than can be used to treat pain are less potent than opioids. (Savage, Tr. 701; CX5002 at 017-18 (¶¶ 45-47) (Savage Report)).

RESPONSE TO FINDING NO. 808:

Respondent has no specific response.

809. From a clinical perspective, the various non-opioid options for the treatment of pain are not reliably interchangeable with Opana ER because they have different indications, different side effect and toxicity profiles, and different mechanisms of action. (Savage, Tr. 702; CX5002 at 014 (¶¶ 31-32) (Savage Report)).

RESPONSE TO FINDING NO. 809:

Respondent has no specific response other than to clarify that different toxicity profiles, different side effects, and different mechanisms of action do not mean medications cannot be interchanged, especially if they have the same indication. Advil, Tylenol, Aleve, and aspirin all have different mechanisms of action, different dosage frequencies, different reactions in certain individuals, and different toxicity profiles. (Savage, Tr. 812-14). Yet Dr. Savage admits that each over-the-counter pain reliever can be used for the same problems. (Savage, Tr. 814-15). And Dr. Savage admits that each over-the-counter pain reliever competes for the same consumers. (Savage, Tr. 815-16).

I. Sales within the United States is the relevant geographic market

810. The geographic area of the relevant market is the United States, which is the area within the jurisdiction of both the patent litigation between Endo and Impax regarding oxymorphone ER and regulation of these products by the FDA and DEA. (CX5000 at 016-17 (¶ 37) (Noll Report)).

RESPONSE TO FINDING NO. 810:

Respondent has no specific response.

811. The parties have stipulated that "the relevant geographic market for purposes of this litigation is the United States." (JX-001 at 002 (¶ 10)).

RESPONSE TO FINDING NO. 811:

Respondent has no specific response.

IX. Endo possessed market power at all relevant times

812. The evidence shows that Endo was able to exclude competitors, accounted for all or nearly all sales in the relevant oxymorphone ER market, and set prices far above

marginal cost from the entry of Opana ER in 2006 until the entry of Impax's generic oxymorphone ER in 2013. Although Endo's market power was not as great after Impax's entry, Endo retained substantial market power into 2017, when it was requested by the FDA to remove Reformulated Opana ER from the market. (*See* CCF ¶¶ 813-96).

RESPONSE TO FINDING NO. 812:

Complaint Counsel's Proposed Finding No. 812 should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Moreover, the individual findings cited do not support the proposed summary finding and are unreliable, inaccurate, misleading, and/or improper proposed legal conclusions, for the reasons set out in Respondent's replies to those findings.

A. Definition of market power

813. Market power is the power to control prices and/or exclude competitors from a market. (Noll, Tr. 1404; CX5000 at 083 (¶ 184) (Noll Report)).

RESPONSE TO FINDING NO. 813:

Complaint Counsel's Proposed Finding No. 813 improperly states a proposed legal conclusion, not a fact, and should be disregarded. The proposed legal conclusion is also misleading and incomplete, in that it ignores the role of output restrictions as a key factor in determining market power. Market power (also known as monopoly power) refers to "the ability to *restrict output* and sustain supracompetitive profits." (RX-547.0008 (Addanki Rep. ¶ 11 n.8)) (emphasis added). As Dr. Addanki explained at trial, "from the economic standpoint, consumer harm comes about because of a reduction in output brought about by a monopolist. The harm to consumers comes from the reduction in output, and so when we see monopoly power being dissipated, we see an expansion in output." (Addanki, Tr. 2372).

814. A rule of reason analysis includes a determination of market power. (Noll, Tr. 1343; CX5000 at 083 (¶ 184) (Noll Report)).

RESPONSE TO FINDING NO. 814:

Complaint Counsel's Proposed Finding No. 814 improperly states a proposed legal conclusion, not a fact, and should be disregarded.

815. Assessing market power helps to determine whether the conduct at issue in a rule-of-reason analysis preserved or enhanced the market power of a company. (CX5000 at 006, 012 (¶¶ 9, 27) (Noll Report); Noll, Tr. 1365). In so doing, the market power analysis aids a rule-of-reason assessment in determining the anticompetitive effects for conduct at-issue in a particular relevant market. (CX5000 at 006 (¶ 9) (Noll Report)).

RESPONSE TO FINDING NO. 815:

Complaint Counsel's Proposed Finding No. 815 improperly states a proposed legal conclusion, not a fact. In addition, the proposed legal conclusion is incomplete and misleading. A market participant cannot harm competition unless that participant possessed monopoly power in the relevant market at the time. As Dr. Addanki explained: "Because the economic harm engendered by an allegedly anticompetitive settlement results directly from its ability to create enhance or maintain monopoly power, if Endo did not possess monopoly power in the relevant market no further inquiry on the competitive effects of the settlement is necessary the settlement cannot be anticompetitive." (RX-547.008 (Addanki Rep. ¶ 11(a))). Professor Noll agrees with Dr. Addanki on this point; as Dr. Noll admitted at trial, the SLA could not have been anticompetitive unless Endo had "[s]ubstantial market power." (Noll, Tr. 1574).

816. Economists can ascertain market power in two ways, indirectly and directly. (CX5000 at 083 (¶ 184) (Noll Report); Noll, Tr. 1404-05).

RESPONSE TO FINDING NO. 816:

Respondent has no specific response.

817. Complaint Counsel's economic expert and Professor Emeritus of Stanford University, Roger G. Noll, applied real-world data to both the indirect and direct methods of assessing market power. (Noll, Tr. 1366, 1693-96; CX5000 at 083-100 (¶¶ 184-227) (Noll Report)).

RESPONSE TO FINDING NO. 817:

Complaint Counsel's Proposed Finding No. 817 is incomplete and misleading. Whether or not Professor Noll "applied real-world data" when assessing market power is not probative of market power without understanding whether that data is relevant to the market power inquiry, especially whether it is reflective of power to constrain output, and whether that data was properly and empirically analyzed. As described in Respondent's responses to Complaint Counsel's Proposed Findings Nos. 818 through 965, Professor Noll and Complaint Counsel's use of supposed "real-world data" is improper to assess market power for the reasons explained in the responses to those proposed findings.

818. Real-world data applied to the indirect and direct methods supports the conclusion that Endo had substantial market power/monopoly power in the market for Opana ER. (Noll, Tr. 1404-05; CX5000 at 087-88, 095, 100 (¶¶ 197, 214, 227) (Noll Report)). This was true at the time of the settlement and remained true for many years following the settlement. (Noll, Tr. 1405; CX5000 at 100 (¶ 227) (Noll Report)).

RESPONSE TO FINDING NO. 818:

Complaint Counsel's Proposed Finding No. 818 is an inaccurate assessment of market power in the relevant antitrust market and is unsupported by the record. First, the "market for Opana ER" is not the relevant market. The proper antitrust market is the market for long-acting opioids. (*See also* RX-547.0047 (Addanki Rep. ¶ 85)). "Because the relevant market is broader than the narrow market definition that Dr. Noll contends, his market concentration analysis does not shed any light on whether Opana ER has had monopoly power." (RX-547.0052 (Addanki Rep. ¶ 98)). Indeed, from January 2009 through December 2012, Opana ER's share of the long-acting opioid market never reached 10 percent. (Addanki, Tr. 2333; RX-547.0050-51, RX-

547.0132 (Addanki Rep. ¶ 94, Ex. 10)). By Endo's own estimate, its market share was just 3.4 percent near the time of the settlement. (CX3273-003). It is "inconceivable" that Endo could command monopoly power with such a small share of the relevant market. (Addanki, Tr. 2333). As Complaint Counsel's own economic expert acknowledged, the SLA could not have been anticompetitive unless Endo had "[s]ubstantial market power." (Noll, Tr. 1574).

Further, Professor Noll identified only three supposed "indicators" of monopoly power under the "direct method": "1) the ability to exclude firms from the market, 2) the attention given by a firm's executives to the prices and likely competitive response of other firms to a contemplated price change a company's internal estimates of the effects of a price change on sales volume and profitability, and 3) the Lerner Index." (RX-547.0052 (Addanki Rep. ¶ 99); *see* Noll, Tr. 1412–14). "But [w]e have known for a very long time now that patents do not confer monopoly power" (Addanki, Tr. 2343), that Endo very much viewed itself as competing with other long-acting opioids (CX2610 at 24; Bingol, Tr. 1311-15; RX-547.0043-47 (Addanki Rep. ¶¶ 80-84)), and Professor Noll himself admitted that a high Lerner Index "doesn't necessarily mean" that a firm has monopoly power, (Noll, Tr. 1415).

B. Indirect method of establishing market power

819. The indirect method of establishing market power measures the impact of market concentration on prices. (CX5000 at 083-84 (¶ 185) (Noll Report); Noll, Tr. 1405). This is the "traditional" way to conduct an antitrust economic analysis for market power. (Noll, Tr. 1365; CX5000 at 012 (¶ 26) (Noll Report)).

RESPONSE TO FINDING NO. 819:

Complaint Counsel's Proposed Finding No. 819 improperly states a proposed legal conclusion, not a fact. It is also inaccurate and misleading. As Dr. Noll admits in his report, the "indirect" method consists of more than "measur[ing] the impact of market concentration on prices." (*See* CX5000-083-84 (Noll Rep. ¶ 185)). The indirect method requires Complaint

Counsel to prove that (1) Endo had a significant share of the relevant market, (2) there are significant "barriers to entry" in the relevant market, and (3) incumbent competitors in the relevant market cannot increase their output in the short run. (RX-547.0014-22 (Addanki Rep. ¶¶ 29-40); *see* CX5000-083-84 (Noll Rep. ¶ 185) (admitting that "indirect" method requires proof of "barriers to entry" and barriers to "capacity expansion by existing firms")).

820. The indicators of market concentration that economists commonly use are the market share of the largest sellers (the concentration ratio) and the Hirschman-Herfindahl Index (HHI). (CX5000 at 084 (¶ 186) (Noll Report); Noll, Tr. 1405, 1410-11). The *Merger Guidelines* sets the threshold above which concentration is likely to cause prices above a competitive level and firms in that market can, therefore, be regarded as possessing substantial market power. (CX6054 at 022 (*Merger Guidelines*); Noll, Tr. 1405; CX5000 at 084 (¶ 186) (Noll Report)).

RESPONSE TO FINDING NO. 820:

Respondent has no specific response.

821. Economic theory predicts that a concentrated market with significant barriers to entry will result in higher prices. (CX5000 at 083-84 (¶ 185) (Noll Report)).

RESPONSE TO FINDING NO. 821:

Complaint Counsel's Proposed Finding No. 821 is inaccurate and misleading. The cited portion of Professor Noll's report does not state that a concentrated market with significant barriers to entry will invariably result in higher prices. Professor Noll admits that, even in a concentrated market, higher prices are unlikely to result unless there not only barriers to entry, but also barriers to incumbent competitors expanding their output. (CX5000-083-84 (Noll Rep. ¶ 185)).

822. Barriers to entry are elements that create a substantial advantage to market incumbents and that a potential market entrant can overcome only by making large expenditures and capturing a large amount of sales. (CX5000 at 086 (¶ 193) (Noll Report); Noll, Tr. 140607). Barriers to entry can include patents, regulatory barriers,

economies of scale, and can be reinforced by product differentiation and loyalty. (CX5000 at 086 (¶ 193) (Noll Report); Noll, Tr. 1406-09).

RESPONSE TO FINDING NO. 822:

Respondent has no specific response, to the extent it speaks to the economic term "barriers to entry," and not the legal term of art.

823. Intellectual property right barriers to entry may be overcome by investing in research to "invent around" the IP rights or disputing the rights through patent litigation. (CX5000 at 086 (¶ 193) (Noll Report); Noll, Tr. 1406-09).

RESPONSE TO FINDING NO. 823:

Respondent has no specific response.

824. Regulatory impediments to enter a market may be overcome only by incurring substantial costs and time delays in the regulatory process. (CX5000 at 086 (¶ 193) (Noll Report); Noll, Tr. 1406-09).

RESPONSE TO FINDING NO. 824:

Complaint Counsel's Proposed Finding No. 824 is incomplete and therefore misleading. Regulations do not necessarily create barriers to entry, and when regulations do represent a barrier to entry the ease with which that barrier can be "overcome" varies substantially.

825. High brand loyalty to incumbent products may be overcome by a potential market entrant only if the entrant substantially invests in product promotions. (CX5000 at 086 (¶ 193) (Noll Report); Noll, Tr. 1402-03, 1406-09).

RESPONSE TO FINDING NO. 825:

Complaint Counsel's Proposed Finding No. 825 is vague and misleading. It is unclear what would constitute "high brand loyalty" or "substantial[]" investment. Proposed Finding No. 825 is also misleading to the extent it suggests that "substantially investing in product promotions" is the only means for a potential entrant to overcome "high brand loyalty." Moreover, the cited portions of Professor Noll's report and testimony say nothing about potential

entrants being required to invest "substantially" in promotion to overcome brand loyalty. (*See* CX5000-086 (Noll Rep. ¶ 193) (stating that high brand loyalty "may be overcome if the entrant invests in product promotions")).

826. Barriers to entry resulting from high fixed costs or economies of scale for efficient capital facilities imply that an entrant must be able to sustain prices above average variable cost of production and must capture a substantial share of the market in order to recover the cost of entry. (CX5000 at 086 (¶ 193) (Noll Report); Noll, Tr. 1406-09).

RESPONSE TO FINDING NO. 826:

Respondent has no specific response, to the extent the proposed finding refers to the economic term "barriers to entry," and not the legal term of art.

827. The indirect method of establishing market power can demonstrate that participants who engaged in the conduct at issue had market power, that the market power was created or maintained or extended by anticompetitive conduct, and that the anticompetitive conduct caused harm to competition. (Noll, Tr. 1365; CX5000 at 083-88 (¶¶ 184-97) (Noll Report)).

RESPONSE TO FINDING NO. 827:

Complaint Counsel's Proposed Finding No. 827 improperly states a proposed legal conclusion, not a fact, and should be disregarded. The proposed finding is also inaccurate, as it conflates the market power inquiry and other aspects of the rule of reason analysis. Establishing market power via the indirect method does not indicate that "the market power was created or maintained by anticompetitive conduct, and that the anticompetitive conduct caused harm to competition." Indeed, the cited portions of Professor Noll's report says *nothing* about anticompetitive conduct, the creation or maintenance of monopoly power through anticompetitive means, or causal harm to competition, (CX5000-083-88 (Noll Rep. ¶¶ 184-97)), and in the cited portion of Professor Noll's testimony, Professor Noll was explicitly discussing

the rule of reason analysis (Noll, Tr. 1365)—not the "indirect method of establishing market power" itself, as Proposed Finding No. 827 wrongly asserts.

As Dr. Addanki explains, the market power inquiry and the rule of reason inquiry are separate analyses, though the latter is unnecessary unless the former is satisfied. Once "the brand's monopoly power has been established," then "the *next step* is to determine whether in fact consumers are worse off under the actual settlement agreement than they would have been in its absence (*i.e.,* in the but-for world). (RX-547.0020 (Addanki Rep. ¶ 20) (emphasis added); *see also* RX-547.00022-23 (Addanki Rep. ¶ 41) (describing monopoly power screen)).

1. At all relevant times, Endo had substantial market power in the relevant market

828. The relevant market is the sale of oxymorphone ER products. (*See* CCF ¶¶ 498-501, above).

RESPONSE TO FINDING NO. 828:

Complaint Counsel's Proposed Finding No. 828 should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Moreover, the individual findings in the cited paragraphs do not support the proposed summary finding and are unreliable, inaccurate, misleading, and/or improper legal conclusions, for the reasons set out in Respondent's replies to those findings.

829. The indirect method of establishing market power supports the fact that Endo had substantial market power in the relevant oxymorphone ER market prior and subsequent to the Impax-Endo Settlement Agreement. (CX5000 at 084-85 (¶ 187) (Noll Report); Noll, Tr. 1406, 1410-11).

RESPONSE TO FINDING NO. 829:

Complaint Counsel's Proposed Finding No. 829 improperly states a proposed legal conclusion, not a fact. The indirect method requires Complaint Counsel to prove that (1) Endo had a significant share of the relevant market, (2) there are significant barriers to entry in the relevant market, and (3) incumbent competitors in the relevant market cannot increase their output in the short run. (RX-547.0014-22 (Addanki Rep. ¶¶ 29-40)). Further, the cited testimony of Professor Noll does not indicate that "Endo had substantial market power in the relevant oxymorphone ER market." The "oxymorphone ER market" is not the relevant market. The proper antitrust market is the market for long-acting opioids. (*See also* RX-547.0022 (Addanki Rep. ¶ 85)). "Because the relevant market is broader than the narrow market definition that Dr. Noll contends, his market concentration analysis does not shed any light on whether Opana ER has had monopoly power." (RX-547.0022 (¶ 98) (Addanki Rep. ¶ 98)). Indeed, from January 2009 through December 2012, Opana ER's share of the long-acting opioid market never reached 10 percent. (Addanki, Tr. 2233; RX-547 (Addanki Rep. ¶ 94, Ex. 10)). By Endo's own estimate, its market share was only 3.4 percent near the time of the settlement. (CX3273-003). It is "inconceivable" that Endo could command monopoly power with such a small share of the relevant market. (Addanki, Tr. 2233).

830. In 2010, Endo had 100% of the market for oxymorphone ER. (CX5000 at 085 (¶189) (Noll Report)).

RESPONSE TO FINDING NO. 830:

Complaint Counsel's Proposed Finding No. 830 is misleading and inconsistent with the record, to the extent it refers to a "market for oxymorphone ER." The record evidence indicates that oxymorphone ER and Opana ER competed in a market for all long-acting opioids. (*See* Addanki, Tr. 2328 (testifying that "the relevant market is no smaller than the market for long-

acting opioids in the United States"); RX-547.0047-48 (Addanki Rep. ¶¶ 85-86); CX3273-003 (Bingol Decl. ¶ 6)). Endo never had more than a 10 percent share of the long-acting opioid market. (Addanki, Tr. 2333; RX-547.0050-51 (Addanki Rep. ¶ 94)). By Endo's own estimate, its market share was only 3.4 percent near the time of the settlement. (CX3273-003 (Bingol Decl.) (referring to a long-acting opioid market)).

> 831. The number of firms in the relevant oxymorphone ER market has always been small. The only branded oxymorphone ER products sold prior to and subsequent to the Impax-Endo Settlement Agreement are Endo's Opana ER products, Original Opana ER and Reformulated Opana ER. (JX-001 at 006 (¶ 8); Bingol, Tr. 1262; CX6050 at 006-13 (FDA Regulatory History of Opana ER); CX5000 at 084-85 (¶¶ 187-88) (Noll Expert Report)).

RESPONSE TO FINDING NO. 831:

Complaint Counsel's Proposed Finding No. 831 is misleading and inconsistent with the record, to the extent it refers to a "market for oxymorphone ER." The record evidence indicates that oxymorphone ER and Opana ER completed in a market for all long-acting opioids. (*See* Addanki, Tr. 2328 (testifying that "the relevant market is no smaller than the market for long-acting opioids in the United States"); RX-547.0047-48 (Addanki Rep. ¶¶ 85-86); CX3273-003 (Bingol Decl. ¶ 6)). The market for long-acting opioids includes a significant number of firms, including the sellers of OxyContin (Purdue Pharma LP), Dragesic/fentanyl patches (Janssen Pharmaceuticals, Inc.), MS Contin/Morphine Sulfate (Purdue Pharma LP), Opana ER/oxymorphone ER, Avinza (King Pharmaceuticals LLC), Kadian (Allergan Sales LLC), Embeda (Alpharma Pharmaceuticals LLC), Exalgo (Mallinckrodt, Inc.), among others. (*See* CX3273-003 (Bingol Decl. ¶ 6); RX-547.0051, RX-547.0133 (Addanki Rep. ¶¶ 95-96, Ex. 11)).

> 832. Original Opana ER was the only product in the relevant market from 2006 until July 2011. July 2011 was when Endo had licensed Actavis, another generic company, to enter with first-to-file exclusivity for the 7.5 and 15 mg doses of generic Opana ER. CX2607 at 009 (¶ 25) (Lortie Decl.); CX0309 at 002; CX5000 at 008 (¶ 14) (Noll

Report)). These dosages were the least profitable dosages of Opana ER and comprised only 5% of Endo's Opana ER revenues. (JX-001 at 007 (¶ 13); CX2607 at 010 (¶ 26) (Lortie Decl.) ("Actavis's sale of the 7.5 and 15 mg dosage strengths did not have a major impact on Endo's brand sales, because together these dosages account for less than 4% of OPANA ER CRF sales.")).

RESPONSE TO FINDING NO. 832:

Complaint Counsel's Proposed Finding No. 832 is inaccurate and inconsistent with the record. The record evidence shows that oxymorphone ER and Opana ER competed in a market for long-acting opioids. (*See* Addanki, Tr. 2328 (testifying that "the relevant market is no smaller than the market for long-acting opioids in the United States"); RX-547.0047-48 (Addanki Rep. ¶¶ 85-86); CX3273-003 (Bingol Decl. ¶ 6)). The market for long-acting opioids includes a significant number of firms, including the sellers of OxyContin (Purdue Pharma LP), Dragesic/fentanyl patches (Janssen Pharmaceuticals, Inc.), MS Contin/Morphine Sulfate (Purdue Pharma LP), Opana ER/oxymorphone ER, Avinza (King Pharmaceuticals LLC), Kadian (Allergan Sales LLC), Embeda (Alpharma Pharmaceuticals LLC), Exalgo (Mallinckrodt, Inc.), among others. (*See* CX3273-003 (Bingol Decl. ¶ 6); RX-547.0047-48, RX-547.0133 (Addanki Rep. ¶¶ 85, 95-96, Ex. 11)).

833. The Actavis generic oxymorphone ER dosages were therapeutically equivalent substitutes for the version of Opana ER that were on the market at the time of generic entry. (CX5000 at 084-85 (¶ 187) (Noll Report); Noll, Tr. 1380). Therapeutic equivalence makes it more likely that a generic will be substituted for the brand drug. (JX-001 at 003 (¶ 18); Noll, Tr. 1309; Reasons, Tr. 1219).

RESPONSE TO FINDING NO. 833:

Respondent has no specific response.

834. Rather than compete with Actavis on these low-profit dosages, Endo simply abandoned the sale of Original Opana ER for these doses, until Endo introduced Reformulated Opana ER. (CX4007 (Lortie, IHT at 124-26); JX-001 at 012 (¶ 49) (Endo introduced Reformulated Opana ER in 2012); CX5000 at 084-85 (¶ 187) (Noll Report)).

RESPONSE TO FINDING NO. 834:

Complaint Counsel's Proposed Finding No. 834 is misleading and inconsistent with the evidence cited. The cited portion of JX-001 stipulates only as to the timing of Endo's launch of reformulated Opana ER and says nothing regarding the reason for why Endo "ceased selling original Opana ER and began selling a 'new formulation' of Opana ER (NDA No. 201655)." (JX-001-012 (¶ 49)). Mr. Lortie's investigational hearing transcript actually contradicts the proposed finding's suggestion that Endo abandoned sales of 7.5 and 15mg Opana ER "[r]ather than compete with Actavis." In his testimony, Mr. Lortie identified multiple reasons why Endo stopped marketing Opana ER 7.5 and 15mg that have nothing to do with generic competitions, including that the dosages were "being utilized at a very low level" and to simplify the number of dosages and more properly allocate limited API. (CX4007 (Lortie, IHT at 124-27)).

835. Endo remained the sole seller of the five most profitable dosages of the Opana ER franchise until 2013, when Impax entered the market with its generic oxymorphone ER product. (CX5000 at 085 (¶ 188) (Noll Report); CX2607 at 010 (Lortie Decl.) (Impax launched its generic on January 4, 2013)).

RESPONSE TO FINDING NO. 835:

Respondent has no specific response.

836. Before Impax's entry with generic oxymorphone ER, however, Endo had stopped selling Original Opana ER and replaced it with Reformulated Opana ER. (JX-001 at 012 (¶ 49) (Endo introduced Reformulated Opana ER in 2012)).

RESPONSE TO FINDING NO. 836:

Respondent has no specific response.

837. Unlike Original Opana ER, Reformulated Opana ER was not a therapeutically-equivalent substitute for generic oxymorphone ER. (CX5000 at 085 (¶ 188) (Noll Report); CX2607 at 006-07 (¶ 20) (Lortie Decl.) (In 2012, Endo announced that the FDA moved Original Opana ER to the Orange Book Discontinued List)). This made it harder for generic oxymorphone ER to gain market share and reduced the intensity of

competition between the generic and brand drugs. (CX5000 at 141-42, 150 (¶¶ 322-23, 340) (Noll Report)).

RESPONSE TO FINDING NO. 837:

Complaint Counsel's Proposed Finding No. 837 is misleading to the extent that it implies that Reformulated Opana ER and Original Opana ER do not have the same active ingredient or were not used for the same purposes. Opana ER and reformulated Opana ER are bioequivalent and are used interchangeably by consumers for the same purpose. (RX-547.0011, 0028-29. 0105-09 (Addanki Rep. ¶¶ 14, 61-64; Ex. 4); CX5000-038 (Noll Rep. ¶ 86)).

838. Nonetheless, since Impax began selling all seven dosage strengths of oxymorphone ER in January 2013 at prices substantially below Endo's prices, Endo's market share has declined. (CX5000 at 008 (¶ 14) (Noll Report); Noll, Tr. 1381-82).

RESPONSE TO FINDING NO. 838:

Complaint Counsel's Proposed Finding No. 838 is vague as to which "market" is being discussed, unsupported by the cited evidence and inconsistent with the record. The record supports that oxymorphone ER competes in the long-acting opioid market. (*See* Addanki, Tr. 2328 (testifying that there is no evidence indicating "the relevant market being no smaller than the market for long-acting opioids in the United States"); RX-547.0047-48 (Addanki Rep. ¶¶ 85-86); CX3273-003 (Bingol Decl. ¶ 6)). The cited sources in this proposed finding of fact evaluate market shares of a purported oxymorphone ER-only market. None of the sources cited speak to Endo's market share in the long-acting opioids market after Impax began selling oxymorphone ER in 2013.

839. The *Merger Guidelines'* threshold for a highly concentrated market is an HHI of 2500. (CX6054 at 022 (*Merger Guidelines*); CX5000 at 084 (¶ 186) (Noll Report)). The preferred measure of market shares is net quarterly sales revenues. In circumstances in which net quarterly sales revenues is not available, market shares can also be measured using total prescriptions. (CX5000 at 085 (¶ 190) (Noll Report)). Regardless of the method uses, at all times the oxymorphone ER market has been much more concentrated

than the minimum threshold of 2500. (CX5000 at 008, 085 (¶¶ 14, 189) (Noll Report); Noll, Tr. 1404-05).

RESPONSE TO FINDING NO. 839:

Complaint Counsel's Proposed Finding No. 839 is misleading, unsupported, and inconsistent with the record. The record indicates that oxymorphone ER competes in the long-acting opioids market. (*See* Addanki, Tr. 2328 (testifying that there is no evidence indicating "the relevant market being no smaller than the market for long-acting opioids in the United States"); RX-547.0047-48 (Addanki Rep. ¶¶ 85-86); CX3273-003 (Bingol Decl. ¶ 6)). The record further reflects that, in the appropriately-defined relevant market for long-acting opioids, Endo never had more than a 10 percent share. (Addanki, Tr. 2333; RX-547.0050-51 (Addanki Rep. ¶ 94); CX3273-003 (Bingol Decl. ¶ 6)). Therefore, any proper HHI calculation would be far lower than indicated in Proposed Finding No. 839. (RX-547.0052 (Addanki Rep. ¶ 98) (noting "[b]ecause the relevant market is broader than the narrow market definition that Dr. Noll contends, his market concentration analysis does not shed any light on whether Opana ER has had monopoly power")).

840. For much of the period after Endo introduced Opana ER, Endo had a monopoly in the relevant market: the HHI equaled 10000, indicating that Endo had a 100% share of the market. (CX5000 at 008, 085 (¶¶ 14, 189) (Noll Report); Noll, Tr. 1404-05).

RESPONSE TO FINDING NO. 840:

Complaint Counsel's Proposed Finding No. 840 is vague as to which "market" is being discussed. The record shows that oxymorphone ER competes in the long-acting opioids market. (*See* Addanki, Tr. 2328 (testifying that there is no evidence indicating "the relevant market being no smaller than the market for long-acting opioids in the United States"); RX-547.0047-48 (Addanki Rep. ¶¶ 85-86); CX3273-003 (Bingol Decl. ¶ 6)). The sources cited in Proposed Finding No. 840 do not speak to the HHI in the long-acting opioids market. Rather, Proposed

Finding No. 840 evaluates only market shares and related HHI calculations using an improper, oxymorphone ER-only market. The record reflects that Endo never had more than a 10 percent share of the appropriately-defined relevant market for long-acting opioids. (Addanki, Tr. 2333; RX-547.0050-51 (Addanki Rep. ¶ 94); CX3273-003 (Bingol Decl. ¶ 6)). Therefore, any proper HHI calculation would be far lower than indicated in the proposed finding. (RX-547.0052 (Addanki Rep. ¶ 98) (noting "[b]ecause the relevant market is broader than the narrow market definition that Dr. Noll contends, his market concentration analysis does not shed any light on whether Opana ER has had monopoly power")). The market for long-acting opioids has never been highly concentrated. (RX-547.0052 (Addanki Rep. ¶ 98) ("Opana ER's market share in the relevant market was and has been too low for Endo to exercise monopoly power.")).

841. Even after Actavis entered in July 2011 and Impax entered in 2013, real-world data indicates that Endo retained a high concentration of market power above the threshold set by HHI. (CX5000 at 085-86, 217-18 (¶¶ 189-192 & Exs. 6A-6B) (Noll Report); Noll, Tr. 1377-79 (discussing IMS data source)). After 2011, Endo's market share was continually above [redacted] (using total prescriptions), above [redacted] (using net sales revenue), and usually was around [redacted] (CX5000 at 085-86 (¶¶ 190-91) (Noll Report) (partially *in camera*)).

RESPONSE TO FINDING NO. 841:

Complaint Counsel's Proposed Finding No. 841 is vague as to which "market" is being discussed, unsupported by the cited evidence, and inconsistent with the record. To the extent the proposed finding is referring the relevant market in this matter, it is inconsistent with record evidence that oxymorphone ER competes in the long-acting opioids market. (*See* Addanki, Tr. 2328 (testifying that there is no evidence indicating "the relevant market being no smaller than the market for long-acting opioids in the United States"); RX-547.0047 (Addanki Rep. ¶¶ 85-86); CX3273-003 (Bingol Decl. ¶ 6)). The cited source for this proposed finding does not speak to market shares and related HHI calculations in the appropriately-defined relevant market for

long-acting opioids, but rather to an improper, oxymorphone ER-only market. In the appropriately-defined relevant market for long-acting opioids, Endo never had more than a 10 percent share of the long-acting opioid market. (Addanki, Tr. 2333; RX-547.0050-51 (Addanki Rep. ¶ 94); CX3273-003 (Bingol Decl. ¶ 6)). Therefore, any proper HHI calculation would be far lower than indicated in Proposed Finding No. 841. (RX-547.0052 (Addanki Rep. ¶ 98) (noting "[b]ecause the relevant market is broader than the narrow market definition that Dr. Noll contends, his market concentration analysis does not shed any light on whether Opana ER has had monopoly power")). The market for long-acting opioids has never been highly concentrated. (RX-547.0052 (Addanki Rep. ¶ 98) ("Opana ER's market share in the relevant market was and has been too low for Endo to exercise monopoly power.")).

842. Under either method, the HHIs are always above [redacted] which far exceeds the *Merger Guidelines* threshold of 2500. (CX5000 at 085-86 (¶¶ 189, 191) (Noll Report) (partially *in camera*)). Thus, publicly-available information and private information produced by the companies indicate that, regardless of the measure used, the oxymorphone ER market has always been highly concentrated. (CX5000 at 085 (¶ 189) (Noll Report); Noll, Tr. 1377-78).

RESPONSE TO FINDING NO. 842:

Complaint Counsel's Proposed Finding No. 842 is misleading and inconsistent with the record. The record shows that oxymorphone ER competes in the long-acting opioids market, and that there is no relevant oxymorphone ER-only market relevant to this case. (*See* Addanki, Tr. 2328 (testifying that there is no evidence indicating "the relevant market being no smaller than the market for long-acting opioids in the United States"); RX-547.0047-48 (Addanki Rep. ¶¶ 85-86); CX3273-003 (Bingol Decl. ¶ 6)). The cited source for this proposed finding of fact does not use market shares and related HHI calculations in the long-acting opioids. The record reflects that Endo never had more than a 10 percent share of the long-acting opioid market. (Addanki, Tr. 2333; RX-547.0050-51 (Addanki Rep. ¶ 94); CX3273-003 (Bingol Decl. ¶ 6)). Therefore,

any proper HHI calculation would be far lower than indicated in the proposed finding. (RX-547.0052 (Addanki Rep. ¶ 98) (noting "[b]ecause the relevant market is broader than the narrow market definition that Dr. Noll contends, his market concentration analysis does not shed any light on whether Opana ER has had monopoly power")). The market for long-acting opioids has never been highly concentrated. (RX-547.0052 (Addanki Rep. ¶ 98) ("Opana ER's market share in the relevant market was and has been too low for Endo to exercise monopoly power.")).

2. There are significant barriers to entry into the relevant market

843. The market for oxymorphone ER also has significant barriers to entry. (*See* CCF ¶¶ 844-52, below).

RESPONSE TO FINDING NO. 843:

Complaint Counsel's Proposed Finding No. 843 finding should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Moreover, the individual findings in the cited paragraphs do not support the proposed summary finding and are inconsistent with the record, unsupported by the evidence cited, and/or unreliable for the reasons set out in Respondent's replies to those findings. Further, the proposed summary finding is inconsistent with the record to the extent it refers to an oxymorphone ER-only market. The record reflects that oxymorphone ER competes in the market for long-acting opioids. (Addanki, Tr. 2333; RX-547.0050-51 (Addanki Rep. ¶ 94); CX3273-003 (Bingol Decl. ¶ 6)). Professor Noll's report demonstrates that entry is common in the long-acting opioid market. (CX5000-194-95 (Noll Rep., Ex. 4)). Indeed, Exhibit 4 to Professor Noll's report lists over 20 long-acting opioid products that have entered the market since 2010. (CX5000-194-95 (Noll Rep., Ex. 4)).

844. The pharmaceutical industry, as a whole, has significant barriers to entry. (Noll, Tr. 1408; CX5000 at 086-87 (¶ 194) (Noll Report)).

RESPONSE TO FINDING NO. 844:

Complaint Counsel's Proposed Finding No. 844 is inaccurate and inconsistent with the record. Professor Noll's report demonstrates that entry is common in the long-acting opioid market (which, of course, is part of the pharmaceutical industry). (CX5000-194-95 (Noll Rep., Ex. 4)). Exhibit 4 to Professor Noll's report lists over 20 long-acting opioid products that have entered the market since 2010. (CX5000-194-95 (Noll Rep., Ex. 4)). Further, at no point does Professor Noll's report attempt to quantify any purported entry barriers. (*See* CX5000-086-88 (Noll Rep. ¶¶ 193-97)).

845. Barriers to entry in the pharmaceutical industry include intellectual property rights (patents), regulatory impediments (such as the Hatch-Waxman Act), and high brand loyalty to incumbent products. (Noll, Tr. 1408-10; CX5000 at 086-87 (¶¶ 194-95) (Noll Report)).

RESPONSE TO FINDING NO. 845:

Complaint Counsel's Proposed Finding No. 845 is misleading and inconsistent with record evidence reflecting regular market entry by long-acting opioids. Exhibit 4 to Professor Noll's report lists over 20 new long-acting opioid products that have entered the market since 2010. (CX5000-194-95 (Noll Rep., Ex. 4)). Therefore, in the long-acting opioid market (which, of course, is part of the pharmaceutical industry), the existence of intellectual property rights, regulatory "impediments" and "high brand loyalty to incumbent products," have not prevented regular and significant entry. Further, at no point does Professor Noll's report attempt to quantify any purported entry barriers. (*See* CX5000-086-88 (Noll Rep. ¶¶ 193-97)).

846. The market for brand name drugs is generally protected from entry by patents. (CX5000 at 086-87 (¶ 194) (Noll Report)).

RESPONSE TO FINDING NO. 846:

Complaint Counsel's Proposed Finding No. 846 is vague in its use of the term "market for brand name drugs." Neither Professor Noll nor Dr. Addanki discuss a "market for brand name drugs." It is unclear which drugs are referred to with the ambiguous phrase, which could potentially encompass an enormous number of "brand name drugs." To the extent the phrase is intended more specifically to refer to a market for long-acting opioids, Exhibit 4 to Professor Noll's report shows that entry is common in this market despite the existence of patents. (CX5000-194-95 (Noll Rep., Ex. 4) (listing over 20 long-acting opioid products that have entered the market since 2010)). Therefore, patents covering brand name long-acting opioids have not prevented regular and significant entry. Indeed, sometimes patents represent no barrier at all: a new entrant can develop products that do not infringe existing patents, license the right to use the patent from the patent owner, or challenge the validity of the patent. (*See* Addanki, Tr. 2343 ("We have known for a long time now that patents do not confer monopoly power.")). Indeed, Complaint Counsel's patent expert testified that it is "usual or normal [] for a licensee" to obtain a license that provides the "freedom to operate" with a product covered by patents. (*See* Hoxie, Tr. 2712-13; CX5007-011-13 (Hoxie Rep. ¶¶ 19-21)).

847. The regulatory procedures imposed by the Hatch-Waxman Act also allow a brand-name drug to be protected against entry. For instance, if a branded drug company files a patent infringement suit against a Paragraph IV ANDA filer, the Hatch-Waxman Act provides a 30-month stay before the FDA can approve the ANDA. (JX-001 at 004 (¶ 23); CX5000 at 086-87 (¶ 194) (Noll Report)).

RESPONSE TO FINDING NO. 847:

Complaint Counsel's Proposed Finding No. 847 is misleading to the extent that it asserts the Hatch-Waxman Act "protects" against generic entry. While Respondent has no specific response to the "example" offered in the second sentence of Proposed Finding No. 847,

Complaint Counsel's own patent expert explained that "[o]bjectively speaking, Hatch-Waxman appears to have been good for generics, judging from how the generic industry has grown since Hatch-Waxman was enacted. In 1984, the year Hatch-Waxman was enacted, generic drugs were 19% of prescriptions in the US, but by 2013, they had reached 86%." (CX5007-044 (Hoxie Rep. ¶ 85)).

848. The 30-month stay benefited Endo in the form of a regulatory entry barrier to the market for oxymorphone ER. (CX5000 at 086-87 (¶ 194) (Noll Report)).

RESPONSE TO FINDING NO. 848:

Complaint Counsel's Proposed Finding No. 848 is inconsistent with the record. First, the record reflects that oxymorphone ER competed in the market for long-acting opioids, that this is the relevant market in this matter, and that there is no cognizable oxymorphone ER market. (Addanki, Tr. 2333; RX-547.0050-51 (Addanki Rep. ¶ 94); CX3273-003 (Bingol Decl. ¶ 6)). Second, the record indicates that the Hatch-Waxman Act was enacted to *eliminate* barriers to entry for generic companies looking enter with a new product. (*See* CX5007-045-46 (Hoxie Rep. ¶¶ 84-85) (noting the Hatch-Waxman Act "streamlines the process by which a company may attempt to market a generic version of an FDA-approved drug" and that the share of generic prescriptions in the United States rose from 19 percent to 86 percent since the Hatch-Waxman Act was enacted)).

849. Likewise, non-first filer Paragraph IV ANDA applicants have to wait at least 180 days after the first-filer has entered before they can enter a market. (CX5000 at 086-87 (¶ 194) (Noll Report)). This regulation increases the value to the brand pharmaceutical company from delaying entry by the first-filer, thereby potentially delaying entry of all ANDA applicants. (Noll, Tr. 1430-32).

RESPONSE TO FINDING NO. 849:

Respondent has no specific response.

850. Even after generic drugs enter, many doctors continue to write prescriptions using the brand name. Such brand loyalty is created by the marketing strategies of brand pharmaceutical firms, including extensive information campaigns. These promotional campaigns refer to a drug by its brand name, not its scientific or chemical name. Once a physician begins writing prescriptions for the drug, normally years pass before generic entry, allowing time to foster brand-preferences that are barriers to entry for generic drug products. (CX5000 at 087 (¶ 195) (Noll Report)).

RESPONSE TO FINDING NO. 850:

The Proposed Finding misstates the evidence in the record and is based on unreliable expert testimony. For example, after Impax entered the long-acting opioid marketing in January 2013 with its generic oxymorphone ER product, it was able to successfully market its generic drug to capture significant sales despite the presence of a number of brand-name long-acting opioids and no reference-listed drug to trigger substitution. (CX5000-196 (Noll Rep., Ex. 5A1) ([redacted]); RX-547.0052 (Addanki Rep. ¶ 98) ("[M]ost pharmacists cannot substitute Impax's product . . . for prescriptions written for reformulated Opana ER.")).

851. Generic substitution rules and formularies can help to alleviate the impact of brand loyalty as an entry barrier for generic drug companies by facilitating switching prescriptions from the brand-name drug to the generic. However, the process of overcoming this barrier is greatly attenuated if the generic and brand-name drugs are not therapeutically equivalent. (CX5000 at 087 (¶¶ 196) (Noll Report)).

RESPONSE TO FINDING NO. 851:

Complaint Counsel's Proposed Finding No. 851 misstates the evidence in the record and is based on unreliable expert testimony. For example, after Impax entered the long-acting opioid marketing in January 2013 with its generic oxymorphone ER product, it was able to successfully market its generic drug to capture significant sales despite the presence of a number of brand-name long-acting opioids and no reference-listed drug to trigger substitution. (CX5000-196 (Noll Rep., Ex. 5A1) ([redacted]); RX-

547.0052 (Addanki Rep. ¶ 98) ("[M]ost pharmacists cannot substitute Impax's product . . . for prescriptions written for reformulated Opana ER.")). Moreover, the record belies the assertion that formularies cannot readily facilitate switching between a branded long-acting opioid and a non-AB-rated generic version of a different long-acting opioid. When UPMC instituted formulary changes to preference Opana ER and various generic long-acting opioids over the branded long-acting opioid OxyContin, nearly 70 percent of OxyContin patients switched to a different long-acting opioid. (RX-087). UPMC reported a significant increase in usage of Opana ER and generic Morphine Sulfate ER (MS ER), and to a lesser extent, generic Fentanyl patches. (RX-087 (Figures 3, 5)).

852. The sources of Endo's market power include the patents on Opana ER, entry barriers that are created by the licensing process for pharmaceuticals by the FDA, regulation of all opioids by the Drug Enforcement Agency (DEA), and brand loyalty created by Endo's marketing campaigns and product-differentiation promotions. (CX5000 at 008-09 (¶ 15) (Noll Report); Noll, Tr. 1402-03). Collectively these factors explain why Endo was a monopolist or near-monopolist in the relevant oxymorphone ER market. (CX5000 at 00809, 087-88 (¶¶ 15, 197) (Noll Report)).

RESPONSE TO FINDING NO. 852:

Complaint Counsel's Proposed Finding No. 852 is inaccurate, misleading, inconsistent with the record, and based on unreliable expert testimony. Endo's patents, licensing procedures, regulations, and brand loyalty have not prevented the entry of over 20 long-acting opioid products since 2010. (CX5000-194-95 (Noll Rep., Ex. 4). Complaint Counsel's Proposed Finding No. 852 also mischaracterizes the relevant market as one for oxymorphone ER, though the record reflects that oxymorphone ER competes in the market for long-acting opioids, and that there is no cognizable oxymorphone ER-only market. (*See* Addanki, Tr. 2328 (testifying that there is no evidence indicating "the relevant market being no smaller than the market for long-acting opioids in the United States"); RX-547.0047-48 (Addanki Rep. ¶¶ 85-86); CX3273-003

(Bingol Decl. ¶ 6)). Endo never had more than a 10 percent share of the long-acting opioid market. (Addanki, Tr. 2333; RX-547.0050-51 (Addanki Rep. ¶ 94); CX3273-003 (Bingol Decl. ¶ 6)). Therefore, the proposed finding is also incorrect in that Endo was a "monopolist or near-monopolist" in the properly defined market. Further, Complaint Counsel seems to concede that Endo may have not truly been a monopolist, only a "near monopolist."

Finally, the proposed finding is wrong to suggest that patents are a source of market power (*see* Addanki, Tr. 2343 ("We have known for a very long time now that patents do not confer monopoly power.")), or that the Hatch-Waxman Act presents a barrier to entry (*see* CX5007-045-46 (Hoxie Rep. ¶¶ 84-85) (noting the Hatch-Waxman Act "streamlines the process by which a company may attempt to market a generic version of an FDA-approved drug" and that the share of generic prescriptions in the United States rose from 19 percent to 86 percent since the Hatch-Waxman Act was enacted)). Nor has brand loyalty prevented Impax from successfully marketing its generic drug despite the presence of a number of brand-name long-acting opioids despite having no reference-listed drug to trigger automatic substitution. (CX5000-196 (Noll Rep., Ex. 5A1) ([redacted]); RX-547.0052 (Addanki Rep. ¶ 98) ("[M]ost pharmacists cannot substitute Impax's product . . . for prescriptions written for reformulated Opana ER.")). Therefore, Proposed Finding No. 852 should be disregarded.

C. Direct evidence of market power

853. Market power can also be established through an analysis of the direct effects from the conduct at issue. (Noll, Tr., 1365-66). The direct effects method simply observes the conduct at issue and assesses how it impacted and harmed the market. (Noll, Tr. 1366; CX5000 at 013-14 (¶¶ 30-31) (Noll Report)).

RESPONSE TO FINDING NO. 853:

Complaint Counsel's Proposed Finding No. 853 improperly states a proposed legal conclusion, not a fact, and should be disregarded. Further, as described by Dr. Addanki, any purportedly "direct" showing of market power must include proof that the firm has reduced output. (RX-547.0008 (Addanki Rep. ¶ 11 n.8) (monopoly power consists of "the ability to *restrict output* and sustain supracompetitive profits") (emphasis added); RX-547.0051 (Addanki Rep. ¶ 96) ("[H]ad Endo in fact exercised monopoly power and restricted the output of Opana ER we would have expected an increase in output after Impax launched its generic versions of original Opana ER.")).

854. The direct effects analysis essentially skips the market definition phase of an economic analysis. (Noll, Tr. 1366). Market definition is unnecessary in a direct effect analysis because conduct that adversely affects market outcomes must have caused the entities that engaged in that conduct to exercise market power in the defined relevant market. (CX5000 at 013-14 (¶¶ 30-31) (Noll Report)).

RESPONSE TO FINDING NO. 854:

Complaint Counsel's Proposed Finding No. 854 improperly states a proposed legal conclusion, not a fact, and should be disregarded. It is also inaccurate. The monopoly power inquiry invariably "begins with defining a relevant market and then assessing competitive conditions within that market." (RX-547.0008 (Addanki Rep. ¶ 11)).

855. The main benefit of the direct effects approach is that it causes the focus of an economic analysis to be on whether conduct by a defendant caused actual harm to competition. (CX5000 at 014-15 (¶ 33) (Noll Report)).

RESPONSE TO FINDING NO. 855:

Complaint Counsel's Proposed Finding No. 855 is inaccurate and incomplete to the extent it implies that defining a relevant market is unnecessary. The monopoly power inquiry

invariably "begins with defining a relevant market and then assessing competitive conditions within that market." (RX-547.0008 (Addanki Rep. ¶ 11)).

856. The direct effects analysis can be conducted when there is evidence of the competitive environment before and after an alleged anticompetitive event at a singular point in time. (Noll, Tr. 1367-68).

RESPONSE TO FINDING NO. 856:

Complaint Counsel's Proposed Finding No. 856 is inaccurate and incomplete to the extent it implies that defining a relevant market is unnecessary. The monopoly power inquiry invariably "begins with defining a relevant market and then assessing competitive conditions within that market." (RX-547.0008 (Addanki Rep. ¶ 11)).

857. Direct indicators of market power include the ability to exclude competitors from the market and the ability to profitably set prices of a product above the price that would be set in a competitive market. (CX5000 at 088 (¶ 198) (Noll Report)).

RESPONSE TO FINDING NO. 857:

Complaint Counsel's Proposed Finding No. 857 is incomplete and misleading. Firms without market power may "set prices above the price that would be set in a competitive market" because "any firm that faces a downward sloping demand curve for its product will increase the price of the product in response to an increase in demand. Not all firms facing downward sloping demand curves have monopoly power." (RX-547.0053 (Addanki Rep. ¶ 100)). Complaint Counsel also neglects to include the requirement to show that the defendant had the ability to restrict output. (RX-547.0008 (Addanki Rep. ¶ 11 n.8) (monopoly power consists of "the ability to *restrict output* and sustain supracompetitive profits") (emphasis added); RX-547.0051 (Addanki Rep. ¶ 96) ("[H]ad Endo in fact exercised monopoly power and restricted the output of Opana ER we would have expected an increase in output after Impax launched its generic versions of original Opana ER.")).

858. There is sufficient evidence to assess the direct effects of the Impax-Endo Settlement Agreement. (Noll, Tr. 1368). Endo's market power in the oxymorphone ER market can be inferred from its success at excluding competitors from the market and its high mark-up of price over marginal cost. (CX5000 at 008 (¶ 14) (Noll Report).

RESPONSE TO FINDING NO. 858:

Complaint Counsel's Proposed Finding No. 858 is inaccurate, misleading and inconsistent with the record. First, the proposed finding refers to a market for oxymorphone ER, although the record reflects that oxymorphone ER competes in the market for long-acting opioids, and that there exists no cognizable oxymorphone ER market. (*See* Addanki, Tr. 2328 (testifying that there is no evidence indicating "the relevant market being no smaller than the market for long-acting opioids in the United States"); RX-547.0047-48 (Addanki Rep. ¶¶ 85-86); CX3273-003 (Bingol Decl. ¶ 6)). Further, Professor Noll's report makes clear that Endo was not successful at excluding competitors from the long-acting opioid market, as shown by his observation that over 20 long-acting opioid products entered the long-acting opioid market since 2010. (CX5000-194-95 (Noll Rep., Ex. 4)). Moreover, patents are not a source of market power. Addanki, Tr. 2343 ("We have known for a very long time now that patents do not confer monopoly power.")). Finally, even if Endo maintained a "high mark-up of price over marginal cost" that "tell[s] you nothing at all about monopoly power." (Addanki, Tr. 2341). This is because this analysis "assumes that the competitive benchmark price is represented by marginal cost. And that just simply cannot be right in the real world in most industries." (Addanki, Tr. 2342). As Professor Noll admitted at trial, a high "markup of price over marginal cost," as measured by a Lerner Index, "doesn't necessarily mean" that a firm has market power. (Noll, Tr. 1413, 1415). Professor Noll testified that in industries with high fixed costs and low marginal costs, including specifically the pharmaceutical industry, a high markup of price over marginal cost is a "normal market outcome." (Noll, Tr. 1415-16).

1. Endo excluded competitors from the oxymorphone ER market by entering agreements with first-to-file generic oxymorphone ER ANDA applicants

859. Under regulatory schemes governing the pharmaceutical industry, brand-named drug manufactures may be entitled by law to try to delay competitive entry by generic manufacturers when the brand's drug is protected by patents. (CX5000 at 088-89 (¶ 199) (Noll Report)).

RESPONSE TO FINDING NO. 859:

Complaint Counsel's Proposed Finding No. 859 improperly states a proposed legal conclusion, not a fact, and should be disregarded. It is also misleading. The Hatch-Waxman Act provides for a 30-month stay in the face of an infringement suit in response to a Paragraph IV filing. (JX-001-004 (¶ 23)). The Hatch-Waxman Act also provides for 180 days of generic exclusivity for the first to file a Paragraph IV filing. (JX-001-005 (¶ 27)). These provisions are intended to enhance competition by "streamlin[ing] the process by which a company may attempt to market a generic version of an FDA-approved drug," and has increased competition from generic drug manufacturers. (*See* CX5007-045-46 (Hoxie Rep. ¶¶ 84-85)).

860. In particular, if the brand-name drug files an infringement suit against the generic firm that filed a Paragraph IV ANDA, the FDA's regulatory procedures protect the brand-name drug against entry by the generic first filer until the end of the 30-month stay, among other things. The regulatory scheme also protects against entry by other generic firms for another 180 days after the first-filer's entry. (JX-001 at 004 (¶ 23); CX5000 at 088-89 (¶ 199) (Noll Report)).

RESPONSE TO FINDING NO. 860:

Complaint Counsel's Proposed Finding No. 860 improperly states a proposed legal conclusion, not a fact, and should be disregarded.

861. At least eight companies submitted ANDAs seeking approval to market a generic version of Opana ER, including Impax and Actavis. (CX2607 at 008-09 (¶ 24) (Lortie Decl.)). Impax was entitled to first-filer exclusivity on the five most profitable doses of generic oxymorphone ER. (JX-001 at 007 (¶ 13)). Impax and Endo's subsequent

litigation over the validity and infringement of Endo's patents was settled by the Impax-Endo Settlement Agreement. (JX-001 at 007-08 (¶¶ 15, 19)).

RESPONSE TO FINDING NO. 861:

Respondent has no specific response.

862. Under the Impax-Endo Settlement Agreement, however, some purchasers of Endo's Opana ER products were denied the possibility that a generic substitute for the most popular dosages would be available to them prior to the date at which Impax was permitted to enter under the agreement. Such an agreement extends the market power of the brand drug's company, regardless of how the relevant market is defined. (CX5000 at 011, 15 (¶¶ 22, 34) (Noll Report)).

RESPONSE TO FINDING NO. 862:

Complaint Counsel's Proposed Finding No. 862 is inaccurate, misleading, and based on unreliable expert testimony. There is no record suggesting any purchaser of Endo's Opana ER was *actually* denied a generic substitute for the most popular dosages that would have otherwise been available to them prior to January 1, 2013. (RX-547.0058-84 (Addanki Rep. ¶¶ 108-57)). Had Endo prevailed in the Paragraph IV infringement litigation, Impax would not have been allowed to market a generic Opana ER until more than eight months after Impax entered under the Settlement and License Agreement, at the earliest. (Figg, Tr. 1973; RX-547.0080 (Addanki Rep. (¶ 147)). But even assuming that Impax would have prevailed in the original patent litigation—and Complaint Counsel's own patent expert does not contend that Impax would have (Hoxie, Tr. 2693, 2852)—it would have had to deal with other patents covering Opana ER by the time once original litigation concluded. (Figg, Tr. 1908-11; Addanki, Tr. 2362-63, 2374-75; JX-001-012 (¶¶ 56-57); JX-003-005 (¶ 31)). Impax thus would have been mired in litigation long past January 1, 2013. (RX-547.0080-83 (Addanki Rep. (¶¶ 148-54); Addanki, Tr. 2497, 2360; Figg, Tr. 1870-72). Thus, as Dr. Addanki testified, "there would not have been entry by Impax, had Impax not been willing to launch at risk, before January 1, 2013." (Addanki, Tr. 2382).

Second, the Settlement and License Agreement did not "extend[] the market power" of the brand-named company "regardless of how the relevant market is defined." In the properly-defined long-acting opioid market, Endo did not have market power at all—meaning that there was no market power to "extend[]." Indeed, the market share of Opana ER was always less than 10 percent and never had market power. (Addanki, Tr. 2333; RX-547.0050-51 (Addanki Rep. ¶ 94); CX3273-003 (Bingol Decl. ¶ 6)).

863. [redacted] (CX5000 at 088-89 (¶ 199) (Noll Report); CX2607 at 009-10 (¶ 26) (Lortie Decl.) (partially *in camera*)). This ability of Endo to exclude firms from the market indicates that Endo possesses market power in sales of oxymorphone ER. (CX5000 at 088-89 (¶ 199) (Noll Report)).

RESPONSE TO FINDING NO. 863:

Complaint Counsel's Proposed Finding No. 863 is misleading and inconsistent with the record to the extent it refers to a market for oxymorphone ER. The record reflects that oxymorphone ER competes in the market for long-acting opioids, and that there is no cognizable oxymorphone ER-only market. (Addanki, Tr. 2333; RX-547.0050-51 (Addanki Rep. ¶ 94); CX3273-003 (Bingol Decl. ¶ 6)). The record further reflects that Endo's patents are not a proper source of market power. (*See* Addanki, Tr. 2343 ("We have known for a very long time now that patents do not confer monopoly power.")). Endo was unable to "exclude firms" from the long-acting opioid market as indicated by Professor Noll's report, which shows over 20 long-acting opioid products have entered the long-acting opioid market since 2010. (CX5000-194-95 (Noll Rep., Ex. 4)).

2. Endo was able to sustain prices above the competitive level

864. An increase in market power can be inferred from the ability to sustain prices above the competitive level. (CX5000 at 089 (¶ 200) (Noll Report)).

RESPONSE TO FINDING NO. 864:

Complaint Counsel's Proposed Finding No. 864 is inaccurate, misleading, and based on unreliable expert testimony. Neither the existence of, nor an "increase" in, market power can be inferred from supracompetitive prices alone; there must also be evidence that the alleged monopolist restricted output. (RX-547.0008 (Addanki Rep. ¶ 11 n.8) (monopoly power consists of "the ability to *restrict output* and sustain supracompetitive profits") (emphasis added); RX-547.0051 (Addanki Rep. ¶ 96) ("[H]ad Endo in fact exercised monopoly power and restricted the output of Opana ER we would have expected an increase in output after Impax launched its generic versions of original Opana ER.")).

865. The attention given by a firm's executives to prices, the likely competitive response of other firms to a contemplated price change, and a company's internal estimates of the effects of a price change on sales volume and profitability are indicators of whether a firm enjoys market power. (CX5000 at 090 (¶ 202) (Noll Report)).

RESPONSE TO FINDING NO. 865:

Respondent has no specific response.

866. Endo's internal pricing documents, thus, provide insight into the extent of competition in the market for oxymorphone ER. (CX5000 at 092 (¶ 208) (Noll Report)).

RESPONSE TO FINDING NO. 866:

Complaint Counsel's Proposed Finding No. 866 is misleading and inaccurate to the extent that it refers to multiple Endo internal pricing documents, and ambiguous to the extent it refers generally to "pricing." First, Professor Noll cites just a *single* document for this proposition in the relevant paragraph of his report. (CX5000-092 (Noll Rep. ¶ 208) (citing CX2673)). Second, that lone document references Wholesale Average Cost ("WAC") or list prices. (CX2673; *see* RX-547.0053-54 (Addanki Rep. ¶ 101(b))). [redacted]

[redacted]

867. Endo's practice for implementing price changes involved executives responsible for a product line submitting price proposals to the Executive Pricing Committee. (CX5000 at 090-95, 219-26 (¶¶ 203-14 & Exs. 7A-7B7) (Noll Report); CX2673 at 003-06 (Mar. 2008 Pricing Proposal); CX2678 at 002-06 (Dec. 2008 Pricing Proposal); CX2670 at 001-08 (Jan. 2010 Pricing Proposal); CX1217 at 001-05 (May 2010 Pricing Proposals)).

RESPONSE TO FINDING NO. 867:

Complaint Counsel's Proposed Finding No. 867 is misleading and inaccurate to the extent it does not distinguish between WAC prices and net prices. As Professor Noll admits in his report, the pricing proposals that Complaint Counsel cites expressly pertain to changes in WAC (list) prices. (*See* CX5000-090 (Noll Rep. ¶ 203) ("These proposals contain a recommendation for list price, which is also called wholesale average cost (WAC)."); *see also* RX-547.0053 (Addanki Rep. ¶ 101(b)) ("As Dr. Noll notes, Endo's internal pricing proposals that he examines concern list prices (*i.e.*, wholesale acquisition cost (WAC))."). As one of the proposals states, Endo's WAC price "does not reflect discounts, rebates, or other price concessions that may be offered by Endo, and does not necessarily represent the actual price paid by wholesalers or direct customers." (CX2673-004). In Professor Noll's words, [redacted] (Noll, Tr. 1681).

Further, one of the pricing proposals cited in Proposed Finding No. 867 relates to the drug Frova rather than Opana ER. (*See* CX2678-002-06).

868. These proposals recommend changes to the list price, which is also called wholesale average cost (WAC). In the drug industry, list price is not the price that is paid by drug wholesalers, large health care providers and pharmacy chains that buy directly from pharmaceutical companies. (CX5000 at 090-91 (¶ 203) (Noll Report)).

RESPONSE TO FINDING NO. 868:

Respondent has no specific response.

869. The price actually paid by many drug purchasers is called the net realized price. Net realized prices reflect discounts, rebates, and other concessions—some of which are determined by formulas that apply to all buyers within a class, others of which are negotiated with a buyer. (CX5000 at 090-91 (¶ 203) (Noll Report)).

RESPONSE TO FINDING NO. 869:

Respondent has no specific response.

870. Usually, the price proposals do not discuss discounts and net floor prices. Nonetheless, discounts and rebates are sufficiently formulaic that the documents that show only list prices inherently incorporate the impact of discounts and net price floors on revenues. (CX5000 at 090-92, 219-26 (¶¶ 203-07 & Exs. 7A-7B7) (Noll Report)).

RESPONSE TO FINDING NO. 870:

Complaint Counsel's Proposed Finding No. 870 is incomplete, misleading, and based on unreliable expert testimony. First, Proposed Finding No. 870 is vague and ambiguous as to what "sufficiently formulaic" is intended to convey. Proposed Finding No. 870 is also inconsistent with record evidence, including Professor Noll's testimony. [redacted] (RX-547.0053-54 (Addanki Rep. ¶ 101(b)): CX5000-219 (Noll Rep., Ex. 7A); Noll, Tr. 1682-83; *see*

Addanki, Tr. 2290 ([redacted])). [redacted]

(Addanki, Tr. 2290). Thus, Professor Noll was forced to concede that the discounts and rebates were not "sufficiently formulaic" for him to accurately calculate, for example, what Endo charges to specific customers. (Noll, Tr. 1512 ("Q. Sir, is that a way of saying you couldn't tell the actual prices Endo was charging its customers from Endo's documents? A. You could not tell the specific price to a specific customer . . .")).

> 871. In March 2008, anticipating the launch of three new doses (7.5mg, 15mg, 30mg) of Opana ER, Endo executives proposed a price increase of 4% for all current doses of Opana ER and initial prices for the new doses. (CX2673 at 004 (Mar. 2008 Price Change Proposal); CX5000 at 092 (¶ 208) (Noll Report)). Endo executives projected a revenue increase of $2 million, or 2.4%, for Opana ER from the price increase. (CX2673 at 005 (Mar. 2008 Pricing Proposal); CX5000 at 092 (¶ 208) (Noll Report)).

RESPONSE TO FINDING NO. 871:

Complaint Counsel's Proposed Finding No. 871 is incomplete and misleading. The cited document is ambiguous as to whether it reflects a projected $2 million revenue increase, because the cited chart is not labeled. (CX2673). Even assuming the projection is one of increased revenue, Complaint Counsel offers no evidence evaluating the *actual* impact of the proposed increase in WAC prices. As the document itself states, Endo's WAC price "does not reflect discounts, rebates, or other price concessions that may be offered by Endo, and does not necessarily represent the actual price paid by wholesalers or direct customers." (CX2673 at 004). Professor Noll himself admitted at trial [redacted] (Noll, Tr. 1681).

872. These calculations imply that price competition against Opana ER was not sufficient to prevent a profitable non-transitory price increase. (CX2673 at 005 (Mar. 2008 Pricing Proposal); CX5000 at 092 (¶ 208) (Noll Report)).

RESPONSE TO FINDING NO. 872:

Complaint Counsel's Proposed Finding No. 872 is an inaccurate and misleading selective characterization of CX2673, and is inconsistent with record evidence. In portions of CX2673 that Complaint Counsel conspicuously omits from its proposed finding, the document analyzes "Market Pricing For Direct Competitors," listing prices of competing long-acting opioids like Avinza, Kadian, and OxyContin. (CX2673-008 (pictured below)).

Attachment A UPDATE
Market Pricing for Direct Competitors

		Price a/o Opana Launch		Price Increase			Price Increase #2		
		WHN[1] Price	Eff. Date	Date	%	New WHN[1] Price	Date	%	New WHN[1] Price
Avinza									
30 MG CAPSULE	100 each	$ 2.5358	4/1/2005	3/1/2007	6.0%	$ 2.6881	5/31/2007	9.0%	$ 2.9300
60 MG CAPSULE	100 each	$ 4.8792	4/1/2005	3/1/2007	6.0%	$ 5.1720	5/31/2007	9.0%	$ 5.6375
90 MG CAPSULE	100 each	$ 7.4044	4/1/2005	3/1/2007	6.0%	$ 7.8487	5/31/2007	9.0%	$ 8.5551
120 MG CAPSULE	100 each	$ 8.6562	4/1/2005	3/1/2007	6.0%	$ 9.1757	5/31/2007	9.0%	$ 10.0015
Kadian									
20 MG CAPSULE	60 each	$ 2.4852	6/1/2006		No change				
20 MG CAPSULE	100 each	$ 2.4850	6/1/2006	3/15/2007	5.0%	$ 2.6093			
50 MG CAPSULE	60 each	$ 4.6873	6/1/2006		No change				
50 MG CAPSULE	100 each	$ 4.6873	6/1/2006	3/15/2007	2.0%	$ 4.7810			
100 MG CAPSULE	60 each	$ 9.0318	6/1/2006		No change				
100 MG CAPSULE	100 each	$ 9.0318	6/1/2006	3/15/2007	5.0%	$ 9.4835			
30 MG CAPSULE	60 each	$ 2.7022	6/1/2006		No change				
30 MG CAPSULE	100 each	$ 2.7022	6/1/2006	3/15/2007	5.0%	$ 2.8373			
60 MG CAPSULE	60 each	$ 5.3920	6/1/2006		No change				
60 MG CAPSULE	100 each	$ 5.3920	6/1/2006	3/15/2007	5.0%	$ 5.6616			
80 MG CAPSULE	100 each	$ 7.2000	11/1/2006	3/15/2007	5.0%	$ 7.5600			
200 MG CAPSULE	100 each	New strength		3/15/2007	n/a	$ 18.9670			
Oxycontin									
10 MG TABLET	100 each	$ 1.3831	3/1/2006	3/1/2007	4.0%	$ 1.4384			
10 MG TABLET	2x10 UD	$ 1.4190	2/1/2006	3/1/2007	4.0%	$ 1.4760			
10 MG TABLET	U-D (25)	$ 1.4188	12/1/2004		No change				
20 MG TABLET	100 each	$ 2.6465	3/1/2006	3/1/2007	4.0%	$ 2.7524			
20 MG TABLET	2x10 UD	$ 2.7150	1/16/2006	3/1/2007	4.0%	$ 2.8235			
20 MG TABLET	U-D (25)	$ 2.7152	12/1/2004		No change				
40 MG TABLET	100 each	$ 4.6959	3/1/2006	3/1/2007	4.0%	$ 4.8837			
40 MG TABLET	2x10 UD	$ 4.8140	2/15/2006	3/1/2007	4.0%	$ 5.0065			
40 MG TABLET	U-D (25)	$ 4.8140	12/1/2004		No change				
80 MG TABLET	100 each	$ 8.8308	3/1/2006	3/1/2007	4.0%	$ 9.1840			
80 MG TABLET	2x10 UD	$ 9.0585	12/15/2005	3/1/2007	4.0%	$ 9.4210			
80 MG TABLET	U-D (25)	$ 9.0584	12/1/2004		No change				

Notes:

This analysis is directly probative of price competition among long-acting opioids and shows that several of Endo's long-acting opioid "direct competitors" had announced that they

were *also* planning on implementing price increases ranging from 4.0 percent to 9.0 percent. (CX2673-008). This suggests that, if anything, Endo's proposed increase was actually a competitive reaction to the increases of prices by competitors in the long-acting opioid market, rather than the unsupported conclusion in Proposed Finding No. 872 that "price competition against Opana ER was not sufficient to prevent a profitable non-transitory price increase."

Moreover, Complaint Counsel's speculation that "price competition against Opana ER was not sufficient to prevent a profitable non-transitory price increase" is unsupported. Professor Noll admitted that he did not calculate cross-elasticity of demand or conduct a "SSNIP" test. (Noll, Tr. 1514, 1517). But his own analysis belies any notion that Endo could profitably increase actual net prices. Whereas CX2673 discusses proposed changes in Endo's WAC price for Opana ER, that price explicitly does *not* "represent the actual price paid by wholesalers or direct customers." (CX2673-004; *see* Noll, Tr. 1681 ([redacted])). As Professor Noll's own report shows, [redacted] (CX5000-219 (Noll Rep., Ex. 7A); *see* Noll, Tr. 1681-82 ([redacted] (emphasis added)).

873. In December 2008, Endo executives proposed a 4.5% price increase, effective January 1, 2009, for all doses of Opana ER. Endo executives forecasted that this price increase would cause net sales of Opana ER to increase by $8.8 million, which is about 4.5% of Endo's net sales revenues. (CX2678 at 001, 07, 18-22 (Dec. 2008 Pricing Proposal); CX5000 at 092-93 (¶ 209) (Noll Report)).

RESPONSE TO FINDING NO. 873:

Complaint Counsel's Proposed Finding No. 873 is an incomplete and misleading characterization of the document cited (CX2678), which refers to an increase in WAC prices. [redacted] (Noll, Tr. 1680 [redacted]

[redacted] As Professor Noll admitted at trial, [redacted] (Noll, Tr. 1681). Moreover, the cited document (CX2678) is merely a forecast. There is no record evidence that Endo's *net* prices actually increased, or that Endo actually increased its revenue as a result of the proposed change in its WAC price. In fact, the evidence shows just the opposite. Professor Noll's own report [redacted] (CX5000-219 (Noll Rep., Ex. 7A (*in camera*) (denoted by the red line below)).

[redacted]

Professor Noll [redacted] (Noll, Tr. 1681-82).

874. This pricing proposal shows that Endo anticipated no loss in sales volume arising from a price increase. (CX2678 at 018-22 (Dec. 2008 Pricing Proposal); CX5000 at 092-93 (¶ 209) (Noll Report)).

RESPONSE TO FINDING NO. 874:

Complaint Counsel's Proposed Finding No. 874 is unsupported by the evidence cited and is based on unreliable expert testimony. The cited document (CX2678) does not reference sales volumes in any way. The cited portion of Professor Noll's report, which claims that "Endo anticipated no loss in sales volume," is a factual assertion not supported by any citation of any kind. (*See* CX5000-092-93 (Noll Rep. ¶ 209)). Moreover, there is no record evidence that Endo's *net* prices actually increased, or that Endo actually increased its revenue as a result of the proposed change in its WAC price. In fact, the evidence shows just the opposite. [redacted] (CX5000-219 (Noll Rep., Ex. 7A) (denoted by the red line in Response to Proposed Finding No. 873)). Professor Noll [redacted] (Noll, Tr. 1681-82).

875. In January 2010, Endo's Executive Pricing Committee approved a 9.9% increase in the list price for all Opana ER dosages, effective February 1, 2010. (CX2670 at 001-02 (Jan. 2010 Pricing Proposal); CX5000 at 093 (¶ 210) (Noll Report)). This pricing proposal originally requested a 5.2% price increase, and noted that the medical care consumer price index had increased by 3.2% in 2009. (CX2670 at 002 (Jan. 2010 Pricing Proposal); CX5000 at 093 (¶ 210) (Noll Report)). The price increase was changed to 9.9% during the process of reviewing the proposal. CX2670 at 002, 005 (Jan. 2010 Pricing Proposal); CX5000 at 093 (¶ 210) (Noll Report)). The document does not include a revenue forecast for the 9.9% price increase, but does forecast that the original 5.2% increase would raise revenues by $9 million, or 4.6%, implying only a slight reduction in sales quantity as a result of the price increase. (CX2670 at 003 (Jan. 2010 Pricing Proposal); CX5000 at 093 (¶ 210) (Noll Report)).

RESPONSE TO FINDING NO. 875:

Complaint Counsel's Proposed Finding No. 875 is an incomplete and misleading characterization of the cited document (CX2670), which refers to an increase in WAC prices. [redacted] (Noll, Tr. 1680 [redacted] Moreover, the cited document (CX2670) is merely a forecast. There is no record evidence that Endo's *net* prices actually increased, or that Endo actually increased its revenue as a result of the proposed change in its WAC price. In fact, the evidence shows just the opposite. [redacted] (CX5000-219 (Noll Rep., Ex. 7A) (denoted by the red line in Response to Proposed Finding No. 873)). Professor Noll [redacted] (Noll, Tr. 1681-82).

876. This proposed price increase substantially exceeded the projected increase in unit costs, which implies that it increased price above the competitive level that is dictated by marginal cost. (CX5000 at 093 (¶ 211) (Noll Report)).

RESPONSE TO FINDING NO. 876:

Complaint Counsel's Proposed Finding No. 876 is incomplete, misleading, and based on unreliable expert testimony. The price increase proposed in the cited document (CX2670) is an increase in WAC prices. [redacted] (Noll, Tr. 1680 [redacted] Moreover, the cited document

(CX2670) is merely a forecast. There is no record evidence that Endo's *net* prices actually increased, or that Endo actually increased its revenue as a result of the proposed change in its WAC price. In fact, the evidence shows just the opposite. [redacted] (CX5000-219 (Noll Rep., Ex. 7A) (denoted by the red line in Response to Proposed Finding No. 873)). Professor Noll [redacted] (Noll, Tr. 1681-82).

877. In May of 2010, Endo employees proposed a pricing plan for Opana ER that was based on the assumption that Impax soon would launch generic oxymorphone ER. This plan anticipated that Endo would launch an authorized generic version of oxymorphone ER and included proposed prices for this drug that were discounted from the January price proposal. (CX1217 at 003 (May 2010 Pricing Proposal); CX5000 at 094 (¶ 212) (Noll Report)).

RESPONSE TO FINDING NO. 877:

Complaint Counsel's Proposed Finding of Fact No. 877 is incomplete and misleading. The document in question (CX1217) does not express a view on whether Impax "would soon launch generic oxymorphone ER," as Complaint Counsel suggests. The document merely states that Impax "can" launch on June 14, 2010—i.e., once the 30-month stay expired—and proposes a set of prices in the event of a "potential" Impax launch. (CX2712-003). The document recognizes that Impax might "not launch on June 14th." (CX2712-003).

878. Despite the discount, Endo concluded that offering an authorized generic was a better strategy than exiting the market. This implies that even after cutting the price of Opana ER, the product remained profitable. This demonstrates that the original price before generic entry occurred was above the competitive level. Consequently, Endo's prices before generic entry reflect the presence of substantial market power. (CX5000 at 094 (¶ 212) (Noll Report)).

RESPONSE TO FINDING NO. 878:

Complaint Counsel's Proposed Finding No. 878 is inaccurate, misleading, and based on unreliable expert testimony. In the paragraph of Professor Noll's report that Complaint Counsel purports to rely upon, Professor Noll focuses only *list* prices. (CX5000-094 (Noll Rep. ¶ 212) ("By comparison, the proposed price of the 5mg 100-tablet bottle of the authorized generic is $119.99, which is a 30 percent discount off of the price after the January price increase of 9.9 percent."); *see* CX1217-003 (proposing $119.99 "List Price" for 5mg 100-tablet bottle of generic Opana ER); CX2670-003-02 (proposing 9.9 percent increase in WAC prices)). Complaint Counsel and Professor Noll both neglect to mention that in the May 2010 proposal, Endo proposed steep discounts (referred to as "A" pricing) on those list prices. (CX1217-003). For example, whereas Endo proposed a $119.99 list price for a 100-tablet bottle of the 5mg dosage strength of generic Opana ER, it proposed a discounted "A" price of just *$24.76* for that same bottle, and specified that the discounted price should be no lower than *$21.05*. (CX1217-003) At $21.05, Endo's gross margin would be just *10%*. (CX1217-003)

In any case, even if Endo's net prices for branded Opana ER exceeded its marginal costs before generic entry, there is no basis for Complaint Counsel's suggestion that pricing above marginal cost is necessarily "above the competitive level," or that it "reflect[s] the presence of substantial market power." As Professor Noll admitted at trial, a high "markup of price over marginal cost," as measured by a Lerner Index, "doesn't necessarily mean" that a firm has market power. (Noll, Tr. 1413, 1415). Professor Noll testified that in industries with high fixed costs and low marginal costs, including specifically the pharmaceutical industry, a high markup of price over marginal cost is a "normal market outcome." (Noll, Tr. 1415-16; *see also* Addanki, Tr. 2339 ("you can have a price above marginal cost and have absolutely no monopoly power,

because you have no power to -- to do things in the marketplace to the detriment of consumers. You just happen to have a high margin because you have a lot of costs you need to cover to remain in business.")).

Moreover, market power cannot be inferred from supracompetitive prices alone; there must also be evidence that the alleged monopolist restricted output. (RX-547.0008 (Addanki Rep. ¶ 11 n.8) (monopoly power consists of "the ability to *restrict output* and sustain supracompetitive profits") (emphasis added); RX-547.0051 (Addanki Rep. ¶ 96) ("[H]ad Endo in fact exercised monopoly power and restricted the output of Opana ER we would have expected an increase in output after Impax launched its generic versions of original Opana ER.")). Complaint Counsel cites no evidence that Endo restricted output.

In addition, the statement in Proposed Finding No. 878 that "Endo concluded that offering an authorized generic was a better strategy than exiting the market" should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2).

879. Endo's internal documents confirm that it was able profitably to increase the price of Opana ER while rarely considering the prices of any other LAOs. (CX5000 at 090 (¶ 202) (Noll Report)). Thus, these forecasts imply that Endo had sufficient market power to adopt profit-enhancing price increases. (CX5000 at 090-95, 219-26 (¶¶ 203-14 & Exs. 7A-7B7) (Noll Report)).

RESPONSE TO FINDING NO. 879:

Complaint Counsel's Proposed Finding No. 879 is misleading, inaccurate, and inconsistent with record evidence. The "internal documents" and "forecasts" referenced in Proposed Finding No. 879 are the same documents cited in Complaint Counsel's Proposed Finding Nos. 870-78. As explained in Respondent's Responses to Complaint Counsel's

Proposed Finding Nos. 870-78, these documents reflect [redacted] (Noll, Tr. 1680 [redacted] Moreover, the cited documents are merely projections, plans, or forecasts. There is no record evidence that Endo's *net* prices actually increased, or that Endo actually increased its revenue as a result of the proposed change in its WAC price. In fact, the evidence shows just the opposite. [redacted] (CX5000-219 (Noll Rep., Ex. 7A) (denoted by the red line in Response to Proposed Finding No. 873)). Accordingly, there is no basis for the proposed finding that Endo "had sufficient market power to adopt profit-enhancing price increases."

880. [redacted] (CX5000 at 090-92, 219-26 (¶¶ 203-07 & Exs. 7A-7B7) (Noll Report) (partially *in camera*)). [redacted] (CX5000 at 090-92, 219-26 (¶¶ 203-07 & Exs. 7A-7B7) (Noll Report) (partially *in camera*)).

RESPONSE TO FINDING NO. 880:

Complaint Counsel's Proposed Finding No. 880 is misleading, inaccurate, and inconsistent with record evidence. Complaint Counsel's statement that "[t]he average net realized price for Opana ER has continued to rise slowly, even after generic entry," is simply false. [redacted] (CX5000-219 (Noll Rep., Ex. 7A) (denoted by the red line in Response to Proposed Finding No. 873)). [redacted]

[redacted] (CX5000-219 (Noll Rep., Ex. 7A)).

Respondent has no specific response to the second sentence in Proposed Finding No. 880.

881. [redacted] (CX5000 at 092, 219-26 (¶ 207 & Exs. 7A-7B7) (Noll Report) (partially *in camera*).

RESPONSE TO FINDING NO. 881:

Complaint Counsel's Proposed Finding No. 881 is inaccurate and based on unreliable expert testimony. The Proposed Finding [redacted] The record evidence indicates that oxymorphone ER and Opana ER competed in a market for all long-acting opioids. (*See* Addanki, Tr. 2328 (testifying that "the relevant market is no smaller than the market for long-acting opioids in the United States"); RX-547.0047-48 (Addanki Rep. ¶¶ 85-86); CX3273-003 (Bingol Decl. ¶ 6)). Endo never had more than a 10 percent share of the long-acting opioid market. (Addanki, Tr. 2333; RX-547.0050-51 (Addanki Rep. ¶ 94)). By Endo's own estimate, its market share was only 3.4 percent near the time of the settlement. (CX3273-003 (Bingol Decl.) (referring to a long-acting opioid market)).

Moreover, the record is inconsistent with the proposed finding that Opana ER has been "protected" against intense competition from brand-name and generic long-acting opioids. In 2017, Opana ER competed directly with at least generic oxymorphone ER, oxycodone products, fentanyl products, morphine sulfate products, hydromorphone products, and tapentadol products. (*See* RX-547.0047, 0105-09 (Addanki Rep. ¶ 85, Ex. 4)). This competition occurred at the payor

level for formulary placement, the prescriber level with detailing activities, and at the patent level with direct rebates to consumers. (RX-547.0035-43 (Addanki Rep. ¶¶ 67-79)). Internal Endo documents indicate that Endo consistently portrayed Opana ER as being in direct competition with other long-acting opioids. (*See* RX-073, RX-078; RX-085; RX-114; RX-115).

3. Lerner Index

882. Another method that is widely used by economists to ascertain whether a firm possesses market power is to calculate the Lerner Index (L) for a product, which is the ratio of the mark-up of price over marginal cost to price. (CX5000 at 095-96 (¶ 215) (Noll Report)).

RESPONSE TO FINDING NO. 882:

Complaint Counsel's Proposed Finding No. 882 is inaccurate and based on unreliable expert testimony. The Lerner Index is not "widely used by economists to ascertain whether a firm possesses market power" in the antitrust context. Dr. Addanki explains that "[t]here has long been a consensus among economists that positive price-cost margins (*i.e.,* the difference between price, p, and marginal cost, mc) generally reveal little if anything about the existence of monopoly power." (RX-547.0055 (Addanki Rep. ¶ 104); *see also* Addanki, Tr. 2342 ("[The Lerner Index] may be useful as a textbook case or a pedagogical example in a classroom, but it's no use at all in analyzing real-world industries where there are substantial fixed costs that need to be covered. And again, antitrust economists and scholars have noted this for a long time.")). Dr. Addanki cites numerous peer-reviewed articles for this proposition. (*See* RX-547.0054-57 (Addanki Rep. ¶¶ 102-07)).

At trial, Professor Noll agreed with Dr. Addanki. As Professor Noll stated during his direct examination, a high "markup of price over marginal cost," as measured by a Lerner Index, "doesn't necessarily mean" that a firm has market power. (Noll, Tr. 1413, 1415). Professor Noll testified that in industries with high fixed costs and low marginal costs, including specifically the

pharmaceutical industry, a high markup of price over marginal cost is a "normal market outcome." (Noll, Tr. 1415-16; *see also* Addanki, Tr. 2339 ("you can have a price above marginal cost and have absolutely no monopoly power, because you have no power to -- to do things in the marketplace to the detriment of consumers. You just happen to have a high margin because you have a lot of costs you need to cover to remain in business.")).

> 883. The Lerner Index is a continuous variable between zero and one that measures the extent of market power. It is based on economic theory of pricing wherein a profit-maximizing price for a firm with market power is related to marginal cost and firm-specific elasticity of demand. For example, if demand becomes more elastic, price and the Lerner Index both fall. (CX5000 at 095-96 (¶¶ 215-16) (Noll Report)).

RESPONSE TO FINDING NO. 883:

Complaint Counsel's Proposed Finding No. 883 is inaccurate because the Lerner Index does not "measure[] the extent of market power." Dr. Addanki explains that "[t]here has long been a consensus among economists that positive price-cost margins (*i.e.*, the difference between price, *p*, and marginal cost, *mc*) generally reveal little if anything about the existence of monopoly power." (RX-547.0055 (Addanki Rep. ¶ 104); *see also* Addanki, Tr. 2342 ("[The Lerner Index] may be useful as a textbook case or a pedagogical example in a classroom, but it's no use at all in analyzing real-world industries where there are substantial fixed costs that need to be covered. And again, antitrust economists and scholars have noted this for a long time.")). Dr. Addanki cites numerous peer-reviewed articles for this proposition. (*See* RX-547.0054-57 (Addanki Rep. ¶¶ 102-07)).

At trial, Professor Noll agreed with Dr. Addanki. As Professor Noll stated during his direct examination, a high "markup of price over marginal cost," as measured by a Lerner Index, "doesn't necessarily mean" that a firm has market power. (Noll, Tr. 1413, 1415). Professor Noll testified that in industries with high fixed costs and low marginal costs, including specifically the

pharmaceutical industry, a high markup of price over marginal cost is a "normal market outcome." (Noll, Tr. 1415-16; *see also* Addanki, Tr. 2339 ("you can have a price above marginal cost and have absolutely no monopoly power, because you have no power to -- to do things in the marketplace to the detriment of consumers. You just happen to have a high margin because you have a lot of costs you need to cover to remain in business.")).

884. In an intensely competitive industry with constant long-run marginal and average cost (i.e., no fixed costs), price equals marginal cost, so the Lerner Index is zero. (CX5000 at 095-96 (¶ 215) (Noll Report)).

RESPONSE TO FINDING NO. 884:

Complaint Counsel's Proposed Finding No. 884 is inaccurate and misleading. As Dr. Addanki explained at trial, the assumption "that the competitive benchmark price is represented by marginal cost . . . may be useful as a textbook case or a pedagogical example in the classroom, but it's no use at all in analyzing real-world industries where there are substantial fixed costs that need to be covered. And again, antitrust economists and scholars have noted this for a long time." (Addanki, Tr. 2342).

At trial, Professor Noll admitted that in industries with high fixed costs and low marginal costs, including specifically the pharmaceutical industry, a high markup of price over marginal cost is a "normal market outcome." (Noll, Tr. 1415-16; *see also* Addanki, Tr. 2339 ("you can have a price above marginal cost and have absolutely no monopoly power, because you have no power to -- to do things in the marketplace to the detriment of consumers. You just happen to have a high margin because you have a lot of costs you need to cover to remain in business.")).

885. Higher values on the Lerner index scale imply greater market power, and any value significantly above zero indicates the presence of market power. (CX5000 at 095-96 (¶ 215) (Noll Report)).

RESPONSE TO FINDING NO. 885:

Complaint Counsel's Proposed Finding No. 885 is incorrect and based on unreliable expert testimony. Dr. Addanki explains that "[t]here has long been a consensus among economists that positive price-cost margins (*i.e.,* the difference between price, *p*, and marginal cost, *mc*) generally reveal little if anything about the existence of monopoly power." (RX-547.0055 (Addanki Rep. ¶ 104); *see also* Addanki, Tr. 2342 ("[The Lerner Index] may be useful as a textbook case or a pedagogical example in a classroom, but it's no use at all in analyzing real-world industries where there are substantial fixed costs that need to be covered. And again, antitrust economists and scholars have noted this for a long time.")).

At trial, Professor Noll agreed with Dr. Addanki. As Professor Noll stated during his direct examination, a high "markup of price over marginal cost," as measured by a Lerner Index, "doesn't necessarily mean" that a firm has market power. (Noll, Tr. 1413, 1415). Professor Noll testified that in industries with high fixed costs and low marginal costs, including specifically the pharmaceutical industry, a high markup of price over marginal cost is a "normal market outcome." (Noll, Tr. 1415-16; *see also* Addanki, Tr. 2339 ("you can have a price above marginal cost and have absolutely no monopoly power, because you have no power to -- to do things in the marketplace to the detriment of consumers. You just happen to have a high margin because you have a lot of costs you need to cover to remain in business.")).

886. If marginal cost is essentially constant over time, a change in price indicates a change in the elasticity of demand. For example, if demand becomes more elastic, price and the Lerner Index both fall. (CX5000 at 096 (¶ 216) (Noll Report)).

RESPONSE TO FINDING NO. 886:

Respondent has no specific response.

887. One possible cause of more elastic firm-specific demand is an increase in competition. In a highly competitive economic environment the Lerner Index is at or near zero. If the Lerner Index is above zero, competition must be less intense, implying that firms possess some degree of market power. (CX5000 at 096 (¶ 217) (Noll Report)).

RESPONSE TO FINDING NO. 887:

Complaint Counsel's Proposed Finding No. 887 is inaccurate and based on unreliable expert testimony. The Lerner Index may not be "at or near zero" in "highly competitive economic environment[s]" that include fixed costs. (*See* Addanki, Tr. 2342 ("The basic problem with the use of the Lerner Index . . . is that it implicitly assumes that the competitive benchmark price is represented by marginal cost. And that just simply cannot be right in the real world in most industries.")). Industries with high fixed costs will have Lerner Indexes above zero—and sometimes significantly so—despite being highly competitive. (*See* Addanki, Tr. 2341). Indeed, Professor Noll admitted at trial that a high Lerner Index "doesn't necessarily mean" that a firm has market power. (Noll, Tr. 1415). Professor Noll testified that in industries with high fixed costs and low marginal costs, including specifically the pharmaceutical industry, a high markup of price over marginal cost is a "normal market outcome." (Noll, Tr. 1415-16; *see also* Addanki, Tr. 2339 ("you can have a price above marginal cost and have absolutely no monopoly power, because you have no power to -- to do things in the marketplace to the detriment of consumers. You just happen to have a high margin because you have a lot of costs you need to cover to remain in business.")).

888. An increase in the Lerner Index for a specific product is a reliable indicator that the profitability of a product has risen. As a result, firms often use the Lerner Index or a similar indicator in long-term financial plans. (CX5000 at 097-98 (¶ 220) (Noll Report)).

RESPONSE TO FINDING NO. 888:

The first sentence of Complaint Counsel's Proposed Finding No. 888 should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll

proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). It is also inaccurate. Because the Lerner Index only accounts for *marginal* costs, but not fixed costs or sunk costs, an increase in the Lerner Index for a specific product does not necessarily mean that "the profitability of [the] product has risen," as Complaint Counsel asserts. (*See* RX-547.0055-57 (Addanki Rep. ¶¶ 104-07)). A product with a positive Lerner Index may still be unprofitable—even after an increase in the Lerner Index—when fixed costs and sunk costs are accounted for. (*See* RX-547.0055-57 (Addanki Rep. ¶¶ 104-07)).

Respondent objects to the second sentence of Proposed Finding No. 888 because the terms "reliable" and "often" are vague and ambiguous.

889. The estimated Lerner Index for Opana ER can be derived from estimates of average net realized price and marginal cost for 2008 through 2014. (CX5000 at 100 (¶ 226) (Noll Report)).

RESPONSE TO FINDING NO. 889:

Respondent has no specific response.

890. [redacted] (Noll, Tr. 1681-82 (*in camera*)).

RESPONSE TO FINDING NO. 890:

Respondent has no specific response.

891. The only feasible measure of net realized price is the average net price, which can be calculated by dividing net revenues by output. (CX5000 at 099 (¶ 223) (Noll Report)). Endo used this procedure to calculate forecasts of product-specific profit. (CX5000 at 099 (¶ 223) (Noll Report); *see, e.g.*, CX3017 at 001, 017 (Hogan/Cuca email & attachment) (May 2010 Opana profit and loss model)).

RESPONSE TO FINDING NO. 891:

Respondent has no specific response.

892. Marginal cost is the additional cost of producing one more unit of output. Because marginal cost is difficult to measure, economists normally use average incremental costs—a company's operating costs divided by the amount of output. (CX5000 at 089 (¶ 200 n.244) (Noll Report)).

RESPONSE TO FINDING NO. 892:

Respondent has no specific response.

893. Endo has produced two cost variables for Opana ER, cost of goods sold (COGS) and total operating expenditures (OPEX). (CX5000 at 099 (¶ 225) (Noll Report)). COGS consists almost exclusively of costs that are genuinely marginal. OPEX contains some operating expenditures that plausibly are marginal, but others, such as conferences and epidemiological research on patients who are taking the drug, that are not marginal. (CX5000 at 099 (¶ 225) (Noll Report)).

RESPONSE TO FINDING NO. 893:

Respondent has no specific response.

894. Marginal costs are estimated by dividing COGS and OPEX data by total output. True marginal costs are likely to be somewhere between these measures. (CX5000 at 099 (¶ 225) (Noll Report)).

RESPONSE TO FINDING NO. 894:

Respondent has no specific response.

895. [redacted] (CX5000 at 100, 227 (¶ 226 & Ex. 8) (Noll Report) (partially *in camera*)). [redacted] (CX5000 at 100, 227 (¶ 226 & Ex. 8) (Noll Report) (partially *in camera*)).

RESPONSE TO FINDING NO. 895:

Respondent has no specific response to the first sentence of Complaint Counsel's Proposed Finding No. 895. Complaint Counsel's assertion that [redacted] should be disregarded because it violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support

factual propositions that should be established by fact witnesses or documents." (*See* Court, Tr. 1859 ("[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.")). The second sentence of the proposed finding is also inconsistent with record evidence. Roberto Cuca, who was involved in financial forecasting at Endo, testified that Endo had no idea when Impax would enter with a generic product. (Cuca, Tr. 663). The sole basis offered in the proposed finding to support a contrary position is paragraph 226 of Professor Noll's Report, but Professor Noll cites no basis or support for this factual assertion. (*See* CX5000-100, 227 (Noll Rep. ¶ 226 & Ex. 8)).

896. [redacted] (CX5000 at 100 (¶ 226) (Noll Report) (partially *in camera*)).

RESPONSE TO FINDING NO. 896:

Complaint Counsel's Proposed Finding No. 896 is inaccurate and inconsistent with record evidence, including testimony from Professor Noll, whose report provides the sole support cited for this proposed finding. Dr. Addanki explains that "[t]here has long been a consensus among economists that positive price-cost margins (*i.e.*, the difference between price, *p*, and marginal cost, *mc*) generally reveal little if anything about the existence of monopoly power." (RX-547.0055 (Addanki Rep. ¶ 104); *see also* Addanki, Tr. 2342 ("[The Lerner Index] may be useful as a textbook case or a pedagogical example in a classroom, but it's no use at all in analyzing real-world industries where there are substantial fixed costs that need to be covered. And again, antitrust economists and scholars have noted this for a long time.")).

Moreover, Professor Noll admitted at trial that a high Lerner Index "doesn't necessarily mean" that a firm has market power. (Noll, Tr. 1415). Professor Noll testified that in industries with high fixed costs and low marginal costs, including specifically the pharmaceutical industry,

a high markup of price over marginal cost is a "normal market outcome." (Noll, Tr. 1415-16; *see also* Addanki, Tr. 2339 ("you can have a price above marginal cost and have absolutely no monopoly power, because you have no power to -- to do things in the marketplace to the detriment of consumers. You just happen to have a high margin because you have a lot of costs you need to cover to remain in business.")). Because the Lerner Index says nothing meaningful about market power in the pharmaceutical industry, Complaint Counsel's Proposed Finding No. 896 should be disregarded.

X. Dr. Addanki's opinions regarding market definition and market power should be disregarded

A. Dr. Addanki ignores or dismisses evidence that shows oxymorphone ER is a relevant market

897. The *Merger Guidelines* state that "market definition focuses solely on demand substitution factors, i.e., on customers' ability and willingness to substitute away from one product to another in response to a price increase or a corresponding non-price change such as a reduction in product quality or service." (CX6054 at 010 (§ 4) (*DOJ and FTC Horizontal Merger Guidelines*)). If a small reduction in price of one product does not cause a significant reduction in sales of another, then the other product is not in the same relevant market. (Noll, Tr. 1374-75; CX5000 at 017-18 (¶¶ 38, 41) (Noll Report); CX5004 at 013 (¶ 23) (Noll Rebuttal Report)). This concept applies even to products that are differentiated or paid for by third parties. (CX5004 at 013 (¶ 23) (Noll Rebuttal Report)).

RESPONSE TO FINDING NO. 897:

Respondent has no specific response to the first sentence of Complaint Counsel's Proposed Finding No. 897.

The second and third sentences of Proposed Finding No. 897 are misleading to the extent they imply the *Merger Guidelines* support them. They do not. In truth, the second and third sentences of Proposed Finding No. 897, which rely solely on the report and testimony of Professor Noll, are inaccurate, misleading, and based on unreliable expert testimony. Complaint Counsel does not define what it means by a "small reduction in price," and the purportedly

supporting portions of Professor Noll's testimony and reports do not use that term. (*See* Noll, Tr. 1374-75; CX5000-017-18 (Noll Rep. ¶¶ 38, 41); CX5004-013 (Noll Rebuttal Rep. ¶ 23)). Rather, as Professor Noll seemingly acknowledges, it is simply not true that a "small reduction" will invariably produce a "significant reduction in sales" in a market that is comprised of multiple competing products. (*See, e.g.*, CX5000-014 (Noll Rep. ¶ 38) (stating that two products compete in the same market where a "small *but significant increase* in price" for one product "would cause a sufficient amount of sales to shift to the other product to make the price increase unprofitable") (emphasis added)).

Because the second sentence of Proposed Finding No. 897 is inaccurate, it is not true that the "concept" expressed therein applies to "products that are differentiated or paid for by third parties," as asserted in the third sentence of Proposed Finding No. 897.

> 898. Products that are close substitutes, and in the same market, will exhibit a high cross-elasticity of demand, that is, an increase in the price of one product will result in a large loss of sales to the other product assuming that prices of other products remain unchanged. (CX5000 at 017-18 (¶¶ 38, 41) (Noll Report)). When the data necessary to econometrically analyze two products' cross-elasticity of demand is not available, as is often the case, economists can use other evidence to determine whether two products are close substitutes for each other. (CX5000 at 019 (¶¶ 42-43) (Noll Report)).

RESPONSE TO FINDING NO. 898:

The first sentence of Complaint Counsel's Proposed Finding No. 898 is inaccurate and misleading. It is simply not true that, where two products are "close substitutes," *any* "increase in the price of one product will result in a large loss of sales to the other product." Rather, as Professor Noll admits, the price increase must be "significant" and "non-transitory." (CX5000-017 (Noll Rep. ¶ 38)).

Respondent has no specific response to the second sentence of Proposed Finding No. 898.

899. When analyzing pharmaceutical product markets, one technique to determine whether drugs are close substitutes is to observe what happens to the price and sales volume of one drug when a lower-priced generic version of another, functionally substitutable, drug is introduced. (Noll, Tr. 1374-1375). This technique is related to the SSNIP test – by observing a product's reaction to changes in the price of another product, we can draw conclusions about the degree of cross-elasticity between two drugs and whether they are close substitutes. (Noll, Tr. 1374; CX5000 at 018 (¶ 41) (Noll Report) (describing how the SSNIP test establishes cross-elasticity)). For example, if Opana ER and morphine sulfate were close economic substitutes, a launch of generic morphine sulfate should result in users of Opana ER switching to generic morphine sulfate. (Noll, Tr. 1374-1375). Dr. Addanki does not use this method for defining a relevant product market. (CX5004 at 006-07 (¶ 9) (Noll Rebuttal Report)).

RESPONSE TO FINDING NO. 899:

Complaint Counsel's Proposed Finding No. 899 is incomplete and misleading. While the first sentence of Proposed Finding No. 899 is true that this is "one technique," this technique is insufficient in itself as it does not account for the unique structure of the pharmaceutical market. As Dr. Addanki explained, for example, insurers use formularies to drive volume to particular drugs over others. (Addanki, Tr. 2219-20, 2225-27, 2231-33). Frequently, when a generic version of a particular drug becomes available, insurers will place that generic drug in a preferred tier and de-preference the corresponding brand-name drug. (Addanki, Tr. 2313-15). Further, automatic substitution laws ensure that "when a prescription is presented to a pharmacy for the branded drug, the pharmacy either is required by law to fill it with the [AB-rated] generic product or has strong financial incentives to do so (or both)." (RX-547.0026-27 (Addanki Rep. ¶ 50)). While these features—formularies and automatic substitution laws—may help to explain the rate of substitution that one typically sees between a generic drug and the corresponding brand-name drug, they do not preclude price-based competition (or cross-elasticity of demand) across a wider universe of therapeutically interchangeable products. (*See* RX-547.0022-31 (Addanki Rep. ¶¶ 41-59)).

In light of the pharmaceutical industry's unique structures, economists often study and draw conclusions about relevant markets from "natural experiments, such as a change in formulary status of a drug, changes in copayment arrangements, introductions or changes in coupons or patient savings cards, etc." (RX-547.0024 (Addanki Rep. ¶ 43); *see* Addanki, Tr. 2348). And that is exactly what Dr. Addanki did here. Dr. Addanki identified and evaluated evidence of significant competition and economic substitution among long-acting opioids at various levels in the prescription drug industry: the payor, prescriber, and patient levels. (RX-547.0035-43 (Addanki Rep. ¶¶ 67-79)). This included direct evidence of cross-elasticity of demand between long-acting opioids. For instance, when UPMC instituted formulary changes to preference Opana ER and various generic long-acting opioids over the branded long-acting opioid OxyContin—which represented a change in relative price for consumers, whereby the prices of Opana ER and the favored long-acting opioids decreased relative to the price of OxyContin—nearly 70 percent of OxyContin patients switched to a different long-acting opioid. (RX-087; *see* Addanki, Tr. 2304-09; RX-547.0042 (Addanki Rep. ¶ 78)). UPMC reported a significant increase in usage of Opana ER and generic Morphine Sulfate ER (MS ER), and to a lesser extent, generic Fentanyl patches. (RX-087 (Figures 3, 5)).

Finally, Proposed Finding No. 899 is misleading to the extent it implies that Professor Noll conducted a SSNIP test. As he admitted at trial, he did not. (Noll, Tr. 1514).

> 900. As Dr. Noll showed, generic oxymorphone ER was sold at a lower price than Opana ER and managed to capture nearly half the sales of oxymorphone ER. (Noll, Tr. 1380-81; CX5000 at 056, 184-90 (¶ 122, Exhibits 2B1 through 2B7) (Noll Report); CX5004 at 014 (¶ 25) (Noll Rebuttal Report)). These facts show that Opana ER and generic oxymorphone ER are economic substitutes to one another, and thus in the same relevant product market. (CX5004 at 014 (¶ 25) (Noll Rebuttal Report)). Dr. Addanki does not discuss this in his report. (CX5004 at 014 (¶ 25) (Noll Rebuttal Report)).

RESPONSE TO FINDING NO. 900:

Complaint Counsel's Proposed Finding No. 900 is incomplete and misleading. That "Opana ER and generic oxymorphone ER are economic substitutes to one another, and thus in the same relevant market" is irrelevant. Dr. Addanki has shown that the relevant market is for all long-acting opioids, including *both* generic oxymorphone ER and branded Opana ER, among a number of other long-acting opioids. (*See* Addanki, Tr. 2328 ("the relevant market is no smaller than the market for long-acting opioids in the United States")). Proposed Finding No. 900 is misleading to the extent that it suggests that branded Opana ER and generic oxymorphone ER are the only long-acting opioids in the relevant market. This is wrong. The trend observed by Dr. Noll described in Proposed Finding No. 900 does not indicate otherwise because, as Dr. Addanki explained, insurers use formularies to drive volume to particular drugs over others. (Addanki, Tr. 2219-20, 2225-27, 2231-33). And frequently, when a generic version of a particular drug becomes available, insurers will place that generic drug in a preferred tier and de-preference the corresponding brand-name drug. (Addanki, Tr. 2313-15). This may help to explain the rate of substitution that one typically sees between a generic drug and the corresponding brand-name drug, but does not preclude price-based competition (or cross-elasticity of demand) across a wider universe of therapeutically interchangeable products. (*See* RX-547.0022-31 (Addanki Rep. ¶¶ 41-59)). Further, Dr. Addanki has shown vigorous price competition among generic oxymorphone ER, branded Opana ER, and numerous other long-acting opioids at the payor, prescriber, and patient levels that demonstrate the relevant market is broader than just generic and branded oxymorphone ER. (RX-547.0035-43 (Addanki Rep. ¶¶ 67-79)). Finally, Dr. Noll's conclusion is not based "any analysis, econometric or statistical analysis." (Addanki, Tr. 2331-32).

901. In contrast to the competitive interplay between generic oxymorphone ER and Opana ER, the data also show that there was far less competitive interaction between oxymorphone ER and other LAOs. (CX5000 at 196-216 (Exhibits 5A1-5G3) (Noll Report); CX5004 at 015 (¶ 27) (Noll Rebuttal Report)). Dr. Addanki ignores this evidence. (CX5004 at 015 (¶ 27) (Noll Rebuttal Report)).

RESPONSE TO FINDING NO. 901:

Complaint Counsel's Proposed Finding No. 901 is incomplete, misleading, and based on unreliable expert testimony. The allegedly greater "competitive interaction" between generic and branded oxymorphone ER is merely a function of certain industry features, namely the use of formularies and (in the case of Actavis' generic oxymorphone ER product) state automatic substitution laws. As Dr. Addanki explained, insurers use formularies to drive volume to particular drugs over others. (Addanki, Tr. 2219-20, 2225-27, 2231-33). Frequently, when a generic version of a particular drug becomes available, insurers will place that generic drug in a preferred tier and de-preference the corresponding brand-name drug. (Addanki, Tr. 2313-15). Further, automatic substitution laws ensure that "when a prescription is presented to a pharmacy for the branded drug, the pharmacy either is required by law to fill it with the [AB-rated] generic product or has strong financial incentives to do so (or both)." (RX-547.0026-27 (Addanki Rep. ¶ 50)). While these features—formularies and automatic substitution laws—may help to explain the rate of substitution that Professor Noll observed between Opana ER and generic oxymorphone ER, they do not preclude price-based competition (or cross-elasticity of demand) across a wider universe of long-acting opioids. (*See* RX-547.0022-47 (Addanki Rep. ¶¶ 41-84)).

Far from "ignor[ing]" Professor Noll's purported evidence, as Proposed Finding No. 901 asserts, Dr. Addanki identified and evaluated evidence of significant competition and economic substitution among long-acting opioids at various levels in the prescription drug industry: the payor, prescriber, and patient levels. (RX-547.0035-43 (Addanki Rep. ¶¶ 67-79)). This included direct evidence of cross-elasticity of demand between long-acting opioids. For instance, when

UPMC instituted formulary changes to preference Opana ER and various generic long-acting opioids over the branded long-acting opioid OxyContin—which represented a change in relative price for consumers, whereby the prices of Opana ER and the favored long-acting opioids decreased relative to the price of OxyContin—nearly 70 percent of OxyContin patients switched to a different long-acting opioid. (RX-087; *see* Addanki, Tr. 2304-09; RX-547.0042 (Addanki Rep. ¶ 78)). UPMC reported a significant increase in usage of Opana ER and generic Morphine Sulfate ER (MS ER), and to a lesser extent, generic Fentanyl patches. (RX-087 (Figures 3, 5)). Professor Noll simply ignores the operation of formularies in the marketplace. (*See* RX-547 (Addanki Rep. ¶ 88)).

Finally, Complaint Counsel's assertion in Proposed Finding No. 901 that "the data . . . show that there was far less competitive interaction between oxymorphone ER and other LAOs" is misleading and based on unreliable expert testimony. At no point did Professor Noll conduct any quantitative or statistical analysis of long-acting opioid sales. (Addanki, Tr. 2331). As Professor Noll admitted at trial, he did not try to calculate the cross-elasticity of demand between Opana ER and any other long-acting opioid product, nor did he conduct a SSNIP test. (Noll, Tr. 1514, 1517). He testified that he merely scanned Opana ER sales trends for any "visible effect," a metric that he never bothered to define. (Noll, Tr. 1384).

> 902. Thus, Dr. Noll used the techniques described in CCF ¶¶ 898-99 above to analyze whether other LAOs were economic substitutes for oxymorphone ER. (Noll, Tr. 1375). Dr. Addanki did not undertake any such analysis. (Noll, Tr. 1395; CX5004 at 006-07 (¶ 9) (Noll Rebuttal Report)).

RESPONSE TO FINDING NO. 902:

Complaint Counsel's Proposed Finding No. 902 is incomplete, misleading, and inconsistent with the record to the extent it implies Professor Noll conducted a serious analysis of the effects of generic entry described in Proposed Finding Nos. 898-899. The record supports

that, instead of such an empirical analysis, Professor Noll merely scanned sales trends for a "visible effect" on Opana ER sales, a metric he did not define. (Noll, Tr. 1384; *see also* Addanki, Tr. 2331-32) (Professor Noll did not conduct "any analysis, econometric or statistical analysis . . . to support his conclusion")).

To the extent Complaint Counsel asserts in Proposed Finding No. 902 that Dr. Addanki did not "analyze whether other LAOs were economic substitutes for oxymorphone ER," it is wrong. Dr. Addanki identified and evaluated evidence of significant competition and economic substitution among long-acting opioids at various levels in the prescription drug industry: the payor, prescriber, and patient levels. (RX-547.0035-43 (Addanki Rep. ¶¶ 67-79)). This included direct evidence of cross-elasticity of demand between long-acting opioids. For instance, when UPMC instituted formulary changes to preference Opana ER and various generic long-acting opioids over the branded long-acting opioid OxyContin—which represented a change in relative price for consumers, whereby the prices of Opana ER and the favored long-acting opioids decreased relative to the price of OxyContin—nearly 70 percent of OxyContin patients switched to a different long-acting opioid. (RX-087; *see* Addanki, Tr. 2304-09; RX-547.0042 (Addanki Rep. ¶ 78)). UPMC reported a significant increase in usage of Opana ER and generic Morphine Sulfate ER (MS ER), and to a lesser extent, generic Fentanyl patches. (RX-087 (Figures 3, 5)). Neither the proposed finding, nor anything in the record, addresses or refutes Dr. Addanki's analysis.

> 903. Dr. Noll's analysis confirms that sales for LAOs other than Opana ER were not materially affected by the introduction of generic oxymorphone ER, and sales of Opana ER were not materially affected by the introduction of generic versions of other LAOs. (Noll, Tr. 1393-94; CX5000 at 196-216 (Exhibits 5A1-5G3) (Noll Report); CX5004 at 015 (¶ 27) (Noll Rebuttal Report); *see also* CCF ¶¶ 654-740 above). These patterns support a conclusion that oxymorphone ER is a distinct market. As explained above, if a small reduction in the price of a product does not cause a reduction in the sales of another, then the products are not close substitutes. (*See* CCF ¶¶ 898-99; Noll, Tr. 1374-

75; CX5000 at 017-18 (¶¶ 38, 41) (Noll Report); CX5004 at 013 (¶ 23) (Noll Rebuttal Report)). As a result, if the introduction of generic oxymorphone ER does not cause a loss of sales of other LAOs, they are not close substitutes. (Noll, Tr. 1374-1375, 138182). Conversely if branded Opana ER is able to grow despite the introduction of cheaper generic versions of other LAOs, that pattern indicates other LAOs are not close substitutes for Opana ER and thus not in the same market. (Noll, Tr. 1374-1375, 138182).

RESPONSE TO FINDING NO. 903:

Complaint Counsel's Proposed Finding No. 903 is incomplete, misleading, and inconsistent with the record to the extent it implies Professor Noll conducted a serious analysis of the effects of generic entry in the long-acting opioid market. At no point did Professor Noll conduct any quantitative or statistical analysis of long-acting opioid sales. (Addanki, Tr. 2331). As Professor Noll admitted at trial, he did not try to calculate the cross-elasticity of demand between Opana ER and any other long-acting opioid product, nor did he conduct a SSNIP test. (Noll, Tr. 1514, 1517). He testified that he merely scanned Opana ER sales trends for any "visible effect," a metric that he never bothered to define. (Noll, Tr. 1384; *see also* Addanki, Tr. 2331-32) (Professor Noll did not conduct "any analysis, econometric or statistical analysis . . . to support his conclusion")).

Professor Noll altogether failed to account for the nature of price competition and economic substitution in the pharmaceutical industry. Unlike Professor Noll, Dr. Addanki identified and evaluated evidence of significant competition and economic substitution among long-acting opioids at various levels in the prescription drug industry: the payor, prescriber, and patient levels. (RX-547.0035-43 (Addanki Rep. ¶¶ 67-79)). This included direct evidence of cross-elasticity of demand between long-acting opioids. For instance, when UPMC instituted formulary changes to preference Opana ER and various generic long-acting opioids over the branded long-acting opioid OxyContin—which represented a change in relative price for consumers, whereby the prices of Opana ER and the favored long-acting opioids decreased

relative to the price of OxyContin—nearly 70 percent of OxyContin patients switched to a different long-acting opioid. (RX-087; *see* Addanki, Tr. 2304-09; RX-547.0042 (Addanki Rep. ¶ 78)). UPMC reported a significant increase in usage of Opana ER and generic Morphine Sulfate ER (MS ER), and to a lesser extent, generic Fentanyl patches. (RX-087 (Figures 3, 5)). Professor Noll simply ignores the operation of formularies in the marketplace. (*See* RX-547 (Addanki Rep. ¶ 88)).

Moreover, the particular competitive dynamic between branded Opana ER and generic oxymorphone ER derives from unique features of the pharmaceutical industry. Frequently, when a generic version of a particular drug becomes available, insurers will place that generic drug in a preferred tier and de-preference the corresponding brand-name drug. (Addanki, Tr. 2313-15). Further, automatic substitution laws ensure that "when a prescription is presented to a pharmacy for the branded drug, the pharmacy either is required by law to fill it with the [AB-rated] generic product or has strong financial incentives to do so (or both)." (RX-547.0026-27 (Addanki Rep. ¶ 50)). While these features—formularies and automatic substitution laws—may help to explain the rate of substitution between Opana ER and generic oxymorphone ER, they do not preclude price-based competition (or cross-elasticity of demand) across a wider universe of long-acting opioids. (*See* RX-547.0022-47 (Addanki Rep. ¶¶ 41-84)).

Finally, the individual findings in the paragraphs cited in Proposed Finding No. 902 do not support the proposed summary finding and are unreliable, inaccurate, misleading, and/or improper for the reasons set out in Respondent's replies to those findings.

> 904. Dr. Addanki also ignores or dismisses other evidence that shows generic oxymorphone ER is a unique competitive constraint on Opana ER. (*See* CCF ¶¶ 579-653, above). In particular, generic oxymorphone ER was expected to have – and actually had – a uniquely dramatic effect on the sales of Opana ER. (*See* CCF ¶¶ 579-653, above). Endo's and Impax's internal forecasts and actual experience shows that the release of generic oxymorphone ER had more effect on Opana ER's sales and oxymorphone ER's

pricing than any events relating to other LAOs. (*See* CCF ¶¶ 579-653, above). Generic oxymorphone ER uniquely constrains branded Opana ER. (*See* CCF ¶¶ 579-653, above).

RESPONSE TO FINDING NO. 904:

Complaint Counsel's Proposed Finding No. 904 should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Moreover, the individual findings in the cited paragraphs do not support the proposed summary finding and are unreliable, misleading, and/or inconsistent with the record for the reasons set out in Respondent's replies to those findings.

905. Despite Dr. Addanki's reliance on the parties' business documents in other contexts, he dismisses Endo's and Impax's forecasts as "just forecasts." (RX-547 at 0054 (¶ 101(c)) (Addanki Report)). But Endo's and Impax's forecasts are significant enough to the companies that they devote considerable resources to preparing them and base their business decisions on them. (*See* CCF ¶¶ 601-02, above). Endo relies on its forecasts for business planning and for communicating to the investing public, and has enough confidence in them that it was willing to use its forecasts before a court in a legal proceeding. (*See* CCF ¶¶ 601, 616-17, above). By dismissing them as "just forecasts," Dr. Addanki rejects probative information.

RESPONSE TO FINDING NO. 905:

The first sentence of Complaint Counsel's Proposed Finding No. 905 is a misleading characterization of Dr. Addanki's analysis regarding the parties' internal forecasts, based on a two-word phrase taken out of context. The remainder of the paragraph in Dr. Addanki's report from which the proposed finding selectively quotes makes clear Dr. Addanki was referring to key role played by the assumptions on which a forecast was based, and to the fact that Endo's assumptions in preparing the forecasts at issue are unknown and not in evidence. (*See* RX-547.0054 (Addanki Rep. ¶ 101(c)) ("The forecasts of revenues associated with proposed price increases are just forecasts. . . . In the absence of knowing the assumptions that Endo made in arriving at those forecasts, they do not provide any evidence whether Opana ER had monopoly

power.")). The remainder of Complaint Counsel's Proposed Finding No. 905 should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Moreover, the individual findings in the cited paragraphs do not support the proposed summary finding and are unreliable, misleading, inaccurate, and/or inconsistent with the record, for the reasons set out in Respondent's replies to those findings.

B. Dr. Addanki dismisses the fact that generic oxymorphone took substantial sales from Opana ER

906. [redacted] (*See* CCF ¶¶ 604, above). Endo launched Reformulated Opana ER prior to Impax launching the five major dosage strengths. (CX5000 at 039-41 (¶¶ 88-89) (Noll Report); Noll, Tr. 1376, 1380). Therefore, most generic oxymorphone ER was not AB-rated to Opana ER. (CX5000 at 040-41 (¶ 89) (Noll Report)).

RESPONSE TO FINDING NO. 906:

The first sentence of Complaint Counsel's Proposed Finding No. 906 should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). The remainder of the proposed finding should be disregarded because it violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." (*See* Court, Tr. 1859 ("[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.")). Moreover, the individual finding in the cited Proposed Finding No. 604 is objectionable for the reasons set forth in Respondent's reply to that proposed finding.

907. The real world facts about the competitive interplay between branded Opana ER and generic oxymorphone are consistent with the academic literature. (CX5000 at 035-36 (¶¶ 77-78) (Noll Report)). Economics research shows that generic drug competition to a

brand-name drug with the same active ingredient is far more intense than competition between brand-name drugs. (CX5000 at 035-36 (¶¶ 77-78) (Noll Report)). Dr. Addanki does not address this literature in his report. (CX5004 at 006-07 (¶ 9) (Noll Rebuttal Report)).

RESPONSE TO FINDING NO. 907:

Complaint Counsel's Proposed Finding No. 907 is incomplete and misleading. While generic oxymorphone ER undoubtedly competed with brand-named Opana ER, so do numerous other long-acting opioids. Indeed, the record shows that Opana ER competed directly with at least generic oxymorphone ER, oxycodone products, fentanyl products, morphine sulfate products, hydromorphone products, and tapentadol products. (*See* RX-547.0050-51 (Addanki Rep., Ex. 4)). This competition occurred at the payor level for formulary placement, the prescriber level with detailing activities, and at the patent level with direct rebates to consumers. (RX-547.0035-43 (Addanki Rep. ¶¶ 67-79)). Internal Endo documents indicate that Endo consistently portrayed Opana ER in direct competition with other long-acting opioids. (*See* RX-073, RX-078; RX-085; RX-114; RX-115).

In addition, statements in the proposed findings regarding the content of economic literature are misleading and unsupported by record evidence. This literature is not in the record. Professor Noll's representations regarding the content of those articles are hearsay.

908. Nearly half of the sales of branded Opana ER diverted to sales of generic oxymorphone ER. (Noll, Tr. 1380-81; CX5000 at 056, 177-83 (¶ 122, Exhibits 2A1 through 2A7) (Noll Report); CX5004 at 014 (¶ 25) (Noll Rebuttal Report)). The fact that generic oxymorphone ER took nearly half of all Opana ER sales indicates that generic oxymorphone ER competitively constrains Opana ER. (Noll, Tr. 1380-81; CX5000 at 056 (¶ 122) (Noll Report) CX5004 at 014 (¶ 25) (Noll Rebuttal Report)). Generic oxymorphone ER could not have had such a dramatic effect on the sales of Opana ER if all the other LAOs that Dr. Addanki contends are in the relevant market were close substitutes. (Noll, Tr. 1381-82; CX5000 at 082 (¶ 182) (Noll Report)).

RESPONSE TO FINDING NO. 908:

Complaint Counsel's Proposed Finding No. 908 is incomplete, misleading, inaccurate, and inconsistent with record evidence when considered together with Professor Noll's complete trial testimony describing the limits of his analysis. Professor Noll explained that it "took several years" for sales of branded Opana ER to fall by nearly half after Impax began marketing its generic oxymorphone ER product. (Noll, Tr. 1380). This change in price—separated from the introduction of Impax's generic launch by "several years"—does not reflect price cross-elasticity that might support Professor Noll's conclusion "that generic oxymorphone ER competitively constrains Opana ER." Further, Professor Noll does not indicate that Endo was forced to reduce the price of Branded Opana ER in response to Impax's marketing of generic oxymorphone ER. In fact, Professor Noll's report and testimony [redacted] (Noll, Tr. 1682; (CX5000-219 (Noll Rep., Ex. 7A)). Finally, the "fact that generic oxymorphone ER took nearly half of all Opana ER sales"—after four years—is unsurprising, since formularies create pricing incentives to prioritize drugs, and frequently place a generic drug in a preferred position over the corresponding branded drug. (Addanki, Tr. 2313-15). But that fact does not preclude price-based competition (or cross-elasticity of demand) across a wider universe of long-acting opioids. (*See* RX-547.0022-47 (Addanki Rep. ¶¶ 41-84)).

> 909. Similarly, the entry of generic oxymorphone ER drove down the average price of oxymorphone ER, but this could not have happened if other LAOs were close substitutes for Opana ER. (Noll, Tr. 1380-81). Dr. Addanki does not explain how the entry of generic oxymorphone ER could have had such significant effects on Opana ER's share and price if other LAOs that were on the market before the release of generic oxymorphone ER were close economic substitutes. (CX5004 at 006-07 (¶ 9) (Noll Rebuttal Report)). Nor does Dr. Addanki explain how other LAOs can be close economic substitutes when they had so little effect on Opana ER sales compared to the effect of generic oxymorphone ER. (CX5004 at 006-07 (¶ 9) (Noll Rebuttal Report)).

RESPONSE TO FINDING NO. 909:

Complaint Counsel's Proposed Finding No. 909 is incomplete, misleading, and contradicted by record evidence. [redacted] (*See* (CX5000-219 (Noll Rep., Ex. 7A) (pictured by the red line in Response to Proposed Finding No. 873)). [redacted] (CX5000 at 219 (Noll Rep., Ex. 7A) (pictured by the red line in Response to Proposed Finding No. 873); Addanki, Tr. 2290; Noll, Tr. 1679-82; RX-547 (Addanki Rep. ¶ 101(b), Ex. 13); *see also* RX-547 (Addanki Rep., Ex. 11) (noting that generic MS Contin, generic Duragesic, and generic Kadian were available during 2008-2012 time period)). Neither Complaint Counsel, Professor Noll, nor any other record source offers any explanation [redacted] as Complaint Counsel contends.

Further, Complaint Counsel's assertion in Proposed Finding No. 909 that Dr. Addanki did not explain why "entry of generic oxymorphone ER could have had such significant effects on Opana ER's share" is false. At trial, Dr. Addanki explained that insurance companies frequently place generic drugs in a preferred formulary position over the corresponding branded

drugs, thereby driving consumers to purchase the generics. (Addanki, Tr. 2313-14; *see also* CX3273-008 (Bingol Decl. ¶ 18) ("It is likely that Impax's product will be immediately positioned on Tier 2 or Tier 1 status.")). Complaint Counsel also fails to appreciate that Impax *specifically marketed* its generic oxymorphone ER product to prescribers of Opana ER in an effort to drive substitution between the products. (RX-547.0037 (Addanki Rep. ¶ 69)). But these facts do not preclude price-based competition (or cross-elasticity of demand) across a wider universe of long-acting opioids. (*See* RX-547.0022-47 (Addanki Rep. ¶¶ 41-84)).

> 910. Dr. Addanki dismisses the substantial effect generic entry had on the market for oxymorphone ER on the basis that generics are "predictably" placed at a favorable formulary tier on health insurance plans. (Addanki, Tr. 2313-14). According to Dr. Addanki, there is no point in looking at the effect of generics' placement on formularies because "I know what's going to happen[,] [g]enerics are going to be on tier one uniformly or virtually uniformly." (Addanki, Tr. 2314-15).

RESPONSE TO FINDING NO. 910:

Complaint Counsel's Proposed Finding No. 910 is an incomplete and misleading characterization of Dr. Addanki's testimony. In the cited portion of the transcript, Dr. Addanki was *specifically* discussing his analysis of formulary data obtained from Managed Markets Insight & Technology, LLC ("MMIT"), which was but *one part* of his relevant market analysis. (Addanki, Tr. 2310-28; *see* RX-547.0038-40 (Addanki Rep. ¶¶ 74-76)). As Dr. Addanki explained at trial, the purpose of this particular analysis was to assess the degree of competition among long-acting opioids for which an AB-rated generic was *not* available—i.e., LAOs on an "equal footing." (Addanki, Tr. 2213-15). Including long-acting opioids with AB-rated generics would not tell him (or the Court) anything new about competition among long-acting opioids, because it is undisputed that generic drugs usually end up on favorable formulary tiers. (Addanki, Tr. 2213-15). Of course, if Dr. Addanki were to add generic long-acting opioids to his MMIT analysis, "all we'd be doing is adding another layer or another bar here or another few

bars there"; it would not change the story about the degree to which Opana ER competed against other long-acting opioids for which a generic was not available during the time period studied, such as OxyContin, Avinza, MS Contin, and Exalgo. (Addanki, Tr. 2214).

In other words, Proposed Finding No. 910 both ignores crucial context (i.e., that Dr. Addanki was discussing just one part of his multi-faceted relevant market study) and misses the point of the particular analysis in question (i.e., that the MMIT analysis deliberately focused on competition between Opana ER and other long-acting opioids for which an AB-rated generic was not available during the relevant period). To the extent the proposed finding suggests that Dr. Addanki did not study competition between Opana ER and generic long-acting opioids, it is simply wrong. By way of example, in the UPMC study described in Dr. Addanki's report and at trial, UPMC changed its formularies to favor Opana ER *and various long-acting opioids* over branded OxyContin. (RX-087; *see* RX-547.0042, 0048 (Addanki Rep. ¶¶ 78, 88); Addanki, Tr. 2305). As a result of UPMC's formulary changes, generic Morphine Sulfate ER and generic Fentanyl patch each saw an uptick in prescriptions. (RX-087 (Figures 3, 5)).

> 911. It is true that when generics enter a market, they usually displace the branded version of the drug from a favorable tier position. (CX2607 at 015-016 (¶ 37) (Lortie Decl.), CX3273 at 008 (¶ 18) (Bingol Decl.)). Putting aside that generics are therapeutically equivalent to a branded drug and thus virtually identical products, there are market features that make a given generic a closer economic substitute to the branded version of the drug than other drugs in the same class. (*See* CCF ¶¶ 16-22, above; *see also* CX5000 at 024-25 (¶ 55) (Noll Report) (generic drugs are bioequivalent to branded drugs, meaning they deliver the same amount of the same drug to a patient); CX5004 at 029-30 (¶ 58) (Noll Rebuttal Report) (generics are generally placed on the most favorable tier, and thus have far more impact on the sales of a branded drug than different brands do)).

RESPONSE TO FINDING NO. 911:

Respondent has no specific response to the first sentence of Proposed Finding No. 911. To the extent that the second sentence of Proposed Finding No. 911 relies on other proposed

findings of fact, it should be disregarded, because it violates the Court's Order on Post-Trial Briefs requiring that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Moreover, the individual findings in the cited paragraphs do not support the proposed summary finding, are unreliable, misleading and/or inconsistent with the record for the reasons set out in Respondent's replies to those findings.

As for the assertion that "there are market features that make a given generic a closer economic substitute to the branded version of the drug than other drugs in the same class," that may very well be true, but it does *not* mean that the brand and generic do not compete against those "other drugs in the same class" in a single relevant market. Frequently, when a generic version of a particular drug becomes available, insurers will place that generic drug in a preferred tier and de-preference the corresponding brand-name drug. (Addanki, Tr. 2313-15). Further, automatic substitution laws ensure that "when a prescription is presented to a pharmacy for the branded drug, the pharmacy either is required by law to fill it with the [AB-rated] generic product or has strong financial incentives to do so (or both)." (RX-547.0026-27 (Addanki Rep. ¶ 50)). While these features—formularies and automatic substitution laws—may help to explain the rate of substitution between a branded drug and its corresponding generic, they do not preclude price-based competition (or cross-elasticity of demand) across a wider universe of drug products. (*See* RX-547.0022-47 (Addanki Rep. ¶¶ 41-84)).

C. Dr. Addanki's view that the welfare effects of generic entry are ambiguous is inconsistent with prevailing economic theory

912. Dr. Addanki testified that consumers do not necessarily benefit from lower prices of generic drugs. (Addanki, Tr. 2429; RX-547 at 0019 (¶¶ 31-32) (Addanki Report)). Dr. Addanki testified that it is "unclear" that entry of a lower-priced generic drug has a positive impact on consumer welfare and that one cannot conclude that entry of a low-priced generic makes consumers "better off." (CX4044 (Addanki, Dep. at 89-92)). Dr.

> Addanki even posits that consumers could be harmed by switching to a lower-priced generic version of a drug. (CX4044 (Addanki, Dep. at 86-87) ("So, in the context of paragraph 32, [entry of a lower-priced generic competitor] creates the potential actually to be of consumer harm.")). Dr. Addanki presents no evidence that consumers who switch from Opana ER to a lower-priced therapeutically-equivalent generic version of Opana ER are harmed by the switch. Dr. Addanki does not cite to a single academic or factual source for his assertion that lowering the price of a product, or the entry of a lower-priced competitor, harms consumers. (Addanki, Tr. 2429; RX-547 at 0019 (¶¶ 31-32) (Addanki Report)).

RESPONSE TO FINDING NO. 912:

Complaint Counsel's Proposed Finding No. 912 is an incomplete misleading characterization of Dr. Addanki's testimony. With respect to the first sentence of Proposed Finding No. 912, Dr. Addanki testified that entry of a lower-priced generic competitor "does not reveal anything useful about whether *monopoly power existed and is being dissipated.*" (Addanki, Tr. 2429). Dr. Addanki clarified that he has not "carried out the analysis of whether the entry of a lower-priced product may or may not benefit some consumers somewhere." (Addanki, Tr. 2429). The first sentence of the proposed finding is simply inaccurate.

Proposed Finding No. 912 also selectively quotes from Dr. Addanki's testimony regarding the potential effects of generic entry on consumer welfare in a manner that is highly misleading and should be disregarded. Dr. Addanki did *not* suggest that consumer welfare is always harmed by generic entry, but rather that payment structures and competition in the pharmaceutical industry are sufficiently complex that one cannot look to price effects alone to determine the overall effect of generic entry on consumer welfare. (CX4044 (Addanki Dep. at 90) ("you don't have quite the situation where you have pure competition on the merits, you've got an institutional overlay there. . . . it would be hard to say without more what the welfare effect is"); CX4044 (Addanki Dep. at 91) ("the payment by a patient is really going to be a co-payment . . .[a]nd that co-payment is institutionally determined, so I don't think I would endorse reaching any quick conclusions about the welfare effect")). Dr. Addanki explained that because

a price reduction *coupled with a decrease in output* would harm competition, one cannot determine whether a consumer benefits from a price reduction without considering corresponding effects on output. (CX4044 (Addanki, Dep. at 92) ("And I think until you get to the bottom of [output changes], you're really not in a position of answering the question of whether this is good for consumers or not."); CX4044 (Addanki, Dep. at 89)) ("if I see output expand as I do see in many pharmaceutical contexts . . . when there's generic entry, I think I can make the reasonable inference that there was an enhancement of consumer welfare.")). Finally, Dr. Addanki explained that if the generic is an inferior product and/or prevents the brand from continuing its educational efforts surrounding the drug, the entry of a lower-priced drug can harm consumers, especially "where there's institutionally mandated substitution." (CX4044 (Addanki, Dep. at 86-87)).

The fourth sentence of Proposed Finding No. 912 should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). It is also highly misleading, since it implies that Dr. Addanki opined on the effect of generic entry on *individual consumers*. He did not. (Addanki, Tr. 2429). Rather, consistent with standard antitrust economics, he offered opinions about potential *aggregate* welfare effects. (RX-547.0018-20 (Addanki Rep. ¶¶ 30-33); *see* CX4044 (Addanki, Dep. at 90-91 (even if "appeared that certain customers were paying less," that does not "give you a sense of what the overall welfare effect is")).

In addition, the fifth sentence of Proposed Finding No. 912 is misleading both in its characterization of Dr. Addanki's opinions and in its implication that Dr. Addanki's views lack support. To begin with, nowhere did Dr. Addanki state that "lowering the price of a product" or

"the entry of a lower-priced competitor" invariably "harms consumers." Rather, he made the point that "the adverse economic effect that is of concern is the antitrust economic analysis of agreements like the one at issue is the reduction in output (and attendant loss of consumer welfare it engenders) that results from an exercise of monopoly power," and that if the entry of a lower priced competitor is not accompanied by an expansion of output, then there is no basis for assuming that the entry increased consumer welfare in the aggregate, "or that the patentee/brand had exercised monopoly power before generic entry." (RX-547.0018-20 (Addanki Rep. ¶¶ 30-33)). Hence the need for a "monopoly power screen." (RX-547.0018-20 (Addanki Rep. ¶¶ 30-33)). Moreover, the suggestion in Proposed Finding No. 912 that Dr. Addanki's opinion lacks support ignores Dr. Addanki's decades of experience as an antitrust economist with expertise in the pharmaceutical industry. (RX-547.0005-06, 0089-92 (Addanki Rep. ¶¶ 1-5, Ex. 1)).

913. The idea that customers do not benefit from lower prices for a product is inconsistent with prevailing economic theory. (CX5004 at 041 (¶ 85) (Noll Report) (citing Steven C. Salop, "Question: What is the Real and Proper Antitrust Welfare Standard? Answer: The *True* Consumer Welfare Standard," *Loyola Consumer Law Review* Vol. 22, No. 3 (2010), pp. 336-53, and John B. Kirkwood, "The Essence of Antitrust: Protecting Consumers and Small Suppliers from Anticompetitive Conduct," *Fordham Law Review* Bol. 81, No. 5 (April 2013), pp. 2425-70)). Economists recognize that increased prices resulting from anticompetitive conduct harm consumers. (Noll, Tr. 1364-5). The *Merger Guidelines* plainly state that price increases represent adverse effects to consumers: "Evidence of observed post-merger price increases or other changes adverse to customers is given substantial weight." (CX6054 at 006 (§ 2.1.1) (*Merger Guidelines*)).

RESPONSE TO FINDING NO. 913:

Complaint Counsel's Proposed Finding No. 913 is misleading and incomplete. As Dr. Addanki has explained, the mere fact that "certain consumers [may be] paying less" in a given scenario does not "give you a sense of what the *overall* welfare effect is." (CX4044 (Addanki, Dep. at 90-91) (emphasis added)). If the entry of a lower-priced competitor is not accompanied by an expansion in output—or is accompanied by an overall *reduction* in output—"then there is

no basis to presume that the lower price resulted in increased consumer welfare or that the [incumbent] had exercised monopoly power before [new] entry." (RX-547.0019-20 (Addanki Rep. ¶ 33); *see* RX-547.0018 (Addanki Rep. ¶ 30) ("the adverse economic effect that is of concern in the antitrust economic analysis of agreements like the one at issue is the reduction in output and attendant loss of consumer welfare it engenders that results from an exercise of monopoly power")). But as Dr. Addanki made clear in his report and at trial, the entry of a lower-priced competitor *can* have "the welfare-improving effect of expanding output." (RX-547.0015 (Addanki Rep. ¶ 30); *see* Addanki, Tr. 2432 ("Consumer benefit may go up or down depending upon the value of those activities and the price that you see in the marketplace. And as I've said before, output is the best test of whether on net consumers are better off or not, because if those activities have real value, you will not see the lower price actually producing more output.")). Proposed Finding No. 913 simply ignores this. (Addanki, Tr. 2432). Respondent has no specific response to the second and third sentences of Proposed Finding No. 913.

> 914. If output of a product is constant, but price increases due to anticompetitive conduct, then wealth is transferred from the consumer to sellers, and consumers are harmed by the price increase. (CX5004 at 040-41 (¶ 85) (Noll Rebuttal Report)). Conversely, if anticompetitive conduct ceases, and price is lowered as a result, then consumers benefit as wealth is transferred from sellers to consumers. (CX5004 at 040-41 (¶ 85) (Noll Rebuttal Report)). The launch of generics in the market for oxymorphone ER lowered the overall average price of oxymorphone ER to the benefit of consumers. (Noll, Tr. 138081; CX5000 at 187-90 (Exhibits 2B4 through 2B7) (Noll Report)).

RESPONSE TO FINDING NO. 914:

Complaint Counsel's Proposed Finding No. 914 is misleading and incomplete. The proposed finding assumes the presence of "anticompetitive" conduct. As Professor Noll admitted at trial—and as Complaint Counsel concedes in its post-trial briefing—conduct cannot be "anticompetitive" unless the firm in question possessed "substantial market power." (Noll,

Tr. 1574; *see* Compl. Counsel's Post-Trial Br. at 47, Dkt. 9373 (F.T.C. Dec. 20, 2017) ("A firm without market power will not be able to harm competition successfully.")). The evidence here establishes that Endo did *not* possess market power in the relevant market, which was comprised of numerous long-acting opioids. (*See* Addanki, Tr. 2328 ("the relevant market is no smaller than the market for long-acting opioids in the United States"); RX-547.0047-48, 0050-51 (Addanki Rep. ¶¶ 85-86, 94)); CX3273-003 (Bingol Decl. ¶ 6)).

Moreover, the hypotheticals constructed in Proposed Finding No. 914—which assume, among other things, that output is "constant"—are mere tautologies. But as Dr. Addanki testified, in the real world, "we know what monopolists do. When a firm has monopoly power, it *restricts output* [and] charges monopoly prices, all of which harm consumers." (Addanki, Tr. 2206 (emphasis added)). And here, there is no evidence that Endo charged supracompetitive prices *or* restricted output. (RX-547.0051, 0054-57 (Addanki Rep. ¶¶ 96, 102-07)).

Respondent has no specific response to the last sentence of Proposed Finding No. 914.

D. Dr. Addanki incorrectly equates therapeutic substitutability with economic substitutability

915. The fact that drugs in the same class can be therapeutic or functional substitutes does not mean, in and of itself, that such drugs are economic substitutes. (Noll, Tr. 1373; CX5004 at 036-037 (¶¶ 74-75) (Noll Rebuttal Report)).

RESPONSE TO FINDING NO. 915:

Respondent has no specific response.

916. As explained above, the data show that sales of LAOs other than Opana ER were not materially affected by the introduction of generic oxymorphone ER, and sales of Opana ER were not materially affected by the introduction of generic versions of other LAOs. (Noll, Tr. 1393-94; CX5000 at 196-216 (Exhibits 5A1-5G3) (Noll Report); CX5004 at 015 (¶ 27) (Noll Rebuttal Report); *see also*, CCF ¶¶ 654-740, above). This fact demonstrates that other LAOs are not in the same product market as oxymorphone ER. (Noll, Tr. 1393-94; CX5004 at 015 (¶ 27) (Noll Rebuttal Report)).

RESPONSE TO FINDING NO. 916:

Complaint Counsel's Proposed Finding No. 916 is incomplete and misleading for the same reasons "as explained above." First, Professor Noll did not substantiate his claims with any quantitative or statistical analysis; he simply scanned for any "visible effect" on Opana ER sales, a metric he never bothered to define. (Noll, Tr. 1384). Second, even if one assumes that generic oxymorphone ER took more sales from branded Opana ER than from other long-acting opioids, that is unsurprising given of the features of the pharmaceutical industry, (Addanki, Tr. 2313-15), and the fact Impax specifically targeted Opana ER prescribers with its marketing efforts, (RX-547.0037 (Addanki Rep. ¶ 69)). Third, Professor Noll's analysis ignores significant price competition at the payor, prescriber, and patient levels. (RX-547.0035-43 (Addanki Rep. ¶¶ 67-79)). Finally, Professor Noll ignores evidence of cross-elasticity among long-acting opioids—namely, that patients actually switched among long-acting opioids in response to changes in relative price, as embodied in formulary changes. (RX-087; RX-547.0042, 0048 (Addanki Rep. ¶¶ 78, 88); RX-549.0007 (Michna Rep. ¶ 23); Michna, Tr. 2125).

> 917. Dr. Addanki ignores this real-world evidence that other LAOs are not economic substitutes for oxymorphone ER. Instead, Dr. Addanki erroneously concludes that other LAOs are economic substitutes based on the fact that they are therapeutic substitutes. (CX5004 at 016-17 (¶ 36) (Noll Rebuttal Report)).

RESPONSE TO FINDING NO. 917:

Complaint Counsel's Proposed Finding No. 917 is a brazen misrepresentation. Dr. Addanki does not conclude long-acting opioids are economic substitutes merely based "on the fact that they are therapeutic substitutes." Dr. Addanki looked at real-world evidence of *economic substitution* among long-acting opioids, including as effectuated through formularies. (*See, e.g.,* RX-547.0024 (Addanki Rep. ¶ 44) ("Such formulary structures can—and as I show below do in this case—provide useful insights about *economic substitutability* among

pharmaceuticals" (emphasis added)); RX-547.0029-30 (¶ 57) ("[T]he willingness of a drug benefit plan to vary the relative positioning of products in a given category underscores that the plan regards the products as *economic substitutes*" (emphasis added)).

Indeed, at trial, Dr. Addanki testified explicitly and at length to *economic substitution* among long-acting opioids. (*See, e.g.*, Addanki, Tr. 2225–26 ("The second thing you can infer [from competition for formulary placement] is that *economic substitutability* is actually happening." (emphasis added)); Addanki, Tr. 2232–33 ("So what you've got going on is you've got *substitution going on in response to price competition*, which is, of course, exactly the kind of competition we're talking about when we're analyzing antitrust cases, when we're analyzing relevant markets." (emphasis added)); Addanki, Tr. 2309 ("competition for formulary coverage was in fact *economic substitution*" (emphasis added)). Dr. Addanki emphasized that "economic evidence" showing that "these products actually compete with one another in the market, in the market place" is "the most important evidence." (Addanki, Tr. 2253). And he expressly distinguished therapeutic substitution from economic substitution. (*E.g.*, Addanki, Tr. 2225-26 (discussing therapeutic substitutability and economic substitutability separately)).

Proposed Finding No. 917 is completely unmoored from record evidence and voluminous trial testimony, and should be disregarded.

> 918. Different drugs may be therapeutic substitutes but have different enough characteristics that they are not economic substitutes. (Noll, Tr. 1373).

RESPONSE TO FINDING NO. 918:

Respondent has no specific response.

> 919. Exhibit 2 of Dr. Noll's Rebuttal Report contains a list of Endo business documents that Dr. Addanki cited for the proposition that Opana ER competes with other LAOs. These documents show that Endo emphasized the product differentiation of Opana ER. (CX5004 at 037-38, 089-90 (¶ 78, Exhibit 2) (Noll Rebuttal Report)). These

documents do not reflect intense price bidding wars between Opana ER and other drugs to gain business, but rather emphasize product differentiation over price competition. (CX5004 at 037-38 (¶ 78) (Noll Rebuttal Report)).

RESPONSE TO FINDING NO. 919:

Complaint Counsel's Proposed Finding No. 919 is an incomplete and misleading mischaracterization of the documents identified. With respect to the second sentence of the proposed finding, the documents regarding these product differentiation efforts discuss a "competitive set," and thus "[p]rovide [u]seful [i]nsights into the [n]ature of [c]ompetition and [r]elevant [m]arkets." (RX-547.0026 (Addanki Rep. ¶¶ 49-50 and header)). Moreover, the proposed finding neglects to mention that the need to engage in promotion was driven by Endo's recognition that long-acting opioids "are not very differentiated." (RX-023.0002).

The third sentence of the proposed finding ignores abundant evidence of significant price competition among long-acting opioid makers at the insurer level. (*See* RX-547.0028-31, 0038-42 (Addanki Rep. ¶¶ 53-58; 72-78)). For example, in 2011 Endo sought to get Opana ER on the formulary [redacted] (Addanki, Tr. 2294; RX-547.0041-42 (Addanki Rep. ¶ 78)). Similarly, in 2011, [redacted] (RX-547.0041-42 (Addanki Rep. ¶ 78); Addanki, Tr. 2294-98). The following year, [redacted] (RX-547.0041-42 (Addanki Rep. ¶ 78); Addanki, Tr. 2294-98). In a 2012 document that Professor Noll cites in his own report, Endo noted that Purdue was offering payors discounts on OxyContin that ranged from 15% to 20%. (CX3206-002). Endo proposed "an additional 11% discount on Opana ER" to "achieve pricing parity to OxyContin," on the expectation that many payors would "see the price differential as

sufficient incentive to utilize Opana ER and make the prescribing formulary change." (CX3206-002)

The third sentence of the proposed finding also overlooks the fact that long-acting opioid makers competed aggressively at the patient level by directly subsidizing consumers' out-of-pocket prices, effectively lowering the prices they paid for the respective drug makers' products. (*See, e.g.*, RX-028.0011 (Endo document describing "[a]ggressive couponing from all direct competitors," including by the makers of OxyContin, Avinza, and Kadian; describing Endo's competitive response); RX-445.0015 [redacted]; RX-448.0020 [redacted]. As Dr. Addanki testified at trial, we simply *do not* see price competition at the patient level with respect to products that lack economic competition. (Addanki, Tr. 2236-37).

> 920. Dr. Addanki concludes that LAOs are in the same market based on the fact that different LAOs have been prescribed to treat the same condition and that the pattern of use of different LAOs is "generally very similar." (RX-547 at 0033 (¶ 64) (Addanki Report)). This conclusion is not well-founded for a number of reasons. First, even if it were true that the pattern of use amongst LAOs is "generally very similar," the fact that different drugs can treat the same condition does not tell us they are in the same relevant market. (CX5004 at 020 (¶ 39) (Noll Rebuttal Report)). The choice of drug to treat a particular condition may be based on price, in which case it could provide insight into whether two drugs are in the same market. (CX5004 at 020 (¶ 39) (Noll Rebuttal Report)). However, the choice of drug to treat a particular condition could also be based on characteristics of the drug and patient. (CX5004 at 020 (¶ 39) (Noll Rebuttal Report)). Without knowing why a doctor chose to treat a given condition with a given drug, it is not possible to conclude that the fact that different drugs can treat a condition means the drugs are in the same relevant market. (CX5004 at 020 (¶ 39) (Noll Rebuttal Report)).
>
> **RESPONSE TO FINDING NO. 920:**

Complaint Counsel's Proposed Finding No. 920 is an incomplete and misleading characterization of paragraph 64 of Dr. Addanki's report, in particular to the extent that it implies

Dr. Addanki's opinions regarding relevant market and competition among long-acting opioids rely exclusively on the therapeutic patterns. Interchangeability as a treatment option is just one of *many* factors on which Dr. Addanki relied for his conclusions on the relevant market definition. Dr. Addanki's relevant market definition is based not on therapeutic substitution by itself, but on evidence that therapeutically interchangeable long-acting opioids were *economic substitutes* that competed *on price* at all levels of the pharmaceutical industry. (RX-547.0035-43 (Addanki Rep. ¶¶ 67-79); *see* Addanki, Tr. 2253 ("Well, to me as an economist, the clinical evidence is important, *but the most important evidence is economic evidence*." (emphasis added)). Indeed, Proposed Finding No. 920 concedes that "[t]he choice of drug to treat a particular condition may be based on price, in which case it could provide insight into whether two drugs are in the same market." This is *exactly* what Dr. Addanki's analysis shows. (RX-547.0038-42 (Addanki Rep. ¶¶ 72-78); Addanki, Tr. 2253-2300).

The final sentence of Proposed Finding No. 920 is incomplete and misleading because it limits analysis of prescriber decisions to "knowing why a doctor chose to treat a given condition with a given drug." This ignores significant record evidence that formulary changes can do routinely do affect prescribing decisions. (*See* Addanki, Tr. 2217-2237; RX-549.0007 (Michna Rep. ¶ 23); Michna, Tr. 2125); *see also* CX4039 (Noll, Dep. at 186-87 ("Q. Would you agree a patient's insurance coverage is an important driver of the initial selection of a long-acting opioid by a physician? A. Well, that's another statement about formularies. Yes.")). For example, Professor Noll ignores the testimony of Dr. Michna—presumably the very type of doctor referenced in Proposed Finding No. 920—that insurance coverage "plays a major role" in the choice of long-acting opioid. (Michna, Tr. 2129).

921. Second, Dr. Addanki's conclusion that there is a similar frequency with which various LAOs are used to treat various conditions is incorrect. (RX-547 at 0033 (¶ 64)

(Addanki Report); CX5004 at 022 (¶ 42) (Noll Rebuttal Report). Dr. Addanki does not offer any objective benchmark to evaluate whether the frequency of use of two opioids is similar. (CX5004 at 022 (¶ 43) (Noll Rebuttal Report)).

RESPONSE TO FINDING NO. 921:

Complaint Counsel's Proposed Finding No. 921 is an incorrect and misleading characterization of Dr. Addanki's analysis. Dr. Addanki provides a robust statistical analysis, tabulated in Exhibit 4 of his report, showing that each long-acting opioid is used to treat a very similar (and broad) range of medical conditions. (RX-547.0033, 105 (Addanki Rep. ¶ 64, Ex. 4); *see* Addanki, Tr. 2245-48). And as he explained at trial, it *does not matter* that long-acting opioids were not all prescribed with the same frequency. (Addanki, Tr. 2248-50 ("Now, there may be specific idiosyncrasies suggesting that physicians who prescribe for a particular indication here may, because of habit, tend to prescribe a certain molecule more often, whereas physicians in another specialty where another indication is more commonplace may, for idiosyncratic reasons, have some preference that drive them in another direction. [¶] But they're all being used for all the indications overwhelmingly, so again there seems to be no reason why clinically, from the data on use over ten years, that they couldn't be substituting.")).

922. Dr. Addanki measures the overall frequency of the use of certain LAOs to treat over 514 conditions, but his Exhibit 4 includes only the 100 most common diagnoses. (CX5004 at 020-21 (¶ 40) (Noll Rebuttal Report)). By spreading the overall frequency of LAO use over 514 diagnoses, all of the values are very small, i.e., near zero. (CX5004 at 020-21 (¶ 40) (Noll Rebuttal Report)). Based on the fact that the frequency of LAO use over 514 diagnoses is near zero, Dr. Addanki concludes that the frequency of LAO use to treat various diagnoses is "generally very similar." (RX-547 at 0033 (¶ 64) (Addanki Report)).

RESPONSE TO FINDING NO. 922:

Complaint Counsel's Proposed Finding No. 922 is inaccurate and misleading. While Respondent has no specific response to the first sentence, the second sentence mischaracterizes Dr. Addanki's report. As is evident from the face of Exhibit 4 to Dr. Addanki's report, many of

the values are *not* "near zero." For Lumbago, the first diagnosis code listed, the values range from 6.58 percent (Tapentadol HCl) to 9.90 percent (Fentanyl). (RX-547.105 (Addanki Rep., Ex. 4)). Further, Complaint Counsel's implication that Dr. Addanki achieved artificial similarity between the various diagnoses by using a sample size so large it would drive all values close to zero is simply not supported by the record. The 100 diagnoses included in Dr. Addanki's analysis account for *nearly 90 of all prescriptions* for the opioids shown. (*See* RX-547.108 (Addanki Rep., Ex. 4) ("All Other Diagnoses" represent only 10.38 percent of cumulative prescriptions for the molecules shown)). These 100 diagnoses account for nearly *93 percent* of Oxymorphone HCl prescriptions. (*See* RX-547.108 (Addanki Rep., Ex. 4) ("All Other Diagnoses" represent only 7.22 percent of Oxymorphone HCl prescriptions)).

Because the 414 diagnoses not included in Dr. Addanki's exhibit account for only a small fraction of opioid usage, the values would not be significantly different if Dr. Addanki "spread[] the overall frequency of LAO use over" all 514 diagnoses.

> 923. But the fact that any particular diagnosis (among 514) accounts for a small fraction of total uses of two LAOs is not economic evidence that the LAOs are in the same relevant market. (CX5004 at 020-21 (¶ 40) (Noll Rebuttal Report)). Arguing as Dr. Addanki does that two products are close substitutes because both are used rarely for a purpose is like arguing that because lactose-intolerant customers account for almost no sales of milk and ice cream, milk and ice cream makers must compete intensively with each other. (CX5004 at 020-21 (¶ 40) (Noll Rebuttal Report)).

RESPONSE TO FINDING NO. 923:

Complaint Counsel's Proposed Finding No. 923 mischaracterizes Dr. Addanki's analysis and opinions. Exhibit 4 of Dr. Addanki's report is valuable both for what it says about specific diagnoses (e.g., that all of the listed molecules treat Lumbago) *and* for what it says about opioid usage in the aggregate: namely, that for the 100 most common diagnoses taken as a whole, *all* of the opioids listed are used with a similar frequency of use. These 100 diagnoses account for

nearly 90 percent if all use for the opioids listed; for specific opioids, the 100 diagnoses account for usages ranging from 84.70 percent (Hydromorphone HCl) to 93.87 percent (Tapentadol). (*See* RX-547.108 (Addanki Rep., Ex. 4) (figured derives from "All Other Diagnoses" row); Addanki, Tr. 2247 ("[T]he striking thing is that all of these products are used to a greater or lesser extent for all of these indications.")).

Proposed Finding No. 923 also misses the broader point: all LAOs are indicated for "management of pain severe enough to require daily around the clock long-term opioid treatment and for which alternative treatment options are inadequate," a broad medical condition that can be further broken down into specific pain-related diagnoses, as reflected in Exhibit 4. (RX-547.0032 (Addanki Rep. ¶ 62)). Dr. Addanki's analysis shows that long-acting opioids are interchangeable in the treatment of chronic pain, *across* diagnoses. (Addanki, Tr. 2248 ("from a clinical standpoint, there doesn't appear to be any reason why those products would not be interchangeable for one another, because they are being used for many of the same things or virtually all of the same things."); *see also* Michna, Tr. 2149). As Dr. Addanki explained at trial, the fact that long-acting opioids are not prescribed with the exact same frequency for each diagnosis *does not matter* for market definition purposes. (Addanki, Tr. 2248-50).

> 924. Moreover, no LAOs are used at all for many of the diagnoses in Dr. Addanki's Exhibit 4. (CX5004 at 021-22 (¶ 41) (Noll Rebuttal Report)). For 81 of the diagnoses, the fraction of reported uses is zero for at least one LAO. For 39 diagnoses, the fraction of all oxymorphone ER uses is zero. (CX5004 at 021-22 (¶ 41) (Noll Rebuttal Report)). The fact that a drug has a zero fraction of total uses for a diagnosis (i.e., the drug is not prescribed for the condition) does not support a conclusion that the drug is a substitute for a drug that is used to treat the condition. (CX5004 at 021-22 (¶ 41) (Noll Rebuttal Report)). Thus, for many diagnoses, Exhibit 4 actually undercuts Dr. Addanki's conclusion that different LAOs are in the same market. (CX5004 at 021-22 (¶ 41) (Noll Rebuttal Report)).

RESPONSE TO FINDING NO. 924:

Complaint Counsel's Proposed Finding No. 924 is false and misleading characterization of Dr. Addanki's analysis. The first sentence to Proposed Finding No. 924 is blatantly and demonstrably false: There is not a single diagnosis listed in Exhibit 4 for which none of the six LAOs included in the study is used. (RX-547.108 (Addanki Rep., Ex. 4)).

The remainder of Proposed Finding No. 924 is irrelevant because it makes no difference that for 81 of the diagnoses "at least one" long-acting opioid is not prescribed. It is frequently the case that, where one opioid is not used for a diagnosis, each of the other five opioids is used. For example, Tapentadol HCl is often not used:

3089	Chronic Pain Syndrome	3.32	0.81	2.99	4.01	4.19	1.00	4.23
7291	Myalgia+Myositis Unsp	5.33	9.27	2.68	3.73	4.34	8.75	3.92
7809	Other General Symptoms	3.57	4.10	3.47	3.04	1.47	2.64	3.26
1629	Mal Neo Bronch+Lung Unsp	3.07	0.76	3.09	1.94	0.35	0.00	2.48
7225	Deg Thorac+Lumb Int Disc	1.11	1.91	3.47	1.84	8.17	2.96	2.44
7249	Back Disorders Unsp	2.96	2.26	1.90	1.99	1.68	0.00	2.16
7228	Postlaminectomy Syndrome	1.43	3.16	1.67	2.78	2.24	4.66	2.11
7240	Spinal Stenosis Not Cerv	2.20	3.63	1.28	2.25	1.30	5.45	1.94
3383	Neoplasm Related Pain	3.84	1.75	2.05	0.81	0.35	0.00	1.91
7229	Disc Disorder Oth+Uns	1.68	1.81	1.69	2.14	3.00	1.54	1.90

As Dr. Addanki testified at trial, the fact that some long-acting opioids are not used for some prescriptions does not undercut the conclusion that they all compete in the same market. (*See* Addanki, Tr. 2247-50).

More fundamentally, Dr. Addanki's analysis undermines Professor Noll's opinion that there is there is a market for *one particular* long-acting opioid, because it shows there is no diagnosis for which Oxymorphone HCl is the only molecule used, (*see* RX-547.0049 (Addanki Rep. ¶ 89) ("there is no condition for which oxymorphone is the only product prescribed"); *see also* Addanki, Tr. 2248 (testifying to same)), or that there is a single diagnosis for which only one long-acting opioid is prescribed. (*See* Addanki, Tr. 2247-50). These findings directly contradict Complaint Counsel's proposed market of a single long-acting opioid molecule.

925. In addition, the data in Dr. Addanki's Exhibit 4 shows that the patterns of use among the six LAOs are not in fact "generally very similar." (CX5004 at 022, 083-85 (¶ 42, Exhibit 1A) (Noll Rebuttal Report)). Exhibit 1A of Dr. Noll's Rebuttal Report examines the frequency of use of each of the six opioids in Dr. Addanki's Exhibit 4 as a percentage of the average use of all opioids used to treat each condition. (CX5004 at 022, 083-85 (¶ 42, Exhibit 1A) (Noll Rebuttal Report)). As expressed in Exhibit 1A, if all of the different LAOs were prescribed in the same amount—i.e., the pattern of LAO use to treat various conditions was "generally very similar"—then the value in each cell would be 100. (CX5004 at 022, 083-85 (¶ 42, Exhibit 1A) (Noll Rebuttal Report)).

RESPONSE TO FINDING NO. 925:

Complaint Counsel's Proposed Finding No. 925 is misleading, inaccurate, and based on unreliable expert testimony. Whether or not competing products are used with similar frequency is a red herring. Dr. Addanki does not claim that long-acting opioids were used with the same frequency for each diagnosis, nor is this relevant to Dr. Addanki's analysis. As Dr. Addanki testified at trial, it *does not matter* that the long-acting opioids studied in his Exhibit 4 are not prescribed with the same degree of frequency for each diagnosis; what matters is "they are all or virtually all prescribed for virtually all of these diagnosis codes." (Addanki, Tr. 2248-50).

And so the criticisms posed in Proposed Finding No. 925 simply miss the point of Dr. Addanki's analysis. The analysis shows that (1) long-acting opioids are used interchangeably to treat dozens upon dozens of the most common pain diagnoses, (*see* Addanki, Tr. 2247 ("these products are used for really a staggering number of different diagnosis codes.")); (2) there is no type of pain for which any long-acting opioid is the only or the superior option, (Addanki, Tr. 2247; Michna, Tr. 2149; Savage, Tr. 791); and (3) there is no medical condition for which Opana ER is the only or the most superior option, (RX-547.033 (Addanki Rep. ¶ 64); Savage, Tr. 743; Michna, Tr. 2149). All of this supports the existence of a long-acting opioid market.

926. When shown as described above, the patterns of use among LAOs are in fact highly variable and do not support Dr. Addanki's conclusion that the pattern of use amongst LAOs are "generally very similar." (CX5004 at 022-23, 083-85 (¶¶ 42-43, Exhibit 1A) (Noll Rebuttal Report)). For 75 of the 100 conditions in Exhibit 1A, the use

of oxymorphone ER varies by more than 50% from the average use of LAOs. (CX5004 at 022-23, 083-85 (¶ 43, Exhibit 1A) (Noll Rebuttal Report)). Even if determining that the pattern of use of different drugs is "generally very similar" told us anything about whether the drugs were in the same relevant market, which is not the case, Dr. Addanki's analysis would not support the conclusion because the data show that the patterns of use are not in fact "generally very similar." (CX5004 at 022-24 (¶¶ 42-46) (Noll Rebuttal Report)).

RESPONSE TO FINDING NO. 926:

Complaint Counsel's Proposed Finding No. 926 is misleading, inaccurate and based on unreliable expert testimony. Whether or not competing products are used with similar frequency is a red herring. Dr. Addanki does not claim that long-acting opioids were used with the same frequency for each diagnosis, nor is this relevant to Dr. Addanki's analysis. As Dr. Addanki testified at trial, it *does not matter* that the long-acting opioids studied in his Exhibit 4 are not prescribed with the same degree of frequency for each diagnosis; what matters is "they are all or virtually all prescribed for virtually all of these diagnosis codes." (Addanki, Tr. 2248-50).

And so the criticisms posed in Proposed Finding No. 926 simply miss the point of Dr. Addanki's analysis. The analysis shows that (1) long-acting opioids are used interchangeably to treat dozens upon dozens of the most common pain diagnoses, (*see* Addanki, Tr. 2247 ("these products are used for really a staggering number of different diagnosis codes.")); (2) there is no type of pain for which any long-acting opioid is the only or the superior option, (Addanki, Tr. 2247; Michna, Tr. 2149; Savage, Tr. 791); and (3) there is no medical condition for which Opana ER is the only or the most superior option, (RX-547.033 (Addanki Rep. ¶ 64); Savage, Tr. 743; Michna, Tr. 2149). All of this supports the existence of a long-acting opioid market.

E. Dr. Addanki erred in basing his definition of the relevant market primarily on a marketing, rather than economic, meaning of that term

927. Dr. Addanki errs by basing his definition of the relevant market primarily on a marketing, rather than economic, meaning of the term. (*See* CCF ¶¶ 928-40, below).

RESPONSE TO FINDING NO. 927:

Complaint Counsel's Proposed Finding No. 927 should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Moreover, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondent's replies to those findings.

1. Dr. Addanki improperly relies on marketing documents rather than economic analysis

928. Dr. Addanki's conclusion that Opana ER is in the same market as other LAOs is based on the fact that Endo's business documents indicate they viewed other LAOs as competitors to Opana ER, and that Purdue viewed Opana ER as a competitor to OxyContin. (RX-547 at 0035-38, 0041-47 (¶¶ 67-71, 78-84) (Addanki Report)). Yet this is consistent with what would be observed if oxymorphone ER was a distinct market—even monopolists face some competition from products outside the monopoly. (CX5004 at 037 (¶ 76) (Noll Rebuttal Report)).

RESPONSE TO FINDING NO. 928:

Complaint Counsel's Proposed Finding No. 928 is an inaccurate and misleading characterization of the documents cited and Dr. Addanki's opinions regarding those documents. Contrary to Complaint Counsel's suggestion, Dr. Addanki's evaluation of ordinary course business documents reflecting Endo's and other long-acting opioid makers' perceptions of competition is just *one* part of his relevant market analysis, which shows that Opana ER competed in a long-acting opioid market. (*See* RX-547.0031-50 (Addanki Rep. ¶¶ 60-92)). Drug makers' recognition that long-acting opioids competed in the same relevant market is borne out by evidence showing that long-acting opioids are reasonably interchangeable for the treatment of chronic pain; that long-acting opioids competed on the basis of price at the payor, patient, and prescriber levels; that long-acting opioids are economic substitutes; and that changes in relative price (particularly as reflected in formulary changes) induce switching among long-

acting opioids. (RX-547.0031-50 (Addanki Rep. ¶¶ 60-92); RX-087; RX-549.0007 (Michna Rep. ¶ 23)). Proposed Finding No. 928 ignores this body of evidence, which refutes the assertion that "oxymorphone ER was a distinct market."

> 929. The decisive question is whether generic oxymorphone ER creates a stronger competitive constraint on branded Opana ER than other LAOs. (CX5000 at 082-83 (¶¶ 180-83) (Noll Report)). The evidence discussed above in Section VIII.D demonstrates that generic oxymorphone ER is indeed a much closer substitute to Opana ER than other LAOs are. (*See* CCF ¶¶ 579-740, above). The fact that in Endo's view it competed with other drugs is not evidence that those other drugs are in the same relevant antitrust market to assess the conduct at issue in this case—rather it is evidence those other drugs are functional substitutes to the product Endo held a monopoly over. (*See* CX5004 at 034, 036-377 (¶¶ 68, 74-76) (Noll Rebuttal Report)).

RESPONSE TO FINDING NO. 929:

Complaint Counsel's Proposed Finding No. 929 is incomplete and inaccurate. The first sentence is inaccurate. Whether "generic oxymorphone ER creates a stronger constraint on branded Opana ER than other LAOs" is irrelevant to the question of relevant market and monopoly power, because other long-acting opioids can—and did—constrain Opana ER, even if they were not the closest substitutes imaginable. [redacted] (CX5000-219 (Noll Rep., Ex. 7A) (denoted by the red line in Response to Proposed Finding No. 873); *see* RX-547.0053-54 (Addanki Rep. ¶ 101(b))). The fact that output did not increase after Impax launched generic oxymorphone ER further shows that Endo was constrained by other long-acting opioids and did not possess monopoly power. (*See* RX-547.0051 (Addanki Rep. ¶¶ 95-96)).

The second sentence of Proposed Finding No. 929 should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Moreover, the individual findings in the cited paragraphs do not support the proposed summary finding and are unreliable, misleading, and/or inconsistent with the record for the reasons set out in Respondent's replies to those findings.

The third sentence of Proposed Finding No. 929 is inconsistent with record evidence establishing that Endo's and other market participants' perception of market realities were accurate. (Addanki, Tr. 2265-67; RX-547.0031-50 (Addanki Rep. ¶¶ 60-92)).

930. By concluding that other LAOs are in the same market as Opana ER based on the fact that Endo's executives viewed Opana ER as facing competition from other LAOs, Dr. Addanki committed the "cellophane fallacy." (CX5004 at 037 (¶ 76) (Noll Rebuttal Report)).

RESPONSE TO FINDING NO. 930:

Complaint Counsel's Proposed Finding No. 930 is inaccurate, misleading, and based on unreliable expert testimony. To begin with, it is simply not true that Dr. Addanki's relevant market conclusions are based entirely on "the fact that Endo's executives viewed Opana ER as facing competition from other LAOs." Dr. Addanki's evaluation of ordinary course business documents reflecting Endo's and other long-acting opioid makers' perceptions of competition is just *one* part of his relevant market analysis, which shows that Opana ER competed in a long-acting opioid market. (*See* RX-547.0031-50 (Addanki Rep. ¶¶ 60-92)). Drug makers' recognition that long-acting opioids competed in the same relevant market is borne out by evidence showing that long-acting opioids are reasonably interchangeable for the treatment of chronic pain; that long-acting opioids competed on the basis of price at the payor, patient, and

prescriber levels; that long-acting opioids are economic substitutes; and that changes in relative price (particularly as reflected in formulary changes) induce switching among long-acting opioids. (RX-547.0031-50 (Addanki Rep. ¶¶ 60-92); RX-087; RX-549.0007 (Michna Rep. ¶ 23)). Proposed Finding No. 930 ignores this body of evidence, which refutes the assertion that oxymorphone ER was a market unto itself.

Complaint Counsel's invocation of the so-called "cellophane fallacy" is unfounded. As Dr. Addanki explained in his report, to "appeal to the fallacy to refute evidence of substitutability is unavailing because it would prove too much; one would never be able to distinguish suppliers that possess monopoly power from those that do not. If one dismissed all evidence of the availability of substitutes on the grounds that a monopolist will set its price sufficiently high for poor substitutes to become attractive one would never be able to establish a relevant market larger than a single product in any industry." (RX-547.0057 (Addanki Rep. ¶ 107 n.182); *see also* Noll, Tr. 1402 (conceding that the concept of the "cellophane fallacy" is derived from a "not very popular anymore Supreme Court case")).

While Professor Noll attacks Dr. Addanki's "strongly worded" explanation for why the cellophane fallacy does not apply here, he notably offers *no affirmative evidence* supporting his claim that the significant competitive interactions identified by Dr. Addanki are an instance of the fallacy. (*See* CX5004-034-37 (Noll Rebuttal Rep. ¶¶ 68-76)). The cellophane fallacy may be a convenient response for dismissing real-world evidence of economic substitution, such as the UPMC study, (Addanki, Tr. 2302-09; *see* CX4039 (Noll, Dep. at 187-88)), but neither the proposed finding of fact, nor the opinions of Professor Noll on which it relies, offers any record evidence to support the naked assertion that the fallacy applies here. The proposed finding also ignores the *Horizontal Merger Guidelines*, which state that evidence of "how customers have

shifted purchases in the past in response to relative changes in price or other terms and conditions" is probative of market definition. U.S. Dep't of Justice & Fed. Trade Comm'n, *Horizontal Merger Guidelines* § 4.1.3 (2010).

> 931. The "cellophane fallacy" describes an error of interpretation in which one concludes that competitive interactions at current prices indicate that a product is sold in a competitive market. (Noll, Tr. 1401-02; CX5004 at 034 (¶ 68) (Noll Rebuttal Report)). A monopolist will raise its price to the point at which further price increases are unprofitable because too many customers would switch away from the monopolized product to another functional substitute. (CX5004 at 034 (¶ 68) (Noll Rebuttal Report)). The managers of the monopoly will perceive the other products as imposing a constraint. (CX5004 at 034 (¶ 68) (Noll Rebuttal Report)). But the fact that managers of a product view another product as competing with their own does not mean the other products are in the same relevant product market. (CX5004 at 034 (¶ 68) (Noll Rebuttal Report)). If the price of a particular product is already elevated due to the presence of market power, then products which are outside a properly-defined relevant product market will become economic substitutes. (CX5004 at 036 (¶ 74) (Noll Rebuttal Report)).
>
> **RESPONSE TO FINDING NO. 931:**

Complaint Counsel's Proposed Finding No. 931 is an improper legal conclusion that is based on unreliable expert testimony and should be disregarded. The case purportedly described in Complaint Counsel's Proposed Finding No. 932 is *United States v. E.I. DuPont de Nemours & Co.,* 351 U.S. 377 (1956), and its contents speak for itself. Indeed, Professor Noll, in his direct testimony, conceded that the cellophane case that gave rise to the concept of the "cellophane fallacy" is derived from a "not very popular anymore Supreme Court case." (Noll, Tr. 1402). Further, as explained by Dr. Addanki, "in order for the cellophane fallacy to apply [in this case,] one would need to conclude that each manufacturer is a monopolist that does not compete with the others in any meaningful way even though all sell pharmaceuticals to treat the same illness, the drugs are good therapeutic substitutes, and there is substantial real world evidence of competition among the manufacturers." (RX-547.0057 (Addanki Rep. ¶ 107 n.182)).

While Professor Noll attacks Dr. Addanki's "strongly worded" explanation for why the cellophane fallacy does not apply here, he notably offers *no affirmative evidence* supporting his claim that the significant competitive interactions identified by Dr. Addanki are an instance of the fallacy. (*See* CX5004-034-37 (Noll Rebuttal Rep. ¶¶ 68-76)). The cellophane fallacy may be a convenient response for dismissing real-world evidence of economic substitution, such as the UPMC study, (Addanki, Tr. 2302-09; *see* CX4039 (Noll, Dep. at 187-88)), but neither the proposed finding of fact, nor the opinions of Professor Noll on which it relies, offers any record evidence to support the naked assertion that the fallacy applies here. The proposed finding also ignores the *Horizontal Merger Guidelines*, which state that evidence of "how customers have shifted purchases in the past in response to relative changes in price or other terms and conditions" is probative of market definition. U.S. Dep't of Justice & Fed. Trade Comm'n, *Horizontal Merger Guidelines* § 4.1.3 (2010).

> 932. In the cellophane case, the question was whether DuPont enjoyed monopoly power in the sale of cellophane, of which it was one of only two suppliers. (CX5004 at 034-35 (¶ 70) (Noll Rebuttal Report)). Cellophane, along with other products (vegetable parchment, greaseproof paper, glassine, wax paper, and aluminum foil) were all used for the same functional purpose—wrapping food. (CX5004 at 034-35 (¶ 70) (Noll Rebuttal Report)). The fact that other products were functional substitutes, and even economic substitutes at monopoly prices, did not tell us they were economic substitutes at *competitive* prices, or that they were within the relevant product market. (CX5004 at 034-37 (¶¶ 70, 74) (Noll Rebuttal Report)).

RESPONSE TO FINDING NO. 932:

Complaint Counsel's Proposed Finding No. 932 is an improper legal conclusion and should be disregarded. The case purportedly described in Complaint Counsel's Proposed Finding No. 932 is *United States v. E.I. DuPont de Nemours & Co.,* 351 U.S. 377 (1956), and its contents speak for itself. Indeed, Professor Noll in his direct testimony conceded that the

concept of the "cellophane fallacy" is derived from a "not very popular anymore Supreme Court case." (Noll, Tr. 1402).

> 933. When priced at a monopoly level, a product will face competition from other products. (CX5004 at 037 (¶ 76) (Noll Rebuttal Report)). Assuming that that competition demonstrates all of the products are in the same relevant market is the commission of the cellophane fallacy. (CX5004 at 037 (¶ 76) (Noll Rebuttal Report)). Dr. Addanki committed the cellophane fallacy.

RESPONSE TO FINDING NO. 933:

Complaint Counsel's Proposed Finding No. 933 is inconsistent with the record and based on unreliable expert testimony to the extent it suggests the cellophane fallacy is present in Dr. Addanki's analysis. Neither Professor Noll nor Proposed Finding No. 933 cites any evidence that Opana ER was "priced at a monopoly level." This is a predicate to the cellophane fallacy, as Proposed Finding No. 933 recognizes. Therefore, without a showing of monopoly-level pricing, any assertion that an analysis involves the cellophane fallacy is without merit.

Indeed, the record is inconsistent with Proposed Finding No. 933's unsupported implication that Opana ER was priced at a monopoly level. The record shows that [redacted] (CX5000-219 (Noll Rep., Ex. 7A) (pictured by the red line in Response to Proposed Finding No. 873)).

Further, as explained by Dr. Addanki, "in order for the cellophane fallacy to apply [in this case,] one would need to conclude that each manufacturer is a monopolist that does not compete with the others in any meaningful way even though all sell pharmaceuticals to treat the same illness, the drugs are good therapeutic substitutes, and there is substantial real world evidence of competition among the manufacturers." (RX-547.0057 (Addanki Rep. ¶ 107 n.182)).

While Professor Noll attacks Dr. Addanki's "strongly worded" explanation for why the cellophane fallacy does not apply here, he notably offers *no affirmative evidence* supporting his claim that the significant competitive interactions identified by Dr. Addanki are an instance of the fallacy. (*See* CX5004-034-37 (Noll Rebuttal Rep. ¶¶ 68-76)). The cellophane fallacy may be a convenient response for dismissing real-world evidence of economic substitution, such as the UPMC study, (Addanki, Tr. 2302-09; *see* CX4039 (Noll, Dep. at 187-88)), but neither the proposed finding of fact, nor the opinions of Professor Noll on which it relies, offers any record evidence to support the naked assertion that the fallacy applies here. The proposed finding also ignores the *Horizontal Merger Guidelines*, which state that evidence of "how customers have shifted purchases in the past in response to relative changes in price or other terms and conditions" is probative of market definition. U.S. Dep't of Justice & Fed. Trade Comm'n, *Horizontal Merger Guidelines* § 4.1.3 (2010).

2. Dr. Addanki ignores economic evidence that other LAOs present a weaker competitive constraint on Opana ER than generic oxymorphone ER

934. As explained in Section X.B above, Dr. Addanki ignored the evidence of competition between generic oxymorphone ER and Opana ER and focused exclusively on documents which he purports show competition between Opana ER and other LAOs. (RX-547 at 0035-38, 0041-47 (¶¶ 67-71, 78-84) (Addanki Report)).

RESPONSE TO FINDING NO. 934:

Complaint Counsel's Proposed Finding No. 934 should be disregarded to the extent it attempts to incorporate the explanation contained in Section X.B. of Complaint Counsel's proposed findings because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Moreover, the individual findings in the cited section

do not support the proposed summary finding, are unreliable, misleading, and inconsistent with record evidence for the reasons set out in Respondent's replies to those findings.

Complaint Counsel's Proposed Finding No. 934 also mischaracterizes Dr. Addanki's analysis. Dr. Addanki addressed competition between oxymorphone ER and Opana ER. (*See, e.g.,* Addanki, Tr. 2313-14 (addressing pricing of Opana ER after Impax's entry)). Indeed, Dr. Addanki concluded that both branded and generic Opana ER belonged in the relevant market—along with other long-acting opioids. (RX-547.0047, 0133 (Addanki Rep. ¶ 85; Ex. 11); Addanki, Tr. 2328). Moreover, the assertion that Dr. Addanki "focused exclusively on documents which he purports show competition between Opana ER and other LAOs" is utterly false. In addition to evaluating reams of ordinary course business documents—which are, in fact, highly probative of the relevant market—Dr. Addanki (1) analyzed clinical guidelines from the FDA and World Health Organization; (2) evaluated FDA and DEA regulations governing the distribution of long-acting opioids; (3) empirically analyzed the extent to which long-acting opioids are used interchangeably for treatment of the 100 most common pain diagnoses; (4) demonstrated the existence of robust economic competition among long-acting opioids at the payor, patient, and prescriber levels; (5) empirically evaluated long-acting opioids' placement on commercial and Medicare formularies, both as of June 2010 and over time; (6) demonstrated that output did not expand when Impax launched generic oxymorphone ER, negating the assertion that Endo was exercising monopoly power; and (7) rebutted Professor Noll's opinions about the relevant market and monopoly power. (*See* RX-547.0018-57 (Addanki Rep. ¶¶ 29-107)). The proposed finding simply ignores this.

> 935. The fact that Endo competed with other LAOs for sales of Opana ER is not, by itself, evidence they are economic substitutes. (CX5004 at 034, 036-37 (¶¶ 68, 74, 76) (Noll Rebuttal Report); *see also* Addanki, Tr. 2468). The key question is whether generic oxymorphone ER presented a greater competitive constraint on branded Opana ER than

other LAOs. The evidence discussed in Section X.B above shows that Opana ER faced stronger competition from generic oxymorphone ER than it did other LAOs. Once released, generic oxymorphone ER took approximately half of Opana ER's share. (Noll, Tr. 1380-81; CX5000 at 056, 177-83 (¶ 122, Exhibits 2A1 through 2A7) (Noll Report) CX5004 at 014 (¶ 25) (Noll Rebuttal Report)). The presence of generics also substantially lowered the average price of oxymorphone ER. (Noll, Tr. 1380-81; CX5000 at 056, 184-90, 219-26 (¶ 122, Exhibits 2B1-2B7, 7A, 7B1-7B7) (Noll Report); CX5004 at 014-15 (¶¶ 25-26) (Noll Rebuttal Report)). No other LAOs had this dramatic effect on Opana ER's market share or price. (*See* CCF ¶¶ 654-740, above). Indeed, despite the fact that multiple branded and generic versions of other LAOs launched between 2006 and 2011, Opana ER grew its sales and maintained its price. (CX5000 at 177-83, 219-226 (Exhibits 2A1 through 2A7, 7A, 7B1-7B7) (Noll Report)). All of this evidence shows that generic oxymorphone ER was a more potent competitive constraint on Opana ER than other LAOs, yet Dr. Addanki ignored it. (CX5004 at 011 (¶ 20) (Noll Rebuttal Report) (noting Dr. Addanki did not attempt to analyze "the *only* issue that is relevant to market definition, which is to determine which products constrain the price of a reference product")).

RESPONSE TO FINDING NO. 935:

Complaint Counsel's Proposed Finding No. 935 is inconsistent with record evidence, based on unreliable expert testimony, and offers a misleading characterization of the applicable economic analysis. Proposed Finding No. 935 should be disregarded to the extent it attempts to incorporate Section X.B. and Paragraphs 654-740 of Complaint Counsel's proposed findings because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Moreover, the individual findings in the cited section and paragraphs do not support the proposed summary finding, are unreliable, misleading, and inconsistent with record evidence for the reasons set out in Respondent's replies to those findings.

The assertion in Proposed Finding No. 935 that "the key question is whether generic oxymorphone ER presented a greater competitive constraint on branded Opana ER than other LAOs" is inaccurate. Whether "generic oxymorphone ER presented a greater competitive constraint on branded Opana ER than other LAOs" is irrelevant to the question of relevant market and monopoly power, because other long-acting opioids can—and did—constrain Opana

ER, even if they were not the closest substitutes imaginable. [redacted] (CX5000-219 (Noll Rep., Ex. 7A) (denoted by the red line in Response to Proposed Finding No. 873); *see* RX-547.0053-54 (Addanki Rep. ¶ 101(b))). The fact that output did not increase after Impax launched generic oxymorphone ER further shows that Endo was constrained by other long-acting opioids and did not possess monopoly power.

With respect to the purported effects of Impax's generic entry on Opana ER sales and price, the fact that generic oxymorphone ER "took approximately half of Opana ER's share" is merely a function of certain industry features, namely the use of formularies. As Dr. Addanki explained, insurers use formularies to drive volume to particular drugs over others. (Addanki, Tr. 2219-20, 2225-27, 2231-33). Frequently, when a generic version of a particular drug becomes available, insurers will place that generic drug in a preferred tier and de-preference the corresponding brand-name drug. (Addanki, Tr. 2313-15; *see also* CX3273-008 (Bingol Decl. ¶ 18) ("It is likely that Impax's product will be immediately positioned on Tier 2 or Tier 1 status.")). Complaint Counsel also fails to appreciate that Impax *specifically marketed* its generic oxymorphone ER product to prescribers of Opana ER in an effort to drive substitution between the products. (RX-547.0037 (Addanki Rep. ¶ 69)). While these facts—the use of formularies and Impax's marketing efforts—may help to explain the particular competitive dynamic between Opana ER and generic oxymorphone ER, they do not preclude price-based

competition (or cross-elasticity of demand) across a wider universe of long-acting opioids. (*See* RX-547.0022-47 (Addanki Rep. ¶¶ 41-84)).

Finally, Complaint Counsel's assertions in Proposed Finding No. 935 about the purported effects of generic long-acting opioids entries on Opana ER sales are misleading and based on unreliable expert testimony. At no point did Professor Noll conduct any quantitative or statistical analysis of long-acting opioid sales. (Addanki, Tr. 2331). As Professor Noll admitted at trial, he did not try to calculate the cross-elasticity of demand between Opana ER and any other long-acting opioid product, nor did he conduct a SSNIP test. (Noll, Tr. 1514, 1517). He testified that he merely scanned Opana ER sales trends for any "visible effect," a metric that he never bothered to define. (Noll, Tr. 1384).

And while the "average price of oxymorphone ER" (i.e., the average price of branded Opana ER and generic oxymorphone ER) dropped when Impax launched its generic product, the entry of generic oxymorphone ER did not force Endo to reduce the price of branded Opana ER. [redacted] (*See* CX5000-219 (Noll Rep., Ex. 7A) (pictured by the red line in Response to Proposed Finding No. 873)). [redacted] (CX5000-219 (Noll Rep., Ex. 7A) (pictured by the red line in Response to Proposed Finding No. 873); Addanki, Tr. 2290; Noll, Tr. 1679-82; RX-547.053 (Addanki Rep. ¶ 101(b), Ex. 13); *see also* RX-547.133 (Addanki Rep., Ex. 11) (noting that generic MS Contin, generic Duragesic, and generic Kadian were available during 2008-2012 time period)). Neither Professor Noll nor any other record source offers any explanation for [redacted]

[redacted]

936. Moreover, the very same documents containing Endo's references to competition from other LAOs illustrate the fact that Endo used those terms in a general business sense, rather than in an economic sense. (*See* CCF ¶¶ 937-939, below).

RESPONSE TO FINDING NO. 936:

Complaint Counsel's Proposed Finding No. 936 should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Moreover, the individual findings in the cited paragraphs do not support the proposed summary finding and are unreliable, misleading, and inconsistent with record evidence for the reasons set out in Respondent's replies to those findings.

937. For instance, the Lortie declaration, discussed above, describes Endo as selling Opana ER in the LAO "market segment," which he characterizes as "highly competitive." (CX2607 at 004 (¶ 10) (Lortie Decl.)). In the same declaration, Mr. Lortie stated that if more oxymorphone ER generics enter, Endo's Opana ER market will be "rapidly and irreversibly devastated." (CX2607 at 012 (¶ 29) (Lortie Decl.)). Endo estimated that, if more generics entered the market, then Endo would lose market share (about 50% after one year) and the average price of oxymorphone ER would be driven down (eventually to a 90% discount if enough generics enter). (CX2607 at 012, 014-15 (¶¶ 29, 32, 34) (Lortie Decl.)). That effect would not occur if other LAOs were close economic substitutes for Opana ER. (CX5000 at 082 (¶ 182) (Noll Report)).

RESPONSE TO FINDING NO. 937:

Complaint Counsel's Proposed Finding No. 937 is misleading and inaccurate to the extent it implies Mr. Lortie's statements about the potential effects of generic entry undermine or contradict his clear testimony that "OPANA ER is sold into a market segment referred to as the long-acting opioid ('LAO') segment, which comprises controlled release opioid products. The LAO segment consists of several oral tablet products and a patch product. At the time of launch

of OPANA ER Original Formulation, the LAO segment was well-established, highly competitive, and consisted of many products that had been on the market for years, such as OxyContin." (CX2607-004 (Lortie Decl. ¶ 10)).

Mr. Lortie's prediction that the entrance of multiple generics of oxymorphone ER would diminish Opana ER's market share must be understood in context: insurance companies generally elevate generic drugs over their corresponding brand alternatives on their formularies, pushing customers to the generic product and amplifying the effects of generic entry as compared to entry of a competing branded product. (Addanki, Tr. 2313-14; *see also* (CX3273-008 (Bingol Decl. ¶ 18) ("It is likely that Impax's product will be immediately positioned on Tier 2 or Tier 1 status.")).

Finally, the third sentences of Proposed Finding No. 937 cites a forward looking forecast that has not proven accurate; as Professor Noll explained, it "took several years" for sales of branded Opana ER to fall by nearly half after Impax began marketing its generic oxymorphone ER product (Noll, Tr. 1380), and this occurred only after Impax embarked on a sustained marketing campaign targeting Opana ER prescribers. (RX-294).

938. Mr. Lortie's declaration also notes that Opana ER grew rapidly, from $5 million in sales in 2006 to $384 million in sales in 2011, and was a "commercial success for Endo." (CX2607 at 004-05 (¶ 13) (Lortie Decl.)). If it were true that other LAOs, branded and generic, were close economic substitutes to Opana ER, then that very rapid growth over so many years would not have been possible. (*See, e.g.*, CX5000 at 076-78 (¶¶ 166, 169) (Noll Report) (the fact that Opana ER was able to grow despite the presence of other LAOs is evidence the other LAOs are not close substitutes)).

RESPONSE TO FINDING NO. 938:

Complaint Counsel's Proposed Finding No. 938 is inaccurate and misleading. The record does not support that the growth in Opana ER sales referenced in Proposed Finding No. 938 signals that other long-acting opioids were not economic substitutes for Opana ER. Indeed,

internal Endo documents indicate that Endo grew its market share in the LAO market because it was successful in *competing against other long-acting opioids*. (*See* RX-547.0041 (Addanki Rep. ¶ 78)). For example, in 2011, Endo offered a [redacted] (RX-547.0041 (Addanki Rep. ¶ 78); Addanki, Tr. 2294-98). As Professor Noll's own report shows, [redacted] (CX5000-219 (Noll Rep., Ex. 7A) (pictured by the red line in Response to Proposed Finding No. 873); Addanki, Tr. 2290; Noll, Tr. 1679-82; RX-547.053 (Addanki Rep. ¶ 101(b), Ex. 13); *see also* RX-547.133 (Addanki Rep., Ex. 11) (noting that generic MS Contin, generic Duragesic, and generic Kadian were available during 2008-2012 time period)). That Endo offered priced reductions to secure a very small market share of 3.4 percent (Bingol, Tr. 1316) to the exclusion of other long-acting opioids is the very definition of competition.

Moreover, Complaint Counsel's assertion in Proposed Finding No. 938 that Opana ER's "very rapid growth over so many years would not have been possible" if "[o]ther LAOs, branded and generic, were close economic substitutes to Opana ER" is unsupported. The cited paragraphs in Professor Noll's report say *nothing* of the sort. (*See* CX5000-076-78 (Noll Rep. ¶¶ 166, 169)). That Endo was successful in accruing a small share of the long-acting opioid market between 2006 and 2011, despite the presence of significant competition, does not make Endo a monopolist.

939. In a similar vein, Mr. Demir Bingol of Endo filed a declaration in Endo's infringement suit against Impax, also discussed above. (CX3273 at 001 (¶ 1) (Bingol Decl.)). Mr. Bingol also described Opana ER as being sold in the LAO "market segment." (CX3273 at 003 (¶ 6) (Bingol Decl.)). But in the same declaration, Mr. Bingol described that Endo grew Opana ER sales despite the launch of other heavily-promoted LAOs, Embeda and Exalgo. (CX3273 at 004 (¶ 8) (Bingol Decl.)). The fact that the launch of other, heavily-promoted, LAOs did not prevent Opana ER's growth (while Opana ER's promotions were being cut back) shows they are not as close substitutes as generic oxymorphone ER. (*See, e.g.*, CX5000 at 076-78 (¶¶ 166, 169) (Noll Report) (the fact that Opana ER was able to grow despite the presence of other LAOs is evidence the other LAOs are not close substitutes)). On the other hand, Mr. Bingol stated that if Impax launched AB-rated generic oxymorphone ER, it would drive down price by about 15 to 20% and take 80% of Endo's market share. (CX3273 at 008 (¶ 18) (Bingol Decl.)).

RESPONSE TO FINDING NO. 939:

Complaint Counsel's Proposed Finding No. 939 is incomplete and inaccurate.

Respondent has no specific response to the first three sentences of Proposed Finding No. 939, except to state that Mr. Bingol's declaration speaks for itself.

But the conclusions reached in the fourth and fifth sentences of Proposed Finding No. 939 are incorrect. Internal Endo documents indicate that Endo grew its market share in the long-acting opioid market because it was *successful in competing against other long-acting opioids*. (*See* RX-547.0041 (Addanki Rep. ¶ 78)). For example, in 2011 Endo [redacted] (RX-547.0041 (Addanki Rep. ¶ 78); Addanki, Tr. 2294-98). As Professor Noll's own report shows, [redacted] (CX5000-219 (Noll Rep., Ex. 7A) (pictured by the red line in Response to Proposed Finding No. 873); Addanki, Tr. 2290; Noll, Tr. 1679-82;

RX-547.053 (Addanki Rep. ¶ 101(b), Ex. 13); *see also* RX-547.133 (Addanki Rep., Ex. 11) (noting that generic MS Contin, generic Duragesic, and generic Kadian were available during 2008-2012 time period)). That Endo offered priced reductions to secure a very small market share of 3.4 percent (Bingol, Tr. 1316) to the exclusion of other long-acting opioids is the very definition of competition.

Moreover, Complaint Counsel's assertion in Proposed Finding No. 939 that the purported fact that "the launch of other, heavily-promoted, LAOs did not prevent Opana ER's growth (while Opana ER's promotions were being cut back) shows they are not as close substitutes as generic oxymorphone ER" is unsupported. The cited paragraphs in Professor Noll's report say *nothing* of the sort—and in fact do not even *mention* anything about Opana ER's promotions supposedly being "cut back." (*See* CX5000-076-78 (Noll Rep. ¶¶ 166, 169)). That Endo was successful in accruing a small share of the long-acting opioid market between 2006 and 2011, despite the presence of significant competition, does not make Endo a monopolist.

F. Dr. Addanki incorrectly concludes that the evidence of promotional activity indicates that Endo views other LAOs as close substitutes

940. Dr. Addanki concludes that Endo viewed other LAOs as competitors because it engaged in promotional activities to compete with other LAOs for physician prescriptions. (RX-547 at 0035-38, 0041-47 (¶¶ 67-71, 78-84) (Addanki Report)). A purpose of such promotional activities of drugs like Opana ER is to convince prescribing physicians of Opana ER's superiority by promoting "the intrinsic qualities of oxymorphone as a molecule that might have had – that might have meaningful importance to clinicians or patients." (Bingol, Tr. 1265, 1270).

RESPONSE TO FINDING NO. 940:

Complaint Counsel's Proposed Finding No. 940 is incomplete and misleading. Dr. Addanki's conclusion that "Endo viewed other LAOs as competitors" does *not* rest on the mere fact that Endo "engaged in promotional activities to compete with other LAOs for physician prescriptions." In documents cited in Dr. Addanki's report, Endo recognized the existence of an

"LAO market," with several "direct competitors" to Opana ER, *independent* of discussions about "promotional activities." (*See, e.g.*, RX-114 (Slides 23-25) (partially *in camera*); RX-078 (Slide 21); RX-083.0003 (Slides 24-25, 34-35, 65); RX-073.0002 (Slides 3-4); *see also* RX-547.0043-47 (Addanki Rep. ¶¶ 80-84)). Many documents expressly address price competition and economic substitution among long-acting opioids. For instance, in an April 9, 2013 "Business Review" for Opana ER, Endo compared Opana ER's formulary coverage and pricing to that of OxyContin and Nucynta ER. (RX-073.0002 (Slides 8, 72)). Endo indicated that it sought to draw share from competitors through "Pricing and Contracting Effectiveness," citing the "UPMC model" as an example by which Endo was able to "block Oxycontin®." (RX-073.0002 (Slide 30)). Indeed, Endo reported that the "Advantaged Formulary Status vs. OxyContin®" showed the "greatest" shifts in market share from OxyContin to Opana ER. (RX-073.0002 (Slide 33)).

Proposed Finding No. 940 also fails to note that Endo's promotional activities did not *solely* aim to highlight Opana ER's unique qualities. Recognizing that prescribers saw Opana ER's lack of formulary coverage as its "most negative aspect" (CX1106-009), Endo made a point of informing prescribers of "OPANA ER formulary access" in its promotional messages (RX-16.0002 (Slide 97)). [redacted] (RX-445.0021-22).

941. Promotional activities focused on product differentiation create and reinforce brand loyalty to particular products. (CX5000 at 087 (¶ 195) (Noll Report)). By doing so, product differentiation tends to make it less likely that a consumer will switch from one product to another based on small price changes. (Noll, Tr. 1402-03; CX5004 at 027 (¶ 53) (Noll Rebuttal Report)). This differentiation creates a barrier to entry which undermines, rather than enhances, price competition. (Noll, Tr. 1402-03; CX5004 at 027 (¶ 53) (Noll Rebuttal Report)). This undermining of price competition also, in turn, undermines the likelihood that two products are in the same relevant product market. (Noll, Tr. 1402-03; CX5004 at 027 (¶ 53) (Noll Rebuttal Report)).

RESPONSE TO FINDING NO. 941:

Complaint Counsel's Proposed Finding No. 941 is incomplete and misleading. Complaint Counsel fails to appreciate that Endo's perceived need to differentiate Opana ER was driven by the reality that long-acting opioids "*are not very differentiated*." (RX-023.0002) (Endo internal business document) (emphasis added)). Unlike Professor Noll, Dr. Addanki recognized this in his analysis: "Pharmaceutical firms often engage in efforts to differentiate their branded product from therapeutic alternatives. *Those efforts are often particularly pronounced where the firm's product is therapeutically very similar to the available alternatives*." (RX-547.0026 (Addanki Rep. ¶ 49) (emphasis added)). Documents describing these efforts nonetheless "provide useful insights into the set of alternatives viewed by the pharmaceutical firm as being the 'competitive set,'" which can be a "good starting point for a candidate relevant market." (RX-547.0026 (Addanki Rep. ¶ 49)). Dr. Addanki then confirmed that the "competitive set" of long-acting opioids identified in Endo's and other long-acting opioid makers' documents in fact competed on price and constituted a relevant market. (RX-547.0031-50 (Addanki Rep. ¶¶ 60-92)).

More generally, Complaint Counsel's assertion that attempts to encourage switching from a competing product to Opana ER indicates a lack of competition fails the sniff test. Complaint Counsel offers no reason for why Endo would expend significant amounts of money to differentiate Opana ER from other long-acting opioids if patients would not or could not switch from one long-acting opioid to another or from Opana ER to a competing long-acting opioid.

942. Dr. Addanki cites as evidence of interdrug competition some incomplete references to discounts offered by [redacted] to consumers to cover their co-payments for [redacted], respectively. (Addanki, Tr. 2237-38, 2281-82) (*in camera*). However, Dr. Addanki provides no information about the size of

these programs or whether or to what extent these programs affected either average net prices or sales of [redacted]. (CX5004 at 033 (¶ 66) (Noll Rebuttal Report)) (*in camera*). The extent to which these programs actually represented any price competition between [redacted] would depend on how widespread the programs were and what actual effect they had on average net prices. (CX5004 at 033 (¶ 66) (Noll Rebuttal Report)) (*in camera*). Without such information, it is impossible to conclude that these programs demonstrate significant price competition between [redacted]. (CX5004 at 033 (¶ 66) (Noll Rebuttal Report)) (*in camera*).

RESPONSE TO FINDING NO. 942:

Complaint Counsel's Proposed Finding No. 942 is inaccurate, incomplete, and misleading. Contrary to Complaint Counsel's assertions, Dr. Addanki provided extensive information regarding the scope and significance of the programs in question. For example, Dr. Addanki noted that [redacted] (RX-547.0043 (Addanki Rep. ¶ 79) (emphasis added)). Indeed, Mr. Bingol of Endo confirmed that offering coupons directly to consumers is a competitive strategy in the long-acting opioid market. (Bingol, Tr. 1325-26). In 2008, Endo observed "[a]ggressive couponing from all direct competitors"; in response, Endo instituted an "Instant Savings Card" that subsidized patients' copayments by $25 per redemption. (RX-028.0011). Between 2009 and mid-2010, Endo offset a portion of nearly *90,000 prescriptions* for Opana ER through its couponing program. (RX-066.0003). In 2011, [redacted] (RX-123.0006; Addanki, Tr. 2285).

Complaint Counsel suggests that these programs do not constitute evidence of "price competition" among long-acting opioids unless we know the precise "effect they had on average net prices." But as a logical and mathematical necessity, reducing the price of *tens of thousands*

of Opana ER prescriptions inherently reduces the "average net price" of Opana ER. And as Professor Noll's own report acknowledges, [redacted] (CX5000-219 (Noll Rep., Ex. 7A) (denoted by the red line in Response to Proposed Finding No. 873); *see* RX-547.0053-54 (Addanki Rep. ¶ 101(b))).

Moreover, Proposed Finding No. 942 fails to account for the fact that, as Dr. Addanki testified at trial, we simply *do not* see this kind of competition at the patient level with respect to products that lack economic competition. (Addanki, Tr. 2236-37).

G. Dr. Addanki incorrectly concluded that evidence relating to formulary placement indicates that LAOs are in the same market

943. Exhibits 7, 8, and 9 of the Addanki Report indicate that LAOs are rarely placed on the same formulary tier and that the placements of the various LAOs on formularies vary across insurance plans. (RX-547 at 0039-40 (¶¶ 74-76) (Addanki Report)). Based on this, Dr. Addanki concludes that differences in formulary placement "were more likely to have been based on economic factors rather than on clinical ones." (RX-547 at 0039 (¶ 74) (Addanki Report)). However, Dr. Addanki provides no evidence whatsoever that differences in relative placements on formularies actually reflect price competition. (Noll, Tr. 1397; CX5004 at 030-31 (¶¶ 59-61) (Noll Rebuttal Report)).

RESPONSE TO FINDING NO. 943:

The conclusion to Complaint Counsel's Proposed Finding No. 943 is inaccurate and misleading. Respondent does not have a specific response to the first two sentences of Proposed Finding No. 943, except to note that, as Dr. Addanki explained at trial, these findings are consistent with the existence of extensive price competition at the payor level. (RX-547.0038-40 (Addanki Rep. ¶¶ 72-76); Addanki, Tr. 2309-2328). As for the third sentence in Proposed Finding No. 943, it is simply not true that "Dr. Addanki provides no evidence whatsoever that

differences in relative placements on formularies actually reflect price competition." The "diversity of outcomes" and "variation and churn" that Dr. Addanki identified in long-acting opioids' formulary placement—both as of June 2010 and as measured over time—are consistent with manufacturers competing on price to secure favorable placement, with competitive bidding producing different "winners." (RX-547.0038-40 (Addanki Rep. ¶¶ 72-76); Addanki, Tr. 2309-2328). The fact that "different plans accorded preferential treatment to different [long-acting opioid] products" indicates that the differences in formulary placement were likely not due to therapeutic factors. (RX-547.0039 (Addanki Rep. ¶ 74)).

This inference is borne out by documentary and testimonial evidence showing that Endo competed on the basis of price to secure favorable formulary positioning for Opana ER. For example, in 2011 [redacted] (RX-547.0041 (Addanki Rep. ¶ 78); Addanki, Tr. 2294-98). And Mr. Bingol of Endo confirmed that competition for formulary placement was priced-based. (Bingol, Tr. 1324-25).

> 944. Dr. Addanki's formulary analysis is flawed for several reasons. First, Dr. Addanki admitted that he did no analysis to confirm that the formulary changes that occurred were a result of a small but significant nontransitory increase in price. (Addanki, Tr. 2477-78). Nor did Dr. Addanki undertake any analysis to determine what caused the insurance companies to change the formulary status of the particular drugs analyzed. (Addanki, Tr. 2478). Because he conceded that he did not analyze why particular formulary changes were made, there is no factual basis for his assertion that differences in formulary placement "were more likely to have been based on economic factors than on clinical ones." (RX-547 at 0039 (¶ 74) (Addanki Report)). For example, he provides no evidence that the differences in formulary placement he observes were not a function of the promotional activity that emphasized the differentiating features of the different LAOs. (*See* CCF ¶¶ 761-792, above).

RESPONSE TO FINDING NO. 944:

Complaint Counsel's Proposed Finding No. 944 is incomplete and misleading.

The first sentence is misleading given that Professor Noll himself asserted that there was insufficient data in this case to reliably calculate cross-elasticity, as required for a SSNIP test. (Noll, Tr. 1516-17; *see* CX5000-019 (Noll Rep. ¶ 42) ("Unfortunately, an econometric analysis of price behavior rarely is feasible because estimating each cross-elasticity of demand can be very difficult, and sometimes impossible.")). In any event, Complaint Counsel neglects to mention that Dr. Addanki *did* testify that Endo's change in pricing to Aetna—moving from a 30 percent discount to a 38 percent discount in order to retain favorable formulary placement—represented a SSNIP. (Addanki, Tr. 2476).

The second and third sentences to Proposed Finding No. 944 are also incomplete and inaccurate. The "diversity of outcomes" and "variation and churn" that Dr. Addanki identified in long-acting opioids' formulary placement—both as of June 2010 and as measured over time—are consistent with manufacturers competing on price to secure favorable placement, with competitive bidding producing different "winners." (RX-547.0038-40 (Addanki Rep. ¶¶ 72-76); Addanki, Tr. 2309-2328). The fact that "different plans accorded preferential treatment to different [long-acting opioid] products" indicates that the differences in formulary placement were likely not due to therapeutic factors. (RX-547.0039 (Addanki Rep. ¶ 74)). Indeed, the very idea of a formulary is founded on the idea that pricing drives *economic substitution*. As Dr. Addanki testified at trial, "if the insurers didn't think they could actually drive volume by adjusting their formularies, drive volume to a favored product versus a nonfavored product—and again I'm talking about the favoring being just the tiers of the formulary. It's not a question of

medical preference; it's a question of economic tiering—the insurers wouldn't bother if they didn't know they could actually drive volume." (Addanki, Tr. 2226).

This inference—that the "diversity of outcomes" and "churn" in long-acting opioids' formulary placement likely resulted from economic competition rather than some other factor—is borne out by documentary and testimonial evidence. (*See* RX-547.0038-41 (Addanki Rep. ¶¶ 72-78); Addanki, Tr. 2294-98; Bingol, Tr. 1324-25).

Finally, the individual findings in the last sentence of Proposed Finding No. 944 do not support the proposed summary finding and are unreliable for the reasons set out in Respondent's replies to those findings.

> 945. Dr. Addanki also does not present any analysis concerning what effect these changes in formulary positions had on the quantities of the particular drugs analyzed. (Addanki, Tr. 2479-80). As explained above, one can draw conclusions about whether products are close substitutes by examining what effect changes in price had on their output. (*See* CCF ¶¶ 544, 654-55, 898-99, above). Because Dr. Addanki does not factor in the quantity effects of these formulary changes, he cannot properly draw any conclusion about what those changes say about whether the products are close substitutes.

RESPONSE TO FINDING NO. 945:

Complaint Counsel's Proposed Finding No. 945 is incomplete, misleading, and based on unreliable expert testimony. The first sentence of Proposed Finding No. 945 misstates Dr. Addanki's testimony. Dr. Addanki testified at trial that he has seen "information on the changes of volumes associated with formulary changes." (Addanki, Tr. 2479-80). But more to the point, the very idea of a formulary is founded on the idea that pricing drives *economic substitution.* As Dr. Addanki testified at trial, "if the insurers didn't think they could actually drive volume by adjusting their formularies, drive volume to a favored product versus a nonfavored product—and again I'm talking about the favoring being just the tiers of the formulary. It's not a question of medical preference; it's a question of economic tiering—the insurers wouldn't bother if they

didn't know they could actually drive volume." (Addanki, Tr. 2226). That formulary changes can and *do* drive switching among long-acting opioids is borne out by the record. (*E.g.*, RX-087.)

The second sentence of Proposed Finding No. 945 should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). The individual paragraphs cited in the second sentence do not support the proposed summary finding and are unreliable for the reasons set out in Respondent's replies to those findings.

Finally, the third sentence of Proposed Finding No. 945 has no citation whatsoever and therefore violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). In any event, it is illogical and contrary to record fact to assert that a formulary substitution of one long-acting opioid for another does not indicate that they are economic substitutes. (*See* RX-547.0038-42 (Addanki Rep. ¶¶ 72-78); Addanki, Tr. 2225-33).

946. Second, Dr. Addanki's analysis systematically excludes generic drugs, which leads to a skewed conclusion. (CX4044 (Addanki, Dep. at 165-66); *see* CCF ¶¶ 910-11, above). Dr. Addanki testified that he ignored the impact of generics on formulary placement because "I know what's going to happen[,] [g]enerics are going to be on tier one uniformly or virtually uniformly." (Addanki, Tr. 2314-15). It is true that when an AB-rated generic version of a drug is released, it is moved to a favorable tier and the branded drug is moved to an unfavorable tier. (CX2607 at 015-16 (¶ 37) (Lortie Decl.); CX3273 at 008 (¶ 18) (Bingol Decl.)).

RESPONSE TO FINDING NO. 946:

Complaint Counsel's Proposed Finding No. 946 is incomplete and inaccurate. The first sentence of Proposed Finding No. 946 should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported

by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Moreover, the individual findings of the paragraphs cited in the first sentence do not support the proposed summary finding and are unreliable for the reasons set out in Respondent's replies to those findings. Further, Dr. Addanki's deposition testimony cited in the first sentence says nothing at all about a "skewed conclusion." (CX4044 (Addanki, Dep. at 165-66)).

The second and third sentences of Proposed Finding No. 946 are incomplete and misleading. In the cited portion of the transcript, Dr. Addanki was *specifically* discussing his analysis of formulary data obtained from MMIT, which was but *one part* of his relevant market analysis. (Addanki, Tr. 2310-28; *see* RX-547.0038-40 (Addanki Rep. ¶¶ 74-76)). As Dr. Addanki explained at trial, the purpose of this particular analysis was to assess the degree of competition among long-acting opioids for which an AB-rated generic was *not* available—i.e., LAOs on an "equal footing." (Addanki, Tr. 2213-15). Including long-acting opioids with AB-rated generics would not tell him (or the Court) anything new about competition among long-acting opioids, because it is undisputed that generic drugs usually end up on favorable formulary tiers. (Addanki, Tr. 2213-15). Of course, if Dr. Addanki were to add generic long-acting opioids to his MMIT analysis, "all we'd be doing is adding another layer or another bar here or another few bars there"; it would not change the story about the degree to which Opana ER competed against other long-acting opioids for which a generic was not available during the time period studied, such as OxyContin, Avinza, MS Contin, and Exalgo. (Addanki, Tr. 2214).

In other words, Proposed Finding No. 946 both ignores crucial context (i.e., that Dr. Addanki was discussing just one part of his multi-faceted relevant market study) and misses the point of the particular analysis in question (i.e., that the MMIT analysis deliberately focused on competition between Opana ER and other long-acting opioids for which an AB-rated generic

was not available during the relevant period). To the extent the proposed finding suggests that Dr. Addanki did not study competition between Opana ER and generic long-acting opioids, it is simply wrong. By way of example, in the UPMC study described in Dr. Addanki's report and at trial, UPMC changed its formularies to favor Opana ER *and various long-acting opioids* over branded OxyContin. (RX-087; *see* RX-547.0042, 0048 (Addanki Rep. ¶¶ 78, 88); Addanki, Tr. 2305). As a result of UPMC's formulary changes, generic Morphine Sulfate ER and generic Fentanyl patch each saw an uptick in prescriptions. (RX-087 (Figures 3, 5)).

Dr. Addanki further testified that he "could absolutely put in the generics" but that "[i]t doesn't actually tell us anything about how the competition at the payer level is going on because that's not what's going on where when the [] manufacturers go in and make their offers to these payers." (Addanki, Tr. 2314-15). Thus, there is no analytical value in including generic drugs in this analysis.

Respondent has no specific response to the final sentence of Proposed Finding No. 946.

947. The fact that generics almost always come in at a cheaper price than the brand and are placed on a favorable tier is evidence that it is generics, and not other branded drugs, that force drug prices to a competitive level. (Noll, Tr. 1397-98). By systematically excluding the most intense source of competition to Opana ER, Dr. Addanki presents a misleading picture about the level of competition between different drugs (even if variation in formulary placement was actually indicative of price competition, which it is not). (Noll, Tr. 1399; CX5004 at 032 (¶ 64) (Noll Rebuttal Report)).

RESPONSE TO FINDING NO. 947:

Complaint Counsel's Proposed Finding No. 947 is inaccurate and misleading. The first sentence of Proposed Finding No. 947 mischaracterizes Professor Noll's testimony. Professor Noll did not testify that generic entry "force[s] drug prices to a competitive level"; he merely stated his belief that "the fact that [formularies] always put generics in category one and that the prices are a lot lower than the brand name drug, is simply evidence that the formularies by

themselves when there's nothing providing the brand name drugs in the market are not sufficient to drive the price to the competitive level." (Noll, Tr. 1397-98). That Professor Noll believes competition for formulary placement is "not sufficient to drive the price to the competitive level" is not testimony that generic entry—and generic entry alone—"force[s] drug prices to a competitive level." [redacted] (CX5000-219 (Noll Rep., Ex. 7A) (pictured by the red line in Response to Proposed Finding of Fact 873); Noll, Tr. 1681-82 ([redacted])).

The second sentence misstates Dr. Addanki's testimony and is misleading. As Dr. Addanki explained at trial, the purpose of his MMIT analysis was to assess the degree of competition among long-acting opioids for which an AB-rated generic was *not* available—i.e., LAOs on an "equal footing." (Addanki, Tr. 2213-15). Including long-acting opioids with AB-rated generics would not tell him (or the Court) anything new about competition among long-acting opioids, because it is undisputed that generic drugs usually end up on favorable formulary tiers. (Addanki, Tr. 2213-15). Of course, if Dr. Addanki were to add generic long-acting opioids to his MMIT analysis, "all we'd be doing is adding another layer or another bar here or another few bars there"; it would not change the story about the degree to which Opana ER competed against other long-acting opioids for which a generic was not available during the time period studied, such as OxyContin, Avinza, MS Contin, and Exalgo. (Addanki, Tr. 2214).

In other words, Proposed Finding No. 947 both ignores crucial context (i.e., that Dr. Addanki was discussing just one part of his multi-faceted relevant market study) and misses the point of the particular analysis in question (i.e., that the MMIT analysis deliberately focused on

competition between Opana ER and other long-acting opioids for which an AB-rated generic was not available during the relevant period). To the extent the proposed finding suggests that Dr. Addanki did not study competition between Opana ER and generic long-acting opioids, it is simply wrong. By way of example, in the UPMC study described in Dr. Addanki's report and at trial, UPMC changed its formularies to favor Opana ER *and various long-acting opioids* over branded OxyContin. (RX-087; *see* RX-547.0042, 0048 (Addanki Rep. ¶¶ 78, 88); Addanki, Tr. 2305). As a result of UPMC's formulary changes, generic Morphine Sulfate ER and generic Fentanyl patch each saw an uptick in prescriptions. (RX-087 (Figures 3, 5)).

> 948. Third, Dr. Addanki chose to include in the analysis three drugs with the same active ingredient, which also leads to a skewed conclusion. In particular, three of the six drugs in the set he looked at contain morphine. (Noll, Tr. 1399-400; CX5004 at 030 (¶ 60) (Noll Rebuttal Report)). Because they share a molecule and the characteristics of that molecule, different versions of morphine are more likely to be good substitutes for each other than they are to Opana ER. (Noll, Tr. 1399-400; CX5004 at 030 (¶ 60) (Noll Rebuttal Report)). Even if the patterns of formulary placement say anything useful about the state of competition, which they do not, the results would be skewed by the fact that three of the six drugs included in the analysis are more likely to be closer competitors to one another than to the drug at issue, Opana ER. (Noll, Tr. 1399-400; CX5004 at 030 (¶ 60) (Noll Rebuttal Report)).

RESPONSE TO FINDING NO. 948:

Complaint Counsel's Proposed Finding No. 948 is inaccurate. The first sentence of Proposed Finding No. 948 should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). As for the remainder of the proposed finding, it is not at all true that Dr. Addanki's analysis of the MMIT data is "skewed" by the fact that three of the drugs use the active ingredient morphine. Dr. Addanki explained at trial that the "changes in formulary status don't depend on how you treat the morphine products," and that "if you do combine the morphine sulfate products . . . and treat

them as one monolithic product you're still going to see the formulary variation and the churn." (Addanki, Tr. 2325-26). Indeed, "when one looks at a product that isn't based on morphine sulfate, one can make reasonable inferences about the relative formulary status" and that inference is "that there is churn, there are differences in the way these formulary competitions play out in terms of the formulary positioning . . . which is entirely consistent with there being . . . competition at the formulary stage." (Addanki, Tr. 2327-28).

> 949. Fourth, the pattern observed in the formulary placement could just as well be observed in a noncompetitive market, so the analysis sheds no light on how competitive the market is. For example, a pattern of variation among formulary placements could very well be a function of a bid rigging cartel by which producers agree to alternate successful bids. (CX5004 at 030-31 (¶¶ 61-62) (Noll Rebuttal Report)). In such a situation, we would see the same variation in formulary placement that Dr. Addanki concludes indicates a level of price competition. (CX4039 (Noll, Dep. at 183-84)). The fact that Dr. Addanki's test does not allow him to distinguish between competitive outcomes and non-competitive outcomes shows that it is not a valid test to determine whether products are competing on price. (CX5004 at 030-31 (¶¶ 61-62) (Noll Rebuttal Report); *see also* CX4039 (Noll, Dep. at 183-84) ("What I'm saying is, since the test that is being proposed by your economic expert is incapable of telling the difference between monopoly and competition, it's not a valid test of whether a firm has market power or whether these firms compete.")).

RESPONSE TO FINDING NO. 949:

Complaint Counsel's Proposed Finding No. 949 is misleading and irrelevant. The first sentence of Proposed Finding No. 949 should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2).

The second sentence of proposed finding should be disregarded because there is no evidence whatsoever that the variation in formulary placement that Dr. Addanki observed was the "function of a bid rigging cartel"; that is rank speculation.

Thus, the third sentence to Proposed Finding No. 949 should similarly be disregarded because it is based on an utterly unsubstantiated claim that there is "bid rigging" occurring in the market.

The fourth sentence of Proposed Finding No. 949 is inaccurate. The "diversity of outcomes" and "variation and churn" that Dr. Addanki identified in long-acting opioids' formulary placement—both as of June 2010 and as measured over time—are consistent with manufacturers competing on price to secure favorable placement, with competitive bidding producing different "winners." (RX-547.0038-40 (Addanki Rep. ¶¶ 72-76); Addanki, Tr. 2309-2328). The fact that "different plans accorded preferential treatment to different [long-acting opioid] products" indicates that the differences in formulary placement were likely not due to therapeutic factors. (RX-547.0039 (Addanki Rep. ¶ 74)). Indeed, the very idea of a formulary is founded on the idea that pricing drives *economic substitution*. As Dr. Addanki testified at trial, "if the insurers didn't think they could actually drive volume by adjusting their formularies, drive volume to a favored product versus a nonfavored product—and again I'm talking about the favoring being just the tiers of the formulary. It's not a question of medical preference; it's a question of economic tiering—the insurers wouldn't bother if they didn't know they could actually drive volume." (Addanki, Tr. 2226).

This inference—that the "diversity of outcomes" and "churn" in long-acting opioids' formulary placement likely resulted from economic competition rather than some other factor—is borne out by documentary and testimonial evidence. (*See* RX-547.0038-41 (Addanki Rep. ¶¶ 72-78); Addanki, Tr. 2294-98; Bingol, Tr. 1324-25).

950. Fifth, Dr. Addanki's selection of drugs presents a misleading picture about their pattern of use. As noted above, Dr. Addanki systematically excluded drugs for which there was a generic on the market. (CCF ¶¶ 946-47; CX4044 (Addanki, Dep. at 165-66)). This leaves a number of LAOs, such as methadone, out of the data set. Therefore, any use

> of such LAOs is not captured at all in the data. If, for example, opioid-addicted newborns are treated with methadone, then we would not see that in this data, because Dr. Addanki left methadone (and certain other LAOs) out of the data set. If a drug Dr. Addanki ignored is heavily used to treat a particular condition, we would not see this at all in his analysis. Therefore, the data on the pattern of use he used is misleading.

RESPONSE TO FINDING NO. 950:

Complaint Counsel's Proposed Finding No. 950 should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Moreover, the individual findings in the cited paragraphs do not support the proposed summary finding and are unreliable for the reasons set out in Respondent's replies to those findings. Proposed Finding No. 950 should be disregarded because it represents a new criticism of Dr. Addanki that was not revealed at trial or in Professor Noll's rebuttal report. Indeed, neither methadone nor "opioid-addicted newborns" was mentioned by Professor Noll at trial.

In any event, this newly invented criticism is baseless. Dr. Addanki's discussion of MMIT data was but *one part* of his relevant market analysis. (Addanki, Tr. 2310-28; *see* RX-547.0038-40 (Addanki Rep. ¶¶ 74-76)). As Dr. Addanki explained at trial, the purpose of this particular analysis was to assess the degree of competition among long-acting opioids for which an AB-rated generic was *not* available—i.e., LAOs on an "equal footing." (Addanki, Tr. 2213-15). Including long-acting opioids with AB-rated generics would not tell him (or the Court) anything new about competition among long-acting opioids, because it is undisputed that generic drugs usually end up on favorable formulary tiers. (Addanki, Tr. 2213-15). Of course, if Dr. Addanki were to add generic long-acting opioids to his MMIT analysis, "all we'd be doing is adding another layer or another bar here or another few bars there"; it would not change the story about the degree to which Opana ER competed against other long-acting opioids for which a

generic was not available during the time period studied, such as OxyContin, Avinza, MS Contin, and Exalgo. (Addanki, Tr. 2214).

In other words, Proposed Finding No. 950 both ignores crucial context (*i.e.*, that Dr. Addanki was discussing just one part of his multi-faceted relevant market study) and misses the point of the particular analysis in question (i.e., that the MMIT analysis deliberately focused on competition between Opana ER and other long-acting opioids for which an AB-rated generic was not available during the relevant period). To the extent the proposed finding suggests that Dr. Addanki did not study competition between Opana ER and generic long-acting opioids, it is simply wrong. By way of example, in the UPMC study described in Dr. Addanki's report and at trial, UPMC changed its formularies to favor Opana ER *and various long-acting opioids* over branded OxyContin. (RX-087; *see* RX-547.0042, 0048 (Addanki Rep. ¶¶ 78, 88); Addanki, Tr. 2305). As a result of UPMC's formulary changes, generic Morphine Sulfate ER and generic Fentanyl patch each saw an uptick in prescriptions. (RX-087 (Figures 3, 5)).

Finally, Proposed Finding No. 950 overlooks the fact that, *even if* the relevant market were strictly limited to the branded LAOs that Dr. Addanki *did* include in the MMIT analysis, Opana ER's market share of the market would still be miniscule. For example, Endo estimated that from February 2012 to February 2013, branded OxyContin's share of the long-acting opioid market was about 28% on average, while branded Opana ER's share hovered between 3.9% and 5.8%. (RX-73.0002 at 4). This is consistent with Dr. Addanki's market share analysis. (*See* RX-547.0132 (Addanki Rep., Ex. 10); *see also* RX-547.0133 (Addanki Rep., Ex. 11 n.12) (noting that from January 2008 onward, almost no generic OxyContin has been available)). If the relevant market were strictly limited to OxyContin and Opana ER, Endo's share would be no higher than approximately 20%. Including Avinza, Exalgo, and/or MS Contin—the other

branded long-acting opioids included in the MMIT analysis—would only further dilute Endo's share.

H. Dr. Addanki incorrectly concludes that Endo lacked market power because Opana ER accounted for a small portion of LAO sales

951. Market power is the ability to sustain prices above the competitive level and/or to exclude competitors from the market. (Noll, Tr. 1404; *see also* CCF ¶¶ 813, above). Dr. Addanki asserts that because Opana ER accounted for a small portion of LAO sales, Endo lacks market power. (RX-547 at 0050-51 (¶ 94) (Addanki Report)). This conclusion only follows if one accepts that all LAOs constitute a properly-defined relevant product market. (CX5004 at 039-40 (¶¶ 81-82) (Noll Rebuttal Report)). The evidence cited in Section VIII, above, and in Dr. Noll's expert report demonstrates that oxymorphone ER constitutes a properly-defined relevant product market. (*See*, CCF ¶¶ 579-809, above; *see also* CX5000 at 082-83 (¶¶ 180-83) (Noll Report) (summary of Dr. Noll's market definition conclusions)). Since the market is oxymorphone ER, Endo's sales accounted for a large portion of them; therefore, Dr. Addanki is incorrect to conclude that Endo lacked market power. (CX5000 at 085-86 (¶ 191) (Noll Report) (market concentration in the sales of oxymorphone ER is high)).

RESPONSE TO FINDING NO. 951:

Complaint Counsel's Proposed Finding No. 951 should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Moreover, the individual findings in the cited paragraphs do not support the proposed summary finding and are unreliable for the reasons set out in Respondent's replies to those findings.

To the extent Proposed Finding No. 951 purports to state any new facts not that were not already proposed in the cited paragraphs—and it does not appear to—it is inaccurate. Market power (also known as monopoly power) refers to "the ability to *restrict output* and sustain supracompetitive profits." (RX-547.0008 (Addanki Rep. ¶ 11 n.8)) (emphasis added). As Dr. Addanki explained at trial, "from the economic standpoint, consumer harm comes about because of a reduction in output brought about by a monopolist. The harm to consumers comes from the reduction in output, and so when we see monopoly power being dissipated, we see an expansion

in output." (Addanki, Tr. 2372; *see also* Addanki, Tr. 2339 ("what [economists] care about is the power of a firm to harm consumers by restricting output or doing something else to prevent consumer benefit from obtaining in a market place")). Dr. Addanki has shown that Endo did not possess monopoly power. (RX-547.0050-57 (Addanki Rep. ¶¶ 93-07)).

I. Dr. Addanki ignores key portions of the IP Guidelines in his contention that intellectual property does not create market power

952. Dr. Addanki asserts that intellectual property ("IP") does not confer market power, based on language from the 1995 *IP Guidelines* which states ". . . the Agencies do not presume that intellectual property creates market power in the antitrust context." (RX-547 at 005253 (¶ 100) (Addanki Report) (quoting the 1995 *IP Guidelines* at 2)). However, Dr. Addanki is selectively quoting the *IP Guidelines*. The 2017 *IP Guidelines* have an entire section titled "Intellectual Property and Market Power." (CX5004 at 043 (¶ 89) (Noll Rebuttal Report) (citing the 2017 *IP Guidelines* at 4-5)). In this section the *IP Guidelines* state: "Although intellectual property right confers the power to exclude with respect to the specific product, process, or work in question, there will often be sufficient actual or potential close substitutes for such product, process, or work to prevent the exercise of market power." (CX5004 at 043 (¶ 89) (Noll Rebuttal Report) (quoting the 2017 *IP Guidelines* at 4)). The *IP Guidelines* actually state, consistent with Dr. Noll's conclusions, that the ability to exclude competitors through intellectual property does confer market power if there are no close substitutes which can counteract that market power. (CX5004 at 043 (¶ 89) (Noll Rebuttal Report)).

RESPONSE TO FINDING NO. 952:

Complaint Counsel's Proposed Finding No. 952 is incomplete and misleading. Respondent has no specific response to the first sentence of Proposed Finding No. 952. The second sentence of Proposed Finding No. 952 should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2).

The second sentence is also manifestly untrue. Dr. Addanki does not "selectively quot[e]" the *IP Guidelines*. The 2017 *IP Guidelines* contain the exact same language as quoted in Dr. Addanki's report. U.S. Dep't of Justice & Fed. Trade Comm'n, *Antitrust Guidelines for the Licensing of Intellectual Property* § 2.0 (2017). The *IP Guidelines* speak for themselves.

The remainder of Proposed Finding No. 952 is incomplete. While the 2017 *IP Guidelines* include the quoted language in Proposed Finding No. 952, that language says nothing about this case. Nor does it refute Dr. Addanki's conclusion that Endo's patents were insufficient to confer market power. As Dr. Addanki explained at trial, "All that a patent does is give you the right to exclude someone from making a direct copy of what you make. [¶] So in this case Endo's patents did prevent competitors from making direct copies of Opana ER. But to the extent that other long-acting opioids competed with Opana ER, the patents had no ability to block them. And in fact, there was entry of competing products even while Endo had its patents." (Addanki, Tr. 2343). The *IP Guidelines* are consistent with Dr. Addanki's testimony. *See* U.S. Dep't of Justice & Fed. Trade Comm'n, *Antitrust Guidelines for the Licensing of Intellectual Property* § 2.2 (2017) ("Although the intellectual property right confers the power to exclude with respect to the specific product, process, or work in question, there will often be sufficient actual or potential close substitutes for such product, process, or work to prevent the exercise of market power.").

> 953. As demonstrated in Section VIII above, oxymorphone ER is a properly defined relevant product market, and other LAOs are not close substitutes. (*See* CCF ¶¶ 654-740, above). The Hatch-Waxman's ANDA filing process creates a legal barrier to entry to firms launching generic versions of oxymorphone ER. (CX5004 at 043 (¶ 90) (Noll Rebuttal Report)). The facts that Endo's patents allowed it to exclude other companies from selling generic oxymorphone ER and that generics could launch only by overcoming the Hatch-Waxman's legal barriers to entry, meant that Endo's patents allowed it to exercise market power in the oxymorphone ER market for a period of time. (CX5004 at 043 (¶ 90) (Noll Rebuttal Report)).

RESPONSE TO FINDING NO. 953:

Complaint Counsel's Proposed Finding No. 953 is incomplete and misleading. The first sentence of Proposed Finding No. 953 should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported

by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Moreover, the individual findings in the cited paragraphs do not support the proposed summary finding and are unreliable for the reasons set out in Respondent's replies to those findings.

The second sentence in Proposed Finding No. 953 is misleading. To the extent the Hatch-Waxman act creates a "legal barrier" to ANDA filers selling specific generic drugs, that cannot be evidence of monopoly power, since the same legal requirements apply to *all* NDA holders with Orange Book-listed patents. And the Hatch-Waxman Act does not preclude all competitive entry. Like a patent, the Hatch-Waxman Act merely erects a barrier to "making a direct copy of what [the brand company] make[s]." (Addanki, Tr. 2343). "[T]o the extent that other long-acting opioids competed with Opana ER, the [Hatch-Waxman Act] had no ability to block them. And in fact, there was entry of competing products," despite the Hatch-Waxman Act's requirement. (Addanki, Tr. 2343).

J. Dr. Addanki's criticism of Dr. Noll's use of the Lerner Index is premised on the muddling of two distinct issues – market power and anticompetitive conduct

954. The Lerner Index is the mark-up of price over marginal cost to price. (CX 5000 at 095 (¶ 215) (Noll Report)).

RESPONSE TO FINDING NO. 954:

Respondent has no specific response.

955. The Lerner Index will always be between zero and one. (CX5000 at 095-96 (¶ 215) (Noll Report)). The higher the firm's Lerner Index (i.e., the higher the price it charges as compared to its own marginal cost), the greater a firm's market power. (CX5000 at 095-96 (¶ 215) (Noll Report)).

RESPONSE TO FINDING NO. 955:

Respondent has no specific response to the first sentence of Complaint Counsel's Proposed Finding No. 955.

The second sentence of Proposed Finding No. 955 inaccurate and misleading. As Dr. Addanki explains, "[t]here has long been a consensus among economists that positive price-cost margins (*i.e.*, the difference between price, *p*, and marginal cost, *mc*) generally reveal little if anything about the existence of monopoly power." (RX-547.0055 (Addanki Rep. (¶ 104)); *see also* Addanki, Tr. 2342 ("[The Lerner Index] may be useful as a textbook case or a pedagogical example in a classroom, but it's no use at all in analyzing real-world industries where there are substantial fixed costs that need to be covered. And again, antitrust economists and scholars have noted this for a long time.")).

Moreover, Professor Noll admitted at trial that a high Lerner Index "doesn't necessarily mean" that a firm has market power. (Noll, Tr. 1415). Professor Noll testified that in industries with high fixed costs and low marginal costs, including specifically the pharmaceutical industry, a high markup of price over marginal cost is a "normal market outcome." (Noll, Tr. 1415-16; *see also* Addanki, Tr. 2339 ("you can have a price above marginal cost and have absolutely no monopoly power, because you have no power to -- to do things in the marketplace to the detriment of consumers. You just happen to have a high margin because you have a lot of costs you need to cover to remain in business.")). Because the Lerner Index says nothing meaningful about market power in the pharmaceutical industry, Complaint Counsel's Proposed Finding No. 955 should be disregarded.

956. Endo has always enjoyed a high Lerner Index for Opana ER: always over [redacted] and often between [redacted] (CX5000 at 100, 227 (¶ 226, Exhibit 8) (Noll Report)) (*in camera*). This indicates that Endo enjoyed substantial market power in the market for oxymorphone ER. (CX5000 at 100 (¶ 227) (Noll Report)). In criticizing Dr. Noll's use of the Lerner Index, Dr. Addanki states that "[i]n the vast majority of cases in which firms price above marginal cost . . . they are not exercising monopoly power. Consequently, a price that exceeds marginal cost rarely suggests that there is an antitrust problem." (RX-547 at 0054-55 (¶¶ 102-03) (Addanki Report)).

RESPONSE TO FINDING NO. 956:

Respondent has no specific response to the first sentence of Complaint Counsel's Proposed Finding No. 956.

The second sentence of Proposed Finding No. 956 is false. As Dr. Addanki explains, "[t]here has long been a consensus among economists that positive price-cost margins (*i.e.*, the difference between price, *p*, and marginal cost, *mc*) generally reveal little if anything about the existence of monopoly power." (RX-547.0055 (Addanki Rep. ¶ 104); *see also* Addanki, Tr. 2342 ("[The Lerner Index] may be useful as a textbook case or a pedagogical example in a classroom, but it's no use at all in analyzing real-world industries where there are substantial fixed costs that need to be covered. And again, antitrust economists and scholars have noted this for a long time.")).

Moreover, Professor Noll admitted at trial that a high Lerner Index "doesn't necessarily mean" that a firm has market power. (Noll, Tr. 1415). Professor Noll testified that in industries with high fixed costs and low marginal costs, including specifically the pharmaceutical industry, a high markup of price over marginal cost is a "normal market outcome." (Noll, Tr. 1415-16; *see also* Addanki, Tr. 2339 ("you can have a price above marginal cost and have absolutely no monopoly power, because you have no power to -- to do things in the marketplace to the detriment of consumers. You just happen to have a high margin because you have a lot of costs you need to cover to remain in business.")). Because the Lerner Index says nothing meaningful about whether Endo possessed market power, Complaint Counsel's Proposed Finding No. 956 should be disregarded.

Finally, Respondent has no specific response to the quote in the third sentence of Proposed Finding No. 956, except to note that—as explained in the preceding paragraph—Professor Noll testified at trial that he *agrees* with Dr. Addanki.

957. Dr. Addanki inappropriately conflated two separate concepts – market power and anticompetitive conduct. (CX5004 at 054-55 (¶¶ 115-16) (Noll Rebuttal Report)). Dr. Addanki used the term "market power" to mean the ability to set price above marginal cost *as a result of anticompetitive conduct*. (CX5004 at 055 (¶ 116) (Noll Rebuttal Report)).

RESPONSE TO FINDING NO. 957:

Complaint Counsel's Proposed Finding No. 957 is inaccurate and misleading. Dr. Addanki did not "conflate" market power and anticompetitive conduct. Complaint Counsel relies entirely on two paragraphs in Professor Noll's report, which specifically and exclusively address Dr. Addanki's statement that "[i]n the vast majority of cases in which firms price above marginal cost . . . they are not exercising monopoly power"—meaning that "a price that exceeds marginal cost rarely suggests that there is an antitrust problem." (CX5004-054-55 (Noll Rebuttal Rep. ¶¶ 115-16) (quoting RX-547.0054 (Addanki Rep. ¶ 102))).

As Professor Noll testified at trial, however, he actually *agrees* with Dr. Addanki on this point. Professor Noll admitted that conduct cannot be "anticompetitive" in the antitrust sense without a showing of monopoly power. (Noll, Tr. 1574). Consistent with the statement in Dr. Addanki's report, Professor Noll further admitted that a high Lerner Index "doesn't necessarily mean" that a firm has market power. (Noll, Tr. 1415). He testified that in industries with high fixed costs and low marginal costs, including specifically the pharmaceutical industry, a high markup of price over marginal cost is a "normal market outcome." (Noll, Tr. 1415-16; *see also* Addanki, Tr. 2339 ("you can have a price above marginal cost and have absolutely no monopoly power, because you have no power to -- to do things in the marketplace to the detriment of

consumers. You just happen to have a high margin because you have a lot of costs you need to cover to remain in business.")).

In other words, Professor Noll's testimony at trial only *confirms* Dr. Addanki's statement that pricing above marginal cost does not show monopoly power, and hence cannot satisfy the monopoly power requirement in an antitrust rule of reason case.

> 958. A high Lerner Index implies the existence of market power, but it does not imply that such market power is the result of anticompetitive conduct. (CX5004 at 055-56 (¶ 117) (Noll Rebuttal Report)). A high Lerner Index indicates a firm is charging a price well above marginal cost; therefore, the firm enjoys market power. (CX5004 at 055-56 (¶ 117) (Noll Rebuttal Report)). Market power can be a result of anticompetitive conduct, but it also can be a result of superior efficiency, which is not anticompetitive. (CX5004 at 05556 (¶ 117) (Noll Rebuttal Report)).
>
> **RESPONSE TO FINDING NO. 958:**

Complaint Counsel's Proposed Finding No. 958 is inaccurate and misleading. Contrary to Complaint Counsel's assertion in the first sentence of the proposed finding, a high Lerner Index does not "impl[y] the existence of market power." Professor Noll himself admitted at trial that a high Lerner Index "doesn't necessarily mean" that a firm has market power. (Noll, Tr. 1415). He testified that in industries with high fixed costs and low marginal costs, including specifically the pharmaceutical industry, a high markup of price over marginal cost is a "normal market outcome." (Noll, Tr. 1415-16; *see also* Addanki, Tr. 2339 ("you can have a price above marginal cost and have absolutely no monopoly power, because you have no power to -- to do things in the marketplace to the detriment of consumers. You just happen to have a high margin because you have a lot of costs you need to cover to remain in business.")). For this same reason, the second sentence of Proposed Finding No. 958 is inaccurate. The ability of a firm to charge a price above marginal cost does not equate with market power without a showing that the firm also has the ability to restrict output.

Respondent has no specific response to the final sentence of Complaint Counsel's Proposed Finding No. 958.

> 959. Endo's high Lerner Index demonstrates that Endo has market power over oxymorphone ER. (CX5000 at 097-98 (¶ 220) (Noll Report)).Contrary to Dr. Addanki's assertion, however, at no point does Dr. Noll suggest that the mere presence of market power is itself indicative of having engaged in anticompetitive conduct. (CX5004 at 055-56 (¶ 117) (Noll Rebuttal Report)). For example, Dr. Noll concluded that enforcing valid patents, which was one source of Endo's market power, was not itself anticompetitive conduct. (CX5004 at 056 (¶ 118) (Noll Rebuttal Report)). The anticompetitive conduct that allowed Endo to improperly maintain its market power was its settlement of the patent infringement case against Impax by purchasing a guarantee that Impax would not enter the market until a specified date. (CX5004 at 056 (¶ 118) (Noll Rebuttal Report)).

RESPONSE TO FINDING NO. 959:

Complaint Counsel's Proposed Finding No. 959 is inaccurate and misleading. First, "Endo's high Lerner Index" does *not* demonstrate market power. As Dr. Addanki explains, "[t]here has long been a consensus among economists that positive price-cost margins (*i.e.*, the difference between price, *p*, and marginal cost, *mc*) generally reveal little if anything about the existence of monopoly power." (RX-547.0055 (Addanki Rep. ¶ 104); *see also* Addanki, Tr. 2342 ("[The Lerner Index] may be useful as a textbook case or a pedagogical example in a classroom, but it's no use at all in analyzing real-world industries where there are substantial fixed costs that need to be covered. And again, antitrust economists and scholars have noted this for a long time.")). Professor Noll himself admitted at trial that a high Lerner Index "doesn't necessarily mean" that a firm has market power. (Noll, Tr. 1415). Professor Noll testified that in industries with high fixed costs and low marginal costs, including specifically the pharmaceutical industry, a high markup of price over marginal cost is a "normal market outcome." (Noll, Tr. 1415-16; *see also* Addanki, Tr. 2339 ("you can have a price above marginal cost and have absolutely no monopoly power, because you have no power to -- to do

things in the marketplace to the detriment of consumers. You just happen to have a high margin because you have a lot of costs you need to cover to remain in business.")).

The second sentence of Proposed Finding No. 959 misrepresents Dr. Addanki's report. Complaint Counsel provides no citation to Dr. Addanki's report, nor do the cited paragraphs of Professor Noll's rebuttal report.

The third sentence of Proposed Finding No. 959 is misleading to the extent it suggests that "enforcing valid patents" was a "source of Endo's market power." As Dr. Addanki explained at trial, "[a]ll that a patent does is give you the right to exclude someone from making a direct copy of what you make. [¶] So in this case Endo's patents did prevent competitors from making direct copies of Opana ER. But to the extent that other long-acting opioids competed with Opana ER, the patents had no ability to block them. And in fact, there was entry of competing products even while Endo had its patents." (Addanki, Tr. 2343). Moreover, Endo did not possess market power. (RX-547.0050-57 (Addanki Rep. ¶¶ 93-107)).

Finally, the fourth sentence of Proposed Finding No. 959 is inaccurate. Endo did not have market power, and the settlement at issue was not anticompetitive. (RX-547.0050-84 (Addanki Rep. ¶¶ 93-157)).

K. Dr. Addanki incorrectly concludes that the entry of generic oxymorphone ER did not expand output

960. Dr. Addanki incorrectly concludes that Endo lacked market power in the market for oxymorphone ER because, Impax's launch of generic oxymorphone ER did not expand output of oxymorphone ER. (RX-547 at 0051, 0135 (¶ 96, Exhibit 12) (Addanki Report)). This conclusion is both conceptually flawed and factually inaccurate.

RESPONSE TO FINDING NO. 960:

Complaint Counsel's Proposed Finding No. 960 is inaccurate and misleading. Dr. Addanki's conclusion that Impax's launch of generic oxymorphone ER did not expand output

was but *one* part of his analysis of the relevant market and Endo's alleged market power. (*See* RX-547.0022-57 (Addanki Rep. ¶¶ 41-107)).

The second sentence of Proposed Finding No. 953 should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2).

961. On a conceptual level, whether output went up or down relates to the competitive effects of generic entry and is not a test for market power. (CX5004 at 040 (¶ 84) (Noll Rebuttal Report)). The test of whether a branded firm has market power in the relevant market for a drug is what happened to price after generic versions launched (i.e., was the branded supplier exercising market power by charging a supracompetitive price?). (CX5004 at 040 (¶ 84) (Noll Rebuttal Report)). If the average price of a drug drops upon the entry of generics, then the branded firm was exercising market power by maintaining a supracompetitive price. (CX5004 at 040 (¶ 84) (Noll Rebuttal Report)).

RESPONSE TO FINDING NO. 961:

Complaint Counsel's Proposed Finding No. 961 is inaccurate and misleading. To begin with, Complaint Counsel's assertion in the first sentence of the proposed finding that "whether output went up or down relates to the competitive effects of generic entry and is not a test for market power" is wrong. Monopoly power consists of "the ability to *restrict output* and sustain supracompetitive profits." (RX-547.0008 (Addanki Rep. ¶ 11 n.8) (emphasis added)).

The second sentence of Proposed Finding No. 961 is inaccurate and incomplete for the reason just stated: monopoly power consists of "the ability to *restrict output* and sustain supracompetitive profits." (RX-547.0008 (Addanki Rep. ¶ 11 n.8) (emphasis added)). Supracompetitive pricing alone does not cut it.

The third sentence of Proposed Finding No. 961 is completely false. By Complaint Counsel's logic, *any* entry by *any* lower-priced competitor would *always* constitute proof that the incumbent competitor(s) possessed market power—no matter how competitive the market was

before the new entrant—because a lower-priced entrant will *invariably* cause the "average price" of the product to drop. Ironically, Complaint Counsel ignores the fact that [redacted] (CX5000-219 (Noll Rep., Ex. 7A) (pictured by the red line in Response to Proposed Finding of Fact 873); Noll, Tr. 1681-82 ([redacted]). If a drop in the average price of a drug is what matters, then Professor Noll must explain [redacted] He does not do so.

962. The data show that Impax and Actavis offered lower-priced generic versions of Opana ER. Once Impax and Actavis entered the oxymorphone ER market, the average price of oxymorphone ER declined. (Noll, Tr. 1380-81; CX5000 at 184-90, 219-26 (Exhibits 2B1-2B7, 7A, 7B1-7B7) (Noll Report); CX5004 at 014-15 (¶¶ 25-26) (Noll Rebuttal Report)). Since generic oxymorphone ER was the only product that was able to lower the average price of oxymorphone ER, this pricing behavior indicates that Endo enjoyed monopoly power in the market for oxymorphone ER prior to generic entry. (CX5004 at 040 (¶ 84) (Noll Rebuttal Report)).

RESPONSE TO FINDING NO. 962:

Complaint Counsel's Proposed Finding No. 962 is incomplete and misleading. Respondent has no specific response to the first sentence of Proposed Finding No. 962. The second and third sentences of Proposed Finding No. 962 are merely a tautology that says nothing about the relevant market or monopoly power. The entrance of a "lower-priced" drug will *always* decrease "the average price" of *that drug*. Indeed, by Complaint Counsel's logic, *any* entry by *any* lower-priced competitor would *always* constitute proof that the incumbent competitor(s) possessed market power—no matter how competitive the market was before the

new entrant—because a lower-priced entrant will *invariably* cause the "average price" of the product to drop.

Ironically, Proposed Finding No. 962 ignores [redacted] (CX5000-219 (Noll Rep., Ex. 7A) (pictured by the red line in Response to Proposed Finding of Fact 873); Noll, Tr. 1681-82 ([redacted])). If generic oxymorphone ER "was the only product that was able to lower the average price of oxymorphone ER," Professor Noll must explain why [redacted] He does not do so.

1. Under appropriate measures, output expanded once Impax entered

963. Dr. Addanki concludes that Impax's entry did not expand output of oxymorphone ER based on his analysis of prescription data that were combined into three-month moving averages. (RX-547 at 0051, 0135 (¶ 96, Exhibit 12) (Addanki Report)). Using three-month moving averages of oxymorphone ER prescriptions is a flawed approach because it does not allow one to isolate the output figure from the month when Impax's entry occurred (January 2013). (CX5004 at 041-42 (¶ 86) (Noll Rebuttal Report)).

RESPONSE TO FINDING NO. 963:

Respondent has no specific response to the first sentence of Complaint Counsel's Proposed Finding No. 963.

The second sentence of Proposed Finding No. 963 is inaccurate and misleading. Complaint Counsel's sole "source" for this proposition is one paragraph of Professor Noll's rebuttal report, which merely asserts, *ipse dixit*, that using a three-month moving average "makes

detecting the response to generic entry in a specific month (January 2013) more difficult." (CX5004-041-42 (Noll Rebuttal Rep. ¶ 86)). But as Professor Noll concedes, "[m]oving averages are sometimes the best way to present data," since "averaging corrects for volatility." (CX5004-041-42 (Noll Rebuttal Rep. ¶ 86 n.49)). Indeed, Professor Noll himself used moving averages to show Opana ER's net price over time. (CX5000-091 (Noll Rep. ¶ 204)).

As Dr. Addanki explained, using a three-month moving average to assess the output effects of Impax's generic launch was entirely appropriate. The "actual month-to-month data are very choppy," and when an economist is trying to determine whether a new entrant is "dissipating monopoly power, I'd expect to see the effects unfold over some period[;] it wouldn't be instantaneous because prescriptions get written, prescriptions get filled, information comes and gets out there." (CX4044 (Addanki, Dep. at 161)). The use of moving averages thus "lets you see if there's an underlying trend." (CX4044 (Addanki, Dep. at 161)). Complaint Counsel's suggestion that one must "isolate the output figure" from a *single* month when entry occurred is unfounded. (*See* CX4044 (Addanki, Dep. at 161) ("So I wouldn't be looking to see what happened in a week or two weeks or a month.")).

964. If one looks instead at quarterly wholesale sales data, then one can see that Impax's entry increased output. (CX5004 at 042, 091 (¶ 87, Exhibit 3) (Noll Rebuttal Report)). [redacted] (CX5004 at 042, 091 (¶ 87, Exhibit 3) (Noll Rebuttal Report) (*in camera*)). Dr. Addanki is factually wrong to conclude that the entry of Impax had no effect on oxymorphone ER's output. (CX5004 at 042, 091 (¶ 87, Exhibit 3) (Noll Rebuttal Report)).

RESPONSE TO FINDING NO. 964:

Complaint Counsel's Proposed Finding No. 964 is inaccurate and misleading. As the proposed finding notes, Professor Noll used "quarterly wholesale sales data" in a purported

attempt to measure the output effects of Impax's generic entry. (CX5004-042, 091 (Noll Rebuttal Rep. ¶ 87; Ex. 3)). But that is *not* an appropriate measure of output. As Dr. Addanki explained, the appropriate measure of output is "what was actually consumed." (CX4044 (Addanki, Dep. at 163)). Professor Noll's metric, which relies on wholesale sales to pharmacies, "is not the same thing as what is going out from the pharmacy" and being consumed. (CX4044 (Addanki, Dep. at 163)).

In fact, focusing on wholesale sales *skews* the results. As Dr. Addanki further explained, where "you have a new product introduction[,] you get a certain amount of shipment just because of the pipeline having to be filled." (CX4044 (Addanki, Dep. at 163); *see* CX4037 (Smolenski, Dep. at 49-50) ("Q. The generic substitution rate starts at 200 percent in month one. Is that, why is it 200 percent in month one? A. This is a, this is an operational forecast, so the forecast is based on what customers would order. And if Impax were able to launch as the first generic, customers would probably order more than a hundred percent of the market to have some safety stock. Q. So during the initial month, the substitution rate is higher because people are building inventory? A. Correct. Q. By 'people,' customers of Impax, such as CVS or Walgreens or whomever, correct? A. Correct.")).

Because Professor Noll relies on a metric that does not measure actual output—that is, consumption by patients—and which skews the results, his conclusion that "output" of oxymorphone ER rose in 2013 is unreliable. When the *correct* measure is used, it is clear that Impax's launch of generic oxymorphone ER in 2013 did not result in an overall expansion of output for oxymorphone ER. (RX-547.0051, 0135 (Addanki Rep. ¶ 96; Ex. 12)).

Finally, the assertion that Impax's generic launch "reversed" a decline in oxymorphone ER sales that began in 2012 is incorrect. Dr. Addanki's analysis shows that, in fact, the 2012

decline had stabilized by mid-2012—months *before* Impax's entry. (RX-547.0051, 0135 (Addanki Rep. ¶ 96; Ex. 12)).

2. Prior to generic entry, the demand for Opana ER and all LAOs was declining; Impax's entry stopped that decline

965. Even if Impax's entry did not increase oxymorphone ER output, Dr. Addanki's conclusion also is flawed because he fails to take into account the fact that, prior to Impax's entry, the entire market for Opana ER was declining. (CX5004 at 042 (¶ 87) (Noll Rebuttal Report); CX4039 (Noll, Dep. at 206-08)). Since the overall trend had been one of decline prior to Impax's entry, a shift to a constant level of output *is* an increase in output compared to the trend. (CX4039 (Noll, Dep. at 207-08)) Even assuming that Impax's entry did not expand output, Impax's entry stopped an overall decline in output. (CX5004 at 042 (¶ 87) (Noll Rebuttal Report)).

RESPONSE TO FINDING NO. 965:

Complaint Counsel's Proposed Finding No. 965 is inaccurate and misleading. To begin with, the proposed finding relies on Professor Noll's rebuttal report, which incorrectly uses quarterly wholesale sales data to measure "output." (CX5004-042, 91 (Noll Rebuttal Rep. ¶ 87; Ex. 3). This is not an appropriate measure of output, since it does not reflect what was actually consumed in the marketplace and skews the results. (CX4044 (Addanki, Dep. at 161-63)).

The assertion that Impax's generic launch "stopped an overall decline in output" is incorrect. Dr. Addanki's analysis shows that, in fact, the 2012 decline had stabilized by mid-2012—months *before* Impax's entry. (RX-547.0051, 0135 (Addanki Rep. ¶ 96; Ex. 12)). Using a correct measure of output, it becomes clear that output of oxymorphone ER remained essentially flat from mid-2012 onward. (RX-547.0051, 0135 (Addanki Rep. ¶ 96; Ex. 12); CX4044 (Addanki, Dep. at 161-63)).

XI. The reverse-payment agreement between Impax and Endo is anticompetitive

A. The competitive process benefits consumers

966. A basic economic principle is that consumers benefit from increased competition in the form of lower prices and increased choice. (CX5000 at 011 (¶ 24) (Noll Report); *see also* CX5000 at 109-10 (¶ 250) (Noll Report)). Harm to competition means that the anticompetitive conduct of one or more firms on one side of a market (usually sellers) inflicts harm on participants on the other side of the market (usually consumers). (CX5000 at 011 (¶ 24) (Noll Report)).

RESPONSE TO FINDING NO. 966:

Respondent has no specific response.

967. Harm to competition is not limited to the certain elimination of competition. Instead, this harm includes eliminating the possibility that participants on the other side of the market will have the opportunity to experience the benefits of competition, such as lower prices. (CX5000 at 011 (¶ 24) (Noll Report)).

RESPONSE TO FINDING NO. 967:

Complaint Counsel's Proposed Finding No. 967 is an improper legal conclusion, not a fact. Moreover, the proposed finding is incorrect as a matter of antitrust economics. The appropriate inquiry is (1) whether the firm in question possessed monopoly power; and (2) if so, whether the challenged conduct left consumers worse off than they otherwise would have been. (*See* RX-547.0008, 0018, 0020 (Addanki Rep. ¶¶ 11(a), 29, 35)).

968. Reverse-payment agreements are almost always entered into before a final decision has been made on the infringement litigation. (CX5000 at 144 (¶ 330) (Noll Report)). In such circumstances, the patent at issue "may or may not be valid and may or may not be infringed." (CX5000 at 144 (¶ 330) (Noll Report), quoting *Federal Trade Comm'n v. Actavis*, 133 S. Ct. 2223, 2231 (2013)).

RESPONSE TO FINDING NO. 968:

The first sentence of Complaint Counsel's Proposed Finding No. 968 should be disregarded because it violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or

documents." (*See* Court, Tr. 1859 ("[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.")). The cited portion of Professor Noll's report, moreover, contains no evidence or analysis to support the proposition. Finally, Professor Noll was not and is not qualified as an expert regarding issues with respect to patent litigation or settlements of the same. (Noll, Tr. 1358). The second sentence of Proposed Fining No. 968 is an improper legal conclusion, not a fact.

> 969. Such settlements harm consumers because they extend the minimum duration of a brand-name firm's monopoly by requiring the generic to forego entering at an earlier date. (CX5000 at 118, 132 (¶¶ 268, 300) (Noll Report); *see also* Noll, Tr. 1422 ("The reason that [the Impax-Endo Settlement Agreement is] anticompetitive is that it extended the period of Endo's monopoly in the market. It gave them an insurance or protection against the possibility of generic entry for two and a half years.")).

RESPONSE TO FINDING NO. 969:

Complaint Counsel's Proposed Finding No. 969 is an improper legal conclusion, not a fact. Proposed Finding No. 969 is also inaccurate in its claim that so-called reverse-payment settlements always "harm consumers." As Dr. Addanki explained at trial, "whether a given settlement of patent litigation between a brand company and a generic company is anticompetitive or not can only be evaluated by considering all of the facts surrounding the settlement and evaluating whether in fact consumers were worse off with the settlement than they would have been without it." (Addanki, Tr. 2205). The analysis is "really not any different from what we would do in any kind of rule of reason case." (Addanki, Tr. 2206). Because of this, the appropriate inquiry is (1) whether the firm in question possessed monopoly power; and (2) if so, whether the challenged conduct left consumers worse off than they otherwise would have been. (*See* RX-547.0008, 0018, 0020 (Addanki Rep. ¶¶ 11(a), 29, 35)). Without performing this analysis, "[t]here is no knowing . . . whether a given settlement is going to be pro- or anticompetitive." (Addanki, Tr. 2205).

Finally, the excerpt from Professor Noll's testimony that is parenthetically quoted in Proposed Finding No. 969 is incorrect. Far from delaying Impax's generic entry, the SLA promoted competition and benefited consumers by permitting Impax to sell generic oxymorphone ER on a sustained basis, free from patent risk, earlier than it otherwise could have. (RX-547.0058-84 (Addanki Rep. ¶¶ 108-57); *see* Figg, Tr. 1928 (the SLA's January 1, 2013 entry date did not represent a "delay of entry compared to the date Impax could have reasonably expected to enter had it not settled")).

> 970. Normally when a generic launches, the competition between the brand-name firm and the generic firm causes the price of the drug to drop, benefiting consumers. (Noll, Tr. 142526). By entering into a reverse-payment settlement, the brand-name firm extends the period of monopoly, pays the generic with a portion of its monopoly profits, and deprives consumers of the benefit of lower pricing for as long as the monopoly is extended. (Noll, Tr. 1425-27).

RESPONSE TO FINDING NO. 970:

Complaint Counsel's Proposed Finding No. 970 in inaccurate and misleading. As explained by Dr. Addanki, "the entry of a lower priced competitor does not, by itself, reveal anything useful about whether consumers are better off as a result of the entry, or whether the incumbent firm had exercised monopoly power or, indeed even *possessed* any monopoly power to be exercised. The incumbent firm's higher price may well have been the result of that firm's having a different business model resulting in higher costs, perhaps because it engages in activities that directly benefit consumers." (RX-547.0019 (Addanki Rep. ¶¶ 31-33) (emphasis in original)). This is why evidence of increased output is key to determining whether the launch of a generic drug benefitted consumers in the aggregate. (RX-547.0019 (Addanki Rep. ¶ 30)).

The second sentence of Proposed Finding No. 970 is also inaccurate because "the brand name firm" only "extends the period of monopoly" if (1) there is proof that the brand company possessed monopoly power; and (2) if so, the evidence shows that (a) an alternative settlement

with an earlier entry date was actually feasible, or (b) there is a high probability that, if the parties had continued litigating, the generic firm would have prevailed in the underlying patent litigation and entered earlier than the settlement entry date. (RX-547.0019-20, 0070-71 (Addanki Rep. ¶¶ 30, 36, 128-30) ("Unless there is compelling evidence of a fully-specified alternative agreement that the parties contemplated . . . the operating assumption must be that the but-for world is one in which the parties litigated the patent suit to its conclusion.")).

> 971. By eliminating the possibility of generic competition for a period of time (thereby extending the brand-name firm's monopoly), reverse-payment settlements interfere with the competitive process. Reverse payments therefore harm consumers by depriving them of the possible benefits of increased competition for the period of time specified in the settlement. (Noll, Tr. 1422-23; CX5000 at 119 (¶ 269) (Noll Report)).

RESPONSE TO FINDING NO. 971:

Complaint Counsel's Proposed Finding No. 971 is an improper legal conclusion, not a fact. Moreover, the first second sentence of Proposed Finding No. 953 should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2).

In any event, Proposed Finding No. 971 is inaccurate in its claim that so-called reverse-payment settlements always "harm consumers." As Dr. Addanki explained at trial, "whether a given settlement of patent litigation between a brand company and a generic company is anticompetitive or not can only be evaluated by considering all of the facts surrounding the settlement and evaluating whether in fact consumers were worse off with the settlement than they would have been without it." (Addanki, Tr. 2205). The analysis is "really not any different from what we would do in any kind of rule of reason case." (Addanki, Tr. 2206). Because of this, the appropriate inquiry is (1) whether the firm in question possessed monopoly power; and

(2) if so, whether the challenged conduct left consumers worse off than they otherwise would have been. (*See* RX-547.0008, 0018, 0020 (Addanki Rep. ¶¶ 11(a), 29, 35)). Without performing this analysis, "[t]here is no knowing . . . whether a given settlement is going to be pro- or anticompetitive." (Addanki, Tr. 2205).

B. The economics of reverse-payment settlements

972. Reverse-payment settlements have two major features: 1) the agreement permits entry by an allegedly infringing product before the relevant patents expire, and 2) the settlement includes a payment (some transfer of value) from the patent holder (the party allegedly damaged by the infringement) to the alleged infringer. (Noll, Tr. 1422-23; CX5000 at 103 (¶ 237) (Noll Report)).

RESPONSE TO FINDING NO. 972:

Complaint Counsel's Proposed Finding No. 972 is an improper legal conclusion, not a fact. But Proposed Finding No. 972 is also overbroad. Even entry-date only settlements include *some* "transfer of value" to the generic company. (Bazerman, Tr. 882). By Complaint Counsel's definition, virtually any patent settlement agreement could be construed as a "reverse-payment settlement."

973. If the payment is large, the presence of a reverse payment implies that the entry date in the settlement is later than the date the patent holder expected the alleged infringer would enter. (CX5000 at 103-04 (¶ 238) (Noll Report); *see also* Bazerman, Tr. 874 ("if Endo would agree to January 2013 with a provision that provides significant payment to Impax, then simple negotiation logic tells me that if – if Endo didn't have to pay tens of millions or, as it turns out, 102 million to Impax, they would have agreed to an earlier date without that amount of money being paid.")). A patent holder would not agree to pay the infringer anything more than saved litigation costs to obtain entry on the date the alleged infringer would have entered anyway. (CX5000 at 103-04 (¶ 238) (Noll Report); *see also* Bazerman, Tr. 874; CX5000 at 006 (¶ 10) (Bazerman Report) ("litigation costs to the parties increase the viability of a negotiated agreement, as both parties save these costs if they can negotiate an agreement")).

RESPONSE TO FINDING NO. 973:

Complaint Counsel's Proposed Finding No. 973 is inaccurate because it is not possible to determine whether "the entry date in the settlement is later than the date the patent holder expected the alleged infringer would enter" without determining a feasible baseline for entry under an alternative settlement or continued litigation. (RX-547.0008, 0018, 0020, 58-60 (Addanki Rep. ¶¶ 11(a), 29, 35, 108-14)). As Dr. Addanki explained at trial, "whether a given settlement of patent litigation between a brand company and a generic company is anticompetitive or not can only be evaluated by considering all of the facts surrounding the settlement and evaluating whether in fact consumers were worse off with the settlement than they would have been without it." (Addanki, Tr. 2205). Without performing this analysis, "[t]here is no knowing . . . whether a given settlement is going to be pro- or anticompetitive." (Addanki, Tr. 2205).

Moreover, because Complaint Counsel cites no record evidence to show that the purported incentives outlined in Proposed Finding No. 973 were present with Endo, Proposed Finding No. 973 should be disregarded. Under this Court's Order on Post-trial Briefs, Complaint Counsel may not rely on "expert testimony to support factual propositions that should be established by fact witnesses or documents." (*See* Court, Tr. 1859 ("[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.")).

974. This payment to the alleged infringer, in exchange for a certain entry date, converts the possibility of substantial loss of the patent holder's monopoly profits into the certainty that it will continue to earn monopoly profits until the settlement's entry date. (CX5000 at 104 (¶ 239) (Noll Report)). As a result, a reverse-payment settlement is a mechanism by which the patent holder shares with the alleged infringer the monopoly profits it will earn during the period before the agreed-upon generic entry date. (CX5000 at 104 (¶ 239) (Noll Report)).

RESPONSE TO FINDING NO. 974:

Proposed Finding No. 974 is inaccurate and misleading. To begin with, a settlement can have no effect on "monopoly profits" unless the brand company was in fact earning "monopoly profits"—that is, unless the brand company possessed market power. (RX-547.0018-20 (Addanki Rep. ¶¶ 29-34); *see* Noll, Tr. 1574 (conceding that an alleged reverse-payment settlement cannot be "anticompetitive" unless the firm in question possessed "substantial market power.")). Assuming monopoly power can be shown, a reverse-payment settlement is not anticompetitive unless it left consumers worse off than they otherwise would have been. (*See* RX-547.0008, 0018, 0020 (Addanki Rep. ¶¶ 11(a), 29, 35)). As Dr. Addanki explained at trial, "whether a given settlement of patent litigation between a brand company and a generic company is anticompetitive or not can only be evaluated by considering all of the facts surrounding the settlement and evaluating whether in fact consumers were worse off with the settlement than they would have been without it." (Addanki, Tr. 2205). Without performing this analysis, "[t]here is no knowing . . . whether a given settlement is going to be pro- or anticompetitive." (Addanki, Tr. 2205).

1. Reverse-payment settlements are unusual because money flows in the wrong direction

975. In a typical infringement case, the producer of allegedly infringing products pays royalties to use a patent or damages if the patent is infringed and no license is obtained. (Noll, Tr. 1423; CX5000 at 103-04 (¶ 238) (Noll Report)). In a reverse-payment settlement, the party allegedly damaged by the infringement (the brand-name firm) pays or otherwise provides value to the party that allegedly committed the infringement (the generic firm). Where a brand-name firm pays the generic firm, the normal stream of payments is reversed and such arrangements are therefore called "reverse-payment" settlements. (Noll, Tr. 1422-23; CX5000 at 103-04 (¶¶ 237-38) (Noll Report)).

RESPONSE TO FINDING NO. 975:

Complaint Counsel's Proposed Finding No. 975 should be disregarded because it violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." (*See* Court, Tr. 1859 ("[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.")). The cited portion of Professor Noll's report, moreover, contains no evidence or analysis to support the propositions. Finally, Professor Noll was not and is not qualified as an expert regarding issues with respect to patent litigation or settlements of the same. (Noll, Tr. 1358).

2. Reverse payments convert potential competition into certainty of no competition

976. A reverse-payment settlement replaces the possibility of successful generic entry with a certainty, but at the cost of extending with certainty the minimum duration of the brand-name firm's monopoly. (CX5000 at 118 (¶ 268) (Noll Report)). Essentially, the brand-name firm is buying an insurance policy by which it pays the generic a premium in exchange for the generic guaranteeing it will not compete prior to the date specified in the settlement. (Noll, Tr. 1427-28).

RESPONSE TO FINDING NO. 976:

Complaint Counsel's Proposed Finding No. 976 is incomplete because there can only be a "possibility of generic entry" if there is a feasible baseline regarding entry, including through an alternative settlement or continued litigation. (RX-547.0058-60 (Addanki Rep. ¶¶ 108-14)). Proposed Finding No. 976 is also misleading because its rests on the unproven assumption that the brand firm has a "monopoly" to extend, which exists only if the branded-firm has market power in a relevant market. (Addanki, Tr. 2371 (testifying that the first step in an analysis is the "monopoly power screen"); RX-547.0018 (Addanki Rep. ¶ 29)). Finally, even entry-date only settlements—with no financial payment or "premium"—include *some* transfer of value to the

generic company and eliminate the theoretical risk of competition. (Bazerman, Tr. 882). By Complaint Counsel's definition, virtually any patent settlement agreement could be construed as a "reverse-payment settlement."

3. Parties in pharmaceutical patent litigation have strong incentives to use reverse payments

977. Both parties in a pharmaceutical patent litigation have strong incentives to engage in reverse-payment settlements. (CX5000 at 126, 128-29 (¶¶ 284-85, 290-92) (Noll Report)).

RESPONSE TO FINDING NO. 977:

Complaint Counsel's Proposed Finding No. 977 is not supported by any record evidence. Professor Noll, moreover, is not qualified as an expert regarding issues related to patent litigation or settlements of the same. (Noll, Tr. 1358). Complaint Counsel, moreover, cites no record evidence indicating that either Endo or Impax had "strong incentives to engage in reverse-payment settlements." Indeed, the record evidence indicates Endo did not anticipate making a payment under the SLA at all. (*See* Cuca, Tr. 664-65; CX4017 (Levin, Dep. at 125-26); *see also* CX4017 (Levin, Dep. at 99-100) ("at the time the transaction was inked I did not expect that Endo would have to make a payment under this provision")).

978. A brand-name firm faces a potential loss of profits from terminating its monopoly. (CX5000 at 126 (¶¶ 284-85) (Noll Report)). Therefore, the brand-name firm will be willing to make a payment to extend its period of monopoly profits so long as the payment is less than the excess monopoly profits it will earn during the period before the agreed-upon generic entry. (CX5000 at 124-26 (¶¶ 280, 284-85) (Noll Report); CX5001 at 023 (¶ 46) (Bazerman Report) ("common pattern" in pharmaceutical industry that brand company's gains from not facing generic competition are greater than cost for generic agreeing not to sell a generic product)). This incentive does not depend on the probability of the generic winning the infringement litigation. (CX5000 at 124-25 (¶ 280) (Noll Report)).

RESPONSE TO FINDING NO. 978:

Complaint Counsel's Proposed Finding No. 978 is not supported by record evidence. Complaint Counsel cites no record evidence indicating that any particular "brand-name firm"—to say nothing of Endo—was "willing to make a payment to extend its period of profits." Under this Court's Order on Post-trial Briefs, Complaint Counsel may not rely on "expert testimony to support factual propositions that should be established by fact witnesses or documents." (*See* Court, Tr. 1859 ("[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.")). Contrary to Complaint Counsel's suggestion, the record evidence indicates Endo did not anticipate making a payment under the SLA at all. (*See* Cuca, Tr. 664-65; CX4017 (Levin, Dep. at 125-26); *see also* CX4017 (Levin, Dep. at 99-100) ("at the time the transaction was inked I did not expect that Endo would have to make a payment under this provision")).

Finally, Proposed Finding No. 978 is misleading because its rests on the unproven assumption that there are "monopoly profits," which exist only if the branded-firm has market power in a relevant market. (Addanki, Tr. 2371 (testifying that the first step in an analysis is the "monopoly power screen"); RX-547.0018 (Addanki Rep. ¶ 29)).

> 979. Generic firms also have an incentive to enter into reverse-payment settlements. By agreeing not to launch its generic product for some period of time, the generic firm loses profits it would earn on sales of its generic product. (CX5000 at 128-29 (¶¶ 290-92) (Noll Report); *see, e.g.*, CX0505 at 001 (Mengler/Hsu email) ("the cost of Jan '11 is lost/delayed sales – you know what they [say] about a bird in the hand...")). However, if the brand-name firm compensates the generic firm with a sufficiently large payment, the generic will be willing to postpone its launch until a later date. (CX5000 at 128-29 (¶¶ 290-92) (Noll Report)). Generally, the brand-name firm will enjoy higher profits from sales of the branded drug than the generic firm will enjoy from sales of its generic drug. (CX5001 at 023 (¶ 46) (Bazerman Report) ("common pattern")). That is so for two reasons: first, the brand-name firm has 100% of the market whereas the generic firm will have to share the market; second, generics usually charge a lower price. (Noll, Tr. 1431-32). Because the sales of the drug are worth more to the brand-name firm than the generic, the payment a generic firm is willing to accept to agree to stay off the market is

small compared to the monopoly profits the brand enjoys by extending the monopoly. (Noll, Tr. 1431-32). In other words, the minimum price the generic is willing to accept to stay off the market is likely to be lower than the maximum amount the brand-name firm is willing to pay. (Noll, Tr. 1432-33).

RESPONSE TO FINDING NO. 979:

Complaint Counsel's Proposed Finding No. 979 is not supported by the record or the cited evidence. The cited portions of Professor Noll's report merely discuss an econometric equation of his own creation, not the pharmaceutical industry generally. Professor Noll, moreover, is not qualified as an expert regarding issues related to patent litigation or settlements of the same. (Noll, Tr. 1358). Neither is Professor Bazerman. (Bazerman, Tr. 844).

Because Complaint Counsel cites no record evidence to show that the purported incentives outlined in Proposed Finding No. 979 were present with Impax or Endo, Proposed Finding No. 979 should be disregarded. Under this Court's Order on Post-trial Briefs, Complaint Counsel may not rely on "expert testimony to support factual propositions that should be established by fact witnesses or documents." (*See* Court, Tr. 1859 ("[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.")). In particular, the proposed finding cites no evidence for the proposition that any particular "generic firm"—to say nothing of Impax—was "willing to postpone its launch until a later date." Contrary to Complaint Counsel's suggestion, Impax's January 1, 2013 licensed entry date did not "delay" the date on which Impax likely would have been able to market its generic oxymorphone ER product. (Figg, Tr. 1928; RX-547.0073 (Addanki Rep. ¶ 135)).

Finally, Proposed Finding No. 979 is misleading because its rests on the unproven assumption that there are "monopoly profits," which exist only if the branded-firm has market power in a relevant market. (Addanki, Tr. 2371 (testifying that the first step in an analysis is the "monopoly power screen"); RX-547.0018 (Addanki Rep. ¶ 29)). Relatedly, Complaint

Counsel's implication that "the market" is limited to the branded drug and any generic versions of it is not invariably true. In this case, the relevant market consists of long-acting opioids generally. (RX-547.022-47 (Addanki Rep. ¶¶ 41-85)).

> 980. A positive reverse payment is in the interest of both firms when the brand-name firm's expected profit from guaranteeing generic entry at a given date exceeds the expected profit of the generic firm if it does not settle. (CX5000 at 129-30 (¶ 294) (Noll Report)). So both firms have an incentive to agree to a reverse-payment settlement when the amount of the payment is larger than the amount the generic expects to make if it does not settle but smaller than the amount of lost profits the brand-name firm saves by paying the generic firm. (CX5000 at 129-30 (¶ 294) (Noll Report)).

RESPONSE TO FINDING NO. 980:

Complaint Counsel's Proposed Finding No. 980 is not supported by the record or the cited evidence. The cited portions of Professor Noll's report merely discuss an econometric equation of his own creation, not the pharmaceutical industry generally. Professor Noll, moreover, is not qualified as an expert regarding issues related to patent litigation or settlements of the same. (Noll, Tr. 1358).

Further, because Complaint Counsel cites no record evidence to show that the purported incentives outlined in Proposed Finding No. 980 were present with Impax or Endo, Proposed Finding No. 980 should be disregarded. Under this Court's Order on Post-trial Briefs, Complaint Counsel may not rely on "expert testimony to support factual propositions that should be established by fact witnesses or documents." (*See* Court, Tr. 1859 ("[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.")).

> 981. The Hatch-Waxman regulatory framework creates additional incentives for pharmaceutical companies to enter into reverse payments. Under Hatch-Waxman, the first firm to file a generic application with a Paragraph IV certification is rewarded with the 180-day exclusivity period. (CX5000 at 104 (¶ 239) (Noll Report) *see also* CCF ¶¶ 14-15, above). By reaching a settlement with the first-filer, the brand company not only eliminates the possibility of entry by the first-filer during the period before the generic entry date in the agreement, but also eliminates the possibility of entry for six

months beyond this period by other potential generic competitors. (CX5000 at 104 (¶ 239) (Noll Report); *see also* CCF ¶¶ 378-382, above). Thus, such a settlement converts the possibility of substantial loss of monopoly profits into the certainty that monopoly profits will be retained until the date of generic entry in the agreement. (CX5000 at 104 (¶ 239) (Noll Report)).

RESPONSE TO FINDING NO. 981:

Complaint Counsel's Proposed Finding No. 981 is inaccurate, unsupported, and misleading. Because Complaint Counsel cites no record evidence to show that the purported incentives outlined in Proposed Finding No. 981 were present with Impax or Endo, Proposed Finding No. 981 should be disregarded. Under this Court's Order on Post-trial Briefs, Complaint Counsel may not rely on "expert testimony to support factual propositions that should be established by fact witnesses or documents." (*See* Court, Tr. 1859 ("[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.")). Likewise, the proposed summary findings in Proposed Finding No. 981 should be disregarded because they violate the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Additionally, the individual findings cited do not support the proposed summary findings and are unreliable for the reasons set out in Respondent's replies to those findings.

Complaint Counsel's Proposed Finding No. 981 is incomplete and misleading because there is only a "possibility of substantial loss of monopoly profits" if the branded-firm has market power in a relevant market. (Addanki, Tr. 2371 (testifying that the first step in an analysis is the "monopoly power screen"); RX-547.0018 (Addanki Rep. ¶ 29)).

982. As noted above, the payment represents an amount of monopoly profits the brand-name firm is preserving by entering into the settlement. (CX5000 at 126 (¶¶ 284-85) (Noll Report)). Those monopoly profits are transferred directly from the savings customers otherwise would enjoy from generic entry. (CX4039 (Noll, Dep. 39, 88)). Therefore, the amount of the payment represents at least a lower bound of the amount of

consumer harm resulting from the reverse-payment agreement. (Noll, Tr. 1460-61; CX4039 (Noll, Dep. 39, 88)).

RESPONSE TO FINDING NO. 982:

Complaint Counsel's Proposed Finding No. 982 is an improper legal conclusion, not a fact. Proposed Finding No. 982 is also misleading because its rests on the unproven assumption that there are "monopoly profits the brand-name is preserving by entering the settlement," which exist only if the branded-firm has market power in a relevant market. (Addanki, Tr. 2371 (testifying that the first step in an analysis is the "monopoly power screen"); RX-547.0018 (Addanki Rep. ¶ 29)). Assuming monopoly power can be shown, a reverse-payment settlement is not anticompetitive unless it left consumers worse off than they otherwise would have been. (*See* RX-547.0008, 0018, 0020 (Addanki Rep. ¶¶ 11(a), 29, 35)). As Dr. Addanki explained at trial, "whether a given settlement of patent litigation between a brand company and a generic company is anticompetitive or not can only be evaluated by considering all of the facts surrounding the settlement and evaluating whether in fact consumers were worse off with the settlement than they would have been without it." (Addanki, Tr. 2205). Without performing this analysis, "[t]here is no knowing . . . whether a given settlement is going to be pro- or anticompetitive." (Addanki, Tr. 2205).

4. A large, unjustified reverse payment is anticompetitive regardless of the likelihood that the patent holder would prevail in the patent case, or whether the parties would reach a settlement without a reverse payment

983. The definition of an anticompetitive reverse-payment settlement is derived from a comparison between the settlement agreement that would maximize expected consumer welfare, and the expected consumer welfare arising from a settlement. The settlement that maximizes expected consumer welfare is one in which the expected profits of the brand-name and generic firms are the same as the expected profits from litigating the case conclusion. (CX5004 at 061 (¶ 130) (Noll Rebuttal Report)). If the expected profits of the brand-name and generic firms are greater from the settlement than from continuing to litigate, the reason is that the parties are sharing the profits that result from preserving the

brand's monopoly at the expense of consumers. (CX5000 at 132-33 (¶¶ 300-01) (Noll Report)).

RESPONSE TO FINDING NO. 983:

Complaint Counsel's Proposed Finding No. 983 is inaccurate, unsupported, and misleading. To begin with, the first sentence in Proposed Finding No. 983 violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2).

The second and third sentences in Proposed Finding No. 983 are inaccurate. A settlement cannot "preserve the brand's monopoly" unless the brand company possessed monopoly power in the first case. (RX-547.0018-20 (Addanki Rep. ¶¶ 29-34); *see* Noll, Tr. 1574 (conceding that an alleged reverse-payment settlement cannot be "anticompetitive" unless the firm in question possessed "substantial market power.")). Assuming monopoly power can be shown, a reverse-payment settlement is not anticompetitive unless it left consumers worse off than they otherwise would have been. (*See* RX-547.0008, 0018, 0020 (Addanki Rep. ¶¶ 11(a), 29, 35)). As Dr. Addanki explained at trial, "whether a given settlement of patent litigation between a brand company and a generic company is anticompetitive or not can only be evaluated by considering all of the facts surrounding the settlement and evaluating whether in fact consumers were worse off with the settlement than they would have been without it." (Addanki, Tr. 2205). Without performing this analysis, "[t]here is no knowing . . . whether a given settlement is going to be pro- or anticompetitive." (Addanki, Tr. 2205).

984. Thus, the anticompetitive nature of a large reverse payment does not depend on the probability that the patent holder (i.e., the brand-name firm) would win the underlying infringement case. (Noll, Tr. 1441-42; CX5000 at 120, 124 (¶¶ 271, 280) (Noll Report); CX5004 at 066 (¶ 140) (Noll Rebuttal Report)). The existence of the payment itself implicitly reflects the parties' assessment of the probability that the brand-name firm may lose the infringement case. (CX5004 at 062, 103-05, 120 (¶¶ 131, 238, 242, 271) (Noll Rebuttal Report)). In particular, a brand-name firm will not agree to make a large,

> unjustified payment to the generic firm if the generic firm is likely to lose the infringement case. (CX5000 at 103-05, 120 (¶¶ 238, 242, 271) (Noll Report)). At the same time, even if the brand-name firm is likely (but not certain) to prevail in the patent infringement suit, it still has the incentive to pay a portion of its monopoly profits to guarantee that generic entry will not occur. Thus, the mere fact that the brand-name firm agreed to make a large payment to the generic firm rules out the possibility the settlement was procompetitive. (CX5000 at 120, 133 (¶¶ 271, 302) (Noll Report)).

RESPONSE TO FINDING NO. 984:

Complaint Counsel's Proposed Finding No. 984 is inaccurate, unsupported, and misleading. Because Complaint Counsel cites no record evidence to show that the purported incentives outlined in Proposed Finding No. 984 were present with Impax or Endo, Proposed Finding No. 984 should be disregarded. Under this Court's Order on Post-trial Briefs, Complaint Counsel may not rely on "expert testimony to support factual propositions that should be established by fact witnesses or documents." (*See* Court, Tr. 1859 ("[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.")).

Likewise, the fourth sentence in Proposed Finding No. 984 violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2).

The remainder of Proposed Finding No. 984 is wrong as a matter of economics, since it treats all "reverse-payment settlements" with "large" payments as *per se* anticompetitive. As Dr. Addanki explained at trial, "whether a given settlement of patent litigation between a brand company and a generic company is anticompetitive or not can only be evaluated by considering all of the facts surrounding the settlement and evaluating whether in fact consumers were worse off with the settlement than they would have been without it." (Addanki, Tr. 2205). The analysis is "really not any different from what we would do in any kind of rule of reason case." (Addanki, Tr. 2206). Because of this, the appropriate inquiry is (1) whether the firm in question possessed monopoly power; and (2) if so, whether the challenged conduct left consumers worse

off than they otherwise would have been. (*See* RX-547.0008, 0018, 0020 (Addanki Rep. ¶¶ 11(a), 29, 35)). Without performing this analysis, "[t]here is no knowing . . . whether a given settlement is going to be pro- or anticompetitive." (Addanki, Tr. 2205).

Complaint Counsel is also wrong in asserting that the probable result of the settling parties' patent litigation is irrelevant to the economic inquiry. To establish that consumers fared worse under the settlement than they otherwise would have, the evidence must show that (1) an alternative settlement with an earlier entry date was actually feasible; or (2) there is a high probability that, if the parties had continued litigating, the generic firm would have prevailed in the underlying patent litigation and entered earlier than the settlement entry date. (RX-547.0020, 0070-71 (Addanki Rep. ¶¶ 36, 128-30) ("Unless there is compelling evidence of a fully-specified alternative agreement that the parties contemplated . . . the operating assumption must be that the but-for world is one in which the parties litigated the patent suit to its conclusion.")). If the brand company was likely to prevail in the patent case, an entry date prior to the expiration of the patents-in-suit would benefit consumers. (*See* Figg, Tr. 1927-28, 1971).

> 985. Indeed, the only roles that are played by the probability of winning the infringement case are: 1) whether the expected profit for each firm from litigation is sufficient to justify spending litigation costs; and 2) how large the reverse payment must be to induce the generic firm to guarantee that it will not enter until the date of the settlement. As a result, the presence of a large, unjustified payment means that it is not necessary to know the probability the brand-name firm would have won the infringement litigation in order to conclude the settlement was anticompetitive. (CX5000 at 120, 131 (¶¶ 271, 302) (Noll Report); CX5004 at 065-66 (¶¶ 139-40) (Noll Rebuttal Report)).

RESPONSE TO FINDING NO. 985:

Complaint Counsel's Proposed Finding No. 985 is inaccurate, unsupported, and misleading. The first sentence in Proposed Finding No. 985 violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Moreover, because

Complaint Counsel cites no record evidence to show that the purported incentives outlined in Proposed Finding No. 985 were present with Impax or Endo, the proposed finding should be disregarded. Under this Court's Order on Post-trial Briefs, Complaint Counsel may not rely on "expert testimony to support factual propositions that should be established by fact witnesses or documents." (*See* Court, Tr. 1859 ("[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.")).

In any event, Proposed Finding No. 985 is wrong as a matter of economics, since it treats all "reverse-payment settlements" with "large" payments as *per se* anticompetitive. As Dr. Addanki explained at trial, "whether a given settlement of patent litigation between a brand company and a generic company is anticompetitive or not can only be evaluated by considering all of the facts surrounding the settlement and evaluating whether in fact consumers were worse off with the settlement than they would have been without it." (Addanki, Tr. 2205). The analysis is "really not any different from what we would do in any kind of rule of reason case." (Addanki, Tr. 2206). Because of this, the appropriate inquiry is (1) whether the firm in question possessed monopoly power; and (2) if so, whether the challenged conduct left consumers worse off than they otherwise would have been. (*See* RX-547.0008, 0018, 0020 (Addanki Rep. ¶¶ 11(a), 29, 35)). Without performing this analysis, "[t]here is no knowing . . . whether a given settlement is going to be pro- or anticompetitive." (Addanki, Tr. 2205).

Complaint Counsel is also wrong in asserting that the probable result of the settling parties' patent litigation is irrelevant to the economic inquiry. To establish that consumers fared worse under the settlement than they otherwise would have, the evidence must show that (1) an alternative settlement with an earlier entry date was actually feasible; or (2) there is a high probability that, if the parties had continued litigating, the generic firm would have prevailed in

the underlying patent litigation and entered earlier than the settlement entry date. (RX-547.0020, 0070-71 (Addanki Rep. ¶¶ 36, 128-30) ("Unless there is compelling evidence of a fully-specified alternative agreement that the parties contemplated . . . the operating assumption must be that the but-for world is one in which the parties litigated the patent suit to its conclusion.")). If the brand company was likely to prevail in the patent case, an entry date prior to the expiration of the patents-in-suit would benefit consumers. (*See* Figg, Tr. 1927-28, 1971).

> 986. It also is not necessary to determine the specific date on which a generic would have entered (either by litigating the matter to conclusion or agreeing to an alternative settlement) in order to conclude that the reverse-payment agreement is anticompetitive. (CX5004 at 076-77 (¶ 160) (Noll Rebuttal Report); CX4039 (Noll, Dep. at 58-59)). The fact that a brand-name firm is willing to make a large, unjustified payment confirms that the brand-name firm recognized the possibility that the generic could enter before the agreed-upon entry date; otherwise the brand-name firm would have no reason to make a large and unjustified payment. (CX5000 at 103-05 (¶¶ 238, 242) (Noll Report)).

RESPONSE TO FINDING NO. 986:

Complaint Counsel's Proposed Finding No. 986 is inaccurate, unsupported, and misleading. Because Complaint Counsel cites no record evidence to show that the purported incentives outlined in Proposed Finding No. 986 were present with Impax or Endo, Proposed Finding No. 986 should be disregarded. Under this Court's Order on Post-trial Briefs, Complaint Counsel may not rely on "expert testimony to support factual propositions that should be established by fact witnesses or documents." (*See* Court, Tr. 1859 ("[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.")).

In any event, Proposed Finding No. 986 is wrong as a matter of economics, since it treats all "reverse-payment settlements" with "large" payments as *per se* anticompetitive. As Dr. Addanki explained at trial, "whether a given settlement of patent litigation between a brand company and a generic company is anticompetitive or not can only be evaluated by considering all of the facts surrounding the settlement and evaluating whether in fact consumers were worse

off with the settlement than they would have been without it." (Addanki, Tr. 2205). The analysis is "really not any different from what we would do in any kind of rule of reason case." (Addanki, Tr. 2206). Because of this, the appropriate inquiry is (1) whether the firm in question possessed monopoly power; and (2) if so, whether the challenged conduct left consumers worse off than they otherwise would have been. (*See* RX-547.0008, 0018, 0020 (Addanki Rep. ¶¶ 11(a), 29, 35)). Without performing this analysis, "[t]here is no knowing . . . whether a given settlement is going to be pro- or anticompetitive." (Addanki, Tr. 2205).

Complaint Counsel is also wrong in asserting that the probable result of the settling parties' patent litigation is irrelevant to the economic inquiry. To establish that consumers fared worse under the settlement than they otherwise would have, the evidence must show that (1) an alternative settlement with an earlier entry date was actually feasible; or (2) there is a high probability that, if the parties had continued litigating, the generic firm would have prevailed in the underlying patent litigation and entered earlier than the settlement entry date. (RX-547.0020, 0070-71 (Addanki Rep. ¶¶ 36, 128-30) ("Unless there is compelling evidence of a fully-specified alternative agreement that the parties contemplated . . . the operating assumption must be that the but-for world is one in which the parties litigated the patent suit to its conclusion.")). If the brand company was likely to prevail in the patent case, an entry date prior to the expiration of the patents-in-suit would benefit consumers. (*See* Figg, Tr. 1927-28, 1971).

> 987. As a result, the existence of the large, unjustified payment indicates that the brand-name firm is extending the monopoly beyond the exclusivity period it would expect to enjoy in the absence of a payment. This concept applies regardless of whether the reverse-payment settlement extends the brand-name firm's exclusivity beyond the date the generic might be expected to enter by litigating the merits of the patent suit or by entering into an alternative no payment settlement agreement. (CX5000 at 103-05 (¶¶ 238, 242) (Noll Report); CX5004 at 062 (¶ 131) (Noll Rebuttal Report)).

RESPONSE TO FINDING NO. 987:

Complaint Counsel's Proposed Finding No. 987 is inaccurate, unsupported, and misleading. The first sentence in Proposed Finding No. 987 violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Moreover, because Complaint Counsel cites no record evidence to show that the purported incentives outlined in Proposed Finding No. 987 were present with Impax or Endo, the proposed finding should be disregarded. Under this Court's Order on Post-trial Briefs, Complaint Counsel may not rely on "expert testimony to support factual propositions that should be established by fact witnesses or documents." (*See* Court, Tr. 1859 ("[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.")).

In any event, Proposed Finding No. 987 is wrong as a matter of economics, since it treats all "reverse-payment settlements" with "large" payments as *per se* anticompetitive. As Dr. Addanki explained at trial, "whether a given settlement of patent litigation between a brand company and a generic company is anticompetitive or not can only be evaluated by considering all of the facts surrounding the settlement and evaluating whether in fact consumers were worse off with the settlement than they would have been without it." (Addanki, Tr. 2205). The analysis is "really not any different from what we would do in any kind of rule of reason case." (Addanki, Tr. 2206). Because of this, the appropriate inquiry is (1) whether the firm in question possessed monopoly power; and (2) if so, whether the challenged conduct left consumers worse off than they otherwise would have been. (*See* RX-547.0008, 0018, 0020 (Addanki Rep. ¶¶ 11(a), 29, 35)). Without performing this analysis, "[t]here is no knowing . . . whether a given settlement is going to be pro- or anticompetitive." (Addanki, Tr. 2205).

Complaint Counsel is also wrong in asserting that the probable result of the settling parties' patent litigation and the feasibility of an alternative settlement are irrelevant to the economic inquiry. To establish that consumers fared worse under the settlement than they otherwise would have, the evidence must show that (1) an alternative settlement with an earlier entry date was actually feasible; or (2) there is a high probability that, if the parties had continued litigating, the generic firm would have prevailed in the underlying patent litigation and entered earlier than the settlement entry date. (RX-547.0020, 0070-71 (Addanki Rep. ¶¶ 36, 128-30) ("Unless there is compelling evidence of a fully-specified alternative agreement that the parties contemplated . . . the operating assumption must be that the but-for world is one in which the parties litigated the patent suit to its conclusion.")). If the brand company was likely to prevail in the patent case, an entry date prior to the expiration of the patents-in-suit would benefit consumers. (*See* Figg, Tr. 1927-28, 1971).

Further, Proposed Finding No. 987 is internally contradictory and does not comport with common sense. Complaint Counsel proposes a finding that "the existence of the large, unjustified payment indicates that the brand-name firm is extending the monopoly power *beyond the exclusivity period it would expect to enjoy in the absence of a payment*"—but then turns around and asserts that the "concept applies *regardless* of whether the reverse-payment settlement *extends the brand-name firm's exclusivity beyond the date the generic might be expected to enter* . . . ." (Emphasis added). These two statements are inconsistent, and demonstrate the impractical nature of Complaint Counsel's proposed findings.

> 988. Dr. Addanki fails to address the implication of this conclusion: Endo would not have agreed to pay Impax more than $100 million if the settlement allowed Impax to enter the market earlier than it otherwise could have. (Noll, Tr. 1487-88; CX5004 at 059-60 (¶ 125) (Noll Rebuttal Report)). The only conclusion one can draw from the fact that Endo made such a large and unjustified payment to Impax is that, taking into account all contingencies (such as allowing the litigation to run its course), Endo expected to earn

monopoly profits for a longer time period under the settlement than it would if it did not settle and pay Impax. (CX5004 at 076 (¶ 159) (Noll Rebuttal Report); *see also* CX5001 at 031 (¶ 57) (Bazerman Report) ("Considering all of these factors together, I fail to see any explanation for the No-AG agreement and the back-up Endo Credit other than to compensate Impax to accept an entry date in January 2013.")).

RESPONSE TO FINDING NO. 988:

Complaint Counsel's Proposed Finding No. 988 is inaccurate, unsupported, and misleading. Proposed Finding No. 988 is premised on the assertion that Endo agreed upfront to "pay Impax more than $100 million," but that is just not true. When it was signed, the SLA did not require Endo to actually pay *anything* to Impax. (RX-364.0012 (SLA § 4.4) (no payment until 90 days after documentation that Endo Credit was triggered is provided)). Nor did Endo expect to make a payment at any point in the future. (CX4017 (Levin, Dep. at 99-100) ("at the time the transaction was inked I did not expect that Endo would have to make a payment under this provision")). Indeed, as Professor Noll admits, Endo could not even estimate whether it would make a payment of any size until after an unexpected supply disruption in 2012. (Cuca, Tr. 665-71, 677; *see* CX5004-070-71 (Noll Rebuttal Rep. ¶ 149)).

Proposed Finding No. 998 ignores the fact that Impax could have derived no "payment" from either the Endo Credit *or* the No-Authorized Generic provision. (RX-547.0067-68 (Addanki Rep. ¶ 126); Addanki, Tr. 2355; *see* Noll, Tr. 1653-54 ("Q. And that example where you get zero of both, you didn't include that on your demonstrative of scenarios, did you? A. No, I didn't."); Addanki, Tr. 2355 (a rational actor like Endo "would manage that transition [to reformulated Opana ER] to minimize its patient loss and to minimize whatever payments it was going to make."); *see also* Court, Tr. 71, 75 ("JUDGE CHAPPELL: Are you going to stand there and tell me that the lowest possible outcome was not going to be zero? You're going to stand there and tell me that because some paid expert tells you that it had to be $62 million floor

that it couldn't have been zero? MR. LOUGHLIN: No, Your Honor. There was a theoretical possibility of zero.")).

> 989. Dr. Addanki has been unwilling to address the question of why Endo would settle with Impax at all, let alone agree to a large payment in the form of the No-AG and the Endo Credit provisions, if it could obtain a better result (i.e., later generic entry) by not settling with Impax. (CX4044 (Addanki, Dep. at 56-57)).

RESPONSE TO FINDING NO. 989:

Complaint Counsel's Proposed Finding No. 989 is inaccurate, unsupported, and misleading. Proposed Finding No. 989 is premised on the assertion that Endo "agree[d] to a large payment in the form of the No-AG and the Endo Credit provisions," but that is false. When it was signed, the SLA did not require Endo to actually pay *anything* to Impax. (RX-364.0012 (SLA § 4.4) (no payment until 90 days after documentation that Endo Credit was triggered is provided)). Nor did Endo expect to make a payment at any point in the future. (CX4017 (Levin, Dep. at 99-100) ("at the time the transaction was inked I did not expect that Endo would have to make a payment under this provision")). It was possible that Impax could have derived no "payment" from either the Endo Credit *or* the No-Authorized Generic provision. (RX-547.0067-68 (Addanki Rep. ¶ 126); Addanki, Tr. 2355; *see* Noll, Tr. 1653-54 ("Q. And that example where you get zero of both, you didn't include that on your demonstrative of scenarios, did you? A. No, I didn't."); Addanki, Tr. 2355 (a rational actor like Endo "would manage that transition [to reformulated Opana ER] to minimize its patient loss and to minimize whatever payments it was going to make."); *see also* Court, Tr. 71, 75 ("JUDGE CHAPPELL: Are you going to stand there and tell me that the lowest possible outcome was not going to be zero? You're going to stand there and tell me that because some paid expert tells you that it had to be $62 million floor that it couldn't have been zero? MR. LOUGHLIN: No, Your Honor.

There was a theoretical possibility of zero.")). Indeed, Professor Noll agrees that the payment pursuant to the SLA could have been zero. (Noll, Tr. 1479-81).

Moreover, Dr. Addanki *did* address Complaint Counsel's contrived "question." As reflected in the cited portion of his deposition transcript, Dr. Addanki refused to speculate about Endo's subjective motivations. (*See* CX4044 (Addanki, Dep. at 56) ("Q. . . . [W]hy did Endo settle at all? A. You have to ask Endo that."); CX4044 (Addanki, Dep. at 57) ("I don't know what Endo regarded as the uncertainties facing it.")). But as Complaint Counsel neglects to mention, he went on to explain that "*the provisions involving the Endo credit and the no-AG provision may not have been viewed as having much value on Endo's part at the time*." (CX4044 (Addanki, Dep. at 57) (emphasis added)). That Endo did not view those provisions as carrying material value in June 2010 is borne out by the record. (*See* CX4017 (Levin, Dep. at 99-100) (Endo did not expect to make a payment); CX4017 (Levin, Dep. at 118-19) (Endo "never seriously considered taking any further steps to prepare for or to do [an authorized generic] because we really didn't want to"); CX4031 (Bradly, Dep. at 198) ("I don't recall having any conversation with any colleagues regarding the launch of an authorized generic."); *see also* Noll, Tr. 1649 (neither Endo nor Impax forecasted or planned for a payment)).

C. Endo paid Impax to eliminate the risk of competition, which harmed consumers and competition

990. Opana ER was a successful product for Endo. (CX2607 at 004-05 (¶ 13) (Lortie Decl.) (Opana ER was a "commercial success for Endo"); *see also* CCF ¶¶ 33-46, above). Opana ER's sales grew rapidly from $5 million in 2006 to $172 million in 2009 to $240 million in 2010. (CX2607 at 004-05 (¶ 13) (Lortie Decl.)). Impax was the first ANDA filer for five dosages of Opana ER (5, 10, 20, 30, and 40). (JX-001 at 007 (¶ 13)). Those five dosages accounted for roughly 95% of Opana ER sales volume. (JX-001 at 007 (¶ 13); CX2607 at 010 (¶ 26) (Lortie Decl.)). Impax's ANDA contained a Paragraph IV certification stating that its generic version of oxymorphone ER did not infringe Endo's patents and/or that Endo's patents were invalid. (JX-001 at 007 (¶ 12)).

RESPONSE TO FINDING NO. 990:

Respondent has no specific response.

991. Endo sued Impax for patent infringement in January 2008. (JX-001 at 007 (¶ 15); CX3163 at 010 (¶ 39) (Impax Answer)). Endo's suit triggered the 30-month stay, which was set to expire on June 14, 2010. (JX-001 at 007 (¶¶ 15-16); CX3163 at 010 (¶ 39) (Impax Answer)).

RESPONSE TO FINDING NO. 991:

Respondent has no specific response.

992. Impax received tentative approval from the FDA on May 13, 2010. (JX-001 at 007 (¶ 17)). Endo's and Impax's infringement case went to trial, and was in trial when the parties settled on June 8, 2010. (JX-001 at 007 (¶ 18)). Impax received final FDA approval to launch generic oxymorphone ER in four dosage strengths on June 14, 2010. (JX-001 at 008 (¶ 21)).

RESPONSE TO FINDING NO. 992:

Respondent has no specific response.

993. Pursuant to the settlement, Impax agreed not to enter for a period of about two and a half years, from June 8, 2010 until January 1, 2013. (RX-364 at 007 (SLA §3.2)). The agreement contained a payment from Endo to Impax in the form of Endo's agreement not to launch an authorized generic version of Opana ER during Impax's 180-day exclusivity period. (RX-364 at 0010 (SLA § 4.1(c))). Endo further agreed that if the market for Opana ER degraded by more than 50% for any reason before Impax could launch, Endo would make a cash payment to Impax, the Endo Credit. (RX-364 at 0012 (SLA § 4.4)). The amount of the cash payment represented compensation to Impax for any decline in sales that Impax experienced during the period of delay. (Cuca, Tr. 612-13 ("The Endo credit established terms based on expectations of Endo product sales and Impax product sales under which there could be a payment from Endo to Impax if those expectations weren't met"); CX3438 at023 (Impax board presentation described the expected Endo Credit payment as "Compensation for declining market")). Endo's payment to Impax under the terms of the Endo Credit was ultimately approximately $102 million. (CX0333 at 001-002 (email dated April 18, 2013 containing wire transfer)).

RESPONSE TO FINDING NO. 993:

Complaint Counsel's Proposed Finding No. 993 mischaracterizes the Settlement Agreement. *First*, it is inaccurate to state Impax agreed "not to enter from June 8, 2010 until

January 1, 2013." Instead, January 1, 2013, was the *latest* licensed entry date contemplated under the Settlement Agreement. (RX-364.001 (SLA §1.1)). *Second*, the "agreement not to launch an authorized generic" does not represent a "payment from Endo to Impax." Endo never intended to launch an authorized generic and instead planned to switch from original Opana ER to a reformulated version. (Bingol, Tr. 1338-39 (an authorized generic "was never, to my knowledge . . . fully realized as a plan or an idea"); CX4019 (Lortie, Dep. at 118-19) ("we never seriously considered taking any further steps to prepare for or to do [an authorized generic] because we really didn't want to."); CX4031 (Bradley, Dep. at 198) ("I don't recall having any conversation with any colleagues regarding the launch of an authorized generic.")). Professor Noll, moreover, did not calculate an expected value to Impax of the No-Authorized Generic provision, and therefore there is no basis to state the term constituted a payment. (Noll, Tr. 1591).

Third, the amount of an Endo Credit payment would not track purportedly lost sales over any period of time. To illustrate, actual quarterly peak sales after settlement were $185,691,457. (CX0332-003). If sales dropped just enough to trigger the Endo Credit, for instance, because sales in the last quarter of 2012 were 49 percent of their quarterly peak, this would mean the resulting liability would be roughly $2 million. If sales dropped only to 49.9 percent of their peak, the resulting liability would be roughly $200,000. (RX-364.0003-04 (any Endo Credit payment is the product of (1) 0.2953 times the annualized quarterly peak sales divided by 100, and (2) the number of percentage points under 50)). *Fourth*, Proposed Finding No. 993 is incomplete because it fails to mention the royalty provision, which was "the mirror image of the Endo Credit." (Cuca, Tr. 613-14; CX4017 (Levin, Dep. at 120-21) (Endo Credit and Royalty Provision "were intended to be looked at hand in hand"); Koch, Tr. 236-37, 240-41).

1. The reverse payment would be expected to push back the expected negotiated entry date in the settlement

994. The reverse payment would be expected to expand the range of settlement negotiations and allow the parties to agree to a settlement with an entry date for Impax's generic version of Opana ER beyond what would have been expected without those payments. (CX5001 at 035 (¶ 66) (Bazerman Report)). The reverse payment functioned as a means to provide Impax with a payment for not entering the market until the negotiated entry date. (CX5001 at 035 (¶ 66) (Bazerman Report)). Essentially, Endo and Impax increased their total profit by allowing Endo to maintain a monopoly, and Endo provided Impax with sufficient compensation. (CX5001 at 035 (¶ 66) (Bazerman Report)). This allowed Endo and Impax to benefit at the expense of consumers. (CX5001 at 035 (¶ 66) (Bazerman Report)).

RESPONSE TO FINDING NO. 994:

Complaint Counsel's Proposed Finding No. 994 should be disregarded because it violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." (*See* Court, Tr. 1858-59 ("[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.")). But Proposed Finding No. 994 is also without support in the record. To begin with, there was no "reverse payment"; when it was signed, the SLA did not require Endo to actually pay anything to Impax. (RX-364.0012 (SLA § 4.4) (no payment until 90 days after documentation that Endo Credit was triggered is provided)). Nor did Endo expect to make a payment at any point in the future. (CX4017 (Levin, Dep. at 99-100) ("at the time the transaction was inked I did not expect that Endo would have to make a payment under this provision")). Professor Noll did not even attempt to calculate the expected value of the Endo Credit or No-AG provisions, either separately or in tandem. (Noll, 1590-92, 1613; CX4039 (Noll, Dep. at 116)). Because there is no evidence that Impax received a reverse payment at the time of the settlement, the premise of Proposed Finding No. 994 is invalid.

Moreover, the assertion that the alleged payment "would be expected to expand the range of settlement negotiations and allow the parties to agree to a settlement with an entry date for

Impax's generic version of Opana ER beyond what would have been expected without those payments" is pure speculation, unmoored from any record evidence. Professor Bazerman did not calculate Impax's or Endo's reservation dates, and as he admitted at trial, he could not even say whether any alternative settlement was possible. (Bazerman, Tr. 912-14). Indeed, there is *no evidence* that Impax could have obtained a more favorable license date through settlement. (Koch, Tr. 239 (Impax "met complete resistance to the concept of an earlier launch date."); Mengler, Tr. 565-67 (testifying that Endo was "adamant about 2013 and not getting anything into 2012" and "was certainly digging in their heels with that date."); Noll, Tr. 1599-1600 ("Impax's attempt to get an earlier date met with complete resistance.")). And the Proposed Finding fails to account for the reality that Impax was more likely than not to lose the underlying patent infringement case (thereby would have been enjoined from launching until at least September 2013). (Figg, Tr. 1927-28, 1936-37; Addanki, Tr. 2376; Noll, Tr. 1670).

Finally, Proposed Finding No. 995 incorrectly assumes that Endo had a "monopoly." In fact, Endo did not have monopoly power. (RX-547.0050-57 (Addanki Rep. ¶¶ 93-107)).

> 995. There is no reason for Endo to agree to pay Impax an amount in excess of saved litigation costs unless Endo believed it would earn greater profits because of later generic entry. (CX5000 at 103-05 (¶¶ 238, 242) (Noll Report); *see also* Bazerman, Tr. 874 ("if Endo would agree to January 2013 with a provision that provides significant payment to Impax, then simple negotiation logic tells me that if – if Endo didn't have to pay tens of millions or, as it turns out, 102 million to Impax, they would have agreed to an earlier date without that amount of money being paid")). If Endo believed Impax would not launch prior to January 1, 2013, it would have no reason to settle with Impax with that agreed-upon entry date and provide Impax value in the form of the No-AG agreement and the Endo Credit. (Noll, Tr. 1487-88; CX5004 at 059-60 (¶ 125) (Noll Rebuttal Report)).

RESPONSE TO FINDING NO. 995:

Complaint Counsel's Proposed Finding No. 995 should be disregarded because it violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual

propositions that should be established by fact witnesses or documents." (*See* Court, Tr. 1859 ("[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.")). But Proposed Finding No. 995 is also without support in the record. Endo did not "agree to pay Impax an amount in excess of saved litigation costs"; when it was signed, the SLA did not require Endo to actually pay anything to Impax. (RX-364.0012 (SLA § 4.4) (no payment until 90 days after documentation that Endo Credit was triggered is provided)). Nor did Endo expect to make a payment at any point in the future. (CX4017 (Levin, Dep. at 99-100) ("at the time the transaction was inked I did not expect that Endo would have to make a payment under this provision")).

Specifically, the No-Authorized Generic provision did not represent a payment since Endo never intended to launch an authorized generic, planning instead to switch from original Opana to a reformulated version. (Bingol, Tr. 1338-39 (an authorized generic "was never, to my knowledge . . . fully realized as a plan or an idea"); CX4019 (Lortie, Dep. at 118-19) ("we never seriously considered taking any further steps to prepare for or to do [an authorized generic] because we really didn't want to."); CX4031 (Bradley, Dep. at 198) ("I don't recall having any conversation with any colleagues regarding the launch of an authorized generic.")). Whether and how much Endo would ever pay under the "Endo Credit" provision was based on contingent future events. (Noll, Tr. 1611-12; Addanki, Tr. 2356). And neither Professor Noll nor Professor Bazerman calculated the expected value of any provision in the settlement agreement, or the overall expected value of the SLA, and therefore have no basis to claim there was a "payment" in excess of anything, including litigation costs. (Noll, Tr. 1590-92, 1613, 1651-52; Bazerman, Tr. 923; CX4039 (Noll, Dep. at 116)).

Proposed Finding No. 995 also ignores the fact that Impax could have derived no "payment" from either the Endo Credit *or* the No-Authorized Generic provision. (RX-547.0067-68 (Addanki Rep. ¶ 126); Addanki, Tr. 2355; *see* Noll, Tr. 1653-54 ("Q. And that example where you get zero of both, you didn't include that on your demonstrative of scenarios, did you? A. No, I didn't."); Addanki, Tr. 2355 (a rational actor like Endo "would manage that transition [to reformulated Opana ER] to minimize its patient loss and to minimize whatever payments it was going to make."); *see also* Court, Tr. 71, 75 ("JUDGE CHAPPELL: Are you going to stand there and tell me that the lowest possible outcome was not going to be zero? You're going to stand there and tell me that because some paid expert tells you that it had to be $62 million floor that it couldn't have been zero? MR. LOUGHLIN: No, Your Honor. There was a theoretical possibility of zero.")). Finally, Proposed Finding No. 995 fails to take into account the uncertainty regarding the underlying patent infringement litigation. (Figg, Tr. 2046).

996. As explained in more detail in Section VII above and Section XII below, the No-AG provision and the Endo Credit were large, unjustified payments. (*See* CCF ¶¶ 452-497, above, and ¶¶ 1031-54, below; CX5000 at 171-72, 240 (¶¶ 381-83, Appendix F) (Noll Report)). Both provisions were valuable to Impax. (*See* CCF ¶¶ 390-444, above).

RESPONSE TO FINDING NO. 996:

The proposed summary finding should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Additionally, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondent's replies to those findings. Proposed Finding No. 996 also states an improper legal conclusion, not a fact.

997. Endo's agreement not to launch an AG was valuable to Impax. (CX5000 at 154-55 (¶ 348) (Noll Report); *see also* CCF ¶¶ 390-417, above). When a brand-name

firm launches an AG against the first-to-file generic, the AG takes sales share away from the first-to-file generic and, as a second generic competitor, depresses the price of the generic. (CX5000 at 154 (¶ 347) (Noll Report); *see also* CCF ¶¶ 28-32, above). Keeping an AG off the market can double the revenues and operating profit of the first-to-file generic during the 180-day exclusivity period. (CX5000 at 154 (¶ 347) (Noll Report); *see also* CCF ¶¶ 3132, 413, above).

RESPONSE TO FINDING NO. 997:

Complaint Counsel's Proposed Finding No. 997 should be disregarded because it violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." (*See* Court, Tr. 1859 ("[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.")). But Proposed Finding No. 997 is also lacks foundation and is without support in the record. Professor Noll did not calculate the expected value of any provision in the settlement agreement, or the overall expected value of the SLA. (Noll, Tr. 1591, 1613, 1651-52; CX4039 (Noll, Dep. at 116)).

Endo, moreover, never intended to launch an authorized generic, planning instead to switch from original Opana ER to a reformulated version. (Bingol, Tr. 1338-39 (an authorized generic "was never, to my knowledge . . . fully realized as a plan or an idea"); CX4019 (Lortie, Dep. at 118-19) ("we never seriously considered taking any further steps to prepare for or to do [an authorized generic] because we really didn't want to."); CX4031 (Bradley, Dep. at 198) ("I don't recall having any conversation with any colleagues regarding the launch of an authorized generic.")).

Proposed Finding No. 997 also ignores the fact that Impax could have derived no value from either the Endo Credit *or* the No-Authorized Generic provision. (RX-547.0067-68 (Addanki Rep. ¶ 126); Addanki, Tr. 2355; *see* Noll, Tr. 1653-54 ("Q. And that example where you get zero of both, you didn't include that on your demonstrative of scenarios, did you? A.

No, I didn't."); Addanki, Tr. 2355 (a rational actor like Endo "would manage that transition [to reformulated Opana ER] to minimize its patient loss and to minimize whatever payments it was going to make."); *see also* Court, Tr. 71, 75 ("JUDGE CHAPPELL: Are you going to stand there and tell me that the lowest possible outcome was not going to be zero? You're going to stand there and tell me that because some paid expert tells you that it had to be $62 million floor that it couldn't have been zero? MR. LOUGHLIN: No, Your Honor. There was a theoretical possibility of zero.")).

998. Launching an AG is generally valuable to the brand-name firm, as it offsets some of the loss of sales the brand-name firm would otherwise experience due to the first-to-file generic's launch. (*See* CCF ¶¶ 28, 399, above). In this case, Endo estimated that it would lose $71 million in sales once Impax launched, but it could recoup $25 million of that if it launched an AG. (CX1314 (Cuca/Levin email) (analyzing the amount of sales Endo could recoup if it launched an AG)). So by agreeing to a No-AG, Endo agreed to forego approximately $25 million in sales, based on sales in 2010. (CX1314 at 001 (June 1, 2010 Cuca/Levin email)).

RESPONSE TO FINDING NO. 998:

The first sentence of Complaint Counsel's Proposed Finding No. 998 should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). The second and third sentences of Proposed Finding No. 998 are inaccurate and misleading. Mr. Cuca, the author of the cited email (CX1314), testified that the figures came from "assuming some specified erosion assumption." (CX4035 (Cuca, Dep. at 66) (discussing CX1314)). Mr. Cuca also testified that under those assumptions, "the bottom-line effect"—Endo's income before taxes, which considers revenues and expenses together—would only be $2 million at the "more aggressive end of the range of cost savings" and $13.5 million if Endo was "less aggressive about cost savings." (CX4035 (Cuca, Dep. at 67) (discussing CX1314)). Mr. Cuca also testified that Endo forecasted different scenarios regarding

the future of its Opana ER product to "analyze the full range of potential outcomes," but did not know if any of the many different assumptions in its forecasts would come true. (Cuca, Tr. 662-64).

Indeed, Endo never intended to launch an authorized generic, planning instead to switch from original Opana ER to a reformulated version. (Bingol, Tr. 1338-39 (an authorized generic "was never, to my knowledge . . . fully realized as a plan or an idea"); CX4019 (Lortie, Dep. at 118-19) ("we never seriously considered taking any further steps to prepare for or to do [an authorized generic] because we really didn't want to."); CX4031 (Bradley, Dep. at 198) ("I don't recall having any conversation with any colleagues regarding the launch of an authorized generic.")).

999. There would be no reason for Endo to agree to the No-AG provision, which is valuable to Impax but costs Endo, unless Endo believed that by doing so it was purchasing a guarantee of continued monopoly profits by pushing back Impax's entry date. (CX5000 at 103-05 (¶¶ 238, 242) (Noll Report); CX5004 at 059-60 (¶ 125) (Noll Rebuttal Report); Bazerman, Tr. 863; CX5001 at 031 (¶ 57) (Bazerman Report)).

RESPONSE TO FINDING NO. 999:

Complaint Counsel's Proposed Finding No. 999 should be disregarded because it violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." (*See* Court, Tr. 1859 ("[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.")). Proposed Finding No. 999 is also wrong. Endo never intended to launch an authorized generic, planning instead to switch from original Opana ER to a reformulated version. (Bingol, Tr. 1338-39 (an authorized generic "was never, to my knowledge . . . fully realized as a plan or an idea"); CX4019 (Lortie, Dep. at 118-19) ("we never seriously considered taking any further steps to prepare for or to do [an authorized generic] because we really didn't want to.");

CX4031 (Bradley, Dep. at 198) ("I don't recall having any conversation with any colleagues regarding the launch of an authorized generic.")). Thus, the No-AG provision did not "cost" Endo anything.

And there was no connection between the Authorized-Generic provision and any entry date. In fact, after Endo proposed the No-Authorized Generic term, Impax's license date only got earlier, moving from March 2013 to January 1, 2013. (RX-333 (initial term sheet including No-AG provision and March 2013 license date); CX2626 (executed settlement agreement with same No-AG provision and January 1, 2013, license date); *see* CX4012 (Donatiello, IHT at 172-73) (no provisions in SLA linked to commencement date)). And Impax did not accept a later license date in exchange for the No-Authorized Generic provision. (Mengler, Tr. 567).

Finally, Proposed Finding No. 999 incorrectly assumes that Endo had a "monopoly." In fact, Endo did not have monopoly power. (RX-547.0050-57 (Addanki Rep. ¶¶ 93-107)).

> 1000. In addition to the No-AG provision, Endo also agreed to provide Impax with consideration in the form of the Endo Credit. Impax feared that the January 1, 2013 entry date was designed to give Endo time to reformulate Opana ER, and thereby destroy the market before Impax could launch its generic oxymorphone ER. (CX1308 (Levin/Mengler email)). To address Impax's concern, Endo and Impax developed a term called the Endo Credit, which guaranteed Impax a cash payment if sales of the original formulation of Opana ER declined by a particular amount before Impax launched. (Cuca, Tr. 613 ("The Endo credit established terms based on expectations of Endo product sales and Impax product sales under which there could be a payment from Endo to Impax if those expectations weren't met.")).

RESPONSE TO FINDING NO. 1000:

The first sentence of Complaint Counsel's Proposed Finding No. 1000 should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). The second sentence of Proposed Finding No. 1000 is not supported by the cited document. It states only "Were [sic] still not comfortable with the 50%

trigger and wonder if your insistence is due to a known strategy to reduce the market." (CX1308). The third sentence of Proposed Finding No. 1000 is similarly unsupported by cited testimony. Mr. Cuca testified that "there *could* be a payment from Endo to Impax if those [sales] expectations weren't met." (Cuca, Tr. 613). Proposed Finding No. 1000 also ignores the fact that Endo did not expect to make any payment. (CX4017 (Levin, Dep. at 99-100) ("at the time the transaction was inked I did not expect that Endo would have to make a payment under this provision")).

> 1001. The Endo Credit was introduced into negotiations after the parties rejected Impax's market degradation acceleration trigger, which would have advanced Impax's entry date if Endo started moving consumers of the Original Opana ER to a new product. (See CCF ¶¶ 251-53, above). The purpose of the market degradation acceleration trigger—like the purpose of the Endo Credit—was to ensure that Impax got value from the No-AG exclusivity period. (CX 4032 (Snowden, Dep. at 104) (Impax wanted a market acceleration provision as "protection in case Endo had any intentions of moving the market to a next-generation product"); CX4026 (Nguyen, Dep. at 165-166) (the "gist" of the Endo Credit was "Mr. Mengler basically telling Endo to put its money where its mouth was"); see also CCF ¶¶ 252, above)). Under the market degradation acceleration, Impax would be ensured of value by moving up its entry date if the market was shifting to a new product. (CX5001 at 027-28 (¶ 53) (Bazerman Report)). And consumers would have benefitted from this accelerated entry date in the form of generic competition. (CX5001 at 027-28 ((¶ 53) (Bazerman Report)).

RESPONSE TO FINDING NO. 1001:

The first sentence of Complaint Counsel's Proposed Finding No. 1001 should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). The second sentence of Proposed Finding No. 1001 is not supported by the cited evidence. Neither Ms. Snowden nor Ms. Nguyen said anything about Impax getting value from the No-Authorized Generic Provision or using any other term to protect that value. Rather, as Complaint Counsel acknowledged at trial, the purpose of the Endo Credit was to discourage Endo from introducing a reformulated version of Opana ER as a

replacement for the original drug. (*See* Snowden, Tr. 389 ("[Complaint Counsel:] And the Endo credit was intended to be an incentive for Endo not to move the market and to protect Impax; correct? A. Correct."); *see also* Mengler, Tr. 533; Koch, Tr. 238-39; CX4037 (Smolenski, Dep. at 244-45)).

The remainder of Proposed Finding No. 1001 makes no sense and is without support in the record. An acceleration clause would have been triggered only if Endo sought to switch demand to a crush-resistant formulation. At that point, a No-Authorized Generic commitment would have been valueless because Endo never would have also launched an authorized generic at the same time as reformulated Opana ER. (CX4019 (Lortie, Dep. at 117-18) (explaining that it would be "morally very difficult to justify at the same time having a crushable authorized generic product" and a non-crushable branded product); Bingol, Tr. 1338-39 (an authorized generic "was never, to my knowledge . . . fully realized as a plan or an idea")).

> 1002. Instead, the parties addressed Impax's concern by creating value for themselves, but at the expense of consumers. (CX5001 at 028 (¶ 53) (Bazerman Report)). In essence, using the Endo Credit instead of the market degradation acceleration provision was a way for Endo to pay Impax not to get an earlier entry date, based on similar triggering events. (CX5001 at 028 (¶ 53) (Bazerman Report)). Endo benefits from getting more reformulated sales before entry of generic versions of Original Opana ER, and Impax gets the protection it sought in the form of a cash payment. (CX5001 at 028 (¶ 53) (Bazerman Report)). But consumers do not get access to the generic product that accelerated entry would have provided. (CX5001 at 028 (¶ 53) (Bazerman Report)).

RESPONSE TO FINDING NO. 1002:

Complaint Counsel's Proposed Finding No. 1002 should be disregarded because it violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." (*See* Court, Tr. 1859 ("[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.")). Proposed Finding No. 1002 also is without support in the record. When it

was signed, the SLA did not require Endo to actually pay anything to Impax. (RX-364.0012 (SLA § 4.4) (no payment until 90 days after documentation that Endo Credit was triggered is provided)). Nor did Endo expect to make a payment at any point in the future. (CX4017 (Levin, Dep. at 99-100) ("at the time the transaction was inked I did not expect that Endo would have to make a payment under this provision")). And Professor Bazerman did not calculate the expected value of any provision in the settlement agreement, or the overall expected value of the SLA, and therefore has no basis to claim Impax received anything of value at the time of settlement. (Bazerman, Tr. 923). Nor did Professor Noll attempt to calculate the expected value of the Endo Credit or No-AG provisions, either separately or in tandem. (Noll, 1590-92, 1613; CX4039 (Noll, Dep. at 116)).

Proposed Finding No. 1002 also ignores the fact that Impax could have derived no "payment" from either the Endo Credit or the No-Authorized Generic provision. (RX-547.0067-68 (Addanki Rep. ¶ 126); Addanki, Tr. 2355; *see* Noll, Tr. 1653-54 ("Q. And that example where you get zero of both, you didn't include that on your demonstrative of scenarios, did you? A. No, I didn't."); Addanki, Tr. 2355 (a rational actor like Endo "would manage that transition [to reformulated Opana ER] to minimize its patient loss and to minimize whatever payments it was going to make."); *see also* Court, Tr. 71, 75 ("JUDGE CHAPPELL: Are you going to stand there and tell me that the lowest possible outcome was not going to be zero? You're going to stand there and tell me that because some paid expert tells you that it had to be $62 million floor that it couldn't have been zero? MR. LOUGHLIN: No, Your Honor. There was a theoretical possibility of zero.")).

Finally, the Endo Credit was designed to encourage Endo to invest in original Opana ER. (Koch, Tr. 241; Snowden, Tr. 386; CX4021 (Ben-Maimon, Dep. at 118, 122) (the Endo Credit

was designed to act as "a deterrent to prevent [Endo] from switching the market."); CX4037 (Smolenski, Dep. at 244-45) (Endo Credit "intended to disincentivize Endo from" introducing a reformulated product)). Complaint Counsel acknowledged as much at trial. (*See* Snowden, Tr. 389 ("[Complaint Counsel:] And the Endo credit was intended to be an incentive for Endo not to move the market and to protect Impax; correct? A. Correct.")). There was no link between the Endo Credit and a later licensed-entry date. (Mengler, Tr. 567; Cuca, Tr. 666; CX4012 (Donatiello, IHT at 172-73) (no provisions in SLA linked to commencement date)).

1003. Indeed, both parties may have preferred the Endo Credit to a market degradation acceleration provision because the former would have allowed Endo to make branded sales for a longer period of time and guaranteed Impax a cash payment even if there were changes in the marketplace. (CX5001 at 028 (¶ 53) (Bazerman Report)).

RESPONSE TO FINDING NO. 1003:

Complaint Counsel's Proposed Finding No. 1003 should be disregarded because it violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." (*See* Court, Tr. 1859 ("[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.")). In any event, the factual record is clear: Impax did desire and seek a "market degradation acceleration provision," but Endo rejected the provision outright. (Koch, Tr. 314-16; Snowden, Tr. 432; Mengler, Tr. 581).

1004. Endo ultimately paid Impax $102 million in cash under the Endo Credit provision. (CX0333 at 001-002 (email dated April 18, 2013 containing wire transfer)).

RESPONSE TO FINDING NO. 1004:

Respondent has no specific response.

1005. There would have been no reason for Endo to agree to the Endo Credit provision unless it secured Endo a later entry date by Impax than Endo otherwise expected.

(CX5000 at 103-05, (¶¶ 238, 242) (Noll Report); CX5004 at 059-60 (¶ 125) (Noll Rebuttal Report); *see also* CX5001 at 031 (¶ 57) (Bazerman Report)). Again, a brand-name firm will not make a large, unjustified payment to a generic company unless it is securing the agreement of the generic company on a later entry date than it would agree to otherwise. (CX5000 at 103-05 (¶¶ 238, 242) (Noll Report); CX5004 at 059-60 (¶ 125) (Noll Rebuttal Report); *see also* Bazerman, Tr. 873-74).

RESPONSE TO FINDING NO. 1005:

Complaint Counsel's Proposed Finding No. 1005 should be disregarded because it violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." (*See* Court, Tr. 1859 ("[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.")). Proposed Finding No. 1005 also is without support in the record. When it was signed, the SLA did not require Endo to actually pay anything to Impax. (RX-364.0012 (SLA § 4.4) (no payment until 90 days after documentation that Endo Credit was triggered is provided)). Nor did Endo expect to make a payment at any point in the future. (CX4017 (Levin, Dep. at 99-100) ("at the time the transaction was inked I did not expect that Endo would have to make a payment under this provision")). And neither Professor Noll nor Professor Bazerman calculated the expected value of any provision in the settlement agreement, or the overall expected value of the SLA, and therefore have no basis to claim there was any so-called "payment" that was large or unjustified. (Noll, Tr. 1613, 1651-52; Bazerman, Tr. 923; CX4039 (Noll, Dep. at 116)).

Proposed Finding No. 1005 also ignores the fact that Impax could have derived no "payment" from either the Endo Credit or the No-Authorized Generic provision. (RX-547.0067-68 (Addanki Rep. ¶ 126); Addanki, Tr. 2355; *see* Noll, Tr. 1653-54 ("Q. And that example where you get zero of both, you didn't include that on your demonstrative of scenarios, did you? A. No, I didn't."); Addanki, Tr. 2355 (a rational actor like Endo "would manage that transition

[to reformulated Opana ER] to minimize its patient loss and to minimize whatever payments it was going to make."); *see also* Court, Tr. 71, 75 ("JUDGE CHAPPELL: Are you going to stand there and tell me that the lowest possible outcome was not going to be zero? You're going to stand there and tell me that because some paid expert tells you that it had to be $62 million floor that it couldn't have been zero? MR. LOUGHLIN: No, Your Honor. There was a theoretical possibility of zero.")).

2. The reverse payment would be expected to result in a later entry date than the expected outcome of the litigation

1006. If a brand-name firm believes it will win the underlying patent case, it has very little incentive to settle with the generic. (Noll, Tr. 1438). The brand-name firm will save several million dollars in litigation costs, but those are very small compared to the potential profits from extending a monopoly. (Noll, Tr. 1438; CX5000 at 168 (¶ 375) (Noll Report) (saved litigation costs were approximately $3 million)). Therefore, the fact that a brand-name firm is willing to make a payment to the generic in excess of litigation costs indicates that the brand-name firm extended its monopoly longer than it expected to if the litigation continued. (CX5000 at 103-05 (¶¶ 238, 242) (Noll Report)).

RESPONSE TO FINDING NO. 1006:

Complaint Counsel's Proposed Finding No. 1006 is inaccurate. A brand-name firm can have incentive to settle with a generic if there is uncertainty in the outcome of the litigation. (Noll, Tr. 1625-26). And whatever a theoretical "brand-name firm" may do, the record is clear about what happened in this case: When it was signed, the SLA did not require Endo to actually pay anything to Impax. (RX-364.0012 (SLA § 4.4) (no payment until 90 days after documentation that Endo Credit was triggered is provided)). Nor did Endo expect to make a payment at any point in the future. (CX4017 (Levin, Dep. at 99-100) ("at the time the transaction was inked I did not expect that Endo would have to make a payment under this provision")).

1007. If Endo expected the outcome of the litigation would keep Impax off the market later than January 1, 2013, there is no reason for it to agree to that date and also agree to make a payment under either the No-AG provision or the Endo Credit. (CX5000 at 105 (¶ 242) (Noll Report) ("a reverse payment settlement in excess of the saved cost of litigation to the brand-name firm can only occur if it extends the period of patent monopoly beyond the brand-name firm's expected remaining life of the patent"); *see also* CX5001 at 031 (¶ 57) (Bazerman Report) ("Considering all of thes factors together, I fail to see any explanation for the No-AG agreement and the back-up Endo Credit other than to compensate Impax to accept an entry date in January 2013"). The fact that Endo paid Impax a reverse payment demonstrates that this secured a later entry date than Endo expected would have occurred if the litigation had taken its course. (CX5000 at 103-05 (¶¶ 238, 242) (Noll Report)).

RESPONSE TO FINDING NO. 1007:

Complaint Counsel's Proposed Finding No. 1007 should be disregarded because it violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." (*See* Court, Tr. 1859 ("[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.")). Proposed Finding No. 1007 also is without support in the record. When it was signed, the SLA did not require Endo to actually pay anything to Impax. (RX-364.0012 (SLA § 4.4) (no payment until 90 days after documentation that Endo Credit was triggered is provided)). Nor did Endo expect to make a payment at any point in the future. (CX4017 (Levin, Dep. at 99-100) ("at the time the transaction was inked I did not expect that Endo would have to make a payment under this provision")). And neither Professor Noll nor Professor Bazerman calculated the expected value of any provision in the settlement agreement, or the overall expected value of the SLA, and therefore have no basis to claim there was any so-called "payment." (Noll, Tr. 1613, 1651-52; Bazerman, Tr. 923; CX4039 (Noll, Dep. at 116)).

Proposed Finding No. 1007 also ignores the fact that Impax could have derived no "payment" from either the Endo Credit or the No-Authorized Generic provision. (RX-547.0067-68 (Addanki Rep. ¶ 126); Addanki, Tr. 2355; *see* Noll, Tr. 1653-54 ("Q. And that example

where you get zero of both, you didn't include that on your demonstrative of scenarios, did you? A. No, I didn't."); Addanki, Tr. 2355 (a rational actor like Endo "would manage that transition [to reformulated Opana ER] to minimize its patient loss and to minimize whatever payments it was going to make."); *see also* Court, Tr. 71, 75 ("JUDGE CHAPPELL: Are you going to stand there and tell me that the lowest possible outcome was not going to be zero? You're going to stand there and tell me that because some paid expert tells you that it had to be $62 million floor that it couldn't have been zero? MR. LOUGHLIN: No, Your Honor. There was a theoretical possibility of zero.")).

> 1008. We do not need to know the merits of the underlying patent litigation to conclude that Endo purchased an extension of its monopoly with the reverse payment. (Noll, Tr. 1441-42; CX5000 at 120 (¶ 271) (Noll Report); CX5004 at 066 (¶ 140) (Noll Rebuttal Report)). One does not have to know the merits of the underlying litigation because the fact that the brand-name firm paid the generic an amount above saved litigation costs demonstrates that the brand was purchasing an extension of the monopoly beyond what it would otherwise enjoy. (CX5000 at 105 (¶ 242) (Noll Report)).

RESPONSE TO FINDING NO. 1008:

Complaint Counsel's Proposed Finding No. 1008 is an improper legal conclusion, not a fact. Proposed Finding No. 1008 also is without support in the record. When it was signed, the SLA did not require Endo to actually pay anything to Impax. (RX-364.0012 (SLA § 4.4) (no payment until 90 days after documentation that Endo Credit was triggered is provided)). Nor did Endo expect to make a payment at any point in the future. (CX4017 (Levin, Dep. at 99-100) ("at the time the transaction was inked I did not expect that Endo would have to make a payment under this provision")). And Professor Noll did not calculate the expected value of any provision in the settlement agreement, or the overall expected value of the SLA, and therefore has no basis to claim there was any so-called "payment" above saved litigation costs. (Noll, Tr. 1613, 1651-52; Bazerman, Tr. 923).

Proposed Finding No. 1008 also ignores the fact that Impax could have derived no "payment" from either the Endo Credit or the No-Authorized Generic provision. (RX-547.0067-68 (Addanki Rep. ¶ 126); Addanki, Tr. 2355; *see* Noll, Tr. 1653-54 ("Q. And that example where you get zero of both, you didn't include that on your demonstrative of scenarios, did you? A. No, I didn't."); Addanki, Tr. 2355 (a rational actor like Endo "would manage that transition [to reformulated Opana ER] to minimize its patient loss and to minimize whatever payments it was going to make."); *see also* Court, Tr. 71, 75 ("JUDGE CHAPPELL: Are you going to stand there and tell me that the lowest possible outcome was not going to be zero? You're going to stand there and tell me that because some paid expert tells you that it had to be $62 million floor that it couldn't have been zero? MR. LOUGHLIN: No, Your Honor. There was a theoretical possibility of zero.")).

Complaint Counsel is also wrong in asserting that the probable result of the settling parties' patent litigation is irrelevant to the economic inquiry. To establish that consumers fared worse under the settlement than they otherwise would have, the evidence must show that (1) an alternative settlement with an earlier entry date was actually feasible; or (2) there is a high probability that, if the parties had continued litigating, the generic firm would have prevailed in the underlying patent litigation and entered earlier than the settlement entry date. (RX-547.0019, 0070-71 (Addanki Rep. ¶¶ 30, 128-30) ("Unless there is compelling evidence of a fully-specified alternative agreement that the parties contemplated . . . the operating assumption must be that the but-for world is one in which the parties litigated the patent suit to its conclusion.")). If the brand company was likely to prevail in the patent case, an entry date prior to the expiration of the patents-in-suit would benefit consumers. (*See* Figg, Tr. 1927-28, 1971).

Finally, Proposed Finding No. 1008 incorrectly assumes that Endo had a "monopoly." In fact, Endo did not have monopoly power. (RX-547.0050-57 (Addanki Rep. ¶¶ 93-107)).

3. Other settlements without payments had earlier entry dates

1009. A second generic company, Actavis, was the first ANDA filer for two dosages of Opana ER (7.5 and 15 mg). (CX2607 at 009 (¶ 25) (Lortie Decl.)). Endo sued Actavis alleging that Actavis's ANDA contained a Paragraph IV certification stating that its generic versions of oxymorphone ER did not infringe Endo's patents and/or that Endo's patents were unenforceable. (RX-456 at 0004 (*Endo v. Actavis* complaint) (admitted for fact of the allegations and Endo's state of mind, not truth of the matter asserted)). Endo and Actavis settled the infringement case and entered a stipulation of dismissal. (CX0309 at 002; RX-460 at 0001 (Stipulation and Order of Dismissal) (admitted as a legally operative document, not for the truth of the matter asserted). Endo and Actavis agreed to an entry date of July 15, 2011, which was just a year after Actavis's 30-month stay expired. (CX0309 at 001-02; CX5000 at 146-47 (¶ 335) (Noll Report)). The Endo-Actavis settlement, in contrast to the Endo-Impax settlement, did not include a payment from Endo to Actavis. (CX5001 at 034 (¶ 65) (Bazerman Report)). Additionally, a number of Endo's other settlements relating to Opana ER (with Barr Laboratories, Inc., Sandoz Inc., Watson Laboratories, Inc., and Roxane Laboratories, Inc.) had a 2012 entry date but no payment. (*See* CCF ¶¶ 1447-52, below).

RESPONSE TO FINDING NO. 1009:

Respondent has no specific response to the first, second, and third sentences of Complaint Counsel's Proposed Finding No. 1009. And Respondent does not dispute that Endo and Actavis agreed to a license date of July 15, 2011. The remainder of Proposed Finding No. 1009 should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings shall be supported by specific references to the evidentiary record," and that there should be no citations "to expert testimony to support factual propositions that should be established by fact witnesses or documents." (*See* Court, Tr. 1859 ("[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.")).

Proposed Finding No. 1009 also is without support in the record. When it was signed, the SLA did not require Endo to actually pay anything to Impax. (RX-364.0012 (SLA § 4.4) (no

payment until 90 days after documentation that Endo Credit was triggered is provided)). Nor did Endo expect to make a payment at any point in the future. (CX4017 (Levin, Dep. at 99-100) ("at the time the transaction was inked I did not expect that Endo would have to make a payment under this provision")). And neither Professor Noll nor Professor Bazerman calculated the expected value of any provision in the settlement agreement, or the overall expected value of the SLA, and therefore have no basis to claim there was any so-called "payment." (Noll, Tr. 1613, 1651-52; Bazerman, Tr. 923; CX4039 (Noll, Dep. at 116)).

Proposed Finding No. 1009 also ignores the fact that Impax could have derived no "payment" from either the Endo Credit or the No-Authorized Generic provision. (RX-547.0067-68 (Addanki Rep. ¶ 126); Addanki, Tr. 2355; *see* Noll, Tr. 1653-54 ("Q. And that example where you get zero of both, you didn't include that on your demonstrative of scenarios, did you? A. No, I didn't."); Addanki, Tr. 2355 (a rational actor like Endo "would manage that transition [to reformulated Opana ER] to minimize its patient loss and to minimize whatever payments it was going to make."); *see also* Court, Tr. 71, 75 ("JUDGE CHAPPELL: Are you going to stand there and tell me that the lowest possible outcome was not going to be zero? You're going to stand there and tell me that because some paid expert tells you that it had to be $62 million floor that it couldn't have been zero? MR. LOUGHLIN: No, Your Honor. There was a theoretical possibility of zero.")).

4. The reverse-payment agreement created a barrier to entry by other generic products

1010. The Hatch-Waxman regime prevents the FDA from approving any generic other than the first-filer until 180 days after the first-filer begins selling its generic product. (*See* CCF ¶ 14, above). Therefore, an agreement by the first-filer not to enter until a certain date creates a barrier to any other ANDA filers entering until 180 days after that date. (*See* CCF ¶¶ 378-82, above).

RESPONSE TO FINDING NO. 1010:

The proposed summary finding should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Additionally, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondent's replies to those findings.

1011. In this case, there were seven ANDA filers apart from Impax for the five dosages for which Impax was the first filer. (CX2607 at 008-09 (¶ 24) (Lortie Decl.)) Those five dosages comprised the vast majority (over 95%) of Opana ER sales. (JX-001 at 007 (¶13)). By agreeing not to enter before January 1, 2013, Impax effectively created a barrier to entry against all other generics (including Actavis, which had received tentative approval) entering with those five dosages until after Impax had used its first-filer exclusivity in 2013. (*See* CCF ¶¶ 378-82, above).

RESPONSE TO FINDING NO. 1011:

Respondent has no specific response to thirst and second sentences of Complaint Counsel's Proposed Finding No. 1011. The third sentence of Proposed Finding No. 1011 is an improper summary finding that should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Additionally, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondent's replies to those findings.

D. Dr. Addanki's competitive effects opinions rely on an incorrect methodology and unsupportable assumptions

1012. Dr. Addanki asserts that the test for anticompetitive conduct used by Dr. Noll is "inappropriate" because it "relies on the assumption that an alternative 'pure' term-split settlement was feasible." (RX-547 at 0009-10 (¶ 11(g)) (Addanki Report)). A pure term-split settlement is one that contains no provisions other than an entry date for the generic. (CX5004 at 057 (¶ 120 n. 81) (Noll Rebuttal Report)). In fact, Dr. Noll's test does not

depend in any way on the feasibility of a pure term-split or no-payment settlement. (CX5004 at 057 (¶ 120) (Noll Rebuttal Report)).

RESPONSE TO FINDING NO. 1012:

Respondent has no specific response to the first and second sentences of Complaint Counsel's Proposed Finding No. 1012. The third sentence of Proposed Finding No. 1012 is incomplete because it fails to note that Professor Noll's test hinges entirely on the fact of an alleged "large" payment. (*See* CX5004-065 (Noll Rebuttal Rep. ¶ 138) ("large, unexplained reverse payments are *inherently* anticompetitive" (emphasis added)); CX5004-058 (Noll Rebuttal Rep. ¶ 122) ("the *reverse payment itself* is a reliable index of the welfare loss of consumers due to a reverse-payment settlement" (emphasis added)); CX4039 (Noll, Dep. at 26-27) (testifying that if a settlement includes a payment in excess of saved litigation costs, "*it's a hundred percent certain it's anticompetitive*" (emphasis added)); CX4039 (Noll, Dep. at 27) ("Q. So if it's—under your test, if it's greater than the combined—if the payment received by the generic is greater than the sum of the litigation costs, it's necessarily anticompetitive; right? A. Right.")).

1. Dr. Addanki improperly relies on a comparison of an unknowable but-for world

1013. Dr. Addanki asserts that if a pure term-split settlement is not feasible, then "the appropriate test for assessing the settlement at issue is to compare consumer benefits under the actual settlement to those under continued litigation. Such a comparison would involve evaluating likely consumer benefits in light of the various events that may have transpired had the parties continued litigating the patent cases instead of reaching the settlement at issue." (RX-547 at 0010 (¶ 11(h)) (Addanki Report)).

RESPONSE TO FINDING NO. 1013:

Respondent has no specific response.

1014. Economic analysis shows that the inquiry Dr. Addanki suggests is unnecessary. As explained above, a brand-name firm will not make a large and unjustified payment to

a generic firm unless the agreement increases the brand-name firm's expected monopoly profits. (CX5000 at 105 (¶ 242) (Noll Report); *see* CCF ¶¶ 1005-07, above). As a result, the existence of a large and unjustified payment shows that the brand-name firm expects the payment to allow it to recover monopoly profits that it otherwise would not earn if the litigation continued. (CX5000 at 105 (¶ 242) (Noll Report)).

RESPONSE TO FINDING NO. 1014:

Complaint Counsel's Proposed Finding No. 1014 is an improper and inaccurate conclusion of law. It is also wrong as a matter of economics. As Dr. Addanki explained at trial, "whether a given settlement of patent litigation between a brand company and a generic company is anticompetitive or not can only be evaluated by considering all of the facts surrounding the settlement and evaluating whether in fact consumers were worse off with the settlement than they would have been without it." (Addanki, Tr. 2205). The analysis is "really not any different from what we would do in any kind of rule of reason case." (Addanki, Tr. 2206). Because of this, the appropriate inquiry is (1) whether the firm in question possessed monopoly power; and (2) if so, whether the challenged conduct left consumers worse off than they otherwise would have been. (*See* RX-547.0008, 0018, 0020 (Addanki Rep. ¶¶ 11(a), 29, 35)). Without performing this analysis, "[t]here is no knowing . . . whether a given settlement is going to be pro- or anticompetitive." (Addanki, Tr. 2205).

As Proposed Finding No. 1014 confirms, Professor Noll's test treats all "reverse-payment settlements" with "large" payments as *per se* anticompetitive. (*See* CX5004-065 (Noll Rebuttal Rep. ¶ 138) ("large, unexplained reverse payments are *inherently* anticompetitive" (emphasis added)); CX5004-058 (Noll Rebuttal Rep. ¶ 122) ("the *reverse payment itself* is a reliable index of the welfare loss of consumers due to a reverse-payment settlement" (emphasis added)); CX4039 (Noll, Dep. at 26-27) (testifying that if a settlement includes a payment in excess of saved litigation costs, "*it's a hundred percent certain it's anticompetitive*" (emphasis added)); CX4039 (Noll, Dep. at 27) ("Q. So if it's—under your test, if it's greater than the combined—if

the payment received by the generic is greater than the sum of the litigation costs, it's necessarily anticompetitive; right? A. Right.")).

2. Dr. Addanki improperly assumes that the parties could not enter any other settlement

1015. Dr. Addanki improperly assumes that the parties could not enter any other settlement. Dr. Addanki claims that there is "no evidence" that indicating that Endo and Impax could have agreed to enter any other settlement. (RX-547 at 0009 (¶ 11(f)) (Addanki Report)).

RESPONSE TO FINDING NO. 1015:

Complaint Counsel's Proposed Finding No. 1015 is inaccurate. The first sentence should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). The second sentence is an inaccurate representation of Dr. Addanki's report. Specifically, Dr. Addanki opined that "there is no evidence indicating that Endo and Impax *would* have agreed to any hypothetical alternative term-split settlement." (RX-547.0009 (Addanki Rep. ¶ 11(f)) (emphasis added)). Thus, Complaint Counsel's proposed finding that Dr. Addanki "claimed there is 'no evidence' indicating that Endo and Impax *could* have entered any other settlement" is a misrepresentation of Dr. Addanki's opinion.

In any event, both Professor Noll and Professor Bazerman admitted that a hypothetical alternative settlement between Impax and Endo may not have been possible. (*See* Noll, Tr. 1596 ("Q. Sir, you're not offering an opinion in this case as to whether a hypothetical alternative settlement with an earlier date would have been feasible between Impax and Endo, are you? A. No."); Bazerman, Tr. 914 ("Q. And you can't say with certainty that an alternative settlement was possible in this case, can you? A. No.")). Professor Noll conceded that "Impax'[s] attempt to get an earlier date met with complete resistance," and that he was "not aware that they actually

came anywhere near agreeing on anything other than what they agreed to." (Noll, Tr. 1597-1600). Professor Bazerman likewise testified that he was aware of no evidence that Endo had ever offered an earlier date, and acknowledged that, in fact, Endo had rebuffed Impax's requests for one. (Bazerman, Tr. 907, 915-16).

> 1016. In reaching his conclusion that the parties could not enter any other settlement, Dr. Addanki ignored that a large payment—in the form of the No-AG provision—was part of the settlement negotiations from the beginning. (CX0320 at 009-10 (Endo-Impax term sheet exchanged May 26, 2010) (§ 2 "License and Covenant" includes an "Exclusivity Period" during which Endo cannot launch an AG)). Dr. Addanki also ignores evidence that Impax stopped pushing for an earlier entry date once Endo agreed to pay the Endo Credit. (CX4018 (Koch, Dep. at 71) ("Q. Okay. So what did Impax give Endo in return for Endo's agreement to accept the carrot and stick? . . . THE WITNESS: What we did was stop pursuing an earlier launch date because we were met with no willingness to consider that . . . ."); Koch, Tr. 239). Thus, once the payment in the form of the Endo Credit was agreed to, Impax was willing to accept Endo's later entry date. This testimony indicates that an alternative settlement with an earlier entry date and without a payment was a possibility, but the possibility was never tested because Impax stopped pushing for an earlier entry date once Endo had agreed to the Endo Credit provision.

RESPONSE TO FINDING NO. 1016:

Complaint Counsel's Proposed Finding No. 1016 is inaccurate and misrepresents Dr. Addanki's report and testimony. First, Dr. Addanki did not state that the parties "could not enter any other settlement"; he said there is no evidence that they would have. (RX-547.0009 (Addanki Rep. ¶ 11(f)). Second, Dr. Addanki noted that "[i]f Endo had discontinued original Opana ER"—as it was planning to do—"it would have likely had no economic incentive to launch an authorized generic version of original Opana ER," and therefore the No-AG provision was likely valueless. (RX-547.0068 (Addanki Rep. ¶ 126); *see* Snowden, Tr. 433-34; Mengler, Tr. 569-70; CX4017 (Levin, Dep. at 118)). Third, the record does not show that "Impax stopped pushing for an earlier entry date once Endo agreed to pay the Endo Credit." Impax continually sought the earliest licensed entry date possible. (CX4026 (Nguyen, Dep. at 160) (Impax "wanted

always to get on the market as quickly as possible and stay in the market."); *see* Mengler, Tr. 564 (the "only way we make money is selling products, so the sooner we can get in, the better off we are")). Mr. Koch clarified the cited deposition testimony at trial, explaining that he wouldn't "characterize it that way." (Koch, Tr. 239). Impax only stopped pursuing an earlier entry date after its efforts were met with "complete resistance." (Mengler, Tr. 565-67; *see* Noll, Tr. 1599-1600 ("Impax's attempt to get an earlier date met with complete resistance.")). Impax repeatedly pushed for earlier entry dates, including July 2011, (Snowden, Tr. 371-73, 423), and early entry via an acceleration trigger, (Koch, Tr. 237-38; Snowden, Tr. 432; Mengler, Tr. 532; RX-318.0001). Moreover, the negotiation of the Endo Credit had no effect on the ultimate licensed entry date; once the Endo Credit was introduced, Impax's negotiated entry date only got *earlier*. (Mengler, Tr. 567-68; *see* CX4012 (Donatiello, IHT at 172-73) (no provisions in SLA linked to commencement date); *compare* RX-333 (Endo's initial term sheet proposed March 2013 entry date with *no* Endo Credit) *to* RX-364 (executed SLA with January 1, 2013 entry date and Endo Credit)).

> 1017. Dr. Addanki testified that he does not know whether or not there were any settlements that Endo and Impax were willing to accept absent any payments. (Addanki, Tr. 2467). Dr. Addanki concedes that he lacks the information to determine the earliest generic entry that Endo was willing to accept, also known as Endo's reservation date. (Addanki, Tr. 2466-67). Dr. Addanki concedes that he lacks the information to determine the latest generic entry that Impax was willing to accept, also known as Impax's reservation date. (Addanki, Tr. 2466-67).

RESPONSE TO FINDING NO. 1017:

Complaint Counsel's Proposed Finding No. 1017 is incomplete and misleading. Dr. Addanki testified that he could not "divine what's in someone's head." (Addanki, Tr. 2466). The proposed finding neglects to mention that Complaint Counsel's negotiation expert, Professor Bazerman, did not calculate Impax's or Endo's reservation dates and could not say whether any

alternative settlement was possible. (Bazerman, Tr. 912-14). Professor Noll likewise admitted that a hypothetical alternative settlement between Impax and Endo may not have been possible. (*See* Noll, Tr. 1596 ("Q. Sir, you're not offering an opinion in this case as to whether a hypothetical alternative settlement with an earlier date would have been feasible between Impax and Endo, are you? A. No."); Bazerman, Tr. 914 ("Q. And you can't say with certainty that an alternative settlement was possible in this case, can you? A. No.")). Professor Noll conceded that "Impax'[s] attempt to get an earlier date met with complete resistance," and that he was "not aware that they actually came anywhere near agreeing on anything other than what they agreed to." (Noll, Tr. 1597-1600). Professor Bazerman similarly testified that he was aware of no evidence that Endo had ever offered an earlier date, and acknowledged that, in fact, Endo had rebuffed Impax's requests for one. (Bazerman, Tr. 907, 915-16).

> 1018. As Dr. Addanki acknowledges, this is in part because the positions taken in a negotiation are often posturing, and tell us nothing about a party's true reservation date. (Addanki, Tr. 2390-91 ("I don't think you can infer anything about what either party's reservation date was from the fact that they didn't agree. They didn't agree. Parties do all sorts of things in negotiation. They've got postures.")). As a result, Dr. Addanki's framework for testing whether an alternative settlement exists requires finding evidence that will likely never exist because, as he testified, parties are unlikely to disclose their true negotiating position. Therefore, his framework is unworkable.

RESPONSE TO FINDING NO. 1018:

Complaint Counsel's Proposed Finding No. 1018 is inaccurate, unsupported, and misleading. To begin with, the second and third sentences of Proposed Finding No. 1018 should be disregarded because they violate the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2).

In any event, Proposed Finding No. 1018 is unfounded. While parties may not be likely to disclose their "true negotiating position" to each other during the actual negotiation, that does

not mean that negotiating positions are impossible to determine in litigation through discovery, witness testimony, and expert analysis. As Dr. Addanki acknowledged in his report, there *may be* "compelling evidence of a fully specified alternative agreement that the parties contemplated, as well as compelling evidence that the parties would have both preferred that alternative agreement to the prospect of litigating the patent suit to its final conclusion." (RX-547.0020 (Addanki Rep. ¶ 36)). But as Dr. Addanki's testimony at trial makes clear, one cannot "infer anything about what either party's reservation date was *from the fact that they didn't agree*." (Addanki, Tr. 2390-91 (emphasis added)). If *that* is the only evidence one has, it is impossible to assert that some alternative settlement was necessarily feasible. (Addanki, Tr. 2390-91).

Contrary to Complaint Counsel's suggestion in Proposed Finding No. 1018, nowhere did Dr. Addanki assert that, if evidence of a feasible alternative settlement is lacking, the economic inquiry ends there. Far from it, Dr. Addanki stated that, in this scenario, "the operating assumption must be that the but-for world is one in which the parties litigated the patent suit to its conclusion." (RX-547.0020 (Addanki Rep. ¶ 36)). The purpose of the inquiry is to determine "whether in fact consumers were worse off with the settlement than they would have been without it." (Addanki, Tr. 2205). In other words, the analysis is "really not any different from what we would do in any kind of rule of reason case." (Addanki, Tr. 2206). This belies Complaint Counsel's unsupported claim that Dr. Addanki's framework is unworkable."

> 1019. In any event, it is not necessary to determine what alternative settlement might have existed to conclude that a settlement is anticompetitive. Even when a no-payment settlement is not possible, it is still in the brand-name firm's and the generic firm's interest to reach a reverse-payment agreement. (CX5000 at 131 (¶ 296) (Noll Report) ("there always exists a feasible reverse payment, S, that would induce the first-to-file generic firm to delay launch until patent expiration and that would increase the expected profits of the brand-name firm over the expected outcome from litigating the infringement case to conclusion"); CX5004 at 062 (¶ 131) (Noll Rebuttal Report)).

RESPONSE TO FINDING NO. 1019:

Complaint Counsel's Proposed Finding No. 1019 is inaccurate, unsupported, and misleading. The first sentence of Proposed Finding No. 1019 should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2).

The second sentence of Proposed Finding No. 1019 is an irrelevant truism. If a "no-payment settlement is not possible," that does not mean the settlement the parties *did* reach is necessarily anticompetitive. Rather, as Dr. Addanki explained at trial, "whether a given settlement of patent litigation between a brand company and a generic company is anticompetitive or not can only be evaluated by considering all of the facts surrounding the settlement and evaluating whether in fact consumers were worse off with the settlement than they would have been without it." (Addanki, Tr. 2205). The analysis is "really not any different from what we would do in any kind of rule of reason case." (Addanki, Tr. 2206).

> 1020. This does not mean that any settlement that includes a payment is necessarily anticompetitive. (CX5004 at 057 (¶ 120 n. 81) (Noll Rebuttal Report)). A settlement agreement is not anticompetitive if it includes 1) payments from the generic to the brand; 2) payments from the brand to the generic that are not substantially greater than saved litigation costs; or 3) reasonable payments from the brand to the generic in exchange for goods, services, or assets provided by the generic firm. (CX5004 at 057 (¶ 120 n. 81) (Noll Rebuttal Report)).

RESPONSE TO FINDING NO. 1020:

Complaint Counsel's Proposed Finding No. 1020 is inaccurate, incomplete, and misleading. While it is indeed true that a settlement that includes a payment is not "necessarily anticompetitive," Proposed Finding No. 1020 conflicts with Professor Noll's repeated testimony that any settlement with a large reverse payment is *per se* anticompetitive. (*See* CX5004-065

(Noll Rebuttal Rep. ¶ 138) ("large, unexplained reverse payments are *inherently* anticompetitive" (emphasis added)); CX5004-058 (Noll Rebuttal Rep. ¶ 122) ("the *reverse payment itself* is a reliable index of the welfare loss of consumers due to a reverse-payment settlement" (emphasis added)); CX4039 (Noll, Dep. at 26-27) (testifying that if a settlement includes a payment in excess of saved litigation costs, "*it's a hundred percent certain it's anticompetitive*" (emphasis added)); CX4039 (Noll, Dep. at 27) ("Q. So if it's—under your test, if it's greater than the combined—if the payment received by the generic is greater than the sum of the litigation costs, it's necessarily anticompetitive; right? A. Right.")).

Moreover, Proposed Finding No. 1020 conflates the initial question of whether a challenged settlement includes a "large and unjustified" payment with the ultimate question of whether the settlement is anticompetitive or procompetitive. As Dr. Addanki explained at trial, "whether a given settlement of patent litigation between a brand company and a generic company is anticompetitive or not can only be evaluated by considering all of the facts surrounding the settlement and evaluating whether in fact consumers were worse off with the settlement than they would have been without it." (Addanki, Tr. 2205). The analysis is "really not any different from what we would do in any kind of rule of reason case." (Addanki, Tr. 2206). Because of this, the appropriate inquiry is (1) whether the firm in question possessed monopoly power; and (2) if so, whether the challenged conduct left consumers worse off than they otherwise would have been. (*See* RX-547.0008, 0018, 0020 (Addanki Rep. ¶¶ 11(a), 29, 35)). Without performing this analysis, "[t]here is no knowing . . . whether a given settlement is going to be pro- or anticompetitive." (Addanki, Tr. 2205).

3. Dr. Addanki improperly assumes that Impax could not have entered prior to January 2013

1021. Dr. Addanki assumes that Impax could not have launched generic oxymorphone ER prior to January 2013. (RX-547 at 0010 (¶ 11(i)) (Addanki Report)). There are a number of problems with that assumption. First, even if true—which it is not—it is irrelevant. (CX5004 at 076 (¶ 159) (Noll Rebuttal Report)). One does not need to prove an alternative entry date to conclude that a reverse-payment settlement is anticompetitive; one only needs to know that such a date was possible. (CX5004 at 076-77 (¶ 160) (Noll Rebuttal Report); CX4039 (Noll, Dep. at 58-59)). We can conclude such a date was possible because Endo otherwise would have no reason to make a large, unjustified payment to Impax to secure a result that it could have obtained by simply not settling. (Noll, Tr. 1487-88; *see also* CX5001 at 031 (¶ 57) (Bazerman Report) ("Considering all of the factors together, I fail to see any explanation for the No-AG agreement and the back-up Endo Credit other than to compensate Impax to accept an entry date in January 2013.")).

RESPONSE TO FINDING NO. 1021:

Complaint Counsel's Proposed Finding No. 1021 is inaccurate and engages in improper legal argumentation. Without determining an alternative entry date, there is no baseline against which to measure the negotiated entry date, and determine whether there was in fact a delay, and therefore whether the negotiated entry date harmed consumers. As Dr. Addanki explained, "[a] sound analysis of the competitive effects of the actual settlement is thus one that compares consumer benefit from the actual settlement to expected consumer benefit in a but-for world." (RX-547.0009 (Addanki Rep. ¶ 128)). The analysis is "really not any different from what we would do in any kind of rule of reason case." (Addanki, Tr. 2206).

Professor Noll's conclusion as stated in Proposed Finding No. 1021 simply *assumes* consumer harm from the mere existence of an alleged "large and unjustified"payment, without looking at actual effects on consumers. (Noll, Tr. 1662 ("Q. Your opinion is that once the payment is large relative to saved litigation costs and unjustified, you're basically done from the standpoint of economics; right? A. That if it's large and unjustified and there was a -- and precluded the possibility of earlier entry, then it's anticompetitive."). As stated at trial, Professor

Noll believes "one can infer whether a settlement is anticompetitive from the terms of the agreement," without consideration of actual competitive effects. (Noll, Tr. 1663). Indeed, he treats any settlement with an allegedly "large" reverse payment as *per se* anticompetitive. (*See* CX5004-065 (Noll Rebuttal Rep. ¶ 138) ("large, unexplained reverse payments are *inherently* anticompetitive" (emphasis added)); CX5004-058 (Noll Rebuttal Rep. ¶ 122) ("the *reverse payment itself* is a reliable index of the welfare loss of consumers due to a reverse-payment settlement" (emphasis added)); CX4039 (Noll, Dep. at 26-27) (testifying that if a settlement includes a payment in excess of saved litigation costs, "*it's a hundred percent certain it's anticompetitive*" (emphasis added)); CX4039 (Noll, Dep. at 27) ("Q. So if it's—under your test, if it's greater than the combined—if the payment received by the generic is greater than the sum of the litigation costs, it's necessarily anticompetitive; right? A. Right.")).

1022. Moreover, Complaint Counsel's assertion that a hypothetical earlier entry date was "possible" is belied by its own experts' testimony. Professor Bazerman did not calculate Impax's or Endo's reservation dates and could not say whether any alternative settlement was possible. (Bazerman, Tr. 912-14). Professor Noll likewise admitted that a hypothetical alternative settlement between Impax and Endo may not have been possible. (*See* Noll, Tr. 1596 ("Q. Sir, you're not offering an opinion in this case as to whether a hypothetical alternative settlement with an earlier date would have been feasible between Impax and Endo, are you? A. No."); Bazerman, Tr. 914 ("Q. And you can't say with certainty that an alternative settlement was possible in this case, can you? A. No.")). Professor Noll conceded that "Impax'[s] attempt to get an earlier date met with complete resistance," and that he was "not aware that they actually came anywhere near agreeing on anything other than what they agreed to." (Noll, Tr. 1597-1600). Professor Bazerman similarly testified that he was aware of no evidence that Endo had ever offered an earlier date, and acknowledged that, in fact, Endo had rebuffed Impax's requests for one. (Bazerman, Tr. 907, 915-16). A large, unexplained reverse payment acts as an insurance policy for the brand-name firm against the generic entering any time before the agreed-upon entry date. (Noll, Tr. 1427-28; CX5004 at 076-77 (¶ 160) (Noll Rebuttal Report)). A brand-name firm will only make such a payment if it extends its monopoly profits, which come at the expense of consumer welfare. (CX5004 at 076-77 (¶ 160) (Noll Rebuttal Report)). That extension of monopoly profits at the expense of consumer welfare is anticompetitive. (CX5000 at 120, 126 (¶¶ 271, 284-85) (Noll Report); CX5004 at 009, 076-77 (¶¶ 14, 160) (Noll Rebuttal Report)). Thus, it is not necessary to demonstrate an alternative, earlier, entry date upon which Impax would have entered.

RESPONSE TO FINDING NO. 1022:

Complaint Counsel's Proposed Finding No. 1022 is inaccurate and engages in improper legal argumentation. Like Professor Noll, the proposed finding treats any settlement with an alleged "large, unexplained reverse payment" as *per se* anticompetitive, without any evaluation of actual competitive effects. (*See* Noll, Tr. 1663 (testifying that "one can infer whether a settlement is anticompetitive from the terms of the agreement," without consideration of actual competitive effects); CX5004-065 (Noll Rebuttal Rep. ¶ 138) ("large, unexplained reverse payments are *inherently* anticompetitive" (emphasis added)); CX5004-058 (Noll Rebuttal Rep. ¶ 122) ("the *reverse payment itself* is a reliable index of the welfare loss of consumers due to a reverse-payment settlement" (emphasis added)); CX4039 (Noll, Dep. at 26-27) (testifying that if a settlement includes a payment in excess of saved litigation costs, "*it's a hundred percent certain it's anticompetitive*" (emphasis added)); CX4039 (Noll, Dep. at 27) ("Q. So if it's—under your test, if it's greater than the combined—if the payment received by the generic is greater than the sum of the litigation costs, it's necessarily anticompetitive; right? A. Right.")).

This analysis is wrong as a matter of economics. As Dr. Addanki explained at trial, the existence of a reverse payment "might be something that would trigger an inquiry as to whether a settlement was anticompetitive in its effect, but *it couldn't possibly substitute for that factual inquiry*." (Addanki, Tr. 2352-53 (emphasis added)). But "whether a given settlement of patent litigation between a brand company and a generic company is anticompetitive or not can only be evaluated by considering all of the facts surrounding the settlement and evaluating whether in fact consumers were worse off with the settlement than they would have been without it." (Addanki, Tr. 2205). The analysis is "really not any different from what we would do in any kind of rule of reason case." (Addanki, Tr. 2206). Because of this, the appropriate inquiry is (1)

whether the firm in question possessed monopoly power; and (2) if so, whether the challenged conduct left consumers worse off than they otherwise would have been. (*See* RX-547.0008, 0018, 0020 (Addanki Rep. ¶¶ 11(a), 29, 35)). Without performing this analysis, "[t]here is no knowing . . . whether a given settlement is going to be pro- or anticompetitive." (Addanki, Tr. 2205).

Finally, Proposed Finding No. 1022 incorrectly assumes that Endo had a "monopoly." In fact, Endo did not have monopoly power. (RX-547.0050-57 (Addanki Rep. ¶¶ 93-107)).

> 1023. Second, Dr. Addanki's assumption that Impax could not have entered before January 2013 is at odds with the evidence. Indeed, just prior to the settlement, Impax was actually manufacturing generic oxymorphone ER and preparing to be able to launch at risk. (*See* CCF ¶¶ 168-213, above; *see also* CX5000 at 165-67 (¶ 371) (Noll Report)). During this same time period, Impax forecasts consistently assumed an entry date of either June 2010 or July 2011. (CX0201 at 001, 005 (July 2009 projection assuming a June 2010 launch date); CX0203 at 001 (November 2009 projection assuming a July 2010 launch date); CX2853 at 001, 013 (February 2010 projection assuming an "upside" launch in June 2010 and a "base" launch in July 2011); CX0222 at 001, 004-05 (May 2010 projection assuming an "upside" launch in June 2010 and a "base" launch in July 2011)). The fact that Impax had actually spent money to make oxymorphone ER product and forecasted launching generic oxymorphone ER demonstrates that Impax was considering a generic launch before January 2013 and is inconsistent with the claim that Impax would never engage in an at-risk launch. (CX5004 at 077-78 (¶ 162) (Noll Rebuttal Report)).

RESPONSE TO FINDING NO. 1023:

Complaint Counsel's Proposed Finding No. 1023 is inaccurate and misrepresents Dr. Addanki's testimony and the evidence on the record. Dr. Addanki never testified that "Impax *could not* have entered before January 2013." (Emphasis added). Dr. Addanki testified that a launch before January 2013 would have resulted in additional patent litigation and "expose Impax to potential damages in the form of lost profits." (Addanki, Tr. 2379; RX-547.0075-76 (Addanki Rep. ¶¶ 138-40)). Moreover, a launch at-risk would have risked forfeiting the value of Impax's first-filer 180-day exclusivity period. (RX-547.0077 (Addanki Rep. ¶ 142)). Because

of this, "there are sound, economic reasons for a firm in Impax's position to have been loath to enter at risk." (RX-547.0077 (Addanki Rep. ¶ 143)).

While Respondent concedes that Impax had manufactured validation batches of oxymorphone ER prior to the settlement, Impax strives to have every product in its generic pipeline "launch ready" at the earliest date allowed by the Hatch-Waxman Act. (CX4023 (Hildenbrand, Dep. at 60-61); CX4030 (Hsu, Dep. at 85-86)). The goal of this approach is to give Impax management a full range of potential launch dates as options, and to avoid missing out on an opportunity to launch under favorable conditions because the product is not ready. (CX4030 (Hsu, Dep. at 86); CX4023 (Hildenbrand, Dep. at 140)). In order to accomplish this goal, Impax begins working towards launch preparedness eighteen months before the earliest possible launch date allowed by the Hatch-Waxman Act. (Camargo, Tr. 952-53, 958; CX4023 (Hildenbrand, Dep. at 79)). This process is routine, consistent with industry practice, and is the same for all products. (CX4023 (Hildenbrand, Dep. at 30); Koch, Tr. 271; CX3278-101).

Forecasting a launch date as part of this process does not mean that Impax has decided whether or when to launch a product. Todd Engle, Impax's Vice President of Sales and Marketing, would forecast potential launch dates based on the earliest possible date allowed by the Hatch-Waxman Act. (Engle, Tr. 1767, 1769, 1772-73). Mr. Engle and the teams on which he worked did not make a decision regarding whether (or when) to launch at risk, or even whether senior management should recommend an at-risk launch to Impax's Board of Directors. (Engle, Tr. 1754-55).

Impax undertook these same preparedness steps for oxymorphone ER, but the Vice President of Impax's supply chain group, Joseph Camargo, believed the odds of actually launching generic oxymorphone ER "may be low" because Impax "tended to shy away from

such risk." (RX-181; Camargo, Tr. 1009-10). Nonetheless, Impax undertook its normal launch preparations because the "upside [was] substantial and [] we may want to plan for" it. (RX-181.0001; *see* Camargo, Tr. 1007). As Impax's CEO at the time of settlement explained, "in order to make sure whatever the discussion or the decision is meaningful, you have to have a supply ready. Then you can talk about [possible launches]. . . . [Y]ou have to have material ready. Then you decide which way you want to go." (CX4014 (Hsu, IHT at 86)). This is "routine" and consistent with industry practice. (Koch, Tr. 271; CX3278-101). There is no "inconsistency" between Impax's routine preparedness efforts and Impax not pursuing an at risk launch.

> 1024. Third, Dr. Addanki does not rely on any factual evidence in concluding that Impax would not have launched at risk. Dr. Addanki concludes that Impax would not have launched at risk based on two pieces of information: 1) Impax's statements made in this case that they would not have launched at risk; and 2) the testimony of five Impax employees and former employees. (CX4044 (Addanki, Dep. at 186-87)). Impax's claims in this case that they would not have launched at risk are self-serving and not credible. The testimony Dr. Addanki relies on to conclude that Impax would not have launched at risk simply does not say that. The five Impax or former Impax witnesses (Dr. Hsu, Dr. Ben-Maimon, Ms. Snowden, Mr. Smolenski, and Mr. Engle) all say that Impax did not make a final decision about whether to launch at risk. (CX4044 (Addanki, Dep. at 181-84)). Not one testified that Impax had made a decision at the time that it would not have launched at risk. (CX4044 (Addanki, Dep. at 181-84)).
>
> **RESPONSE TO FINDING NO. 1024:**
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> Complaint Counsel's Proposed Finding No. 1024 is inaccurate and internally inconsistent. As an initial matter, Dr. Addanki never said that "Impax would not have launched at risk." (Tellingly, Complaint Counsel makes that assertion without any factual support, in violation of this Court's Order on Post-trial Briefs). Rather, Dr. Addanki testified that Impax's *economic incentives* cut against launching at-risk. (RX-547.0073-77 (Addanki Rep. ¶¶ 137-43); Addanki, Tr. 2380-2381).

Moreover, Proposed Finding No. 1024 overlooks the unequivocal testimony *that Impax did not intend to launch at risk*. (*See, e.g.*, Snowden, Tr. 470-71; Koch, Tr. 324-25 ("JUDGE CHAPPELL: Are you a hundred percent certain you would be aware of whether or not Impax planned an at-risk launch of Opana ER? WITNESS: Absolutely. I would have a key role in that. JUDGE CHAPPELL: Do you know in fact whether Impax intended an at-risk launch of Opana ER? . . . THE WITNESS: I do know. JUDGE CHAPPELL: Did they intend to do an at-risk launch of Opana ER? THE WITNESS: No."); Mengler, Tr. 584-85). Complaint Counsel's claim that this testimony—consistent across each and every witness—should be disregarded as "self-serving" and "not-credible" is baseless. Complaint Counsel cites nothing to indicate these statements are inaccurate or not credible.

Finally, Complaint Counsel's reliance on the fact that Impax had not affirmatively ruled out an at-risk launch misrepresents the realities of how these decisions are made: Impax did not have a practice of seeking approval *not* to launch a product at-risk. (Koch, Tr. 277 (if the "executive committee was not in favor of recommending a launch at risk" that "work would stop" and no board action would ensue). Impax's practice was the opposite: if Impax was considering at at-risk launch, it would recommend the at-risk launch to the Board and seek a formal Board authorization, which was an absolute prerequisite to any at-risk launch decision. (Koch, Tr. 276-77 ("every at-risk launch is a board-level decision"); Snowden, Tr. 426; CX4030 (Hsu, Dep. at 128); CX4021 (Ben-Maimon, Dep. at 160)). Impax management never recommended an at-risk launch of generic Opana ER to the Board. (Koch, Tr. 299, 324-25; Snowden, Tr. 470-71).

1025. Despite the evidence cited above, Dr. Addanki and Mr. Figg suggest that Impax would never engage in an at-risk launch because of the risk it would be found liable for infringement and pay damages to Endo. Dr. Addanki and Mr. Figg assert that Impax could have been required to pay treble damages if it had been found to infringe on Endo's

patents. (RX-547 at 0082 (¶ 152) (Addanki Report); RX-548 at 0042 (¶ 90) (Figg Report)). The real world data on at-risk launches shows that such a possibility was remote. In all of the at-risk launches that occurred between 2001 and the present, not one firm was required to pay treble damages. (CX5004 at 078, 092-115 (¶ 164, Exhibit 4) (Noll Rebuttal Report)). Most firms that were found to have infringed paid less than the brand-name firm's lost profits, and at-risk launches often result in a settlement that involves no payment to the brand-name firm. (CX5004-078, 092-115 (Noll Rebuttal Rep. ¶ 164, Ex. 4)).

RESPONSE TO FINDING NO. 1025:

Complaint Counsel's Proposed Finding No. 1025 is inaccurate and misleading. The first sentence of Proposed Finding No. 1025 should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). It is simply unsupported mischaracterization.

The second sentence of Proposed Finding No. 1025 is inaccurate and incomplete. The cited paragraph in Dr. Addanki's report says nothing about "treble damages." (RX-547.0082 (Addanki Rep. ¶ 152)). And Mr. Figg made clear that Impax could have been required to pay treble damages if it had launched generic Opana ER at risk and was found have *willfully* infringed Endo's patents. (*See* RX-548.0039 (Figg Rep. ¶ 85) ("the generic could also be at risk of treble (3x) damages based on willful infringement")).

The third sentence of Proposed Finding No. 1025 should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). It is an unsupported mischaracterization. It is also not true. The Proposed Finding is apparently referring to Exhibit 4 of Professor Noll's rebuttal report. That Complaint Counsel supposedly did not find a case in which treble damages were assessed after an at-risk launch does not mean the possibility was remote. Treble damages can be assessed for willful infringement.

(Hoxie, Tr. 2786). Willfulness is likely to be found only should the generic launch at risk and the district court finds that the generic is infringing a valid patent. (RX-548.0039 (Figg Rep. ¶ 85)). But Professor Noll's exhibit 4 does not include a single case where a generic launched at risk and the district court ruled against it. (CX5004-078, 092-115 (Noll Rebuttal Rep. ¶ 164, Ex. 4)) (listing the "status of litigation at time of launch" as either "ongoing" or coming after a favorable outcome at the district court)). Thus, exhibit 4 says nothing about the prevalence of treble damages in a situation where the generic loses at the district court level. And losing at the district court level was a real possibility for Impax, especially after the Court's decision adopting Endo's proposed claim constructions. (*See* Figg, Tr. 1870). Therefore, the purported "data" in Professor Noll's Exhibit 4 is not a useful comparison to Impax's situation.

Finally, Exhibit 4 does not support the proposition in the fourth sentence of Proposed Finding No. 1025. Exhibit 4 indicates that Professor Noll did not have information about the amounts paid in most of the cases cited. Exhibit 4 also only indicates "Brand Revenue" and not "profits."

> 1026. Moreover, even under Dr. Addanki's and Mr. Figg's timeframes, it was possible that Impax would be in a position to launch oxymorphone ER free and clear of legal risk prior to January 2013. Dr. Addanki, Mr. Figg, and Dr. Noll all agree that it was possible that the underlying patent litigation between Endo and Impax would be resolved in the second half of 2011. (CX5004 at 079-80 (¶¶ 166-67) (Noll Rebuttal Report); RX-547 at 0082 (¶ 152) (Addanki Report); RX-548 at 0036-37 (¶ 80) (Figg Report)). Even Impax's experts agree that Impax could have launched free and clear of any patent risk in the second half of 2011, well before January 2013. (RX-547 at 0082 (¶ 152) (Addanki Report); RX-548 at 0036-37 (¶ 80) (Figg Report)). Moreover, the fact that Impax was spending money challenging the patent demonstrates that Impax recognized there was some probability it would ultimately win the infringement case and be able to launch oxymorphone ER free and clear of legal risk. (Noll, Tr. 1438-39).

RESPONSE TO FINDING NO. 1026:

Complaint Counsel's Proposed Finding No. 1026 is completely false. It is emphatically not true that Impax could have launched generic oxymorphone ER "free and clear of legal risk"

at the conclusion of its original patent litigation with Endo, even assuming Impax would have prevailed in that litigation—and none of Impax's experts have said anything to the contrary.

It is true that the original patent litigation between Impax and Endo would not have reached a final conclusion any sooner than late 2011—although it could have extended for much longer than that. (Figg, Tr. 1908-09). Even if Impax won that litigation (and there is no evidence it would have), it *still* could not have launched generic oxymorphone ER "free and clear of legal risk." That is because another patent that covered Opana ER (the "'482 patent") issued to Johnson Matthey *in December 2010*. (JX-003-005 (¶ 31)). In the real world, Johnson Matthey put Impax on notice of that patent by *May 2011*—well before the original patent litigation could have been resolved. (CX3329.003-6; Snowden, Tr. 443-44). In other words, any Impax launch of oxymorphone ER in 2011 (or thereafter) would have been at-risk as to the '482 patent.

It is nothing short of dishonest for Complaint Counsel to assert that "Impax's experts agree that Impax could have launched free and clear of any patent risk in the second half of 2011, well before January 2013." Mr. Figg expressly stated in his report that "the '482 patent would have been considered a material patent infringement risk for any company seeking to make or sell a generic version of Opana® ER" prior to 2013. (RX-548.0050-51 (Figg Rep. ¶ 113 n.19)). Dr. Addanki's report likewise recognizes that if Impax had prevailed against Endo in the original patent litigation, it still "may well not have launched its generic versions of Opana ER until final adjudication of potential patent litigation regarding the '482 patent." (RX-547.0082 (Addanki Rep. ¶ 152)). In fact, at trial, Dr. Addanki testified that Impax could *not* have launched generic oxymorphone in ER free from risk in November 2011 (again, assuming a litigation victory) because of the '482 patent. (Addanki, Tr. 2362-63).

Finally, the fact that Impax instituted a Paragraph IV challenge to Endo's original patents says *nothing* about the "probability [that] it would ultimately win the infringement case and be able to launch oxymorphone ER free and clear of legal risk." The cited portion of Professor Noll's trial testimony says nothing of the sort. (*See* Noll, Tr. 1438-39). In fact, Professor Noll describes the generic company's litigation costs as "tiny." (Noll, Tr. 1438-39). None of Complaint Counsel's experts testified to the probability that Impax would have prevailed in the original patent litigation—to say nothing of any follow-on suits involving the '482 patent or Endo's other later-acquired patents. (Noll, Tr. 1623; Hoxie, Tr. 2693, 2852; Bazerman, Tr. 904, 913).

> 1027. Dr. Addanki speculates that even if Impax could win the underlying patent litigation with Endo, it could be blocked by subsequent patents Endo might obtain. (RX-547 at 0080-83 (¶¶ 148-54) (Addanki Report)). However, this conclusion assumes that the sellers of the patent would obtain the greatest value by selling exclusively to Endo. (CX5004 at 080-81 (¶ 168) (Noll Rebuttal Report)). It is possible the patent holder would obtain greater value from the patent by licensing both Endo and Impax rather than Endo alone. (CX5004 at 080-81 (¶ 168) (Noll Rebuttal Report)). Dr. Addanki's conclusion relies on pure speculation that a third party, not under Endo's control, would have been willing to license a patent to Endo under terms acceptable to Endo. Moreover, if Endo was confident it could adopt this strategy to keep Impax off the market, it would have had no reason to pay Impax $112 million. (Noll, Tr. 1487-88).

RESPONSE TO FINDING NO. 1027:

Complaint Counsels' Proposed Finding No. 1027 is inaccurate and misleading, and conflicts with its own economic expert's analysis. First, the cited portion of Dr. Addanki's analysis specifically addresses Endo's incentives to acquire *the '482 patent*, not some unspecified "subsequent patents" in the abstract. (RX-547.0080-81 (Addanki Rep. ¶¶ 148-51)). Dr. Addanki's conclusions are not speculative; they follow from Endo's economic incentives. (RX-547.0080-81 (Addanki Rep. ¶¶ 148-51)). Dr. Addanki's conclusions are further borne out by the fact that, *in the real world*, Endo actually acquired the '482 patent and enforced it against

other generic companies. (Snowden, Tr. 442-43; RX-127 (Endo's February 2011 evaluation of the Johnson Matthey patent); Addanki, Tr. 2362; Figg, Tr. 1949; *see also* RX-495 (Endo complaint alleging, among other things, infringement of the '482 patent); RX-497 (same); RX-498 (same)).

Second, the assumption that "sellers of the patent would obtain the greatest value by selling exclusively to Endo alone" is not subject to reasonable dispute. Professor Noll himself repeatedly asserts that a brand company would pay more to preserve its exclusivity than a competing generic company would stand to make if it entered. (*See, e.g.*, CX5000-105-06 (Noll Rep. ¶ 243) (opining that "[t]he profits of continuing the brand-name monopoly exceed the sum of the profits that the generic firm and the brand-name firm can earn after generic entry.")). Again, real-world evidence supports Dr. Addanki's conclusions. Johnson Matthey proposed an agreement to Endo that was expressly tied to the Opana ER franchise's potential to generate $500 million in revenue per year. (RX-127.0008). Ultimately, Endo ended up acquiring the '482 patent. (JX-003-006 (¶ 36)). There is simply no record evidence that Johnson Matthey was interested in anything other than exclusively licensing or outright selling the '482 patent to Endo. Complaint Counsel's suggestion that Johnson Matthey "would [not] have been willing to license [or sell] a patent to Endo under terms acceptable to Endo" is belied by the fact that that is *exactly what Johnson Matthey did in the real world*.

To the extent Proposed Finding No. 1027 alludes to other "patents," it is simply nonsensical. The U.S. Patent and Trademark Office issued the '060 patent, '122 patent, '216 patent, and '737 patent directly to Endo. (JX-003-006-07 (¶¶ 37-38, 45)). Endo did not have to acquire those patents from any third party.

Finally, Complaint Counsel's implicit suggestion that Endo paid Impax "$112 million" at the time of settlement is simply false. The SLA did not require Endo to pay Impax anything at the time it was signed, and the $10 million payment that Endo made under the DCA was justified as fair value compensation for the bundle of rights Endo received. (RX-364.0012 (SLA § 4.4) (no payment until 90 days after documentation that Endo Credit was triggered is provided); Cobuzzi, Tr. 2564). The fact and amount of the ultimate Endo Credit payment were unknown at the time of settlement, and resulted from an unforeseen "perfect storm" of events. (Addanki, Tr. 2354-56; *see* Noll, Tr. 1612 ("Whether the Endo credit would be paid or the amount that would be paid depends on contingent events.")). As Professor Noll acknowledged, the Endo Credit payment could have been zero. (Noll, Tr. 1479-80).

4. Dr. Addanki uses an unworkable framework for assessing the size of a reverse payment

1028. Dr. Addanki presents a conceptually flawed and unworkable framework for assessing the size of a reverse payment. Rather than assessing the value of the payment when the agreement is entered into, Dr. Addanki urges assessing the value of the payment based on subsequent information. (CX 4044 (Addanki, Dep. 49) ("Q. Right. So if you, Dr. Addanki, were hired in June of 2010 on behalf of Impax to assess the expected value of continued litigation, you might come up with one number in June of 2010 and if you were asked to assess that again in 2017 knowing what happened, you might come up with a different number; is that accurate? A. Yes, in other words, different information – the availability of different information will change your calculations.")).

RESPONSE TO FINDING NO. 1028:

Complaint Counsel's Proposed Finding No. 1028 is inaccurate and grossly misstates Dr. Addanki's deposition testimony. As is evident from the face of the cited transcript, Dr. Addanki was discussing how to calculate the *expected outcome of continued litigation*, which requires one to calculate the probabilities associated with the various possible outcomes, and not "the size of a reverse payment." (*See* CX4044 (Addanki, Dep. at 44-51) ("Q. So the probabilities that you're looking at . . . *are the probabilities of who's going to win the patent case; is that right?* A.

That's correct." (emphasis added)). In determining the expected outcome of continued litigation, it only makes sense to "use all of the information we have," including real-world. (CX4044 (Addanki, Dep. at 48-49)). As better information about comes to light, that information can lead to different conclusions about the probabilities underlying expected values. (CX4044 (Addanki, Dep. at 49)). In this context, "expected" does not refer to "the sense of the English meaning of the word[,] as in anticipated," but rather to its technical meaning of mathematically resolving uncertainty by assigning probabilistic values. (CX4044 (Addanki, Dep. at 45-46)).

As Dr. Addanki stated in his report, the value of a reverse payment should be assessed *ex ante*, as of the time of the settlement. (*See* RX-547.0066-70 (Addanki Rep. ¶¶ 125-27)).

> 1029. Dr. Addanki's framework is conceptually flawed. The relevant question in determining whether a reverse-payment agreement is anticompetitive is whether the brand-name firm provided the generic firm with a large enough payment to induce the generic firm to guarantee it will not launch before a particular date. (CX 5000 at 114-15, 127-28 ((¶¶ 260, 289-90) (Noll Rebuttal Report)). Thus the relevant question is whether the payment induces the generic to enter the agreement, which of course is an assessment made at the time the generic enters the settlement. Whatever subsequent events transpire have little bearing on what induced the generic to enter the settlement.

RESPONSE TO FINDING NO. 1029:

Complaint Counsel's Proposed Finding No. 1029 is inaccurate and unsupported. The first, third, and fourth sentences of Proposed Finding No. 1029 should be disregarded because they violate the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). These proposed "findings" are not facts, but rather unsupported argumentation.

Proposed Finding No. 1029 merely confirms that Professor Noll treats all "reverse-payment settlements" with "large" payments as *per se* anticompetitive. (*See* CX5004-065 (Noll Rebuttal Rep. ¶ 138) ("large, unexplained reverse payments are *inherently* anticompetitive"

(emphasis added)); CX5004-058 (Noll Rebuttal Rep. ¶ 122) ("the *reverse payment itself* is a reliable index of the welfare loss of consumers due to a reverse-payment settlement" (emphasis added)); CX4039 (Noll, Dep. at 26-27) (testifying that if a settlement includes a payment in excess of saved litigation costs, "*it's a hundred percent certain it's anticompetitive*" (emphasis added)); CX4039 (Noll, Dep. at 27) ("Q. So if it's—under your test, if it's greater than the combined—if the payment received by the generic is greater than the sum of the litigation costs, it's necessarily anticompetitive; right? A. Right.")).

This proposed test is wrong as a matter of economics. As Dr. Addanki explained at trial, "whether a given settlement of patent litigation between a brand company and a generic company is anticompetitive or not can only be evaluated by considering all of the facts surrounding the settlement and evaluating whether in fact consumers were worse off with the settlement than they would have been without it." (Addanki, Tr. 2205). The analysis is "really not any different from what we would do in any kind of rule of reason case." (Addanki, Tr. 2206). Because of this, the appropriate inquiry is (1) whether the firm in question possessed monopoly power; and (2) if so, whether the challenged conduct left consumers worse off than they otherwise would have been. (*See* RX-547.0008, 0018, 0020 (Addanki Rep. ¶¶ 11(a), 29, 35)). Without performing this analysis, "[t]here is no knowing . . . whether a given settlement is going to be pro- or anticompetitive." (Addanki, Tr. 2205).

> 1030. Moreover, Dr. Addanki's framework is unworkable. According to Dr. Addanki, the payment could have one value in 2010, another value in 2017 following a trial court decision, and yet another value once the Court of Appeals has rendered a decision. (CX 4044 (Addanki, Dep. 49-50) ("Q. And if subsequent to today, there were reversals by the Court of Appeals on certain patent cases that are between – that relate to Endo's patents, that could cause you, yet, to have a third calculation of expected values of continued litigation, correct? A. If you have more information and you perform the analysis at a later time for the benefit of more information, you may have different conclusions.")). Following this approach would mean the legality of a reverse-payment agreement would

fluctuate—an agreement could be unlawful when entered into, lawful after a district court decision, and perhaps unlawful again after an appellate court decision.

RESPONSE TO FINDING NO. 1030:

Complaint Counsel's Proposed Finding No. 1030 is inaccurate, unsupported, and misleading. As an initial matter, the first and final sentences of Proposed Finding No. 1030 should be disregarded because they violate the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). These proposed "findings" are not facts, but rather unsupported argumentation.

Proposed Finding No. 1030 grossly misrepresents Dr. Addanki's deposition testimony. As is evident from the face of the cited transcript, Dr. Addanki was discussing how to calculate the *expected outcome of continued litigation*, which requires one to calculate the probabilities associated with the various possible outcomes, and not the value of "the payment." (*See* CX4044 (Addanki, Dep. at 44-51) ("Q. So the probabilities that you're looking at . . . *are the probabilities of who's going to win the patent case; is that right?* A. That's correct." (emphasis added)). In determining the expected outcome of continued litigation, it only makes sense to "use all of the information we have," including real-world. (CX4044 (Addanki, Dep. at 48-49)). As better information about comes to light, that information can lead to different conclusions about the probabilities underlying expected values. (CX4044 (Addanki, Dep. at 49)). In this context, "expected" does not refer to "the sense of the English meaning of the word[,] as in anticipated," but rather to its technical meaning of mathematically resolving uncertainty by assigning probabilistic values. (CX4044 (Addanki, Dep. at 45-46)). As Dr. Addanki stated in his report, the value of a reverse payment should be assessed *ex ante*, as of the time of the settlement. (*See* RX-547.0066-70 (Addanki Rep. ¶¶ 125-27)).

XII. The payments to Impax are not justified

A. The No-AG/Endo Credit payment was not justified

1. Endo did not get any product or service for the No-AG/Endo Credit payment (other than the entry date)

1031. The combination of the No-AG provision and the Endo Credit provided Impax with considerable value from Endo, either by Endo forgoing profitable sales of an authorized generic or by Endo paying Impax if Endo reformulated Opana ER and moved the market to a product for which Impax's generic would not be automatically substitutable. (CX5000 at 170-72 (¶¶ 379-382) (Noll Report)).

RESPONSE TO FINDING NO. 1031:

Complaint Counsel's Proposed Finding No. 1031 should be disregarded because it violates the Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." Proposed Finding No. 1031 also misstates the record and lacks foundation. Professor Noll did not calculate the expected value of any provision of the settlement agreement, or the expected value of the "combination of the No-AG provision and the Endo Credit." (Noll, Tr. 1613, 1651-52).

In any event, the record is clear that when it was signed, the SLA did not require Endo to actually pay anything to Impax. (RX-364.0012 (SLA § 4.4) (no payment until 90 days after documentation that Endo Credit was triggered is provided)). Nor did Endo expect to make a payment at any point in the future. (CX4017 (Levin, Dep. at 99-100) ("at the time the transaction was inked I did not expect that Endo would have to make a payment under this provision")). And numerous witnesses testified that, at the time of the settlement, it was uncertain whether or not the "combination of the No-AG provision and the Endo Credit provided Impax" with any value at all, and if any, how much. (Cuca, Tr. 629; Snowden, Tr. 437-38). Indeed, Impax knew that the settlement could result in zero value. (CX4032 (Snowden, Dep. at

204-06); CX4002 (Smolenski, IHT at 128-30); Cuca, Tr. 628-29; CX4017 (Levin, Dep. at 143-44)).

Both Complaint Counsel and Professor Noll admitted it was possible that both the Endo Credit and No-Authorized Generic provisions would have zero value. (Court, Tr. 71, 75 ("JUDGE CHAPPELL: Are you going to stand there and tell me that the lowest possible outcome was not going to be zero? You're going to stand there and tell me that because some paid expert tells you that it had to be $62 million floor that it couldn't have been zero? MR. LOUGHLIN: No, Your Honor. There was a theoretical possibility of zero."); Noll, Tr. 1654 ("Q. And that example where you get zero of both, you didn't include that on your demonstrative of scenarios, did you? A. No, I didn't.")).

1032. Other than agreeing not to sell generic Opana ER until January 2013, Impax provided nothing to Endo in exchange for the No-AG/Endo Credit payment. (*See* CCF ¶¶1033-1043).

RESPONSE TO FINDING NO. 1032:

The proposed summary finding should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Additionally, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondent's replies to those findings.

1033. Under the SLA, Impax does not provide any products or services to Endo in exchange for the No-AG/Endo Credit payment. (RX-364 at 0019 (SLA § 9.3) ("This Agreement, including the Appendix attached hereto, together with the Development Agreement between Endo and Impax, dated as of the date hereof, contains the entire agreement between the Parties with respect to the subject matter hereof . . . .")).

RESPONSE TO FINDING NO. 1033:

Respondent has no specific response.

a) The No-AG/Endo Credit payment was directly linked to the January 2013 entry date

1034. From the start of negotiations, a No-AG provision was coupled in the settlement discussions between Impax and Endo with a 2013 entry date, and the Endo Credit evolved to protect the value of the period of No-AG exclusivity. (*See* CCF ¶¶ 10351039). The No-AG/Endo Credit payment imposes costs on Endo that can only be explained by Endo receiving a later entry date than it could have expected to get without such a payment. (*See* CCF ¶¶ 1040-1043). Further, the No-AG/Endo Credit payment explains why Impax was willing to forgo sales of generic Opana ER until January 2013. (*See* CCF ¶¶ 1044-1047).

RESPONSE TO FINDING NO. 1034:

The proposed summary finding should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Additionally, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondent's replies to those findings.

1035. Before Impax and Endo started having substantive negotiations in May 2010, Impax executives were concerned about postponing its projected oxymorphone ER entry date beyond 2010, but were willing to do so for a settlement with a No-AG provision. (CX0505 at 001 (May 14, 2010 Mengler/Hsu email chain) (showing generics division president objecting to "postponing the launch of Oxymorphone" until Impax CEO suggested a settlement "with No AG")).

RESPONSE TO FINDING NO. 1035:

Complaint Counsel's Proposed Finding No. 1035 is inaccurate and misleading. The only document cited for this proposition is an email in which Dr. Hsu stated, "I want to consider pros and cons on postponing the launch of Oxymorphone in January 2011." (CX0505-001). Mr. Mengler noted the truism that "you know what they [s]ay [sic] about a bird in the hand . . ." in response. (CX0505-001). Mr. Mengler never "objects" to "postponing the launch of Oxymorphone ER," as Complaint Counsel attempts to suggest. Finally, Proposed Finding No. 1035 ignores significant record evidence that Impax valued a robust opportunity to make and sell

oxymorphone ER, not the absence of an authorized generic. (CX4030 (Hsu, Dep. at 76-77); CX4014 (Hsu, IHT at 68-69) (if no authorized generic means you "delay the entry date, that's a different story. . . . Because there is a very important factor here, which is . . . to have an entry date, have a launch as soon as possible"); Mengler, Tr. 528-30 (Impax derives value "by selling the drug [] with or without an" authorized generic)).

1036. The first written proposal Endo and Impax exchanged—draft term sheets sent on May 26, 2010—included an agreement that Impax would not sell generic Opana ER until 2013 and a No-AG provision that lasted until the end of Impax's first-filer exclusivity period. (CX0320 at 009-010 (Ex. A, Draft License Agreement, §§ 1(a)-(b), 2(a))).

RESPONSE TO FINDING NO. 1036:

Respondent has no specific response other than to note that the term sheet contained no "agreements," it contained on party's proposed terms for negotiation.

1037. Every subsequent written proposal between Impax and Endo contained provisions keeping Impax off the market until 2013 and some form of the No-AG/Endo Credit payment. (CX0321 at 001-02 (May 27, 2010 Mengler/Levin email) (launch date of January 1, 2013 and "no authorized generic"); CX0323 at 003-04, 006, -007, 008, 010-12 (draft SLA sent by Endo on June 4, 2010, Definitions of "Commencement Date," "Pre-Impax-Amount," and Trigger Threshold," §§ 3.2, 4.1(a)-(c), 4.4) (Impax does not sell until January 2013 and gets a No-AG provision and a provision under which Endo would pay Impax if shipments of branded Opana ER dropped below a Trigger Threshold before the Commencement Date); CX3349 at 001-02 (June 6, 2010 Koch/Levin email chain) (no Impax sales until January 2013 and "[a]ll terms regarding oxymorphone settlement and license remain the same including market protection . . . .")).

RESPONSE TO FINDING NO. 1037:

Complaint Counsel's Proposed Finding No. 1037 is inaccurate. Every written proposal did not include "some form" of the Endo Credit and, as the record makes clear, no proposal guaranteed any "payment." (Court, Tr. 71, 75 ("JUDGE CHAPPELL: Are you going to stand there and tell me that the lowest possible outcome was not going to be zero? You're going to stand there and tell me that because some paid expert tells you that it had to be $62 million floor

that it couldn't have been zero? MR. LOUGHLIN: No, Your Honor. There was a theoretical possibility of zero."); Noll, Tr. 1654 ("Q. And that example where you get zero of both, you didn't include that on your demonstrative of scenarios, did you? A. No, I didn't.")).

Impax initially sought a market degradation trigger, which would have allowed Impax to launch a generic version of Opana ER immediately if Endo introduced a reformulated product that degraded sales of original Opana ER. (Koch, Tr. 237-38; Snowden, Tr. 432; Mengler, Tr. 532; RX-318.0001). Endo categorically refused a market degradation trigger, considering it a "nonnegotiable" concept, even though Impax pressed the issue "very hard." (Koch, Tr. 314-16; *see* Snowden, Tr. 432; Mengler, Tr. 581). It was only after Endo refused Impax's attempts to include a market degradation trigger that Impax and Endo discussed the Endo Credit provision. (Mengler, Tr. 533; Koch, Tr. 238-39; Reasons, Tr. 1202-03).

Finally, Impax pushed for earlier license dates in telephonic and in-person meetings, and those efforts did not involve any other terms. (Snowden, Tr. 371-73, 423; Mengler, Tr. 565-67).

> 1038. The Endo Credit was added to protect the value of Impax's first-filer exclusivity period and the profits it would have achieved from being the only generic seller for 180 days. (Mengler, Tr. 533 ("in the worst-case scenario, where the market was in fact destroyed, I at least wanted to be made whole for the profits that we would have otherwise achieved")).
>
> **RESPONSE TO FINDING NO. 1038:**

Complaint Counsel's Proposed Finding No. 1038 is inaccurate and misleading. The record makes clear that the Endo Credit was intended to disincentivize Endo from degrading the opportunity for Impax to enter with an AB-substitutable generic version of Opana ER, and to incentivize Endo to make investments in its original Opana ER product. (Koch, Tr. 241; Snowden, Tr. 386; CX4021 (Ben-Maimon, Dep. at 118, 122); CX4026 (Nguyen, Dep. at 163-64); CX4037 (Smolenski, Dep. at 244-45) (Endo Credit "intended to disincentivize Endo from"

introducing a reformulated product)). The term was not intended to generate income. (Mengler, Tr. 582-83). And a payment under the provision was not guaranteed to match Impax's profits, as the Proposed Finding attempts to suggest. To illustrate, actual quarterly peak sales after settlement were $185,691,457. (CX0332-003). If sales dropped just enough to trigger the Endo Credit, for instance, because sales in the last quarter of 2012 were 49 percent of their quarterly peak, this would mean the resulting liability would be roughly $2 million. If sales dropped only to 49.9 percent of their peak, the resulting liability would be roughly $200,000. (RX-364.0003-04 (any Endo Credit payment is the product of (1) 0.2953 times the annualized quarterly peak sales divided by 100, and (2) the number of percentage points under 50)).

1039. The entry date and reverse payment were so intertwined that the 2013 entry date was never discussed by Impax and Endo without reference to a reverse payment. (CX5001 at 024 (¶ 49) (Bazerman Report)).

RESPONSE TO FINDING NO. 1039:

Complaint Counsel's Proposed Finding No. 1039 violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." (*See also* Court, Tr. 1859 ("[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.")). Proposed Finding No. 1039 is also inaccurate. The record shows that the No-Authorized Generic term was not linked to any commencement date. (CX4012 (Donatiello, IHT at 172-73); CX4017 (Levin, Dep. at 156-57); Snowden, Tr. 428-29; Mengler, Tr. 567).

1040. From Endo's perspective, the No-AG/Endo Credit imposed costs that make no sense for a rational business unless it was getting something in return. (CX5001 at 024, 031 (¶¶ 49, 57) (Bazerman Report)).

RESPONSE TO FINDING NO. 1040:

Complaint Counsel's Proposed Finding No. 1040 violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." (*See also* Court, Tr. 1859 ("[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.")).

Proposed Finding No. 1040 is also wrong. When it was signed, the SLA did not require Endo to actually pay anything to Impax. (RX-364.0012 (SLA § 4.4) (no payment until 90 days after documentation that Endo Credit was triggered is provided)). Nor did Endo expect to make a payment at any point in the future. (CX4017 (Levin, Dep. at 99-100) ("at the time the transaction was inked I did not expect that Endo would have to make a payment under this provision")). This is why Endo did not book a reserve of any sort for a payment under the SLA. (Cuca, Tr. 664-65; CX4017 (Levin, Dep. at 125-26)). Nor did Endo intend to launch an authorized generic of Opana ER. (Bingol, Tr. 1337-39 (testifying that an authorized generic "was never, to my knowledge . . . fully realized as a plan or an idea"); CX4019 (Lortie, Dep. at 118-19) ("we never seriously considered taking any further steps to prepare for or to do [an authorized generic] because we really didn't want to"); CX4031 (Bradley, Dep. at 198) ("I don't recall having any conversation with any colleagues regarding the launch of an authorized generic.")).

1041. The cost of the No-AG provision was forgone sales of an AG that Endo would otherwise have the incentive to make if it was still selling Original Opana ER at Impax's licensed entry date. (*See* CCF ¶¶ 350, 399-401, 998).

RESPONSE TO FINDING NO. 1041:

The proposed summary finding should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported

by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Additionally, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondent's replies to those findings.

> 1042. The cost of the Endo Credit was the cash payment that Endo would have to make to Impax if sales declined following a reformulation, which turned out to be approximately $102 million paid by Endo. (*See* CCF ¶¶ 431-433, 439-444).

RESPONSE TO FINDING NO. 1042:

The proposed summary finding should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Additionally, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondent's replies to those findings.

> 1043. What Endo received in exchange for the No-AG/Endo Credit payment was the ability to sell branded Opana ER without generic competition until January 2013. (CX5001 at 029, 031 (¶¶ 54, 57) (Bazerman Report)). The payment resulted in a later entry date than what Endo could expect without a payment. (CX5001 at 035 (¶ 66) (Bazerman Report)).

RESPONSE TO FINDING NO. 1043:

Complaint Counsel's Proposed Finding No. 1043 violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." (*See also* Court, Tr. 1859 ("[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.")).

The first sentence of Proposed Finding No. 1043 is also wrong. It was *Endo's patents* that allowed it to sell branded Opana ER without generic competition until *September 2013*. (Hoxie, Tr. 2834 (testifying that if Impax lost the litigation it would "not be able to market its oxymorphone ER product until at least September 2013 when the patents expired")). The second

sentence of Proposed Finding No. 1043 is also inaccurate because had Endo prevailed in the underlying litigation, Impax could not have entered until September 2013, eight months later than the licensed-entry date in the SLA. (Hoxie, Tr. 2834). Further, the second sentence assumes Endo expected to make a "payment," which was not the case at the time of settlement. (CX4017 (Levin, Dep. at 99-100) ("at the time the transaction was inked I did not expect that Endo would have to make a payment under this provision"); Cuca, Tr. 664-65 (Endo did not book reserve for any payment because it was not "probable and estimable")).

1044. Impax also experienced costs from the SLA—specifically the costs of waiting to sell generic Opana ER until January 2013—that were addressed by the No-AG/Endo Credit payment. (*See* CCF ¶¶ 1045-1048).

RESPONSE TO FINDING NO. 1044:

The proposed summary finding should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Additionally, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondent's replies to those findings.

1045. Prior to entering the SLA, Impax was preparing to launch generic Opana ER in 2010 or 2011. (*See* CCF ¶¶ 127-202).

RESPONSE TO FINDING NO. 1045:

The proposed summary finding should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Additionally, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondent's replies to those findings.

1046. Staying out of market would impose costs on Impax, including lost or delayed sales of generic Opana ER and uncertainty about the market opportunity for Impax's product in 2013. (CX0505 at 001 (Mengler/Hsu email chain describing the cost of "postponing the launch of Oxymorphone" as "lost/delayed sales"); Mengler, Tr. 527 ("the biggest concern that Opana ER somehow in its original form disappears or becomes so insignificant, because . . . the way generic drugs are sold is by having a substitute, and if there's no substitute, I get nothing")).

RESPONSE TO FINDING NO. 1046:

Complaint Counsel's Proposed Finding No. 1046 is incomplete and misleading. First, Proposed Finding No. 1046 inappropriately assumes Impax would have entered the market at-risk, but no record evidence supports that proposition. (*See, e.g.*, Koch, Tr. 324-25). Second, had Impax continued to litigate with Endo, it was more likely than not to lose on the merits. (Figg, Tr. 1870, 1884, 1904). Third, continuing to litigate created uncertainty and imposed costs on Impax, including the likelihood that Impax would be precluded from selling oxymorphone ER for a much longer period of time. (Figg, Tr. 1972 (testifying that but for the settlement Impax would likely be enjoined from selling oxymorphone ER until 2029)).

1047. The No-AG/Endo Credit payment compensated Impax for the costs of waiting until January 2013, either through increased revenues from generic Opana ER during Impax's first-filer exclusivity period or a cash payment to replicate the value that Impax would have earned during that 180-day period. (Reasons, Tr. 1215 ("Having a no-AG provision, Impax could charge a higher price for generic Opana ER"); Mengler, Tr. 533 (describing the Endo Credit as being "made whole for the profits that we would have otherwise achieved"); CX5001 at 034 (¶ 63) (Bazerman Report) ("The branded-to-generic payments provide a bridge to compensate Impax for sacrificing those potential near-term and future profits")).

RESPONSE TO FINDING NO. 1047:

Complaint Counsel's Proposed Finding No. 1047 is not supported by the record and lacks foundation. Professor Noll did not calculate the expected value of any provision in the settlement agreement, or the overall expected value of the SLA, at the time of settlement. (Noll, Tr. 1613, 1651-52; Addanki, Tr. 2384). Both Complaint Counsel and Professor Noll concede

that the Endo Credit and No-Authorized Generic provisions could have resulted in zero value to Impax. (Court, Tr. 71, 75 ("JUDGE CHAPPELL: Are you going to stand there and tell me that the lowest possible outcome was not going to be zero? You're going to stand there and tell me that because some paid expert tells you that it had to be $62 million floor that it couldn't have been zero? MR. LOUGHLIN: No, Your Honor. There was a theoretical possibility of zero."); Noll, Tr. 1654 ("Q. And that example where you get zero of both, you didn't include that on your demonstrative of scenarios, did you? A. No, I didn't.")).

Indeed, the record is clear that it was "entirely plausible" that Endo could employ a late switch in products such that there was a reduced generic opportunity for Impax—and thus no benefit from a No-AG provision—while Endo still made no Endo Credit payment. (Mengler, Tr. 589-90; *see* CX4002 (Smolenski, IHT at 50-51, 129, 187-88); Bingol, Tr. 1338 (Endo had no intention of launching both an authorized generic and a reformulated version of Opana ER. Endo "intended to replace one product with the other, and that would be the only product that we had on the market," (CX4019 (Lortie, Dep. at 117-18)), but Endo still "did not expect to make a payment to Impax," (CX4017 (Levin, Dep. at 126)).

Finally, the claim that the any payment under the Endo Credit provision would replicate Impax's profits is wrong. To illustrate, actual quarterly peak sales after settlement were $185,691,457. (CX0332-003). If sales dropped just enough to trigger the Endo Credit, for instance, because sales in the last quarter of 2012 were 49 percent of their quarterly peak, this would mean the resulting liability would be roughly $2 million. If sales dropped only to 49.9 percent of their peak, the resulting liability would be roughly $200,000. (RX-364.0003-04 (any Endo Credit payment is the product of (1) 0.2953 times the annualized quarterly peak sales divided by 100, and (2) the number of percentage points under 50)). The term was instead

intended to disincentivize Endo from degrading the opportunity for Impax to enter with an AB-substitutable generic version of Opana ER, and to incentivize Endo to make investments in its original Opana product. (Koch, Tr. 241; Snowden, Tr. 386; CX4021 (Ben-Maimon, Dep. at 118, 122); CX4037 (Smolenski, Dep. at 244-45) (Endo Credit "intended to disincentivize Endo from" introducing a reformulated product)).

1048. Use of the Endo Credit explicitly ties payment to the January 2013 entry date, because it was used instead of an earlier proposal that would have allowed Impax to enter before 2013 if sales of Original Opana ER declined below certain levels. (*See* CCF ¶¶ 1049-1053).

RESPONSE TO FINDING NO. 1048:

The proposed summary finding should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Additionally, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondent's replies to those findings. In any event, Proposed Finding No. 1048 is wrong. Adding the Endo Credit to the proposed settlement did not lead to a later license date, just the opposite. Introduction of the Endo Credit term hastened Impax's license date to an earlier date. (CX2626 (executed settlement agreement including Endo Credit and January 1, 2013 license date); CX4017 (Levin, Dep. at 117, 121)).

1049. In May 2010, to address the market uncertainty of staying out of market until 2013 and the possibility of Endo moving the market away from Original Opana ER, Impax proposed an acceleration trigger. (Snowden, Tr. 385).

RESPONSE TO FINDING NO. 1049:

Complaint Counsel's Proposed Finding No. 1049 misrepresents Ms. Snowden's testimony. Ms. Snowden said nothing about "the market uncertainty of staying out of the

market." Ms. Snowden answered "yes" to the question "Impax negotiated for protections in case Endo moved the market away from original formulation of Opana ER; correct?" (Snowden, Tr. 385). This testimony is wholly consistent with the record, which makes clear that the Endo Credit was intended to disincentivize Endo from degrading the opportunity for Impax to enter with an AB-substitutable generic version of Opana ER, and to incentivize Endo to make investments in its original Opana product. (Koch, Tr. 241; Snowden, Tr. 386; CX4021 (Ben-Maimon, Dep. at 118, 122); CX4037 (Smolenski, Dep. at 244-45) (Endo Credit "intended to disincentivize Endo from" introducing a reformulated product)).

> 1050. Under an acceleration trigger, Impax's date of entry for its generic oxymorphone ER product would be accelerated to earlier than January 2013 in the event of a specified condition precedent, such as sales of Original Opana ER decreasing by 50%. (Snowden, Tr. 385). Impax would thereby be ensured of realizing value from the sale of its generic product by entering before the market had shifted to the new, reformulated product. (CX5001 at 027-28 (¶ 53) (Bazerman Report)).

RESPONSE TO FINDING NO. 1050:

Respondent has no specific response to the first sentence of Complaint Counsel's Proposed Finding No. 1050 other than to clarify that Ms. Snowden did not testify about any relevant condition precedents, and said nothing about a 50 percent threshold. (Snowden, Tr. 385).

The second sentence of Proposed Finding No. 1050 is improper because it cites "to expert testimony to support factual propositions that should be established by fact witnesses or documents." Professor Bazerman, for his part, cites no factual support for the statement in his report. In any event, there is no evidence that an "acceleration trigger" would "ensure[]" Impax realized value from the sale of its generic product. In fact, Professor Bazerman did not calculate any expected values. (Bazerman, Tr. 923-24). Whether Impax realized value from the

accelerated licensed-entry date would depend on a number of factors, including how quickly Endo switched products and how quickly Impax could launch its product.

1051. When Endo rejected the acceleration trigger, the parties moved instead to what eventually became the Endo Credit. (Snowden, Tr. 385).

RESPONSE TO FINDING NO. 1051:

Respondent has no specific response.

1052. Under the Endo Credit, Endo paid Impax rather than face earlier entry through an acceleration provision. If the SLA contained a 50% acceleration trigger (like the trigger in the Endo Credit formula), Impax may have started selling generic Opana ER in the second quarter of 2012. (CX4003 (Snowden), IHT at 197; RX-364 at 0006 (SLA Definition of "Trigger Threshold")). Instead, Impax stayed out of the market until 2013 and got a $102 million Endo Credit payment. (CX0333 at 001-002 (wire transfer from Endo to Impax for Endo Credit)).

RESPONSE TO FINDING NO. 1052:

The first sentence of Complaint Counsel's Proposed Finding No. 1052 is not supported by any record evidence and should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). The first sentence is also inaccurate. When it was signed, the SLA did not require Endo to actually pay anything to Impax. (RX-364.0012 (SLA § 4.4) (no payment until 90 days after documentation that Endo Credit was triggered is provided)). Nor did Endo expect to make a payment at any point in the future. (CX4017 (Levin, Dep. at 99-100) ("at the time the transaction was inked I did not expect that Endo would have to make a payment under this provision")).

The second sentence of Proposed Finding No. 1052 lacks foundation, is speculative, and is not supported by the record. Ms. Snowden was asked a hypothetical question, and explained that "[y]ou talked about how a market degradation trigger would work, and I agreed with that.

Preparation and launch readiness and [the] ability to launch wasn't factored in. And then if you ask me about others, then there is the same issue. I don't know a whole lot about them. In fact, some of them still haven't launched for reasons I don't understand." (CX4003 (Snowden, IHT at 197)). There is no indication that the parties ever discussed a 50 percent threshold for an acceleration trigger or that the term would have been accepted as part of any settlement. Indeed, the record is clear that Endo refused to discuss an acceleration trigger outright. (Koch, Tr. 314-16; Snowden, Tr. 432; Mengler, Tr. 581). Any suggestion that the "parties would have agreed to a settlement that was materially different from the settlement they actually agreed to, the one before us, is pure speculation." (Addanki, Tr. 2359). "To hypothesize a settlement and say they would have agreed to it would be the purest speculation." (Addanki, Tr. 2374).

The third sentence of Proposed Finding No. 1052 is inaccurate and misleading in its suggestion that the parties agreed to, or knew the size of, any payment at the time of settlement. Impax never analyzed or forecasted whether it would receive a payment under the Endo Credit at the time of settlement, and it knew the Endo Credit could result in zero value. (Reasons, Tr. 1219; Mengler, Tr. 582; CX4038 (Engle, Dep. at 187-88)). Endo similarly had no "expectation that a payment would have to be made." (CX4017 (Levin, Dep. at 99-100) ("at the time the transaction was inked I did not expect that Endo would have to make a payment under this provision"); Cuca, Tr. 664-65 (Endo did not book a reserve because no Endo Credit payment was "probable and estimable" at settlement); *see* Noll, Tr. 1611, 1649 (neither party estimated value of Endo Credit at the time of settlement)).

Indeed, the first time that Endo knew its sales would be zero in the last quarter of 2012 was after the Novartis plant shutdown and resulting supply interruption. (Cuca, Tr. 677; RX-094.0003-06 (supply chain disruption for original Opana ER resulted in Endo Credit liability)).

Until that point, Endo expected to sell Opana ER through the fourth quarter of 2012. (CX4017 (Levin, Dep. at 131); RX-094.0006 ("Prior to March [2012], it would have been reasonable to assume that prescriptions of old formulation [Opana ER] would have occurred in Q4 2012"); RX-108.0002 at 10).

> 1053. From a negotiating perspective, using the Endo Credit rather than an acceleration provision could be preferable for Impax (because it guaranteed payment regardless of any uncertainty in the marketplace) and for Endo (because it could make branded sales for a longer period of time). (CX5001 at 028 (¶ 53) (Bazerman Report)). But this option was less desirable for consumers, who would have benefitted from earlier generic competition afforded by an accelerated entry date under an acceleration provision. (CX5001 at 028 (¶ 53) (Bazerman Report)).

RESPONSE TO FINDING NO. 1053:

Complaint Counsel's Proposed Finding No. 1053 violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." (*See also* Court, Tr. 1859 ("[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.")).

Proposed Finding No. 1053 is also not supported by the record and lacks foundation. The Endo Credit did not guarantee a payment of any kind. (Cuca, Tr. 628-29; CX4017 (Levin, Dep. at 143-44)). And Professor Bazerman did not actually assess the benefits consumers received as a result of the Endo-Impax settlement agreement when compared to any benefits they might have gotten if there had been another settlement. (Bazerman, Tr. 897). Indeed, Professor Bazerman did not conduct any analysis regarding consumer impact even though he has the technical skills to do so. (Bazerman, Tr. 897-99).

Finally, the proposition that Impax preferred the Endo Credit to the acceleration trigger is not supported by any evidence in the record. In fact, just the opposite is clear: Impax proposed the acceleration trigger and pushed for it in negotiations, considering other terms only when

Endo rejected an acceleration trigger outright. (Koch, Tr. 237-38; Snowden, Tr. 432; Mengler, Tr. 532; RX-318.0001).

1054. With the No-AG/Endo Credit payment, Endo received what it bargained for, that is, Impax not selling generic Opana ER until 2013. (CX5001 at 029 (¶ 54) (Bazerman Report) ("My professional opinion is that Endo would not negotiate for this negative net value without getting something in return, specifically, no generic competition until January 2013")).

RESPONSE TO FINDING NO. 1054:

Complaint Counsel's Proposed Finding No. 1054 violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." (*See also* Court, Tr. 1859 ("[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.")).

b) Impax's attempt to redefine the Endo Credit as part of a "carrot and stick" approach does not comport with logic or the facts

1055. Years after entering the SLA, Impax now attempts to redefine the Endo Credit by combining it with a royalty provision and calling it a "carrot and stick" approach to inducing Endo to maintain and grow Opana ER sales. By "carrot," Impax now means a royalty that Endo would be paid if it grew Original Opana ER sales by a certain percentage prior to Impax's launch. (Koch, Tr. 239). By "stick," Impax refers to the Endo Credit. (Koch, Tr. 239).

RESPONSE TO FINDING NO. 1055:

The first sentence of Complaint Counsel's Proposed Finding No. 1055 is not supported by any record evidence and should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Respondent has no specific response to the second and third sentences of Proposed Finding No. 1055 other than to clarify that the nature (and description) of the royalty and Endo Credit terms is neither new nor a

view held only by Impax. (Cuca, Tr. 613-14 (Endo employee and author of the Endo Credit explained that "the mirror image of the Endo Credit" was the royalty provision); CX4017 (Levin, Dep. at 120-21) (Endo CFO explained that the Endo Credit and Royalty Provision "were intended to be looked at hand in hand"); CX4001 (Koch, IHT at 44) (explaining "we agreed to pay them a royalty on the sales of our generic if the market was robust at the time of our launch in 2013, and we struck a penalty if the market wasn't robust" and "we tried to find economic reasons for them to develop and enhance, grow the market for Opana"); CX4001 (Koch, IHT at 81) ("what we tried to come up with were economic reasons why they would continue to develop the market, and the economic reasons we came up with were we would pay them a royalty if the market is robust, or they pay us a penalty if it isn't")).

> 1056. But at the time of settlement, Impax viewed the Endo Credit as market protection, not as part of a "carrot and stick" approach. (*See* CCF ¶¶ 1057-1058). Moreover, the Endo Credit functioned—as it was designed—to reimburse Impax, not to deter Endo. (*See* CCF ¶¶ 1059-1063). Finally, the royalty provisions were not designed to act as a "carrot" because they still imposed costs on Endo through forgone sales of an authorized generic. (*See* CCF ¶¶ 1064-1065).

RESPONSE TO FINDING NO. 1056:

The proposed summary finding should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Additionally, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondent's replies to those findings.

> 1057. "Carrot and stick" was not a concept that Impax used at the time it was negotiating the SLA. For example, Meg Snowden—Impax's chief in-house lawyer and one of Impax's lead negotiators—could not recall anybody using the term "stick" or the phrase "carrot and stick" during the period of negotiations to refer to the Endo Credit. (Snowden, Tr. 391). Indeed, no documents from the period of negotiations refer to the "carrot" or the "stick" now alleged by Impax. (*See* CCF ¶¶ 1059 (showing that, rather

than using the term "carrot and stick," Impax's documents refer to the Endo Credit as a "make whole provision" or a "make good" payment)).

RESPONSE TO FINDING NO. 1057:

Complaint Counsel's Proposed Finding No. 1057 is misleading and inaccurate. While Ms. Snowden did not recall the use of the specific words "carrot" and "stick," she was unequivocal about the underlying concept: the Endo Credit and royalty provision were both intended to incentivize Endo to support original Opana ER. (Snowden, Tr. 386; CX4003 (Snowden, IHT at 159-60)). Mr. Koch explained that "it was understood when we entered into negotiations we had developed what we called a carrot and stick as a way to get more control." (Koch, Tr. 237; *see* CX4001 (Koch, IHT at 81) ("what we tried to come up with were economic reasons why they would continue to develop the market, and the economic reasons we came up with were we would pay them a royalty if the market is robust, or they pay us a penalty if it isn't")).

Roberto Cuca, Endo's Vice President of Financial Planning and Analysis and the author of the Endo Credit, agreed that the Royalty Provision acted as an "Impax Credit" and was "the mirror image of the Endo Credit." (Cuca, Tr. 613-14; *see* CX4017 (Levin, Dep. at 120-21) (Endo CFO explained that the Endo Credit and Royalty Provision "were intended to be looked at hand in hand")). That Meg Snowden could not remember the use of the specific term "carrot and stick" over seven years later is not probative of the purpose of the Endo Credit and Royalty Provision.

The third sentence of Proposed Finding No. 1057 should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2).

1058. Moreover, the purported "carrot and stick" were not proposed together. A royalty for growth in sales of Original Opana ER prior to Impax's launch was in the first written proposal exchanged on May 26, 2010. (CX0320 at 010 (Ex. A, License Agreement, § 3)). In contrast, a variant of the Endo Credit does not appear in a written proposal exchanged between Impax and Endo until June 4, 2010. (CX0323 at 012 (draft SLA § 4.4)).

RESPONSE TO FINDING NO. 1058:

Complaint Counsel's Proposed Finding No. 1058 is incomplete and misleading. Even if one term took longer to draft, that does not indicate the terms were not discussed together. Mr. Mengler, one of Impax's negotiators, explained that the royalty provision and Endo Credit were discussed either in "the same exact conversation or close." (Mengler, Tr. 582). Endo's negotiator and CFO said the same thing. (CX4017 (Levin, Dep. at 120-21) (Endo CFO explained that the Endo Credit and Royalty Provision "were intended to be looked at hand in hand")).

The second sentence of Proposed Finding No. 1058 is inaccurate. The royalty provision first proposed by Endo was *not* contingent on "growth in sales." (CX 2616 (May 26, 2010 Guy Donatiello email to Chris Mengler stating: "The royalty rate from Impax to Endo during the exclusivity (35%) should have no trigger. . . . The Agreement should be for a 35% royalty for all sales regardless of the size of the market.")). The very next day, Impax counter-proposed a contingent royalty. (*See* RX-318 (May 27, 2010 Chris Mengler email to Alan Levin stating: "Generic profit sharing: if most recent 4 months prior to launch is less than 150M, no royalty to Endo. If greater than 150M and less than 175M, 10% profit split; if greater than 175M, 15% profit split.")).

1059. Rather than a "stick" used against Endo, Impax viewed the Endo Credit as a provision to protect itself and its revenue stream by making Impax "whole" if sales of Original Opana ER declined. (Koch, Tr. 238; Mengler, Tr. 545, 582; CX0407 at 002 (June 3, 2010 Mengler/Koch email); *see also* CX0506 at 001 (June 1-2, 2010 Mengler/Nestor email chain) (referencing the "'make good' payment")).

RESPONSE TO FINDING NO. 1059:

Complaint Counsel's Proposed Finding No. 1059 is incomplete and misleading. While Mr. Koch testified that he remembered calling the Endo credit term a "make-whole provision," he explained that the "make-whole was part of the carrot and stick." (Koch, Tr. 238-39). Thus, the terms "make-whole" provision and "carrot and stick" are not mutually exclusive. (CX4001 (Koch, IHT at 81) ("what we tried to come up with were economic reasons why they would continue to develop the market, and the economic reasons we came up with were we would pay them a royalty if the market is robust, or they pay us a penalty if it isn't"); CX4021 (Ben-Maimon, Dep. at 118, 122) (Endo Credit was "a deterrent to prevent [Endo] from switching the market"); CX4037 (Smolenski, Dep. at 244-45) (Endo Credit "intended to disincentivize Endo from" introducing a reformulated product); CX4026 (Nguyen, Dep. at 163-64) (Endo Credit was used to "put [Endo] to [its] word" with respect to reformulation)).

> 1060. The Endo Credit was designed as insurance for Impax, not a deterrence against Endo reformulating. (Koch, Tr. 265-66 ("We viewed [the Endo Credit] as insurance"); Cuca, Tr. 617 (stating the Endo Credit "was designed to insulate against a substantial decrease in sales of the innovator product"); CX5001 at 027 (¶ 52) (Bazerman Report) ("It is therefore difficult to understand how paying Impax a portion of Impax's generic sales for a six-month period would discourage Endo from reformulating to a new branded drug, considering all of the branded revenues from the reformulated product that Endo would be able to make over the course of several years")).

RESPONSE TO FINDING NO. 1060:

Complaint Counsel's Proposed Finding No. 1060 is incomplete, misleading, and not supported by the cited evidence. The fact that the Endo Credit provided Impax with some protection for its generic opportunity does not mean that the term did not simultaneously seek to deter reformulation. In fact, the record is clear that the Endo Credit was intended to do just that. (Koch, Tr. 241; Snowden, Tr. 386; CX4021 (Ben-Maimon, Dep. at 118, 122) (the Endo Credit was designed to act as "a deterrent to prevent [Endo] from switching the market"); CX4037

(Smolenski, Dep. at 244-45) (Endo Credit "intended to disincentivize Endo from" introducing a reformulated product); CX4026 (Nguyen, Dep. at 163-64) (Endo Credit was used to "put [Endo] to [its] word" with respect to reformulation); CX4001 (Koch, IHT at 81) ("what we tried to come up with were economic reasons why they would continue to develop the market, and the economic reasons we came up with were we would pay them a royalty if the market is robust, or they pay us a penalty if it isn't")).

> 1061. When negotiators were designing the Endo Credit, they focused the mathematical formula on the profits that Impax would be losing during its first six months of sales, when it would be the only generic on the market. (Cuca, Tr. 617 (stating that the objective of the Endo Credit, which Mr. Cuca drafted, was "[h]elping them [Impax] achieve cash flows that would have been similar to what they would have achieved had the change in the marketplace not occurred")). Indeed, in the first written draft to include a variant of the Endo Credit, the section is entitled "Impax Sales During Exclusivity Period." (CX0323 at 012 (draft SLA § 4.4)).

RESPONSE TO FINDING NO. 1061:

Complaint Counsel's Proposed Finding No. 1061 is inaccurate. The mathematical formula underlying the Endo Credit did not ensure Impax would receive a payment equal to the profits it would earn during six months of exclusivity. To illustrate, actual quarterly peak sales after settlement were $185,691,457. (CX0332-003). If sales dropped just enough to trigger the Endo Credit, for instance, because sales in the last quarter of 2012 were 49 percent of their quarterly peak, this would mean the resulting liability would be roughly $2 million. If sales dropped only to 49.9 percent of their peak, the resulting liability would be roughly $200,000. (RX-364.0003-04 (any Endo Credit payment is the product of (1) 0.2953 times the annualized quarterly peak sales divided by 100, and (2) the number of percentage points under 50)). There is no evidence that such potential liabilities under the Endo Credit are approximations of Impax's expected profits over six months. Terms in the settlement agreement referencing things like

profit margin and substitution rate meant only that annualized quarterly peak sales (after being divided by 100) would be multiplied by a specific figure: 0.2953. (RX-364.0003-04).

> 1062. The mathematical formula was not designed to deter Endo from reformulating by causing Endo to divest any profits that it received from reformulation. In fact, none of the input provisions that comprise the Endo Credit focus on Endo's profits. (RX-364 at 0004 (SLA Definition of "Market Share Profit Factor")). Instead, the input provisions relate to what Impax would have made absent reformulation, including the generic substitution rate (i.e., Impax's share of oxymorphone ER sales, assuming a No-AG provision), the generic price (i.e., 75% of WAC price), Impax's net profit margin, and the 180-day period of Impax's first-filer exclusivity. (RX-364 at 0004 (SLA Definition of "Market Share Profit Factor")).

RESPONSE TO FINDING NO. 1062:

Complaint Counsel's Proposed Finding No. 1062 is incomplete and misleading. First, the record is clear that the Endo Credit was designed to encourage Endo to support original Opana ER and deter reformulation, even if Complaint Counsel posits that some other formula could have been used. (Koch, Tr. 241; Snowden, Tr. 386; CX4021 (Ben-Maimon, Dep. at 118, 122) (the Endo Credit was designed to act as "a deterrent to prevent [Endo] from switching the market."); CX4037 (Smolenski, Dep. at 244-45) (Endo Credit "intended to disincentivize Endo from" introducing a reformulated product)).

Second, although Respondent does not dispute that the specific terms identified in the second sentence of Proposed Finding No. 1062 were included in the settlement agreement, the cited evidence does not support the proposition that those terms ensured Impax would receive a payment approximating what Impax would have made absent reformulation. They simply meant that annualized quarterly peak sales (after being divided by 100) would be multiplied by a specific figure: 0.2953. (RX-364.0003-04). To illustrate, actual quarterly peak sales after settlement were $185,691,457. (CX0332-003). If sales dropped just enough to trigger the Endo Credit, for instance, because sales in the last quarter of 2012 were 49 percent of their quarterly

peak, this would mean the resulting liability would be roughly $2 million. If sales dropped only to 49.9 percent of their peak, the resulting liability would be roughly $200,000. (RX-364.0003-04 (any Endo Credit payment is the product of (1) 0.2953 times the annualized quarterly peak sales divided by 100, and (2) the number of percentage points under 50)). There is no indication that such potential liabilities under the Endo Credit are approximations of Impax's expected net profits over six months.

> 1063. Consequently, the Endo Credit did not deter Endo from reformulating and transitioning sales to the new product. (CX3241 at 001 (June 14, 2012 Endo Press Release, "Endo Completes Transition of OPANA® ER Franchise to New Formulation Designed to be Crush Resistant")). Instead, Endo paid the Endo Credit amount of approximately $102 million, much less than what Endo made in a single year of Reformulated Opana ER sales. (CX0333 at 002 (notice of wire transfer of $102,049,199.64 on April 18, 2013); CX3215 at 010 (Endo 10-K for 2012 showing Opana ER annual sales of $299.3 million, including sales after "Endo transitioned to the crush-resistant formulation in March 2012")).

RESPONSE TO FINDING NO. 1063:

The first sentence of Complaint Counsel's Proposed Finding No. 1063 is misleading and not supported by the cited evidence. There is no indication that the Endo Credit failed to deter Endo. In fact, Endo had no "expectation that a payment would have to be made" when it entered the settlement agreement. (CX4017 (Levin, Dep. at 99-100) ("at the time the transaction was inked I did not expect that Endo would have to make a payment under this provision"); Cuca, Tr. 664-65 (Endo did not book a reserve because no Endo Credit payment was "probable and estimable" at settlement); *see* Noll, Tr. 1611, 1649 (neither party estimated value of Endo Credit at the time of settlement)).

Indeed, Endo expected to sell Opana ER through the fourth quarter of 2012. (CX4017 (Levin, Dep. at 131); RX-094.0006 ("Prior to March [2012], it would have been reasonable to assume that prescriptions of old formulation [Opana ER] would have occurred in Q4 2012");

RX-108.0002 at 10). When the Novartis plant at which Endo manufactured original Opana ER shut down at the end of 2011, Endo was forced to rush the launch reformulated Opana ER and the FDA ordered Endo to stop selling original Opana ER. (CX4017 (Levin, Dep. at 136-39, 155) ("supply chain crisis" altered Endo's plans); RX-094.0003-04; RX-100.0001 ("Several of [Endo's] strategies envisioned [Endo] selling both [original and reformulated Opana ER] products at the same time. It was only upon [Endo's] discussions with the FDA in February [2012] that they told [Endo] not to do this in order to avoid patient confusion.")). Professor Bazerman, one of Complaint Counsel's own experts, admits that the FDA's actions shutting down Novartis' plant "took matters out of [Endo's] hands." (Bazerman, Tr. 923-24).

Respondent has no specific response to the second sentence of Proposed Finding No. 1063.

> 1064. The royalty provision—which Impax now calls the "carrot"—did not eliminate the No-AG provision or eliminate Endo's losses from forgone AG sales. The royalty provision is triggered only if sales of Original Opana ER grew by a specific percentage. (RX-364 at 0012 (SLA § 4.3) (royalty paid if Original Opana ER sales in the quarter before Impax's licensed entry "exceed $46,973,081 compounded quarterly at an annual rate of ten percent")). If sales of Original Opana ER did not grow by those amounts, Endo got nothing. (RX-364 at 0012 (SLA § 4.3) ("Otherwise, no royalty shall be due")).

RESPONSE TO FINDING NO. 1064:

The first sentence of Complaint Counsel's Proposed Finding No. 1064 should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). The first sentence is also inaccurate. Endo did not forgo sales of an authorized generic because Endo never intended to launch an authorized generic. (CX4019 (Lortie, Dep. at 117-18) (testifying it would be "morally very difficult to justify at the same time having a crushable authorized generic product" and a non-crushable branded product); Bingol,

Tr. 1337-39 (testifying that an authorized generic "was never, to my knowledge . . . fully realized as a plan or an idea"); CX4019 (Lortie, Dep. at 118-19) ("we never seriously considered taking any further steps to prepare for or to do [an authorized generic] because we really didn't want to.")).

Respondent has no specific response to the second and third sentences of Proposed Finding No. 1064 other than to clarify that these provisions mirrored the Endo Credit, through which Endo would make a payment only if sales decreased by a certain amount, otherwise Impax got nothing. (RX-364.0003-04).

> 1065. In addition, even if sales of Original Opana ER grew enough to require a royalty, the No-AG provision would remain in place, and Endo could not sell an AG into a marketplace that now had greater opportunity for generic products because of the increased branded product sales. (RX-364 at 0010 (SLA § 4.1(c))). While Endo would receive 28.5% of profits from Impax's generic sales, it would lose 100% of profits it could have earned from sales of an Endo AG. (RX-364 at 0010, 0012 (SLA §§ 4.1(c), 4.3)).

RESPONSE TO FINDING NO. 1065:

Complaint Counsel's Proposed Finding No. 1065 is misleading and irrelevant because the record shows that Endo never intended to launch an authorized generic. (CX4019 (Lortie, Dep. at 117-18) (testifying it would be "morally very difficult to justify at the same time having a crushable authorized generic product" and a non-crushable branded product); Bingol, Tr. 1337-39 (testifying that an authorized generic "was never, to my knowledge . . . fully realized as a plan or an idea"); CX4019 (Lortie, Dep. at 118-19) ("we never seriously considered taking any further steps to prepare for or to do [an authorized generic] because we really didn't want to.")). Accordingly, it did not stand to lose any potential sales while earning a 28.5 percent royalty. (RX-364.0012 (SLA § 4.3)).

B. The $10 million payment under the DCA was not justified

1. The negotiation history confirms that the $10 million payment to Impax was linked to Impax's willingness to accept the January 2013 entry date in the Opana ER Settlement Agreement

1066. The DCA and SLA were not independent transactions, confirming that Endo's $10 million payment to Impax under the DCA was linked to Impax's willingness to accept the January 2013 entry date in the SLA. (*See* CCF ¶¶ 1067-1084).

RESPONSE TO FINDING NO. 1066:

Complaint Counsel's Proposed Finding No. 1066 should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Moreover, the individual findings cited do not support the proposed summary finding and are misleading or incorrect for the reasons set out in Respondent's replies to those findings.

1067. Section 9.3 of the SLA states that "[t]his agreement, including the Appendix attached hereto, together with the Development Agreement between Endo and Impax, dated as of the date hereof, contains the entire agreement between the Parties . . . ." (RX-364 at 0019 (SLA § 9.3)). Under this provision, settlement of the Opana ER patent litigation was legally and formally linked to the DCA. (CX5001 at 016-17 (¶ 35) (Bazerman Report)).

RESPONSE TO FINDING NO. 1067:

Respondent has no specific response to the first sentence of Complaint Counsel's Proposed Finding No. 1067. The second sentence of Proposed Finding No. 1067 is an improper legal conclusion, not a fact. The second sentence is also contradicted by the record. Alan Levin, Endo's CFO at the time of settlement and one of Endo's lead negotiators, testified that the SLA and DCA "were stand-alone legal documents." (CX4017 (Levin, Dep. at 157-58)).

1068. The DCA and SLA were negotiated together, with contract terms for both agreements analyzed in the same documents. When the initial term sheet for the SLA was

distributed, the email also included the first term sheet for the DCA. (CX0320 (May 26, 2010 email attaching term sheets for SLA and DCA)). A number of subsequent email communications demonstrated that the terms of both the DCA and SLA were discussed and analyzed together. (CX3183 at 001 (June 7, 2010 Koch/Levin email outlining terms for SLA and DCA); CX0406 at 001 (June 2, 2010 Mengler email relaying status of term negotiations of the SLA and DCA); CX0407 at 001-02 (June 3, 2010 Mengler/Koch email chain relaying status of negotiations of the SLA and DCA); Koch, Tr. 244 (both agreements negotiated and completed at the same time); CX5001 at 17-18 (¶ 36) (Bazerman Report)).

RESPONSE TO FINDING NO. 1068:

Respondent has no specific response.

1069. Most of the negotiations were conducted by telephone. (Koch, Tr. 245). Terms relating to both the DCA and SLA were discussed on the same telephone calls and meetings. (Koch, Tr. 244-45). Impax Generics Division President Chris Mengler was Impax's primary negotiator with Endo. (Mengler, Tr. 524-25; Snowden, Tr. 366). Mr. Mengler was not normally involved in negotiations for branded drug products. (CX4022 (Mengler, Dep. at 71)). Mr. Mengler did not know why he negotiated the DCA, which involved a branded product. (CX4022 (Mengler, Dep. at 160-61)). Other Impax employees thought it was unusual that Mr. Mengler would negotiate an agreement for a branded drug and did not know why he had that role. (CX4036 (Fatholahi, Dep. at 96); CX4033 (Nestor, Dep. at 51-52)).

RESPONSE TO FINDING NO. 1069:

Complaint Counsel's Proposed Finding No. 1069 is misleading and unsupported by the testimony cited to the extent that it claims "Impax employees" viewed Mr. Mengler's role in negotiating the DCA as unusual. Mr. Nestor did not testify that it was unusual for Mr. Mengler to discuss the DCA with Mr. Cobuzzi, only that he did not know why Mr. Mengler would be doing so. (CX4033 (Nestor, Dep. at 51-52)). Elsewhere in Mr. Nestor's testimony, he provided context for Mr. Mengler's role with respect to the DCA, noting that "Chris had pretty substantial business development experience himself prior to coming to Impax. So he knows his way around these kinds of discussions as well." (CX4033 (Nestor, Dep. at 72)). And Mr. Fatholahi testified only that Mr. Mengler's role was "not common." (CX4036 (Fatholahi, Dep. at 96)).

Proposed Finding No. 1069 also ignores the record, which makes clear that while Mr. Mengler was the point of contact for negotiations, "Impax had separate teams for each of the projects because one [DCA] was brand and one was generic [SLA]." (Koch, Tr. 245-46). Impax's negotiating positions regarding and analysis of the DCA came from Michael Nestor, the President of Impax's Branded Division, and his team. (Mengler, Tr. 586; Koch, Tr. 311-12).

> 1070. Moreover, individuals involved in the evaluation and negotiation of both deals characterized the agreements as related. Mr. Levin stated that he viewed the DCA as an integral part of the total collaboration between Endo and Impax. (CX4017 (Levin, Dep. at 157-158)). Ms. Snowden stated that neither Impax nor Endo proposed reaching agreement on the DCA without also reaching a settlement of the patent litigation. (CX4032 (Snowden, Dep. at 189)). Dr. Cobuzzi also stated that the DCA and SLA were being negotiated together. (Cobuzzi, Tr. 2632, 2633).

RESPONSE TO FINDING NO. 1070:

The first sentence of Proposed Finding No. 1070 is not supported by any record evidence and should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2).

Respondent has no specific response to the second sentence of Proposed Finding No. 1070 other than to clarify that Mr. Levin testified that the SLA and DCA "were stand-alone legal documents" that were part of a collaboration. (CX4017 (Levin, Dep. at 157-58)).

The third sentence of Proposed Finding No. 1070 is not supported by the cited evidence to the extent that it presents Ms. Snowden's testimony as "characteriz[ing] the agreements as related." Not only is this an inaccurate description of the testimony cited, but Ms. Snowden testified that the parties could reach agreement on the settlement without also reaching agreement on the development and co-promotion agreement. (CX4032 (Snowden, Dep. at 188)).

Finally, the fourth sentence of Proposed Finding No. 1070 is not supported by the cited testimony, in which Dr. Cobuzzi stated "I wasn't privy to all the reasons why we were doing it," but that he knew "they were being done together." (Cobuzzi, Tr. 2633). Dr. Cobuzzi said nothing about how the deals were being negotiated.

> 1071. The timing of the negotiation of the two agreements further supports the linkage between payments under the DCA and the January 2013 entry date in the SLA. Impax and Endo first discussed collaborating on a potential business opportunity in 2009, but they only discussed entering into a business development opportunity at the same time as discussing settlement of the patent litigation. (CX1301 at 110-112 (Endo Response to February 20, 2014 Civil Investigative Demands, Response No. 2, Attachment C) (showing discussions of "potential settlement" and "potential transaction involving Impax developmental product" occurring between September 1, 2009 and December 7, 2009); CX0310 at 003-004 (Impax Narrative Response to CID Specifications, Response No. 5 (showing two discussions in October 2009 relating to settlement of the Opana ER patent litigation and potential areas of mutual business interest)).

RESPONSE TO FINDING NO. 1071:

The first sentence of Complaint Counsel's Proposed Finding No. 1071 is not supported by any evidence and should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2).

The remainder of Complaint Counsel's Proposed Finding No. 1071 is inaccurate, inconsistent with record evidence, and unsupported by the evidence cited. Impax and Endo communicated regarding a potential collaboration [redacted] well before any settlement discussions with Endo had begun. (*See* RX-234; CX2927-020; RX-393.0014). While the parties discussed potential settlement and "a potential brand agreement related to Frova" in October 2009, (CX0310-004), this does not suggest that the co-development deal contemplated by the parties beginning several months prior was "part of a

potential settlement of the patent infringement litigation." Nor is there any record testimony suggesting that Impax and Endo discussed a Frova transaction as part of a potential settlement.

1072. These discussions halted simultaneously and there were no discussions on either agreement again until May 2010, approximately six months later. (CX0310 at 003-004 (Impax Narrative Response to CID Specifications, Response No. 5) (showing no discussions of potential settlement or potential transaction after December 2009 until May 2010); Koch, Tr. 242-43 (Impax had not talked to Endo about the DCA before entering into patent settlement negotiations)).

RESPONSE TO FINDING NO. 1072:

Complaint Counsel's Proposed Finding No. 1072 is incomplete and misleading. Impax and Penwest—Endo's Opana ER partner, an entity later acquired by Endo, and a party to the SLA—discussed a possible Parkinson's treatment collaboration in April 2010. (RX-296 (Apr. 2, 2010 Email from L. Zhu to A. Baichwal re: Interested in Partnership Opportunities)).

1073. Discussions about both the DCA and SLA resumed again, in the May 17-19, 2010 timeframe. (RX-316 at 0001 (May 17, 2010 Donatiello/Snowden email resuming settlement discussions); CX2966 at 002 (May 19, 2010 Cobuzzi/Mengler email regarding IPX-066)).

RESPONSE TO FINDING NO. 1073:

Respondent has no specific response.

1074. The timing of executing the DCA and SLA showed that Impax and Endo viewed the agreements as part of a single negotiation. Executed versions of both the DCA and SLA were circulated on the evening of June 7, 2010. (RX-312 (SLA); CX0326 (DCA)). But the agreements were impounded and neither went into effect until Endo had signed an unrelated settlement agreement on generic Opana ER with Sandoz. (CX3186 at 001 (June 8, 2010 Snowden/Donatiello email)). Unless the DCA and SLA were connected, there is no reason that finalizing the DCA would be tied to Sandoz's settlement. (CX5001 at 020 (¶ 39) (Bazerman Report)).

RESPONSE TO FINDING NO. 1074:

The first sentence of Complaint Counsel's Proposed Finding No. 1074 is not supported by any evidence and should be disregarded because it violates the Court's Order on Post-Trial

Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2).

Respondent has no specific response to the second sentence of Proposed Finding No. 1074.

The third sentence of Proposed Finding No. 1074 is not supported by the cited evidence and represents an improper legal conclusion to the extent it purports to state when the agreements took effect. The cited document says nothing about when the documents took effect. Moreover, the DCA itself expressly states that it "is entered into and effective as of this 7th day of June, 2010." (RX-365.0002).

The fourth sentence of Proposed Finding No. 1074 lacks foundation for the proposition that the DCA was not finalized until the Sandoz settlement and violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents."

1075. Professor Max Bazerman of the Harvard University Business School is an expert in negotiations. Professor Bazerman's research focuses on decision making, negotiation, and creating value in society. He is the author or coauthor of over 200 research articles and 20 books, including the leading textbook on behavioral decision research. Professor Bazerman's teaching experience includes instruction on negotiating intellectual property, negotiating in contexts connected to antitrust issues, value creation, and decision making. He has extensive experience teaching and consulting to executives in the pharmaceutical firms, including advising pharmaceutical companies in settling litigation and negotiating other agreements. Professor Bazerman holds a Ph.D. from the Graduate School of Industrial Administration at Carnegie-Mellon University and a Bachelor of Science in Economics from the Wharton School, University of Pennsylvania. (CX5001 at 003-05; 038-63 (¶¶ 2-8; Appendix A) (Bazerman Report)).

RESPONSE TO FINDING NO. 1075:

Respondent has no specific response.

1076. Based on Professor Bazerman's experience as a scholar of negotiation and in advising pharmaceutical firms on patent settlement issues, coordination on the timing of

the DCA and SLA are in clear contrast to the negotiation process that would have occurred if the agreements had been independent. (CX5001 at 020 (¶ 40) (Bazerman Report)). If Impax and Endo negotiated the DCA and SLA independently, both agreements would not have been coordinated such that they would be finalized together. (CX5001 at 020 (¶ 39) (Bazerman Report)).

RESPONSE TO FINDING NO. 1076:

Complaint Counsel's Proposed Finding No. 1076 lacks foundation for any proposition about how Endo and Impax would have conducted themselves in other situations and violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." Professor Bazerman did not speak to any individual employed by Endo or Impax. (Bazerman, Tr. 880).

1077. In the context of negotiations, the quality of the relationship between the parties is important for value creation to occur. (Bazerman, Tr. at 869; CX5001 at 020-21 (¶ 41) (Bazerman Report) (the quality of the relationship between the parties affects their ability to create value)). Value creation has been described as problem solving behaviors that identify, enlarge, and act upon the parties' common interest. (CX5001 at 006-07 (¶ 11) (Bazerman Report)). Value creating deals maximize the negotiating parties' joint benefit and often increase social welfare. (CX5001 at 020-21 (¶ 41) (Bazerman Report)).

RESPONSE TO FINDING NO. 1077:

Respondent has no specific response.

1078. Further confirmation that the DCA and SLA were linked is that the relationship between Impax and Endo was not conducive to a value-creating settlement. (CX5001 at 020-21 (¶ 41) (Bazerman Report)).

RESPONSE TO FINDING NO. 1078:

Complaint Counsel's Proposed Finding No. 1078 violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." Proposed Finding No. 1078 is also at odds with Professor Bazerman's testimony, during which he explained that contingency contracts create value by allowing negotiators to stop arguing about their divergent beliefs and instead leverage

their differences through bets that both sides expect to win. (Bazerman, Tr. 926-27). This includes licensing agreements whereby the licensor either receives money if the licensed product sells well or owes money if the licensed product does not sell well. (Bazerman, Tr. 927-28). The SLA was an example of this kind of contingency contract, with the Endo Credit and Royalty provisions creating value by addressing Impax's and Endo's different beliefs about what was going to happen to Opana ER sales. (Bazerman, Tr. 928). Finally, Proposed Finding No. 1078 provides no support for the proposition that the ability of two parties to generate value has any bearing on whether or not a settlement agreement is related to any other agreement.

> 1079. Impax and Endo had very little connection to each other prior to the settlement. (Koch, Tr. 242-43 (Impax and Endo had not talked about the development and co-promotion agreement before actually entering into the patent settlement negotiations); CX4003 (Snowden, IHT at 53-54) (as to discussions regarding a potential business deal prior to settlement of the Opana ER litigation, Ms. Snowden recalled some interest by Impax in Endo's Frova product, but could not recall specifics and noted that no agreement on Frova was ever reached between the parties)).

RESPONSE TO FINDING NO. 1079:

Complaint Counsel's Proposed Finding No. 1079 is inaccurate and not supported by the testimony cited. Ms. Snowden testified that she recalled communications between Impax and Endo in early 2009 regarding Frova. (Snowden, Tr. 434-35). Michael Nestor likewise testified that Endo-Impax collaboration communications took place in early 2009. (Nestor, Tr. 2932-33). That Ms. Snowden could not recall specifics regarding these discussions does not undermine the fact that such discussions occurred, as is reflected in board-level reports. (*See* RX-234 ([redacted]); CX2927-020 (Impax Interrogatory Responses)). Mr. Koch's cited testimony says nothing about whether Impax and Endo discussed possible collaborations related to Frova in early 2009. Finally, Impax had been

in contact with Penwest, now part of Endo, as early as 2006 regarding potential collaborations. (RX-296 (Email from L. Zhu to A. Baichwal re: Interested in Partnership Opportunities)).

> 1080. The relationship that did exist between Impax and Endo appeared to be negative. They were adversaries in a high stakes patent litigation. (JX-003 at 003 (¶ 9)). During settlement negotiations, Impax directly accused Endo of lying about its post-settlement plans. (CX4032 (Snowden, Dep. at 113-14)). Endo employees called Impax "piggy" and "Oinkpax" due to the "porcine nature of the requests thus far" while negotiating the DCA. (CX2534 at 001 (June 6, 2010 Levin/Cobuzzi email chain)).

RESPONSE TO FINDING NO. 1080:

The first sentence of Proposed Finding No. 1080 is not supported by any record evidence and violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Respondent has no specific response to the second, third, and fourth sentences of Proposed Finding No. 1080.

> 1081. The adversarial relationship between Impax and Endo would have made independently negotiating the DCA highly unlikely, unless the business transaction was linked to settlement discussions. (CX5001 at 021-22 (¶ 43) (Bazerman Report)).

RESPONSE TO FINDING NO. 1081:

Complaint Counsel's Proposed Finding No. 1081 should be disregarded because it violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." (*See* Court, Tr. 1859 ("[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.")). Proposed Finding No. 1081 is also contrary to the record. Impax and Endo communicated regarding a potential collaboration [redacted] well before any settlement discussions with Endo had begun. (*See* RX-234; CX2927-020; RX-393.0014). Impax had also been in contact with Penwest, now part of Endo, as early as

2006 regarding potential collaborations. (RX-296 (Email from L. Zhu to A. Baichwal re: Interested in Partnership Opportunities)).

> 1082. Rather than reflecting the particular benefits or risks of the subject of the DCA, the negotiation history shows that Endo's $10 million upfront payment was linked to Impax's entry date in the SLA. Despite changing the focus of the DCA from Impax's late development stage product, IPX-066, to its early development stage product, IPX-203, Endo did not reduce the $10 million upfront payment offered to Impax. (CX0320 at 003 (May 26, 2010 Draft Term Sheet between Impax and Endo) (stating that "Endo shall pay Impax a one-time fee of $10 million" when product was intended to be IPX-066); CX2534 at 002-03 (June 6, 2010 Levin/Koch email proposing a $10 million upfront payment for IPX-203)). In the typical case, payments are provided commensurate with the progress made on the project. (CX5003 at 029 (¶ 45) (Geltosky Report)).

RESPONSE TO FINDING NO. 1082:

The first sentence of Complaint Counsel's Proposed Finding No. 1082 should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2).

The second sentence of Proposed Finding No. 1082 is misleading, incomplete, and not supported by the documents cited. While Endo's initial term sheet did include a $10 million upfront payment for a deal involving the entire IPX-066 franchise, it also contained much more limited profit-sharing rights than those reflected in the final DCA. Specifically, the co-promotion option in Endo's initial term sheet proposed a $10 million upfront payment, and provided that Endo would retain only 50 percent of the profits from sales generated by non-neurologist targets. (CX0302-002 (May 27, 2010 Endo initial term sheet)). The final DCA, by contrast, gives Endo 100 percent profit sharing rights from sales generated by non-neurologists. (CX0320). Moreover, the day after receiving Endo's initial term sheet, Impax proposed a deal with different terms and licensing rights, *including a different upfront payment*. (CX0320-002 (Endo's initial DCA term sheet); RX-318.0001 (Impax's response to Endo's initial term sheet)).

In fact, a $10 million upfront payment did not reappear until June 2, 2010, when Chris Mengler indicated that the proposal then on the table included a $10 million upfront payment as well as an option for Endo to purchase IPX-203, retain profits from 10 percent of all sales (not just those generated by non-neurologists), or retain 100 percent of profits from sales generated by non-neurologists, all with no license fee to Impax. (CX0406).

The third sentence of Complaint Counsel's Proposed Finding No. 1082 is vague and inconsistent with record evidence. It is unclear what constitutes a "typical case." But whatever Dr. Geltosky considers typical, he has never worked for Endo and has not had any contact with the individuals involved in the negotiation and review of the DCA. (Geltosky, Tr. 1129). Dr. Cobuzzi, Endo's Senior Vice President of Corporate Development, testified that he did not view the payment terms of the DCA as unusual, and that he believed the terms mitigated Endo's financial risk by capping its exposure at pre-determined payment amounts and requiring demonstrable progress before additional payments came due. (Cobuzzi, Tr. 2543). Moreover, Dr. Geltosky's report hardly mentions Impax at all, and he offers no opinions about Impax's practices, procedures, or intent. (*See generally* CX5003 (Geltosky Rep.); Geltosky, Tr. 1129 (noting Dr. Geltosky had not met or spoken to any Impax employees); Geltosky, Tr. 1183 (testifying that his criticisms do not apply "to anything that Impax did")). Dr. Geltosky, moreover, lacks any significant experience with net buyers similar to Endo, or with discovery-stage development candidates like IPX-203. (Geltosky, Tr. 1143, 1177).

Finally, Proposed Finding No. 1082 is inconsistent with the record to the extent it implies the "focus of the DCA" was ever IPX-066. As Ms. Snowden testified, "Endo was interested in the Parkinson's space and wanted the deal to cover both products, the original IPX-066 and the follow-on product [IPX-203], but Impax wasn't interested in doing the deal on IPX-066. So

there wasn't actually . . . a switch as much as Endo was trying to negotiate for both product rights and Impax was only interested in doing product rights on the one product." (Snowden, Tr. 405-06). In fact, when Endo proposed an agreement covering all of Impax's Parkinson's products on May 26, 2010, Impax immediately rejected the idea, responding the very next day that any collaboration would only be "for a product I will designate as [IPX]-066a. This is our next generation of [IPX]-066." (RX-318.0001 (Impax's response to Endo's initial term sheet); RX-565.0001; CX0320-002 (Endo's initial DCA term sheet)).

> 1083. The negotiation history further shows the linkage between Endo's $10 million payment and the SLA, because Endo offered to pay Impax $10 million in upfront payments before Impax provided it with any information about IPX-203. As early as June 2, 2010, Endo and Impax had agreed upon $10 million in upfront payments for a deal on IPX-203. (CX0406 at 001 (Mengler email indicating the current status of negotiations on the DCA and SLA); CX1011 at 001 (June 2, 2010 Levin-Mengler email stating that Endo would agree to $10 million in upfront payments for IPX-203)). But, Endo did not receive substantive information about IPX-203 for its due diligence analysis until June 4, 2010. (CX3164 at 012-13 (Impax Response to Requests for Admission No. 23); Cobuzzi, Tr. 2601).

RESPONSE TO FINDING NO. 1083:

The first sentence of Complaint Counsel's Proposed Finding No. 1083 should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Respondent has no specific response to the second sentence of Proposed Finding No. 1083.

The third sentence of Proposed Finding No. 1083 is incorrect, misleading, and inconsistent with record evidence. Before June 4, 2010, Impax had in fact identified IPX-203 to Endo as the follow-on to IPX-066, and had provided Endo with extensive information regarding the predecessor drug. This information was relevant to understanding IPX-203, and "tremendously valuable" to Endo in assessing IPX-203. (Cobuzzi, Tr. 2625-26, 2602).

1084. Contemporaneous Endo and Impax documents explicitly link the DCA to protection of Opana ER revenues. A July 2010 Corporate Development Update prepared by Robert Cobuzzi, one of Endo's primary negotiators of the DCA, stated that the "Impax deal adds significant topline revenue for Opana." (CX1701 at 005 (July 2010 Endo Corporate Development Update)). The Impax deal for an early stage asset to treat Parkinson's disease can "add significant topline revenue for Opana" a pain relief product, only because it is directly linked to Impax's willingness to accept the January 2013 entry date for oxymorphone ER. (CX1701 at 005 (July 2010 Endo Corporate Development Update)). In a 2010 budget update following the Endo settlement, Impax listed the $10 million it received under the DCA as [redacted] (CX2701 at 004 (2010 Budget Update And 2011 Budget Preview)).

RESPONSE TO FINDING NO. 1084:

The first sentence of Complaint Counsel's Proposed Finding No. 1084 should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2).

The second and third sentences of the Proposed Finding should be disregarded as a mischaracterization of the document and improper speculation. Complaint Counsel cites no evidence for the naked assertion that the "only" reason the language identified would appear in CX1701 is that the DCA was linked to the SLA. Complaint Counsel never asked Dr. Cobuzzi (or any other witness, for that matter) what he actually meant with these six words. (Cobuzzi, Tr. 2568-2574).

The third sentence of Proposed Finding No. 1084 is misleading, given that no witness has been able to speak to the meaning of the two words Complaint Counsel identifies ("Endo settlement"). Art Koch, Impax's former CFO and the only witness Complaint Counsel asked about the meaning of this shorthand reference, did not recognize the document. Mr. Koch also testified that the document did not appear to be an accounting document, and that other aspects of the document were inconsistent with Impax's common budgeting practices. (CX4018 (Koch, Dep. at 148)).

2. At the time the DCA was entered into, early-stage Parkinson's disease treatments were not a focus of Endo's corporate strategy

1085. [redacted] (Cobuzzi, Tr. 2621 (*in camera*); Geltosky, Tr. 1092) (*in camera*)).

RESPONSE TO FINDING NO. 1085:

Respondent has no specific response.

1086. At the time of the DCA, Endo's business was not focused on pursuing Parkinson's disease treatments. (*See* CCF ¶¶ 1087-1095).

RESPONSE TO FINDING NO. 1086:

The proposed summary finding should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Additionally, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondent's replies to those findings.

1087. In 2010, Endo had a new CEO, whose primary areas of interest were urology, endocrinology, and oncology. (Cobuzzi, Tr. 2519). Endo's business focused on those therapeutic areas, as well as pain, a long-standing area of interest. (CX1001 at 015-25 (Feb. 2010 Endo Corporate Development Update)).

RESPONSE TO FINDING NO. 1087:

Complaint Counsel's Proposed Finding No. 1087 is misleading and incomplete to the extent that it implies the identified areas of focus were Endo's only areas of interest in 2010. Dr. Cobuzzi testified that, in 2010, Endo continued to be interested in "compatible markets for the pharmaceutical sales force to sell products." (Cobuzzi, Tr. 2518-19). At that time, Endo still had a pain medication sales force, and was therefore still interested in products that could be marketed to the same audience. (Cobuzzi, Tr. 2519). Dr. Cobuzzi further testified that Endo was specifically interested in Parkinson's disease products because they had "possible utility or

compatibility with the existing sales force at the time." (Cobuzzi, Tr. 2524; *see* CX4016 (Cobuzzi, IHT at 136-37) (Endo "looked for a number of years to find products" in the Parkinson's disease space)).

1088. In a March 2010 update to Endo's corporate development department, Parkinson's disease was not listed as a primary therapeutic area for pursuing business opportunities. (Cobuzzi, Tr. 2583; CX1002 at 016 (Mar. 2010 Endo Corporate Development and Strategy Presentation)).

RESPONSE TO FINDING NO. 1088:

Respondent has no specific response.

1089. Endo's corporate development update from February 2010 verifies that Endo was not actively pursuing any Parkinson's disease treatments at that time. (Cobuzzi, Tr. 2582; CX1001 at 015-25 (Feb. 2010 Endo Corporate Development Update)).

RESPONSE TO FINDING NO. 1089:

Respondent has no specific response.

1090. In 2008, Endo had engaged L.E.K., a market and analytics research group to prepare a presentation on late stage product opportunities for Endo to consider pursuing. (Cobuzzi, Tr. 2576-77; CX1005 (May 2008 L.E.K Transaction Opportunities Update for Endo)). The L.E.K. analysis specifically rejected Impax's carbidopa/levodopa Parkinson's disease products from the list of potential opportunities for Endo. (Cobuzzi, Tr. 2578-80; CX1005 at 064 (May 2008 L.E.K Transaction Opportunities Update for Endo)).

RESPONSE TO FINDING NO. 1090:

Respondent has no specific response.

1091. L.E.K.'s stated rationale for excluding Impax's carbidopa/levodopa products from the list of potential opportunities for Endo was the fact that generic versions of carbidopa/ levodopa products were already on the market. (Cobuzzi, Tr. 2580; CX1005 at 064 (May 2008 L.E.K Transaction Opportunities Update for Endo)). Generic competition was viewed as undesirable, and likely to eat into the potential revenues of the product of interest. (CX1005 at 063 (May 2008 L.E.K Transaction Opportunities Update for Endo) (discussing selection criteria for L.E.K. analysis)).

RESPONSE TO FINDING NO. 1091:

Complaint Counsel's Proposed Finding No. 1091 is misleading to the extent that it implies that "[g]eneric competition was viewed as undesirable" by Endo (rather than by L.E.K.). There is no indication that Endo adopted or agreed with the L.E.K. rationale described in the cited document. Elsewhere in this same document, by contrast, L.E.K. explicitly identifies Endo as the source of other bases for excluding drugs from the list of potential candidates. (CX1005-063 ("Endo is not interested in ex-U.S. Pre-Reg./ Reg products")). Moreover, Dr. Robert Cobuzzi—who actually works for Endo—explained why generic competition did *not* make improved carbidopa-levodopa formulations like IPX-066 or IPX-203 less attractive to Endo. (Cobuzzi, Tr. 2634-37 (IPX-203 likely more effective than other treatments); Cobuzzi, Tr. 2622-23 ([redacted])).

1092. Both IPX-066 and IPX-203 were Parkinson's disease treatments containing carbidopa and levodopa from Impax Laboratories. IPX-066 and IPX-203 both would have been excluded from consideration by Endo under the L.E.K. rational, because they would not meet the selection criteria. (Cobuzzi, Tr. 2579-80; CX1005 at 064 (May 2008 L.E.K Transaction Opportunities Update for Endo)).

RESPONSE TO FINDING NO. 1092:

Complaint Counsel's Proposed Finding No. 1092 is misleading to the extent it implies Endo ever adopted or implemented the L.E.K. recommendations or the rationale L.E.K. used for identifying investment candidates. No record evidence suggests as much.

1093. Prior to 2010, Endo considered a potential acquisition or deal regarding clinical stage Parkinson's disease treatments with an Italian company known as Newron, and also a Finnish company. (CX4016 (Cobuzzi, IHT at 109-110)). However, Endo never completed a deal with either company on a Parkinson's disease treatment. (Cobuzzi, Tr. 2575-76).

RESPONSE TO FINDING NO. 1093:

Respondent has no specific response.

1094. Prior to 2010, Endo had limited experience with marketing a Parkinson's disease treatment. For a time, Endo marketed a generic immediate release version of the Parkinson's disease treatment, Sinemet. (CX3161 at 040 (Endo White Paper to FTC); CX1007 at 001 (May 25, 2010 Cobuzzi email); Cobuzzi, Tr. 2633). Endo discontinued sales of generic Sinemet IR by the time the DCA was negotiated. (Cobuzzi, Tr. 2524; CX1209 at 003 (Endo's Final Opportunity Evaluation Worksheet for IPX-203) (Endo used to sell the IR formulation for Sinemet)).

RESPONSE TO FINDING NO. 1094:

Complaint Counsel's Proposed Finding No. 1094 is not supported by the cited evidence to the extent it attempts to suggest Endo's experience marketing Parkinson's disease treatments was "limited." Complaint Counsel cites no evidence regarding the extent to which Endo marketed generic Sinemet, and thus has no basis to claim it was limited. And the Endo White Paper listed in the Proposed Finding is not admitted into evidence in this matter. (*See* JX-2). In any event, the actual evidence in the record is clear: "this is an area we know well as a company both in terms of past evaluations, and by virtue of the fact that we previously held the rights to IR Sinemet." (RX-1007.0001; *see* Cobuzzi, Tr. 2524 ("We actually sold as Endo in the past an immediate-release form of the drug Sinemet, which was the original formulation of carbidopa and levodopa. It was in the marketplace. And I personally have comfort with the area just because I'm quite familiar with Parkinson's disease.")).

1095. At Endo, the Senior Vice President of Corporate Development, Dr. Robert Cobuzzi, along with a team of employees, were responsible for evaluating potential pharmaceutical business deals for further development. (Cobuzzi, Tr. 2567-68). Endo's corporate development group, however, did not seek out the opportunity on Impax's Parkinson's disease treatment IPX-066. (Cobuzzi, Tr. 2584). Dr. Cobuzzi first learned about IPX-066 from Endo's chief financial officer, Alan Levin, who was not part of the commercial group. (Cobuzzi, Tr. 2584).

RESPONSE TO FINDING NO. 1095:

Respondent has no specific response.

3. At the time the DCA was entered into, Endo was interested in investing in market-ready products that would provide near term revenues

1096. In 2010, Endo's business plans showed that it was interested in investing in marketed or market-ready assets that would provide near term revenues. (CX1002 at 005 (Mar. 2010 Endo Corporate Development & Strategy document stating that one of Endo's business development goals was to complete in-license or acquisition transaction(s) for marketed/market-ready assets representing more than $100 million in net sales in 2010); CX1701 at 005 (July 2010 Endo Corporate Development Update); CX1001 at 009 (Feb. 2010 Endo Corporate Development Update)).

RESPONSE TO FINDING NO. 1096:

Complaint Counsel's Proposed Finding No. 1096 is misleading and unsupported by the evidence cited to the extent it implies Endo was interested in investing in only market-ready or marketed assets. The documents cited list this as one of several aspirational goals for the company in 2010. (CX1002-005 (Mar. 2010 Endo Corporate Development & Strategy document stating that one of Endo's business development goals was to complete in-license or acquisition transaction(s) for marketed/market-ready assets representing more than $100 million in net sales in 2010); CX1701-005 (July 2010 Endo Corporate Development Update); CX1001-009 (Feb. 2010 Endo Corporate Development Update)). Indeed, Dr. Cobuzzi testified that because Endo has "no discovery pipeline ourselves in place," Endo must also enter "very early, very speculative agreements" for promising drugs. (Cobuzzi, Tr. 2516).

1097. Endo was focused on pursuing immediate and near term revenue generating business opportunities, so that it could enhance its revenue line. Such deals would relate to products already commercially sold or in the late stages of pharmaceutical development and that would not require a complex development program or more than three to four years to come to market. (CX4016 (Cobuzzi, IHT at 135-36)).

RESPONSE TO FINDING NO. 1097:

Respondent has no specific response.

1098. IPX-203, the ultimate subject product of the DCA, did not fit Endo's profile for a market-ready product that would provide near term revenues. IPX-203 was still conceptual, and Impax did not yet have a final formulation. (Nestor, Tr. 2945-46). [redacted] (Cobuzzi, Tr. 2612 (*in camera*); CX1209 at 012 (Endo's Final Opportunity Evaluation Worksheet for IPX-203)).

RESPONSE TO FINDING NO. 1098:

The first sentence of Complaint Counsel's Finding No. 1098 should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). The Proposed Finding is also misleading and inconsistent with the documents cited to the extent that it refers to "Endo's profile" for market-ready products. The documents Complaint Counsel cites identify investment in such products as one of several corporate development goals, not a specific profile for every investment. (CX1002-005 (Mar. 2010 Endo Corporate Development & Strategy document stating that one of Endo's business development goals was to complete in-license or acquisition transaction(s) for marketed/market-ready assets representing more than $100 million in net sales in 2010); CX1701-005 (July 2010 Endo Corporate Development Update); CX1001-009 (Feb. 2010 Endo Corporate Development Update)). Indeed, Dr. Cobuzzi testified that because Endo has "no discovery pipeline ourselves in place," Endo must also enter "very early, very speculative agreements" for promising drugs. (Cobuzzi, Tr. 2516).

Respondent has no specific responses to the second and third sentences of Proposed Finding No. 1098.

4. Endo's desire to enter a deal on a product that it could promote alongside its marketed migraine drug, Frova, would not be satisfied by IPX-203

1099. Endo expressed interest in entering a deal with Impax on a product that its existing sales force could promote alongside Endo's migraine treatment Frova. (CX3010 at 001-02 (May 2010 Cobuzzi email chain)).

RESPONSE TO FINDING NO. 1099:

Complaint Counsel's Proposed Finding No. 1099 is misleading and incomplete in its description of CX3010. In addition to expressing an interest in an Impax product Endo could promote alongside Frova, the document describes other strategic needs and notes that "we would consider other alternatives to get neurology assets that meet our needs, if not IPX066." (CX3010-002).

1100. [redacted] (Cobuzzi, Tr. 2611 (*in camera*); CX1208 at 003) (Opportunity Evaluation Worksheet for IPX-066)). When Frova's patent protection expired and generic competition entered, Endo likely would have stopped promoting Frova. (CX2607 at 021 (¶ 50) (Lortie Declaration) ("In essence, it is not cost effective to invest in promotion of a branded drug in the face of generic competition because the promotional effort benefits the generics more than the branded product.")).

RESPONSE TO FINDING NO. 1100:

Respondent has no specific response to the first sentence of Complaint Counsel's Proposed Finding No. 1100. The second sentence of Proposed Finding No. 1100 lacks foundation, is speculative, and is not supported by the documents cited. The sole document cited for this proposition—a declaration by Brian Lortie discussing pharmaceutical marketing generally—does not say anything about what Endo intended to do with respect to Frova.

1101. In 2010, IPX-066 was scheduled to enter the market in late 2012. (CX1208 at 007-08 (Opportunity Evaluation Worksheet for IPX-066)). Because IPX-066 would come to market while Endo's sales force was still promoting Frova, IPX-066 could be detailed alongside Frova. (CX3010 at 001-02 (May 2010 Cobuzzi email chain) ("IPX-066 . . . would be a great addition for a sales force that will still be selling Frova at a time when it comes to market. As, such, IPX-066 is my first choice for Endo")).

RESPONSE TO FINDING NO. 1101:

Respondent has no specific response.

1102. [redacted] (Cobuzzi, Tr. 2612 (*in camera*); CX1209 at 012 (Endo's Final Opportunity Evaluation Worksheet for IPX-203)). As a result, IPX-203 could not be promoted alongside Frova. (CX5003 at 018-19 (¶ 30) (Geltosky Report)).

RESPONSE TO FINDING NO. 1102:

Complaint Counsel's Proposed Finding No. 1102 is inaccurate, unsupported by the documents cited, and based on inadmissible expert testimony. Complaint Counsel offers no evidence to support its suggestion that Endo would stop promoting Frova after patent protection. Moreover, the citations to Dr. Geltosky's report represent improper expert opinion, as Dr. Geltosky has not been offered as an expert regarding, nor does he have any expertise or special knowledge about, Endo's detailing practices. (Geltosky, Tr. 1058 (Complaint Counsel tendering Dr. Geltosky as pharmaceutical business development expert to offer expert testimony on "whether the overall strategic fit, negotiation history, due diligence efforts, and terms of the development and co-promotion agreement between Endo and Impax are consistent with the usual and expected practice in the pharmaceutical industry")).

5. The truncated negotiation process of the DCA was unusual when compared to industry standards, as well as Endo's own process for reviewing pharmaceutical development business opportunities

1103. When considering whether to pursue a development and co-promotion opportunity, there are a number of critical factors that firms typically evaluate, such as conducting scientific (also known as "technical") due diligence, assessing regulatory risks associated with the product, performing a financial analysis of the potential deal, and evaluating the intellectual property landscape. (CX5003 at 011-12 (¶¶ 19, 20) (Geltosky Report)). Firms analyze each of these factors to determine if a particular drug product has a good chance at FDA approval during the projected time and if it will have a competitive profile. (CX5003 at 016 (¶ 27) (Geltosky Report)).

RESPONSE TO FINDING NO. 1103:

Complaint Counsel's Proposed Finding No. 1103 is misleading and based on unreliable expert testimony to the extent it implies there is a single or standard process for evaluating pharmaceutical development candidates. Proposed Finding No. 1103 relies exclusively on the opinions of Dr. Geltosky. But Dr. Geltosky has no basis to opine on what all pharmaceutical companies—and particularly mid-sized companies looking to invest in discovery-stage candidates—"typically" do in their due diligence efforts.

Dr. Geltosky acknowledged that the primary basis for his opinions is his personal experience. (Geltosky, Tr. 1128; Geltosky, Tr. 1133-34 (in reaching his opinions in this matter, Dr. Geltosky "read documents drafted by people that [he has] never met and … tell[s] us what [he] think[s] about those documents based on [his] experience in the industry")). Yet Dr. Geltosky has no experience performing or advising on due diligence performed by a mid-sized pharmaceutical company like Endo. (Geltosky, Tr. 1141-43, 1171). All but a few of the deals on which Dr. Geltosky has worked have involved a net buyer—the party investing in or purchasing the asset—that is a big pharmaceutical company like Bristol-Meyers Squibb and SmithKline Beecham. (Geltosky, Tr. 1141, 1160). Indeed, Dr. Geltosky testified that, as a consultant, his clients hire him for his knowledge of how such large companies approach pharmaceutical collaborations. (Geltosky, Tr. 1180). Those companies have annual sales and research and development budgets exponentially larger than Endo's. (Geltosky, Tr. 1141). While large institutions like those may be able to follow extensive, standard diligence procedures, this is not always possible for smaller companies. (Cobuzzi, Tr. 2626-27). Nor has Dr. Geltosky worked on more than a "handful" of deals involving a discovery-stage asset. (Geltosky, Tr. 1144-45). Dr. Geltosky consequently admitted at trial that he cannot speak to how the universe of mid-

sized pharmaceutical companies approach the evaluation of discovery-stage pharmaceutical development candidates. (Geltosky, Tr. 1143).

1104. The due diligence process of evaluating the technical, regulatory, financial, and legal aspects of a potential drug product takes at least three to four months to complete. (Geltosky, Tr. 1079; CX5003 at 016 (¶ 27) (Geltosky Report).

RESPONSE TO FINDING NO. 1104:

Complaint Counsel's Proposed Finding No. 1104 is inaccurate, inconsistent with record evidence, and based on unreliable expert testimony. Proposed Finding No. 1104 relies exclusively on the opinions of Dr. Geltosky, who acknowledges that the sole basis for his opinions regarding the typical diligence timeline is his experience. (Geltosky, Tr. 1063, 1128, 1140). Yet Dr. Cobuzzi, who himself has over two decades of pharmaceutical industry experience, (CX4016 (Cobuzzi, IHT at 12-13)), testified that there is no typical, one-size-fits-all timeline for performing due diligence on a pharmaceutical collaboration, particularly at Endo. (Cobuzzi, Tr. 2543). Nor does Dr. Geltosky have any significant experience with pharmaceutical collaborations in which the net buyer—i.e., the party performing the diligence—is a small or mid-sized company. (Geltosky, Tr. 1141-43, 1171). Indeed, Dr. Geltosky testified that, as a consultant, his clients hire him for his knowledge of how big pharmaceutical companies approach collaborations. (Geltosky, Tr. 1180).

1105. The entire process of evaluating, negotiating, and completing an early-stage pharmaceutical development deal typically takes twelve months from start to finish. (Geltosky, Tr. 1063-64; CX5003 at 017 (¶ 27) (Geltosky Report).

RESPONSE TO FINDING NO. 1105:

Complaint Counsel's Proposed Finding No. 1105 is inaccurate, inconsistent with record evidence, and based on unreliable expert testimony. Proposed Finding No. 1105 relies exclusively on the opinions of Dr. Geltosky, who acknowledges that the sole basis for his

opinions regarding the typical diligence timeline is his experience. (Geltosky, Tr. 1063, 1128, 1140). Yet Dr. Cobuzzi, who himself has over two decades of pharmaceutical industry experience, (CX4016 (Cobuzzi, IHT at 12-13)), testified that there is no typical, one-size-fits-all timeline for performing due diligence on a pharmaceutical collaboration, particularly at Endo. (Cobuzzi, Tr. 2543). Nor does Dr. Geltosky have any significant experience with pharmaceutical collaborations in which the net buyer—i.e., the party performing the diligence—is a small or mid-sized company. (Geltosky, Tr. 1141-43, 1171). Indeed, Dr. Geltosky testified that, as a consultant, his clients hire him for his knowledge of how big pharmaceutical companies approach collaborations. (Geltosky, Tr. 1180).

1106. Endo's documents reflected a process for evaluating pharmaceutical development assets consistent with the industry standards. (CX2784 at 033, 034, 036, 038, 048 (Aug. 2009 Endo Business Development Process Orientation document)).

RESPONSE TO FINDING NO. 1106:

Complaint Counsel's Proposed Finding No. 1106 is inaccurate and unsupported by the cited evidence in its suggestion that multiple Endo documents reflect a particular process. The Proposed Finding cites a single document. Dr. Cobuzzi testified that this document (CX2784) described procedures he has never seen implemented at Endo, and that they are "ideal state" procedures "almost never" implemented outside the big pharma context. (Cobuzzi, Tr. 2626-27; 2573).

1107. Endo's documents explained that due diligence is a "[t]horough evaluation of all aspects of [an] asset." Due diligence should address the question of whether an asset can "be successfully developed, manufactured & commercialized for the stated indication." (CX2784 at 033 (Aug. 2009 Endo Business Development Process Orientation document)).

RESPONSE TO FINDING NO. 1107:

Complaint Counsel's Proposed Finding No. 1107 is inaccurate and unsupported by the cited evidence in its suggestion that multiple Endo documents reflect a particular process. The Proposed Finding cites a single document. Dr. Cobuzzi testified that this document (CX2784) described procedures he has never seen implemented at Endo, and that they are "ideal state" procedures "almost never" implemented outside the big pharma context. (Cobuzzi, Tr. 2626-27; 2573).

1108. Similar to industry standards, Endo's evaluation process included conducting technical due diligence, assessing regulatory risks, performing a financial analysis, and evaluating the relevant intellectual property landscape. (CX2784 at 034, 036, 038, 048 (Aug. 2009 Endo Business Development Process Orientation document)).

RESPONSE TO FINDING NO. 1108:

Complaint Counsel's Proposed Finding No. 1108 is inaccurate and unsupported by the cited evidence in its suggestion that Endo had a set "evaluation process." Dr. Cobuzzi testified that this document (CX2784) described procedures he has never seen implemented at Endo, and that they are "ideal state" procedures "almost never" implemented outside the big pharma context. (Cobuzzi, Tr. 2626-27; 2573). He also testified that there is no typical, one-size-fits-all timeline for performing due diligence on a pharmaceutical collaboration, particularly at Endo. (Cobuzzi, Tr. 2543).

1109. Similar to industry standards, Endo expects its process to take approximately "≤ 4 months" to reach a "diligence output." (CX2784 at 050 (Aug. 2009 Endo Business Development Process Orientation document)).

RESPONSE TO FINDING NO. 1109:

Complaint Counsel's Proposed Finding No. 1109 is inaccurate and unsupported by the cited evidence in its suggestion that Endo had a set "evaluation process." Dr. Cobuzzi testified

that this document (CX2784) described procedures he has never seen implemented at Endo, and that they are "ideal state" procedures "almost never" implemented outside the big pharma context. (Cobuzzi, Tr. 2626-27; 2573). He also testified that there is no typical, one-size-fits-all timeline for performing due diligence on a pharmaceutical collaboration, particularly at Endo. (Cobuzzi, Tr. 2543).

1110. Similar to industry standards, Endo expects its process to take approximately "6 months-1 year from initial evaluation to deal close." (CX2784 at 054 (Aug. 2009 Endo Business Development Process Orientation document)).

RESPONSE TO FINDING NO. 1110:

Complaint Counsel's Proposed Finding No. 1110 is inaccurate and unsupported by the cited evidence in its suggestion that Endo had a set "evaluation process." Dr. Cobuzzi testified that this document (CX2784) described procedures he has never seen implemented at Endo, and that they are "ideal state" procedures "almost never" implemented outside the big pharma context. (Cobuzzi, Tr. 2626-27; 2573). He also testified that there is no typical, one-size-fits-all timeline for performing due diligence on a pharmaceutical collaboration, particularly at Endo. (Cobuzzi, Tr. 2543).

1111. The DCA was negotiated and finalized in approximately three weeks. (CX3164 at 014 (Impax Response to FTC's Requests for Admission, Response 27)). This abbreviated negotiation timeline of the DCA was highly unusual when compared to industry standards, as well as Endo's own internal review processes, both of which predict completion of a deal in the six months to one year timeframe. (CX5003 at 019-21 (¶¶ 32, 33), 038-42 (¶¶ 63-70) (Geltosky Report)).

RESPONSE TO FINDING NO. 1111:

Respondent has no specific response to the first sentence of Proposed Finding No. 1111. The second sentence of Proposed Finding No. 1111 is inaccurate. Dr. Cobuzzi testified that there is no typical, one-size-fits-all process for performing due diligence on a pharmaceutical

collaboration, particularly at Endo. (Cobuzzi, Tr. 2543). He also explained that Endo regularly reviews potential agreements in "very, very short periods of time," and that he could not identify "any instance where [Endo] followed the perfect sequence" when conducting due diligence. (Cobuzzi, Tr. 2566, 2627). And Dr. Cobuzzi testified that Endo had sufficient time to assess IPX-203 before entering into the Development and Co-Promotion Agreement, particularly in light of Dr. Cobuzzi's and Endo's familiarity with Parkinson's disease treatments and the detailed nature of the information Impax provided on IPX-066. (Cobuzzi, Tr. 2543, 2625).

1112. Dr. John Geltosky is an expert in pharmaceutical business development with over 35 years of experience. Dr. Geltosky holds a Ph.D. in biochemistry from the California Institute of Technology and has worked at numerous pharmaceutical companies, including Smithkline Beecham Pharmaceuticals, Bristol Myers Squibb, and Johnson and Johnson. As the Vice President and Director of Scientific Licensing at Smithkline Beecham Pharmaceuticals, Dr. Geltosky managed the identification of and technical due diligence for all in-licensed compounds. As the Vice President of External Science, Technology, and Licensing at Bristol Myers Squibb, Dr. Geltosky directed all evaluation activities for compounds in all stages of development. Since 2008, Dr. Geltosky has been the Managing Director of JEG and Associates Biotech and Pharmaceutical Development Consulting. At JEG, Dr. Geltosky has provided licensing and business advice to biotech firms, including strategic input on research, development, marketing, and negotiations with other pharmaceutical companies. (CX5003 at 003-004 (¶¶ 2-7) (Geltosky Report)). Over the course of his career, Dr. Geltosky has been involved in evaluating thousands of potential pharmaceutical development opportunities. (Geltosky, Tr. 1054-55).

RESPONSE TO FINDING NO. 1112:

Respondent has no specific response.

1113. In Dr. Geltosky's 35-plus years of experience in the industry, he has not been involved in a licensing, co-development, or co-promotion deal that has taken less than six months to negotiate and finalize. (CX5003 at 017 (¶ 27) (Geltosky Report); Geltosky, Tr. 1064 (stating that the deals he recalls seeing taking less than 12 months have been completed in 9 months)).

RESPONSE TO FINDING NO. 1113:

Respondent has no specific response other than to clarify that Dr. Geltosky's 35 years of experience do not include any significant experience with pharmaceutical collaborations in

which the net buyer was a small or mid-sized pharmaceutical company, or experience with more than a "handful" of discovery-stage development deals. (Geltosky, Tr. 1141-45, 1177).

1114. After initial discussions in 2009, Impax and Endo resumed settlement discussions and negotiation of a potential business transaction on or around May 19, 2010. (CX1301 at 112 (Endo Response to Feb. 20, 2014 and Mar. 25, 2014 Civil Investigative Demands, Response No. 2, Attachment B)).

RESPONSE TO FINDING NO. 1114:

Respondent has no specific response.

1115. When Endo and Impax resumed negotiations in May of 2010, the parties were discussing a potential deal relating to IPX-066, Impax's Parkinson's disease treatment, which was in the Phase III stage of development. (CX0320 at 002 (May 26, 2010 Draft Term Sheet between Impax and Endo); Cobuzzi, Tr. 2583-84)).

RESPONSE TO FINDING NO. 1115:

Complaint Counsel's Proposed Finding No. 1115 is inaccurate and not supported by the documents cited. Dr. Cobuzzi testified that "Endo was initially discussing a product called IPX-066" "with respect to Impax." (Cobuzzi, Tr. 2583-84). Dr. Cobuzzi does not state that it ever discussed a potential deal regarding that product *with* Impax. And while Endo proposed a potential deal regarding the entire IPX-066 franchise in its initial draft term sheet, Impax immediately rejected the proposal. (CX0320; CX0502; CX1305). As Ms. Snowden testified, "Endo was interested in the Parkinson's space and wanted the deal to cover both products, the original IPX-066 and the follow-on product [IPX-203], but Impax wasn't interested in doing the deal on IPX-066. So there wasn't actually . . . a switch as much as Endo was trying to negotiate for both product rights and Impax was only interested in doing product rights on the one product." (Snowden, Tr. 405-06).

1116. Phase III development is the last stage of pharmaceutical development before submitting an application to the FDA. (Nestor, Tr. at 3003; CX 5003 at 007-08 (¶ 15)

(Geltosky Report)). [redacted] (Nestor, Tr. at 2959 [redacted] (*in camera*)).

RESPONSE TO FINDING NO. 1116:

Respondent has no specific response.

1117. On or about May 27, 2010, Impax informed Endo that any development and co-promotion agreement negotiated between the parties would relate to Impax's Parkinson's disease treatment known as IPX-203, which was in the early stages of development. (CX1305 at 001 (Mengler email noting "R&D Collaboration: for a product I will designate as 066a. This is our next generation of 066."); Nestor, Tr. 2945 (IPX-066a was the initial name for IPX-203)). [redacted] (Nestor, Tr. 2959 (*in camera*)).

RESPONSE TO FINDING NO. 1117:

Respondent has no specific response to the first sentence of Complaint Counsel's Proposed Finding No. 1117. The second sentence of Proposed Finding No. 1117 provides a misleading paraphrase of Mr. Nestor's testimony. [redacted] (Nestor, Tr. 2959; RX-387 (Mr. Nestor explaining that risk associated with IPX-203 development in 2010 was simply "part of the process")). Dr. Geltosky acknowledged that the risks associated with early-stage development candidates do not stop companies from collaborating on such candidates "all the time," and that all stages of pharmaceutical development carry an inherent level of risk. (Geltosky, Tr. 1134).

1118. Despite the change in product, as of June 1, 2010, Dr. Cobuzzi, Endo's Senior Vice President of Corporate Development, still believed that Endo and Impax were discussing a deal on IPX-066. (Cobuzzi, Tr. 2594).

RESPONSE TO FINDING NO. 1118:

Respondent has no specific response.

1119. Impax did not provide Endo with specific information regarding the IPX-203 product until June 4, 2010, just three days before the DCA was signed. (CX3164 at 012-13 (Impax Response to Requests for Admission No. 23); Cobuzzi, Tr. 2601-03)).

RESPONSE TO FINDING NO. 1119:

Complaint Counsel's Proposed Finding No. 1119 is inaccurate and misleading to the extent it suggests Impax did not provide Endo with information relevant to assessing IPX-203 before June 4, 2010. Before June 4, 2010, Impax had identified IPX-203 to Endo as the follow-on to IPX-066, and had provided extensive information to Endo regarding that predecessor drug, which was relevant to understanding IPX-203, and which was "tremendously valuable" to Endo in assessing IPX-203. (Cobuzzi, Tr. 2625-26, 2602).

1120. In view of industry standards, it is highly atypical to perform a technical due diligence evaluation, integrated financial analysis, negotiate deal terms and finalize a development and co-promotion deal for a late stage product like IPX-066 in a three-week period. (CX5003 at 020 (¶ 32) (Geltosky Report)).

RESPONSE TO FINDING NO. 1120:

Complaint Counsel's Proposed Finding No. 1120 is inaccurate. Dr. Cobuzzi testified that there is no typical, one-size-fits-all process for performing due diligence on a pharmaceutical collaboration, particularly at Endo. (Cobuzzi, Tr. 2543). He also explained that Endo regularly reviews potential agreements in "very, very short periods of time," and that he could not identify "any instance where [Endo] followed the perfect sequence" when conducting due diligence. (Cobuzzi, Tr. 2566, 2627). And Dr. Cobuzzi testified that Endo had sufficient time to assess IPX-203 before entering into the Development and Co-Promotion Agreement, particularly in light of Dr. Cobuzzi's and Endo's familiarity with Parkinson's disease treatments and the detailed nature of the information Impax provided on IPX-066. (Cobuzzi, Tr. 2543, 2625).

1121. Endo would have violated its own processes by evaluating, negotiating, and finalizing a development and co-promotion deal for a late stage product like IPX-066 in a

three-week period. (CX2784 at 050, 054 (August 2009 Endo Business Development Process Orientation document, stating it takes approximately "≤ 4 months" to reach a "diligence output" and approximately "6 months-1 year from initial evaluation to deal close.")).

RESPONSE TO FINDING NO. 1121:

Complaint Counsel's Proposed Finding No. 1121 is inaccurate. Dr. Cobuzzi testified that this document (CX2784) described procedures he has never seen implemented at Endo, and that they are "ideal state" procedures "almost never" implemented outside the big pharma context. (Cobuzzi, Tr. 2626-27; 2573). Dr. Cobuzzi also testified that there is no typical, one-size-fits-all process for performing due diligence on a pharmaceutical collaboration, particularly at Endo. (Cobuzzi, Tr. 2543). He explained that Endo regularly reviews potential agreements in "very, very short periods of time," and that he could not identify "any instance where [Endo] followed the perfect sequence" when conducting due diligence. (Cobuzzi, Tr. 2566, 2627). And Dr. Cobuzzi testified that Endo had sufficient time to assess IPX-203 before entering into the Development and Co-Promotion Agreement, particularly in light of Dr. Cobuzzi's and Endo's familiarity with Parkinson's disease treatments and the detailed nature of the information Impax provided on IPX-066. (Cobuzzi, Tr. 2543, 2625).

1122. In view of industry standards, it is extraordinarily unusual to perform a technical due diligence evaluation, integrated financial analysis, negotiate deal terms and finalize a development and co-promotion deal for an early stage product like IPX-203 in three days. (CX5003 at 020 (¶ 32) (Geltosky Report); Geltosky, Tr. 1065).

RESPONSE TO FINDING NO. 1122:

Complaint Counsel's Proposed Finding No. 1122 is inconsistent with record evidence and not based on reliable expert testimony to the extent it refers to industry standards for evaluating pharmaceutical development assets, including specific timelines for that evaluation. There is no typical, one-size-fits-all process for evaluating pharmaceutical development assets.

(Cobuzzi, Tr. 2543). This is particularly true for discovery-stage development collaborations, with which Dr. Geltosky has virtually no experience. (Geltosky, Tr. 1144-45). Finally, the Proposed Finding is misleading to the extent it implies Endo spent insufficient time evaluating IPX-203 or the DCA. Dr. Cobuzzi testified that he had sufficient time to analyze the opportunity, particularly in light of the information regarding IPX-066 Endo received. (Cobuzzi, Tr. 2543, 2625; CX2748-001 (June 7, 2010 email from Robert Cobuzzi noting that the attached IPX-203 opportunity evaluation worksheet "provides adequate and fair representation of what I would define as a good deal for Endo")). In fact, Endo had been assessing information that was "tremendously helpful" in evaluating IPX-203 and the DCA since May 2010. (Cobuzzi, Tr. 2525-26, 2602, 2625).

> 1123. Endo did in fact violate its own processes by evaluating, negotiating, and finalizing a development and co-promotion deal for Impax's early stage product, IPX-203, in three days. (CX2784 at 050, 054 (August 2009 Endo Business Development Process Orientation document, stating it takes approximately "≤ 4 months" to reach a "diligence output" and approximately "6 months-1 year from initial evaluation to deal close.")).

RESPONSE TO FINDING NO. 1123:

Complaint Counsel's Proposed Finding No. 1123 is inaccurate and misleading to the extent it refers to procedures described in a single Endo document as Endo's "own processes." Complaint Counsel identifies no further evidence suggesting that this single document embodies procedures ever implemented or followed at Endo. To the contrary, Dr. Cobuzzi testified that this document (CX2784) described procedures he has never seen implemented at Endo, and that they are "ideal state" procedures "almost never" implemented outside the big pharma context. (Cobuzzi, Tr. 2626-27; 2573).

Proposed Finding No. 1123 is also inaccurate to the extent that it describes Endo "evaluating, negotiating, and finalizing a development and co-promotion deal for Impax's early

stage product, IPX-203, in three days." In truth, the record reflects that Endo had been assessing information that was "tremendously helpful" in evaluating IPX-203 and the DCA since May 2010. (Cobuzzi, Tr. 2525-26, 2602, 2625).

Finally, the Proposed Finding is misleading to the extent it implies Endo spent insufficient time evaluating IPX-203 or the DCA. Dr. Cobuzzi testified that he had sufficient time to analyze the opportunity, particularly in light of the information regarding IPX-066 Endo received. (Cobuzzi, Tr. 2543, 2625; CX2748-001 (June 7, 2010 email from Robert Cobuzzi noting that the attached IPX-203 opportunity evaluation worksheet "provides adequate and fair representation of what I would define as a good deal for Endo")).

1124. Endo recognized that the highly abbreviated timeframe for evaluating the DCA was unusual. (*See* CCF ¶¶ 1125-1127).

RESPONSE TO FINDING NO. 1124:

The proposed summary finding should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Moreover, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondent's replies to those findings.

1125. Dr. Robert Cobuzzi and a team of Endo employees conducted the evaluation of the DCA. (Cobuzzi, Tr. 2523). Dr. Cobuzzi gave his group two days to complete the initial evaluation of IPX-066. (Cobuzzi, Tr. 2592). In an email to Endo's research and development group on May 25, 2010, Dr. Cobuzzi, recognized that there was "very little time" for Endo to complete an evaluation of Impax's IPX-066 asset. (CX1007 at 001). Dr. Cobuzzi acknowledged the rushed timeframe, worrying that his group may "starting sending [him] a lot of disparaging emails or slandering [him] personally for the condensed timeline for this review."(CX1007 at 001)). Impax recognized that Endo was "on a tight time table" to complete with DCA "if they wish[ed] to settle prior to June 17." (CX2625 at 001 (May 22, 2010 Nestor email to Paterson)).

RESPONSE TO FINDING NO. 1125:

Complaint Counsel's Proposed Finding No. 1125 is misleading and unsupported by the cited documents to the extent that it characterizes the timing of Endo's efforts as "rushed." The cited documents indicate that Endo proceeded on a "condensed timeline" and that the efforts needed to be completed within a certain amount of time, but do not speak to whether or not Endo was "rushed." In fact, Dr. Cobuzzi testified that Endo had sufficient time to assess IPX-203 before entering into the Development and Co-Promotion Agreement, particularly in light of Dr. Cobuzzi's and Endo's familiarity with Parkinson's disease treatments and the detailed nature of the information Impax provided on IPX-066. (Cobuzzi, Tr. 2543, 2625).

1126. Similarly, when engaging the Equinox Group consulting firm to help with the valuation of the IPX-066 opportunity, Endo's Director of Corporate Development, Sam Rasty, requested an abbreviated version of a full financial analysis. He described an "urgent forecasting need" and noted that "[t]here is no time for market research on this as we need the forecast by Wed. of next week (that's right, it's not a typo!!"). (CX1009 at 005 (May 21, 2010 Rasty to Equinox Group email)).

RESPONSE TO FINDING NO. 1126:

Respondent has no specific response.

1127. The short timeframe for review was given to Dr. Cobuzzi by Mr. Levin. (Cobuzzi, Tr. 2631). The reason for the short time frame for review was that the DCA was being negotiated in connection with settlement negotiations. (Cobuzzi, Tr. 2632, 2633 (stating that the DCA and SLA were being negotiated together)).

RESPONSE TO FINDING NO. 1127:

Respondent has no specific response.

1128. It is highly unusual for pharmaceutical companies to change the focus of a deal for a product at the Phase III stage of development to an early stage development product in the middle of negotiations. (Geltosky, Tr. 1069; CX5003 at 021-22 (¶ 35) (Geltosky Report)).

RESPONSE TO FINDING NO. 1128:

Complaint Counsel's Proposed Finding No. 1128 is inconsistent with record evidence and based on unreliable expert testimony. Proposed Finding No. 1128 relies exclusively on the opinions of Dr. Geltosky, who acknowledges that the sole basis for his opinions regarding the typical diligence timeline is his experience. (Geltosky, Tr. 1063, 1128, 1140). Yet Dr. Cobuzzi, who himself has over two decades of pharmaceutical industry experience, (CX4016 (Cobuzzi, IHT at 12-13)), testified that there is no typical, one-size-fits-all process for performing due diligence on a pharmaceutical collaboration, particularly at Endo. (Cobuzzi, Tr. 2543). Dr. Geltosky does not have any significant experience with pharmaceutical collaborations in which the net buyer—i.e., the party performing the diligence—is a small or mid-sized company. (Geltosky, Tr. 1141-43, 1171). Indeed, Dr. Geltosky testified that, as a consultant, his clients hire him for his knowledge of how big pharmaceutical companies approach collaborations. (Geltosky, Tr. 1180).

Proposed Finding No. 1128 is also inaccurate and misleading in its suggestion that there was a switch in products. As Ms. Snowden testified, "Endo was interested in the Parkinson's space and wanted the deal to cover both products, the original IPX-066 and the follow-on product [IPX-203], but Impax wasn't interested in doing the deal on IPX-066. So there wasn't actually . . . a switch as much as Endo was trying to negotiate for both product rights and Impax was only interested in doing product rights on the one product." (Snowden, Tr. 405-06).

1129. Endo was displeased when Impax changed the focus of the DCA from its Phase III development stage product, IPX-066, to its early development stage product, IPX-203. (CX1015 at 001 (December 2010 Pong-Cobuzzi-Bradley email) (stating that Impax "yanked [IPX-066] out from under us"); CX0502 at 001 (May 26, 2010 Mengler email regarding deal negotiations with Endo) (stating "[r]eading tea leaves: structure OK, not happy with product tbd.")). Nevertheless, Endo rushed to finalize and enter into the DCA. (CX5003 at 021-022 (¶35) (Geltosky Report)).

RESPONSE TO FINDING NO. 1129:

Complaint Counsel's Proposed Finding of Fact No. 1129 is misleading to the extent it suggests that the "focus of the DCA" for both parties was ever IPX-066. As Ms. Snowden testified, "Endo was interested in the Parkinson's space and wanted the deal to cover both products, the original IPX-066 and the follow-on product [IPX-203], but Impax wasn't interested in doing the deal on IPX-066. So there wasn't actually . . . a switch as much as Endo was trying to negotiate for both product rights and Impax was only interested in doing product rights on the one product." (Snowden, Tr. 405-06). Indeed, when Endo initially proposed a collaboration covering IPX-066 and "all improvements, modifications, derivatives, formulations and line extensions thereof," which would have included IPX-203, Impax immediately rejected the proposal. (CX0502; CX0320). The President of Impax's branded drug division, Michael Nestor, testified unequivocally he would never have agreed to such a collaboration. (Nestor, Tr. 2941).

The final sentence of Proposed Finding No. 1129 violates this Court's Order on Post-Trial Briefs by improperly citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents," and should be disregarded.

1130. Once it became clear that IPX-066 was no longer the focus of the negotiations, Endo should have suspended or delayed the deal negotiations to better assess the new product, IPX-203. (CX5003 at 022-23 (¶¶ 35-36) (Geltosky Report)). Rather than rushing to complete the deal, Endo should have taken the time to perform a new due diligence analysis focused on IPX-203. (CX5003-022-23 (¶ 36) (Geltosky Report)).

RESPONSE TO FINDING NO. 1130:

Complaint Counsel's Proposed Finding of Fact No. 1130 is misleading to the extent it suggests that IPX-066 was ever the focus of negotiations for both parties. (Snowden, Tr. 456-57; Koch, Tr. 319-20). As Ms. Snowden testified, "Endo was interested in the Parkinson's space and

wanted the deal to cover both products, the original IPX-066 and the follow-on product [IPX-203], but Impax wasn't interested in doing the deal on IPX-066. So there wasn't actually . . . a switch as much as Endo was trying to negotiate for both product rights and Impax was only interested in doing product rights on the one product." (Snowden, Tr. 405-06). Indeed, when Endo initially proposed a collaboration covering IPX-066 and "all improvements, modifications, derivatives, formulations and line extensions thereof," which would have included IPX-203, Impax immediately rejected the proposal. (CX0502; CX0320). The President of Impax's branded drug division, Michael Nestor, testified unequivocally he would never have agreed to such a collaboration. (Nestor, Tr. 2941).

The Proposed Finding is also unsupported by the documentary evidence to the extent it suggests Endo "rushed" to complete a deal or that it had insufficient time to assess the DCA. Dr. Cobuzzi testified that Endo had sufficient time to assess IPX-203 before entering into the Development and Co-Promotion Agreement, particularly in light of Dr. Cobuzzi's and Endo's familiarity with Parkinson's disease treatments and the detailed nature of the information Impax provided on IPX-066. (Cobuzzi, Tr. 2543, 2625).

Finally, Proposed Finding No. 1130 is based on improper and unreliable expert testimony. Dr. Geltosky has no basis for speculating as to what Endo "should have done" in negotiations. Dr. Geltosky has no expertise—and was not offered as an expert regarding—Endo's strategic business goals, Endo's negotiation strategies, Endo's finances, or Endo's development pipeline, all of which affect what Endo "should do" in negotiating a particular pharmaceutical development collaboration. (Geltosky, Tr. 1058 (Complaint Counsel tendering Dr. Geltosky as pharmaceutical business development expert)). Nor does Dr. Geltosky have more than a few experiences negotiating pharmaceutical collaborations involving a net buyer

similar to Endo in size and research and development capability. (Geltosky, Tr. 1143, 1177). Dr. Geltosky's thoughts on what Endo "should have done" are therefore beyond the scope of his expertise, lack foundation, are pure speculation, and should be disregarded as improper expert opinion.

6. Endo's due diligence evaluation of the DCA was not consistent with the usual and expected practice in the industry or with Endo's own process for evaluating pharmaceutical development business opportunities

1131. Endo did not perform a comprehensive and integrated due diligence analysis of IPX-203 before agreeing to the terms of the DCA. (*See* CCF ¶¶ 1132-1218; (CX5003 at 023 (¶ 37) (Geltosky Report)).

RESPONSE TO FINDING NO. 1131:

Complaint Counsel's Proposed Finding No. 1131 is inaccurate. Dr. Cobuzzi testified that Endo had sufficient time to assess IPX-203 before entering into the Development and Co-Promotion Agreement, particularly in light of Dr. Cobuzzi's and Endo's familiarity with Parkinson's disease treatments and the detailed nature of the information Impax provided on IPX-066. (Cobuzzi, Tr. 2543, 2625). Contemporaneous documents support that conclusion. (CX1007; CX2748-001 (June 7, 2010 email from Robert Cobuzzi noting that the attached IPX-203 opportunity evaluation worksheet "provides adequate and fair representation of what I would define as a good deal for Endo")). To the extent Proposed Finding No. 1131 attempts to incorporate and summarize other findings, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondent's replies to those findings.

1132. The industry standard for due diligence evaluation of pharmaceutical development opportunity is a thorough scientific review informed by an equally thorough regulatory, financial, and legal evaluation, designed to assure a firm that the opportunity is worthy of the investment contemplated. (CX5003 at 023 (¶ 37) (Geltosky Report)).

[redacted]
(Geltosky, Tr. 1095 (*in camera*)).

RESPONSE TO FINDING NO. 1132:

Complaint Counsel's Proposed Finding No. 1132 is misleading in its suggestion of an industry standard. Dr. Cobuzzi testified that there is no typical, one-size-fits-all process for performing due diligence on a pharmaceutical collaboration, particularly at Endo. (Cobuzzi, Tr. 2543). Moreover, the Proposed Finding relies exclusively on the opinions of Dr. Geltosky, who acknowledges that the sole basis for his opinions regarding the typical diligence timeline is his personal experience. (Geltosky, Tr. 1063, 1128, 1140). Yet Dr. Geltosky does not have any significant experience with pharmaceutical collaborations in which the net buyer—i.e., the party performing the diligence—is a small or mid-sized company. (Geltosky, Tr. 1141-43, 1171). Indeed, Dr. Geltosky testified that, as a consultant, his clients hire him for his knowledge of how big pharmaceutical companies approach collaborations. (Geltosky, Tr. 1180). And Dr. Geltosky has virtually no experience with discovery-stage development collaborations. (Geltosky, Tr. 1144-45 (only a "handful" of deals involving a discovery-stage asset)).

1133. Pharmaceutical companies evaluate many potential pharmaceutical product deals each year. For example, Dr. Cobuzzi testified that "a large number of deals come to Endo in any given year." (Cobuzzi, Tr. 2565; *see also*, Geltosky, Tr. 1055-56 (stating that in the year 2006, while at Bristol Myers Squibb, Dr. Geltosky reviewed 3000 potential deals)). Pharmaceutical companies of every size follow the due diligence process in order to understand, measure, quantitate, and put a dollar value on the risks of doing a particular deal. (Geltosky, Tr. 1062-3). Endo has never made an upfront payment for any license or co-promotion agreement for which Endo completed due diligence in a matter of days. (Cobuzzi, Tr. 2565).

RESPONSE TO FINDING NO. 1133:

Respondent has no specific response to the first and second sentences of Complaint Counsel's Proposed Finding No. 1133. Respondent has no specific response to the third

sentence of Proposed Finding No. 1133 except to the extent the phrase "the diligence process" refers to any particular, unidentified standard, it is not supported by the record.

The final sentence of Proposed Finding No. 1133 is misleading to the extent it attempts to suggest a comparison between the DCA and other Endo collaboration deals. Dr. Cobuzzi testified that Endo's other collaborations required Endo to take on responsibility for some of the development work. (Cobuzzi, Tr. 2629). By comparison, the DCA did not require Endo to perform any development work, or take on any financial responsibility for the development, beyond the agreed upon upfront and milestone payments. (Geltosky, Tr. 1124-25; Cobuzzi, Tr. 2543-44, 2558; CX1209-003).

1134. A due diligence analysis helps companies to manage risk. (Geltosky, Tr. 1062-3). Development and approval of pharmaceutical drugs is a difficult and complicated process, where only a few candidates achieve commercial success. (CX5003 at 011 (¶ 19) (Geltosky Report) (noting that the overall likelihood that a drug entering clinical trials will be approved is less than 12%)). There is an opportunity cost to spending money on a particular deal: money spent on one deal is not available to spend on additional deals. (Geltosky, Tr. 1074). Therefore, a firm seeks to invest in a product where it believes it will make a return on its investment. (Geltosky, Tr. 1074).

RESPONSE TO FINDING NO. 1134:

Respondent has no specific response.

a) Prior to entering into the DCA, Endo obtained little scientific information during technical due diligence about the composition, pharmacokinetics, mechanism of action, and manufacture of IPX-203

1135. Technical due diligence refers to reviewing the preclinical and clinical data available about a compound and developing an opinion on whether or not that data supports the program, if the product will likely meet FDA standards, if the compound is likely to be approved in a reasonable time frame, and whether the product will ultimately have a competitive profile. (Geltosky, Tr. 1094; CX5003 at 011-12 (¶ 20) (Geltosky Report)).

RESPONSE TO FINDING NO. 1135:

Respondent has no specific response.

1136. Technical due diligence is conducted by a team of experts representing all disciplines applied to the development of a pharmaceutical drug product: pharmacology, toxicology, process development, formulation development, manufacturing, and quality. It is a rigorous and careful examination of key study reports that the originator firm provides to the investing firm. In addition to providing these important documents, originator firms usually give detailed presentations of the drug development program. Intense Q&A between the originator firm and investing firm is often a part of this exercise. (CX5003 at 011-13 (¶ 20) (Geltosky Report)).

RESPONSE TO FINDING NO. 1136:

Complaint Counsel's Proposed Finding No. 1136 is based on unreliable expert testimony. Dr. Geltosky has virtually no experience with discovery-stage development deals like the DCA. (Geltosky, Tr. 1144-45 (only a "handful" of deals involving a discovery-stage asset)). And Dr. Geltosky acknowledged that he cannot speak to how the universe of mid-sized pharmaceutical companies approach partnerships for discovery-stage products. (Geltosky, Tr. 1177). Dr. Cobuzzi testified that there is no typical, one-size-fits-all procedure for performing due diligence on a pharmaceutical collaboration, particularly at Endo. (Cobuzzi, Tr. 2543).

1137. For an early stage product, technical due diligence focuses on the "preclinical proof of concept" for the drug candidate, which refers to data regarding the pharmacology, efficacy, and toxicity of the drug candidate. The preclinical proof of concept addresses whether the drug works as predicted in validated animal models and is acceptably safe. A firm evaluating a pharmaceutical development opportunity would also want to consider the feasibility of manufacturing the potential drug candidate as part of the technical due diligence. (CX5003 at 011-13 (¶ 20) (Geltosky Report)).

RESPONSE TO FINDING NO. 1137:

Complaint Counsel's Proposed Finding No. 1137 is based on unreliable expert testimony. Dr. Geltosky has virtually no experience with discovery-stage development deals like the DCA. (Geltosky, Tr. 1144-45 (only a "handful" of deals involving a discovery-stage asset)). And Dr.

Geltosky acknowledged that he cannot speak to how the universe of mid-sized pharmaceutical companies approach partnerships for discovery-stage products. (Geltosky, Tr. 1177). Dr. Cobuzzi testified that there is no typical, one-size-fits-all procedure for performing due diligence on a pharmaceutical collaboration, particularly at Endo. (Cobuzzi, Tr. 2543).

1138. Similar to industry standards, Endo's own business development process identified several areas for evaluation when conducting a technical due diligence of an asset, including pharmacology, toxicology, Chemistry, Manufacturing and Control (CMC), regulatory, manufacturing, analytical and packaging. (CX2784 at 034 (Aug. 2009 Endo Business Development Process Orientation document); CX5003 at 13 n.50 (definition of "Chemistry, Manufacturing, and Control")).

RESPONSE TO FINDING NO. 1138:

Complaint Counsel's Proposed Finding No. 1138 is inaccurate and unsupported by the cited evidence in its suggestion that Endo had a set "development process." Dr. Cobuzzi testified that this document (CX2784) described procedures he has never seen implemented at Endo, and that they are "ideal state" procedures "almost never" implemented outside of large pharmaceutical companies. (Cobuzzi, Tr. 2626-27; 2573). He also testified that there is no typical, one-size-fits-all timeline for performing due diligence on a pharmaceutical collaboration, particularly at Endo. (Cobuzzi, Tr. 2543).

1139. During the due diligence process and before it signed the DCA, Endo obtained very little scientific information on the composition, pharmacokinetics, mechanism of action, and manufacture of IPX-203. (*See* CCF ¶¶ 1140-1167).

RESPONSE TO FINDING NO. 1139:

The proposed summary finding should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Moreover, the

individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondent's replies to those findings.

1140. [redacted] (CX5003 at 009 (¶ 17) (Geltosky Report) (*in camera*)).

RESPONSE TO FINDING NO. 1140:

Complaint Counsel's Proposed Finding No. 1140 should be disregarded because it violates this Court's Order on Post-Trial Briefs, which prohibits using "expert testimony to support factual propositions that should be established by fact witnesses or documents."

1141. [redacted] (CX1209 at 003 (Endo's Final Opportunity Evaluation Worksheet for IPX-203) (*in camera*); Nestor, Tr. 3004 (stating that the levodopa compound is approximately 50 years old); Cobuzzi, Tr. 2524 (original formulation of carbidopa and levodopa was a drug named Sinemet)).

RESPONSE TO FINDING NO. 1141:

Respondent has no specific response.

1142. [redacted] (CX1209 at 003 (Endo's Final Opportunity Evaluation Worksheet for IPX-203) (*in camera*)).

RESPONSE TO FINDING NO. 1142:

Respondent has no specific response.

1143. [redacted] (Geltosky, Tr. 1097 (*in camera*)). [redacted] (Geltosky, Tr. 1100-101 (*in camera*)).

RESPONSE TO FINDING NO. 1143:

Complaint Counsel's Proposed Finding No. 1143 should be disregarded because it violates this Court's Order on Post-Trial Briefs, which prohibits using "expert testimony to support factual propositions that should be established by fact witnesses or documents."

1144. [redacted] (Nestor, Tr. 3042 (*in camera*); Cobuzzi, Tr. 2532) (*in camera*)).

RESPONSE TO FINDING NO. 1144:

Respondent has no specific response.

1145. [redacted] (CX5003 at 024 (¶ 39) (Geltosky Report) (*in camera*)).

RESPONSE TO FINDING NO. 1145:

Respondent has no specific response.

1146. [redacted] (Geltosky, Tr. 1096) (*in camera*)).

RESPONSE TO FINDING NO. 1146:

Respondent has no specific response.

1147. [redacted] (Nestor, Tr. 3041-42 (*in camera*); Cobuzzi, Tr. 2532 (*in camera*); CX2780 at 023, 030, 053-60 (Impax presentation on IPX-203[redacted] (*in camera*)).

RESPONSE TO FINDING NO. 1147:

Respondent has no specific response.

1148. [redacted] (CX3167 at 044 (Aug. 2010

Impax Brand R&D presentation) [redacted] (*in camera*).

RESPONSE TO FINDING NO. 1148:

Respondent has no specific response.

1149. In addition to selecting a lead compound, a formulation for the particular pharmaceutical product must be developed. (CX5003 at 011-12 (¶ 20) (Geltosky Report)).

RESPONSE TO FINDING NO. 1149:

Respondent has no specific response.

1150. [redacted] (CX5003 at 024 (¶ 38 n.89) (Geltosky Report) (*in camera*)).

RESPONSE TO FINDING NO. 1150:

Respondent has no specific response.

1151. It is necessary to come up with a formulation for a particular drug product prior to conducting any preclinical testing of the product. (Nestor, Tr. 3030).

RESPONSE TO FINDING NO. 1151:

Respondent has no specific response.

1152. Often a company will need to try many different formulations before coming across the right formulation that will be used in the eventual product. (Nestor, Tr. 2947 ("Whenever you come up with an idea for a formulation, many times you will end up trying different formulations before you come across the right formulation that you end up going forward with. It's just part of the normal course of developing pharmaceutical products.")).

RESPONSE TO FINDING NO. 1152:

Respondent has no specific response.

1153. [redacted] (CX3163 at 014 (¶ 60) (Impax Answer); Cobuzzi, Tr. 2613 (*in camera*); CX1209 at 007 (Endo's Final Opportunity Evaluation Worksheet for IPX-203)). As of June 4, 2010, IPX-203 was in the beginning of the formulation stage. (Nestor, Tr. 3030-31).

RESPONSE TO FINDING NO. 1153:

Respondent has no specific response.

1154. Because IPX-203 was due to launch years after IPX-066 was already established on the market, a thorough scientific analysis of the potential deal with Impax would need to include an assessment of whether IPX-203 functioned better than IPX-066. (CX5003 at 027 (¶ 42) (Geltosky Report)).

RESPONSE TO FINDING NO. 1154:

Complaint Counsel's Proposed Finding No. 1154 is based on unreliable expert testimony. Dr. Geltosky has virtually no experience with discovery-stage development deals like the DCA. (Geltosky, Tr. 1144-45 (only a "handful" of deals involving a discovery-stage asset)). And Dr. Geltosky acknowledged that he cannot speak to how the universe of mid-sized pharmaceutical companies approach partnerships for discovery-stage products. (Geltosky, Tr. 1177). Dr. Cobuzzi testified that there is no typical, one-size-fits-all procedure for performing due diligence on a pharmaceutical collaboration, particularly at Endo. (Cobuzzi, Tr. 2543). In the case of the DCA, Endo had sufficient information to analyze the opportunity and conclude that the deal was "what I would define as a good deal for Endo." (CX2748-001; Cobuzzi, Tr. 2533-37, 2563 (Endo had adequate time and "the information we needed" to evaluate IPX-203)).

1155. A comparison of the pharmacokinetic data for IPX-203 with that of IPX-066 should have been conducted to determine whether IPX-203 was a competitive product. (CX5003 at 027 (¶ 42) (Geltosky Report)).

RESPONSE TO FINDING NO. 1155:

Complaint Counsel's Proposed Finding No. 1155 is based on unreliable expert testimony. Dr. Geltosky has virtually no experience with discovery-stage development deals like the DCA. (Geltosky, Tr. 1144-45 (only a "handful" of deals involving a discovery-stage asset)). And Dr. Geltosky acknowledged that he cannot speak to how the universe of mid-sized pharmaceutical companies approach partnerships for discovery-stage products. (Geltosky, Tr. 1177). Dr. Cobuzzi testified that there is no typical, one-size-fits-all procedure for performing due diligence on a pharmaceutical collaboration, particularly at Endo. (Cobuzzi, Tr. 2543). In the case of the DCA, Endo had sufficient information to analyze the opportunity and conclude that the deal was "what I would define as a good deal for Endo." (CX2748-001; Cobuzzi, Tr. 2533-37, 2563 (Endo had adequate time and "the information we needed" to evaluate IPX-203)).

1156. [redacted] (Cobuzzi, Tr. 2547-48; Nestor, Tr. 2957 (*in camera*)).

RESPONSE TO FINDING NO. 1156:

Respondent has no specific response.

1157. [redacted] (Geltosky, Tr. 1102) (*in camera*). [redacted] (Geltosky, Tr. 1101-102 (*in camera*); *see also* Cobuzzi, Tr. 2634 (noting that IPX-203's market opportunity would have been affected if it was not superior to IPX-066)).

RESPONSE TO FINDING NO. 1157:

Complaint Counsel's Proposed Finding No. 1157 should be disregarded because it violates this Court's Order on Post-Trial Briefs, which prohibits using "expert testimony to support factual propositions that should be established by fact witnesses or documents." Dr.

Geltosky's opinion with respect to how Medicare and third party payors purportedly would react to a particular drug is outside the scope of his tendered expertise in "whether the overall strategic fit, negotiation history, due diligence efforts, and terms of the development and co-promotion agreement between Endo and Impax are consistent with the usual and expected practice in the pharmaceutical industry." (Geltosky, Tr. 1058).

1158. [redacted] (CX5003 at 027-28 (¶ 42) (Geltosky Report) (*in camera*); CX4033 (Nestor, Dep. at 30) ("[T]he objective with IPX203 would be to offer even better symptom control for Parkinson's patients, which is critical for them, than Rytary . . . .").

RESPONSE TO FINDING NO. 1158:

Complaint Counsel's Proposed Finding No. 1158 should be disregarded because it violates this Court's Order on Post-Trial Briefs, which prohibits using "expert testimony to support factual propositions that should be established by fact witnesses or documents." The Proposed Finding is also inaccurate. That the objective of IPX-203 was to develop a better version of IPX-066 does not mean that "there would be no reason to pursue" the drug if it did not show superior pharmacokinetics. Dr. Geltosky acknowledged that he cannot speak to how the universe of mid-sized pharmaceutical companies approach partnerships for discovery-stage products. (Geltosky, Tr. 1177). Dr. Geltosky similarly has no basis for speculating about what Endo "should have done" in its diligence of IPX-203 and the DCA. Dr. Geltosky has no expertise in—and was not offered as an expert regarding—Endo's strategic business goals, Endo's negotiation strategies, Endo's finances, or Endo's development pipeline, all of which affect what Endo "should do" when considering possible collaborations. Nor does Dr. Geltosky have experience with more than a few deals involving a net buyer similar to Endo in size and research and development capability. (Geltosky, Tr. 1143, 1177).

1159. [redacted] (Cobuzzi, Tr. 2635 (stating "[w]e had no empiric data."); CX3167 at 048 (Aug. 2010 Impax Brand R&D presentation) [redacted] (*in camera*)). At the time the DCA was signed, no clinical data for IPX-203 was available. (Nestor, Tr. 3026-27). Therefore, Impax did not send any clinical data to Endo for review. (Nestor, Tr. 3028).

RESPONSE TO FINDING NO. 1159:

Complaint Counsel's Proposed Finding No. 1159 is inaccurate and misleading in its suggestion that Endo did not assess the likelihood that IPX-203 would offer a superior clinical benefit to patients when compared to IPX-066. [redacted] (*See* Cobuzzi, Tr. 2533-37).

Specifically, Endo [redacted] (Cobuzzi, Tr. 2533 [redacted]

1160. [redacted] (Geltosky, Tr. 1092-93 (*in camera*); CX5003 at 051 (¶ 86 n.199) (Geltosky Report) (*in camera*)). [redacted]

[redacted] (Geltosky, Tr. 1092-93 (*in camera*); CX1209 at 006-07 (Endo's Final Opportunity Evaluation Worksheet for IPX-203) (no discussion of Teva and Lundbeck study in scientific opportunity summary section of OEW)).

RESPONSE TO FINDING NO. 1160:

Complaint Counsel's Proposed Finding No. 1160 should be disregarded because it violates this Court's Order on Post-Trial Briefs, which prohibits using "expert testimony to support factual propositions that should be established by fact witnesses or documents." Proposed Finding No. 1160 is also improper and inadmissible. The Proposed Finding purports to summarize academic literature that is not in evidence and, if it were, that literature would be the best evidence of its contents. In any event, Dr. Geltosky acknowledged the purported study did not test the specific improvements Endo and Impax believed IPX-203 would achieve. (*See* CX3181-005 ([redacted]); Geltosky, Tr. 1194-1196 ([redacted]); Geltosky, Tr. 1117-18 ([redacted])).

1161. As of April of 2013, almost three years after signing and entering into the DCA, Impax had yet to complete a pharmacokinetic study for IPX-203. (Nestor, Tr. 3034).

RESPONSE TO FINDING NO. 1161:

Complaint Counsel's Proposed Finding No. 1161 is inaccurate, inconsistent with record evidence, and unsupported by the testimony cited. Impax's internal documents, specifically R&D presentations and detailed time entry records, reflect that Impax [redacted] and spent a substantial amount of

time working on them in 2011 as well. (*See* CX3166-039-42 [redacted]; RX-242 (IPX-203 Hours Spreadsheet) (Tab 2012 Project Detail reflecting results from IPX-203 pharmacokinetic studies—for example, "IPX203-B12-01 PK results"—and work on additional pharmacokinetic studies involving different IPX-203 formulations—for example "IPX203-B12-03 study"); RX-242 (IPX-203 Hours Spreadsheet) (Tab 2011 Project Detail entries showing work regarding IPX-203 pharmacokinetic studies in 2011, including "IPX203 new study," "IPX203 next PK," "study design formulation," "IPX203-B12-01 protocol," and "IPX203-B12-01 draft protocol"); *see also* CX0310-026-27 (Impax Narrative Responses to CID) (listing various IPX-203 pharmacokinetic studies completed by Impax as of the date of the response, as well as the IPX-203 formulation numbers tested)).

These documents reflect several rounds of pharmacokinetic studies on IPX-203 formulations. The testimony of Michael Nestor, on which the Proposed Finding attempts to rely, reflects only that as of April 2013, Impax was "still planning on doing a PK study of IPX-203," not that it had never completed one. (Nestor, Tr. 3034). In this respect, the Proposed Finding misunderstands the role of pharmacokinetic studies in pharmaceutical development generally, and the development work on IPX-203 specifically. [redacted] (Nestor, Tr. 2962-

61; CX0310-026-27; RX-242 (reflecting pharmacokinetic study work on various formulations in 2011, 2012, and 2013); CX3166-039-42 ([redacted])).

Proposed Finding No. 1161 is also misleading in its description of the timeline for Impax's development work on IPX-203, because it ignores the fact that some work was temporarily delayed after Impax experienced delays in the development of IPX-066, the brand drug IPX-203 was intended to extend and improve upon. (Reasons, Tr. 1237-38; CX4021 (Ben-Maimon, Dep. at 145) (IPX-066 development was delayed for a "[c]ouple years"); CX4033 (Nestor, Dep. at 135-36)). Bryan Reasons, Impax's current Chief Financial Officer, explained that when IPX-066 was delayed, "resources were put to focus on the approval of Rytary [IPX-066] so that we could get that to market, grow that . . . commercially, and it would also be beneficial to [] when we launched the next generation of [IPX-]203." (Reasons, Tr. 1237-38).

1162. Since IPX-203 had not yet been formulated, Endo reviewed the clinical data on IPX-066 as a "surrogate." (CX1209 at 007 (Endo's Final Opportunity Evaluation Worksheet for IPX-203) ("Although IPX-203 has not yet been formulated . . . Endo has had the opportunity to review the clinical data on IPX-066 as a surrogate.")).

RESPONSE TO FINDING NO. 1162:

Complaint Counsel's Proposed Finding No. 1162 is misleading and incomplete in its description of the manner in which the Endo diligence team utilized IPX-066 clinical data when assessing IPX-203. Dr. Cobuzzi and his team used information about IPX-066 to supplement the research Endo had received describing the IPX-203 program and product concept. (Cobuzzi, Tr. 2533, 2625).

1163. [redacted]

[redacted] (CX5003 at 027 (¶ 41) (Geltosky Report); Geltosky, Tr. 1101 (*in camera*)).

RESPONSE TO FINDING NO. 1163:

Complaint Counsel's Proposed Finding No. 1163 is inconsistent with the record. Both Dr. Geltosky and Dr. Cobuzzi agree that the use of comparator or benchmark drugs in assessing pharmaceutical development candidates is commonplace. (Geltosky, Tr. 1155-56; Cobuzzi, Tr. 2624). Endo does this "all the time" and it makes the assessment "much easier." (Cobuzzi, Tr. 2624-25). Dr. Geltosky acknowledged that information about IPX-066 would inform "key parameters" in an assessment of IPX-203 and the DCA, including the parameters of the project and the burdens associated with it. (Geltosky, Tr. 1153). Consistent with this, Dr. Cobuzzi and his team found information about IPX-066, including clinical information, "tremendously" helpful in assessing IPX-203 and supplementing the research Endo had received describing the IPX-203 program and product concept. (Cobuzzi, Tr. 2533, 2625).

1164. [redacted] (Geltosky, Tr. 1101) (*in camera*)). [redacted] (Geltosky, Tr. 1101) (*in camera*)).

RESPONSE TO FINDING NO. 1164:

Complaint Counsel's Proposed Finding No. 1164 should be disregarded because it violates this Court's Order on Post-Trial Briefs, which prohibits using "expert testimony to support factual propositions that should be established by fact witnesses or documents."

1165. Outside of conducting the relevant testing on a specific formulation of IPX-203, there was no way for Endo to know how IPX-203 would compare with IPX-066. (CX5003 at 027 (¶ 41) (Geltosky Report)).

RESPONSE TO FINDING NO. 1165:

Complaint Counsel's Proposed Finding No. 1165 should be disregarded because it violates this Court's Order on Post-Trial Briefs, which prohibits using "expert testimony to support factual propositions that should be established by fact witnesses or documents."

Proposed Finding No. 1165 is also misleading and inconsistent with the record. Endo knew "the underlying molecules, the carbidopa and levodopa, and we looked at a number of Parkinson's opportunities in the past, so we knew the general landscape of the area in which we were looking at this as a commercial opportunity." (Cobuzzi, Tr. 2548-49; *see* CX1007-001 ("this is an area we know well as a company both in terms of past evaluations, and by virtue of the fact that we previously held the rights to IR Sinemet")).

1166. Endo points to the fact that Dr. Robert Cobuzzi conducted his Ph.D. dissertation on putative toxins that could have been causative agents of Parkinson's disease, as relevant to experience in the Parkinson's disease field. (Cobuzzi, Tr. 2511-12). However, prior academic experience in the Parkinson's disease area is not a substitute for preclinical and clinical testing. (CX5003 at 018 (¶ 29) (Geltosky Report)).

RESPONSE TO FINDING NO. 1166:

Respondent has no specific response to the first sentence of Complaint Counsel's Proposed Finding No. 1166. The second sentence of Proposed Finding No. 1166 is not supported by any record evidence. Dr. Cobuzzi did not claim to "substitute" his academic experience for preclinical or clinical testing. [redacted] (*See* Cobuzzi, Tr. 2533-36).

1167. [redacted] (CX3167 at 027 (Aug. 2010 Impax Brand R&D presentation) (*in camera*)).

RESPONSE TO FINDING NO. 1167:

Respondent has no specific response.

1168. Endo recognized that it had insufficient information about the stability and feasibility of manufacture of IPX-203, prior to entering into the DCA. (CX1209 at 009) (Endo's Final Opportunity Evaluation Worksheet for IPX-203) ("[B]ecause of the limited amount of information, potential issues around manufacturing and stability could not be fully determined . . . insufficient information has been provided in due diligence to completely characterize the pharmaceutical development and manufacturing risks for IPX-203.")).

RESPONSE TO FINDING NO. 1168:

Complaint Counsel's Proposed Finding No. 1168 is misleading and incomplete in its description of Endo's Opportunity Evaluation Worksheet (CX1209). Indeed, on the very same page Complaint Counsel cites, Endo concluded that "[b]ased on the information provided for IPX-066, the formulation appears acceptable and behaves clinically as designed." (CX1209-009). And Dr. Cobuzzi testified that information about IPX-066, taken together with Endo's familiarity with Parkinson's disease and carbidopa-levodopa therapies, was sufficient to analyze opportunity and prepare an "adequate and fair representation of what I would define as a good deal for Endo." (CX2748-001; Cobuzzi, Tr. 2533-37, 2563 (Endo had adequate time and "the information we needed" to evaluate IPX-203)).

The Proposed Finding is also misleading because [redacted] (Cobuzzi, Tr. 2533). For every successful collaboration agreement, Dr. Cobuzzi wants more time and information. (Cobuzzi, Tr. 2627). And [redacted] (Cobuzzi, Tr. 2533). By comparison, the DCA dealt with two well-known molecules: carbidopa and levodopa. (Cobuzzi, Tr. 2629).

1169. [redacted] (CX5003 at 28 (¶ 43) (Geltosky Report) (*in camera*)).

RESPONSE TO FINDING NO. 1169:

Complaint Counsel's Proposed Finding No. 1169 should be disregarded because it violates this Court's Order on Post-Trial Briefs, which prohibits using "expert testimony to support factual propositions that should be established by fact witnesses or documents."

b) Given the lack of technical information available about IPX-203, Endo did not appropriately account for the scientific risks associated with the DCA prior to agreeing to pay $10 million in upfront payments and potentially $30 million in additional milestone payments

1170. [redacted] (Nestor, Tr. 2959 (*in camera*); CX4033 (Nestor, Dep. at 95); Geltosky, Tr. 1092 (*in camera*), 1146-47)).

RESPONSE TO FINDING NO. 1170:

The first sentence to Complaint Counsel's Proposed Finding No. 1170 should be disregarded because it is not supported by any record evidence and violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). The second sentence of Proposed Finding No. 1170 is inaccurate and misleading because it incorrectly paraphrases Mr. Nestor's testimony. Mr. Nestor explained that [redacted] (Nestor, Tr. 2959-60). Indeed, in a contemporaneous document, Mr. Nestor described the risk associated

with IPX-203's development as simply "part of the process." (RX-387). Dr. Geltosky similarly acknowledged that the risks associated with early-stage development candidates do not stop companies from collaborating on such products "all the time," and that *all* stages of pharmaceutical development carry an inherent level of risk. (Geltosky, Tr. 1134).

1171. [redacted], a firm would not take for granted that an untested compound like IPX-203 would be superior to a known compound such as IPX-066. (CX5003 at 028 (¶ 43) (Geltosky Report) (*in camera*)).

RESPONSE TO FINDING NO. 1171:

Complaint Counsel's Proposed Finding No. 1171 should be disregarded because it violates this Court's Order on Post-Trial Briefs, which prohibits using "expert testimony to support factual propositions that should be established by fact witnesses or documents." Proposed Finding No. 1171 is also inaccurate. Endo [redacted] (Cobuzzi, Tr. 2533-37).

1172. [redacted] (Geltosky, Tr. 1100 [redacted] (*in camera*); CX5003 at 028 (¶ 43) (Geltosky Report)).

RESPONSE TO FINDING NO. 1172:

The first sentence of Complaint Counsel's Proposed Finding No. 1172 is based on unreliable expert testimony. Dr. Geltosky has virtually no experience with discovery-stage development deals like the DCA. (Geltosky, Tr. 1144-45 (only a "handful" of deals involving a discovery-stage asset)). And Dr. Geltosky acknowledged that he cannot speak to how the

universe of mid-sized pharmaceutical companies approach partnerships for discovery-stage products. (Geltosky, Tr. 1177). Dr. Geltosky similarly has no basis for speculating about what Endo "should have done" in its diligence of IPX-203 and the DCA. Dr. Geltosky has no expertise in—and was not offered as an expert regarding—Endo's strategic business goals, Endo's negotiation strategies, Endo's finances, or Endo's development pipeline, all of which affect what Endo "should do" when performing due diligence. Nor does Dr. Geltosky have experience with more than a few deals involving a net buyer similar to Endo in size and research and development capability. (Geltosky, Tr. 1143, 1177). Dr. Cobuzzi, an actual Endo employee, testified that there is no typical, one-size-fits-all procedure for performing due diligence on a pharmaceutical collaboration, particularly at Endo. (Cobuzzi, Tr. 2543).

1173. The customary approach in the pharmaceutical industry to mitigate substantial uncertainty and risk is to provide payments commensurate with progress on the program. (CX5003 at 029 (¶ 45) (Geltosky Report)).

RESPONSE TO FINDING NO. 1173:

Complaint Counsel's Proposed Finding No. 1173 is based on unreliable expert testimony. Dr. Geltosky has virtually no experience with discovery-stage development deals like the DCA. (Geltosky, Tr. 1144-45 (only a "handful" of deals involving a discovery-stage asset)). And Dr. Geltosky acknowledged that he cannot speak to how the universe of mid-sized pharmaceutical companies approach partnerships for discovery-stage products. (Geltosky, Tr. 1177).

1174. Endo could have made a smaller upfront payment at signing, when risk was at its highest, and then offered more money if and when pharmacokinetic studies showed improved effectiveness of IPX-203. (CX5003 at 029 (¶ 45) (Geltosky Report); *see also* CX4016 (Cobuzzi, IHT at 69-70) ("if you pay too much up front, you may never actually get to the point of realizing that value.")). [redacted] (Geltosky, Tr. at 1100 (*in camera*); (CX5003 at 029 (¶ 45) (Geltosky Report)).

RESPONSE TO FINDING NO. 1174:

Complaint Counsel's Proposed Finding No. 1174 should be disregarded because it violates this Court's Order on Post-Trial Briefs, which prohibits using "expert testimony to support factual propositions that should be established by fact witnesses or documents." Proposed Finding No. 1174 also lacks foundation and is not supported by the record. Dr. Geltosky was not tendered to offer opinions on possible alternative DCA structures Endo could have pursued. (*See* Geltosky, Tr. 1058). The alternative structure suggested in the Proposed Finding, moreover, was not viable for Impax, given its difficulty funding IPX-203; had Impax waited until later in development to receive funding, it likely would not have been able to pursue IPX-203 at all. (Nestor, Tr. 3052-53).

1175. Endo did not take any of these steps. Instead, Endo chose to enter the DCA with minimal scientific information about IPX-203 and without applying any risk mitigation strategies. (CX5003 at 029 (¶ 45) (Geltosky Report)).

RESPONSE TO FINDING NO. 1175:

Complaint Counsel's Proposed Finding No. 1175 should be disregarded because it violates this Court's Order on Post-Trial Briefs, which prohibits using "expert testimony to support factual propositions that should be established by fact witnesses or documents." Proposed Finding No. 1175 is also inaccurate. Dr. Cobuzzi, who was responsible for the overall evaluation of the IPX-203 opportunity, testified that Endo understood the risks associated with IPX-203, and that those were accounted for and mitigated in the DCA deal structure. (Cobuzzi, Tr. 2523, 2543; *see also* Geltosky, Tr. 1136-37 (financial risk to Endo under the DCA was capped)).

c) Endo did not appropriately account for the regulatory risks

1176. Under industry standards, analysis of the regulatory risks is a key component of the due diligence process of evaluating a pharmaceutical development opportunity. Regulatory risks determine the likelihood and timing of FDA approval, timing of product launch, and the potential for any development costs. (CX5003 at 029-30 (¶ 46) (Geltosky Report)).

RESPONSE TO FINDING NO. 1176:

The first sentence of Complaint Counsel's Proposed Finding No. 1176 is based on unreliable expert testimony. Dr. Geltosky has virtually no experience with discovery-stage development deals like the DCA. (Geltosky, Tr. 1144-45 (only a "handful" of deals involving a discovery-stage asset)). And Dr. Geltosky acknowledged that he cannot speak to how the universe of mid-sized pharmaceutical companies approach partnerships for discovery-stage products. (Geltosky, Tr. 1177). Dr. Cobuzzi testified that there is no typical, one-size-fits-all procedure for performing due diligence on a pharmaceutical collaboration, particularly at Endo. (Cobuzzi, Tr. 2543).

1177. Similar to industry standards, Endo's own business development processes contemplated reviewing the regulatory risks of a particular pharmaceutical business opportunity. (CX2784 at 038 (Aug. 2009 Endo Business Development Process Orientation document) (seeking regulatory filings and correspondence from the sponsor company as part of the due diligence information request)).

RESPONSE TO FINDING NO. 1177:

Complaint Counsel's Proposed Finding No. 1177 is inaccurate and unsupported by the cited evidence in its suggestion that Endo had a set "development process." Dr. Cobuzzi testified that this document (CX2784) described procedures he has never seen implemented at Endo, and that they are "ideal state" procedures "almost never" implemented outside of large pharmaceutical companies. (Cobuzzi, Tr. 2626-27; 2573). He also testified that there is no

typical, one-size-fits-all timeline for performing due diligence on a pharmaceutical collaboration, particularly at Endo. (Cobuzzi, Tr. 2543).

1178. Endo did not properly account for the regulatory risks associated with the IPX-203 opportunity. (*See* CCF ¶¶ 1179-1186).

RESPONSE TO FINDING NO. 1178:

The proposed summary finding should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Moreover, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondent's replies to those findings.

1179. [redacted] (Geltosky, Tr. 1097 (*in camera*); CX5003 at 013-14 (¶ 22) (Geltosky Report)). [redacted] (Geltosky, Tr. 1097 (*in camera*); CX5003 at 013-14 (¶ 22) (Geltosky Report)).

RESPONSE TO FINDING NO. 1179:

Respondent has no specific response.

1180. [redacted] (Geltosky, Tr. 1097-98 (*in camera*)).

RESPONSE TO FINDING NO. 1180:

Complaint Counsel's Proposed Finding No. 1180 should be disregarded because it violates this Court's Order on Post-Trial Briefs, which prohibits using "expert testimony to support factual propositions that should be established by fact witnesses or documents."

1181. [redacted]
(CX2780 at 024 (June 3, 2010 Impax IPX-203 presentation) [redacted] (*in camera*)). [redacted] (Geltosky, Tr. 1098 (*in camera*)). [redacted] (Geltosky, Tr. 1098 (*in camera*)); CX2780 at 058 (June 3, 2010 Impax IPX-203 presentation) [redacted] (*in camera*); CX3167 at 048 (Aug. 2010 Impax Brand R&D presentation) [redacted] (*in camera*)).

RESPONSE TO FINDING NO. 1181:

Respondent has no specific response.

1182. To obtain NCE status, the FDA may require additional pharmacological, ADME (absorption, distribution, metabolism, and excretion), toxicity, and CMC-related testing of the product. (CX5003 at 014 (¶ 22) (Geltosky Report)). Additional testing could have resulted in increased time for review by the FDA and additional development costs. (CX5003 at 014 (¶ 22) (Geltosky Report)).

RESPONSE TO FINDING NO. 1182:

Respondent has no specific response.

1183. Endo speculated that the FDA may require additional studies in order to approve the levodopa ester in IPX-203 for human use, noting that "it is possible that the FDA could ask for additional studies to be conducted." (CX1209 at 008 (Endo's Final Opportunity Evaluation Worksheet for IPX-203)).

RESPONSE TO FINDING NO. 1183:

Respondent has no specific response.

1184. Endo stated that "[u]nlike IPX-066, IPX-203 will be classified as an NCE as it contains a novel LD ester as an API, and so it is not possible to rule-out the occurrence of development-related challenges, including the potential need for non-clinical and pharmaceutical development work not anticipated in Impax's development plan. . . ." (CX1209 at 008 (Endo's Final Opportunity Evaluation Worksheet for IPX-203).

RESPONSE TO FINDING NO. 1184:

Respondent has no specific response.

1185. Endo also noted potential [redacted] (CX1209 at 009 (Endo's Final Opportunity Evaluation Worksheet for IPX-203) (*in camera*)).

RESPONSE TO FINDING NO. 1185:

Respondent has no specific response.

1186. [redacted] (CX5003 at 035 (¶ 57) (Geltosky Report) (*in camera*)). Nor did Endo account for the possibility that IPX-203 would not receive NCE status. (CX4031 (Bradley, Dep. at 121-22)).

RESPONSE TO FINDING NO. 1186:

The first sentence of Complaint Counsel's Proposed Finding No. 1186 should be disregarded because it violates this Court's Order on Post-Trial Briefs, which prohibits using "expert testimony to support factual propositions that should be established by fact witnesses or documents." The second sentence of Proposed Finding No. 1186 is not supported by the cited evidence. Mr. Bradley did not say anything about whether Endo did or did not account for the possibility IPX-203 would not receive NCE status.

d) Endo did not conduct a freedom to operate analysis or independent assessment of the intellectual property covering IPX-203

1187. A comprehensive patent review, including a freedom to operate analysis ("FTO") and an assessment of the strength of the patents covering the product in question, is normally conducted as part of the due diligence evaluation of a pharmaceutical product development opportunity. (CX5003 at 031 (¶¶ 49, 50) (Geltosky Report)). A freedom to operate analysis is an assessment of whether a firm may make, use or sell the product with the freedom from being sued for patent infringement. (Hoxie, Tr. 2712; Figg, Tr. 1936; Geltosky, Tr. 1080).

RESPONSE TO FINDING NO. 1187:

The first sentence of Complaint Counsel's Proposed Finding No. 1187 is inaccurate and is based on unreliable expert testimony. Dr. Geltosky has virtually no experience with

discovery-stage development deals like the DCA. (Geltosky, Tr. 1144-45 (only a "handful" of deals involving a discovery-stage asset)). And Dr. Geltosky acknowledged that he cannot speak to how the universe of mid-sized pharmaceutical companies approach partnerships for discovery-stage products. (Geltosky, Tr. 1177). Dr. Cobuzzi testified that there is no typical, one-size-fits-all procedure for performing due diligence on a pharmaceutical collaboration, particularly at Endo. (Cobuzzi, Tr. 2543). Respondent has no specific response to the second sentence of Proposed Finding No. 1187.

1188. Similar to industry standards, Endo's own business development process called for a freedom to operate analysis and review of the duration of patent exclusivity and extension as part of the due diligence analysis. (CX2784 at 048 (Aug. 2009 Endo Business Development Process Orientation document (stating that "FTO, duration of patent exclusivity & extension" are "[o]ther [c]ritical [o]utputs [e]xpected [f]rom [d]iligence"); at 038 (seeking to obtain information on intellectual property from sponsor firm)).

RESPONSE TO FINDING NO. 1188:

Complaint Counsel's Proposed Finding No. 1188 is inaccurate and unsupported by the cited evidence in its suggestion that Endo had a set "development process." Dr. Cobuzzi testified that this document (CX2784) described procedures he has never seen implemented at Endo, and that they are "ideal state" procedures "almost never" implemented outside of large pharmaceutical companies. (Cobuzzi, Tr. 2626-27; 2573). He also testified that there is no typical, one-size-fits-all timeline for performing due diligence on a pharmaceutical collaboration, particularly at Endo. (Cobuzzi, Tr. 2543).

1189. [redacted] (CX1209 at 013-14 (Endo's Final Opportunity Evaluation Worksheet for IPX-203); Cobuzzi, Tr. 2618 (*in camera*); CX5003 at 031 (¶ 49) (Geltosky Report) (freedom to operate analysis is standard practice in the pharmaceutical industry); CX2784 at 048 (Aug. 2009 Endo Business Development Process Orientation document (stating that "FTO, duration of

patent exclusivity and extension" are "[o]ther [c]ritical [o]utputs [e]xpected [f]rom [d]iligence")).

RESPONSE TO FINDING NO. 1189:

Complaint Counsel's Proposed Finding No. 1189 is incomplete. The cited document (CX1209) states that [redacted] (CX1209-013-14 (instructions state "Summarize the IP status")).

1190. Endo also failed to independently conduct an assessment of the strength of the patents covering the product to determine how long those patents might be used to maintain exclusivity. (CX1209 at 013-14 (Endo's Final Opportunity Evaluation Worksheet for IPX-203) (relying on Impax's assessment of which patents cover the product and length of protection). [redacted] Endo should have also conducted a comprehensive review of the patents covering IPX-203 prior to entering the deal. (CX5003 at 031 (¶ 50) (Geltosky Report) (*in camera*)).

RESPONSE TO FINDING NO. 1190:

Respondent has no specific response to the first sentence of Complaint Counsel's Proposed Finding No. 1190. The second sentence of Proposed Finding No. 1190 is based on improper and unreliable expert testimony. Dr. Geltosky has no basis for speculating about what Endo "should have done" in its diligence of IPX-203 and the DCA. Dr. Geltosky has no expertise in—and was not offered as an expert regarding—Endo's strategic business goals, Endo's negotiation strategies, Endo's finances, or Endo's development pipeline, all of which affect what Endo "should do" when performing due diligence. (Geltosky, Tr. 1058). Nor does Dr. Geltosky have experience with more than a "handful" of deals involving a net buyer similar to Endo in size and research and development capability. (Geltosky, Tr. 1143, 1177). Dr.

Cobuzzi, an actual Endo employee, testified that there is no typical, one-size-fits-all procedure for performing due diligence on a pharmaceutical collaboration, particularly at Endo. (Cobuzzi, Tr. 2543).

e) Endo's rushed financial analysis did not provide an accurate valuation of the deal

1191. A financial analysis of a pharmaceutical development business deal is essential to understanding the particular market opportunity and accounting for all of the risks inherent to the transaction. Financial analysis ultimately influences the negotiation of the financial terms of the opportunity, including how upfront and milestone payments are structured. Firms must have enough information about a particular drug to prepare a realistic sales forecast, often relying on market research for this information. (CX5003 at 014 (¶ 23) (Geltosky Report)).

RESPONSE TO FINDING NO. 1191:

Respondent has no specific response.

1192. In the context of a pharmaceutical development deal, a financial analysis provides an estimate of what the particular asset is worth. (Geltosky, Tr. 1080-81). It informs a company about whether or not the deal is profitable and how much to pay for the asset. (Geltosky, Tr. 1081).

RESPONSE TO FINDING NO. 1192:

Respondent has no specific response.

1193. The output of a financial analysis is a net present value (NPV) and internal rate of return (IRR). (Geltosky, Tr. 1082; CX5003 at 014-15 (¶ 24) (Geltosky Report)). An NPV compares the amount invested in an opportunity to the future cash receipts from the investment, discounted by a specified rate of return. (CX5003 at 014-15 (¶ 24) (Geltosky Report)). Typically a positive value of an NPV means that the asset is worthy of investment. (Geltosky, Tr. 1082). The IRR is the rate of return that has to be achieved to break even. (CX5003 at 014-15 (¶ 24) (Geltosky Report)).

RESPONSE TO FINDING NO. 1193:

Complaint Counsel's Proposed Finding No. 1193 is based on improper and unreliable expert opinion. Dr. Geltosky has no expertise in financial analyses, nor was he tendered as an

expert on this topic. (*See* Geltosky, Tr. 1058). Dr. Geltosky has never personally performed a financial analysis, (Geltosky, Tr. 1146, 1179-80), nor does he hold any degrees in finance, accounting, or business, (Geltosky, Tr. 1149). Moreover, Dr. Geltosky admitted that there are numerous approaches to performing financial valuation analyses. (Geltosky, Tr. 1149; CX4042 (Geltosky, Dep. at 135-36)).

1194. NPV and IRR values are used heavily in the pharmaceutical industry to make investment decisions. (CX5003 at 015 (¶ 24) (Geltosky Report); Geltosky, Tr. 1082). It is critical to have high quality and carefully vetted numbers to enter into the analysis. (CX5003 at 015 (¶ 24) (Geltosky Report); CX4031 (Bradley, Dep. at 53-54) (stating that that if the assumptions that went into the valuation were not accurate, "garbage in, garbage out, right?")).

RESPONSE TO FINDING NO. 1194:

Respondent has no specific response.

1195. Firms rely on a number of assumptions and adjustments to prepare realistic NPV and IRR values. (CX5003 at 015 (¶ 24) (Geltosky Report). A thorough financial analysis would include sensitivity analyses and probability adjustments to account for the uncertainties and risks associated with the transaction. (CX5003 at 015 (¶ 24) (Geltosky Report)).

RESPONSE TO FINDING NO. 1195:

Complaint Counsel's Proposed Finding No. 1195 is based on improper and unreliable expert opinion. Dr. Geltosky has no expertise in financial analyses, nor was he tendered as an expert on this topic. (*See* Geltosky, Tr. 1058). Dr. Geltosky has never personally performed a financial analysis, (Geltosky, Tr. 1146, 1179-80), nor does he hold any degrees in finance, accounting, or business, (Geltosky, Tr. 1149). Moreover, Dr. Geltosky admitted that there are numerous approaches to calculating a risk-adjusted internal rate of return, calculating a net present value, and performing financial valuation analyses. (Geltosky, Tr. 1149; CX4042 (Geltosky, Dep. at 135-36) (discussing various approaches for conducting financial analysis of a

pharmaceutical collaboration)). Endo, for its part, would only "sometimes" conduct sensitivity analyses. (CX4031 (Bradley, Dep. at 38, 41)).

1196. A firm will conduct sensitivity analyses of a pharmaceutical asset by considering multiple scenarios involving clinical parameters, such as number of pills for dosing and onset and duration of action. (CX5003 at 015 (¶ 24) (Geltosky Report)). These variables can then be weighted to determine how each scenario affects the financial analysis. (CX5003 at 015 (¶ 24) (Geltosky Report)).

RESPONSE TO FINDING NO. 1196:

Complaint Counsel's Proposed Finding No. 1196 is based on improper and unreliable expert opinion. Dr. Geltosky has no expertise in financial analyses, nor was he tendered as an expert on this topic. (*See* Geltosky, Tr. 1058). Dr. Geltosky has never personally performed a financial analysis, (Geltosky, Tr. 1146, 1179-80), nor does he hold any degrees in finance, accounting, or business, (Geltosky, Tr. 1149). Moreover, Dr. Geltosky admitted that there are numerous approaches to calculating a risk-adjusted internal rate of return, calculating a net present value, and performing financial valuation analyses. (Geltosky, Tr. 1149; CX4042 (Geltosky, Dep. at 135-36) (discussing various approaches for conducting financial analysis of a pharmaceutical collaboration)). Endo, for its part, would only "sometimes" conduct sensitivity analyses. (CX4031 (Bradley, Dep. at 38, 41)).

1197. To make a valuation more closely reflect risks associated with the development of a pharmaceutical product, risk adjusted NPV values are calculated. (CX5003 at 015 (¶24) (Geltosky Report). [redacted] (Geltosky, Tr. 1084; Cobuzzi, Tr. 2620 [redacted] (*in camera*)). Probability adjustments of this type can address the risk that a drug is not developed, does not receive FDA approval, or may launch later than expected. (CX5003 at 015 (¶ 24) (Geltosky Report); Geltosky, Tr. 1082 ("An NPV without taking into consideration the risk of failure in development is really a number that doesn't have a lot of power, a lot of worth to it.")).

RESPONSE TO FINDING NO. 1197:

Complaint Counsel's Proposed Finding No. 1197 is based on improper and unreliable expert opinion. Dr. Geltosky has no expertise in financial analyses, nor was he tendered as an expert on this topic. (*See* Geltosky, Tr. 1058). Dr. Geltosky has never personally performed a financial analysis, (Geltosky, Tr. 1146, 1179-80), nor does he hold any degrees in finance, accounting, or business, (Geltosky, Tr. 1149). Moreover, Dr. Geltosky admitted that there are numerous approaches to calculating a risk-adjusted internal rate of return, calculating a net present value, and performing financial valuation analyses. (Geltosky, Tr. 1149; CX4042 (Geltosky, Dep. at 135-36) (discussing various approaches for conducting financial analysis of a pharmaceutical collaboration)). Finally, Proposed Finding No. 1197 is misleading in its selective quotation of Mr. Cobuzzi, who actually testified, [redacted] (Cobuzzi, Tr. 2620 (emphasis added)).

1198. Similar to industry standards, Endo's own business development processes recognized the importance of conducting a financial analysis of a pharmaceutical product development opportunity. Endo stated that "[c]ritical [o]utputs [e]xpected [f]rom [d]iligence" include forecasting, pricing assumptions, market timing, projected asset valuation, and market share. (CX2784 at 048, 055 (Aug. 2009 Endo Business Development Process Orientation document)).

RESPONSE TO FINDING NO. 1198:

Complaint Counsel's Proposed Finding No. 1198 is inaccurate and unsupported by the cited evidence in its suggestion that Endo had a set "development process." Dr. Cobuzzi testified that this document (CX2784) described procedures he has never seen implemented at Endo, and that they are "ideal state" procedures "almost never" implemented outside the big pharma context. (Cobuzzi, Tr. 2626-27; 2573). He also testified that there is no typical, one-

size-fits-all timeline for performing due diligence on a pharmaceutical collaboration, particularly at Endo. (Cobuzzi, Tr. 2543).

> 1199. The financial analysis conducted by Endo prior to entering into the DCA did not provide an accurate valuation of the deal. (CX5003 at 031 (¶ 51) (Geltosky Report)). Endo used incorrect assumptions in its financial model and did not account for the many risks associated with IPX-203. (CX5003 at 031-32 (¶ 51) (Geltosky Report)). A valuation based on inappropriate assumptions and without any adjustment for risk is not a credible way to assess a $40 million business deal. (CX5003 at 038 (¶ 62) (Geltosky Report)).

RESPONSE TO FINDING NO. 1199:

Complaint Counsel's Proposed Finding No. 1199 should be disregarded because it violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." (*See* Court, Tr. 1859 ("[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.")).

Proposed Finding No. 1199 is also based on improper and unreliable expert opinion. Dr. Geltosky has no expertise in financial analyses, nor was he tendered as an expert on this topic. (*See* Geltosky, Tr. 1058). Dr. Geltosky has never personally performed a financial analysis, (Geltosky, Tr. 1146, 1179-80), nor does he hold any degrees in finance, accounting, or business, (Geltosky, Tr. 1149). Moreover, Dr. Geltosky admitted that there are numerous approaches to calculating a risk-adjusted internal rate of return, calculating a net present value, and performing financial valuation analyses. (Geltosky, Tr. 1149; CX4042 (Geltosky, Dep. at 135-36) (discussing various approaches for conducting financial analysis of a pharmaceutical collaboration)).

Finally, Dr. Cobuzzi, who was responsible for the overall evaluation of the IPX-203 opportunity, testified that Endo did understand the risks associated with IPX-203, and that those risks were accounted for and mitigated in the DCA deal structure. (Cobuzzi, Tr. 2523, 2543; *see*

also Geltosky, Tr. 1136-37 (financial risk to Endo under the DCA was capped)). Moreover, Endo did perform valuation analyses and concluded that they were an "adequate and fair representation of what I would define as a good deal for Endo." (CX2748-001 (June 7, 2010 email from Robert Cobuzzi to Endo management); *see* Cobuzzi, Tr. 2563 (Endo had adequate time and "the information we needed" to evaluate IPX-203)).

> 1200. In May of 2010, when the parties were still discussing IPX-066 as a potential product for a development deal, Endo engaged a consulting firm, the Equinox Group, to provide an abbreviated market analysis. (CX1009 at 005 (May 21, 2010 Rasty/Equinox Group email); Cobuzzi, Tr. 2587 ("[W]e didn't even ask for a fully vetted sales forecast.")).

RESPONSE TO FINDING NO. 1200:

Complaint Counsel's Proposed Finding No. 1200 is inaccurate to the extent it suggests the parties were "discussing IPX-066 as a potential product for a development deal." As Ms. Snowden testified, "Endo was interested in the Parkinson's space and wanted the deal to cover both products, the original IPX-066 and the follow-on product [IPX-203], but Impax wasn't interested in doing the deal on IPX-066. So there wasn't actually . . . a switch as much as Endo was trying to negotiate for both product rights and Impax was only interested in doing product rights on the one product." (Snowden, Tr. 405-06). When Endo proposed a collaboration covering IPX-066 and "all improvements, modifications, derivatives, formulations and line extensions thereof," which would have included IPX-203, Impax immediately rejected the proposal. (CX0502; CX0320). Indeed, the President of Impax's branded drug division, Michael Nestor, testified unequivocally he would never have agreed to such a collaboration. (Nestor, Tr. 2941). Proposed Finding No. 1200 is also inconsistent with the cited evidence. Dr. Cobuzzi testified that he did not remember if Endo received "fully vetted sales forecasts," but that a particular email did not contain that request. (Cobuzzi, Tr. 2587).

1201. Using assumptions from the Equinox analysis, Endo prepared a discounted cash flow and determined NPV values and IRR values for a deal on IPX-066. (CX4031 (Bradley, Dep. at 25, 62, 64, 86-87, 97, 161); CX5003 at 032 (¶ 52) (Geltosky Report)).

RESPONSE TO FINDING NO. 1201:

Respondent has no specific response.

1202. When Impax changed the focus of the DCA from IPX-066 to IPX-203, Endo did not ask Equinox to provide a new market analysis. (Cobuzzi, Tr. 2587-88).

RESPONSE TO FINDING NO. 1202:

Complaint Counsel's Proposed Finding No. 1202 is inaccurate to the extent it suggests the parties were "discussing IPX-066 as a potential product for a development deal." As Ms. Snowden testified, "Endo was interested in the Parkinson's space and wanted the deal to cover both products, the original IPX-066 and the follow-on product [IPX-203], but Impax wasn't interested in doing the deal on IPX-066. So there wasn't actually . . . a switch as much as Endo was trying to negotiate for both product rights and Impax was only interested in doing product rights on the one product." (Snowden, Tr. 405-06). When Endo proposed a collaboration covering IPX-066 and "all improvements, modifications, derivatives, formulations and line extensions thereof," which would have included IPX-203, Impax immediately rejected the proposal. (CX0502; CX0320). Indeed, the President of Impax's branded drug division, Michael Nestor, testified unequivocally he would never have agreed to such a collaboration. (Nestor, Tr. 2941). Proposed Finding No. 1202 is also inconsistent with the cited evidence. Dr. Cobuzzi testified that he did not remember whether Equinox did any work with respect to IPX-203. (Cobuzzi, Tr. 2587-88).

1203. Instead, Endo used almost all of the market assumptions from its analysis of IPX-066 to prepare its financial analysis of IPX-203, and assumed that IPX-203 would launch four years after IPX-066. (CX2772 at 001 (June 6, 2010 Levin email chain) (stating that "IPX066 would be an appropriate proxy from a commercial perspective for the

economics on IPX-203."); CX4031 (Bradley, Dep. at 103) ("As I recall, we leveraged a lot of the information related to the IPX066 valuation in the IPX203 valuation."); CX2533 at 001 (June 5, 2010 McHugh email stating "I think we can hold to the original forecast assumptions with a shift out in the sales line to reflect the 2017 launch versus the 2013 launch with IMPAX-066.")).

RESPONSE TO FINDING NO. 1203:

Respondent has no specific response.

1204. Changing only the launch date of the product and failing to re-evaluate all of the assumptions used in the market analysis was inconsistent with industry standards for preparing financial valuations. (CX5003 at 033 (¶ 53) (Geltosky Report)).

RESPONSE TO FINDING NO. 1204:

Complaint Counsel's Proposed Finding No. 1204 is based on improper and unreliable expert opinion. Dr. Geltosky has no expertise in financial analyses, nor was he tendered as an expert on this topic. (*See* Geltosky, Tr. 1058). Dr. Geltosky has never personally performed a financial analysis, (Geltosky, Tr. 1146, 1179-80), nor does he hold any degrees in finance, accounting, or business, (Geltosky, Tr. 1149). Moreover, Dr. Geltosky admitted that there are numerous approaches to calculating a risk-adjusted internal rate of return, calculating a net present value, and performing financial valuation analyses. (Geltosky, Tr. 1149; CX4042 (Geltosky, Dep. at 135-36) (discussing various approaches for conducting financial analysis of a pharmaceutical collaboration)).

1205. Applying the assumptions for IPX-066 to the financial analysis of IPX-203 was unusual because the two products were at vastly different stages of development. (Geltosky, Tr. 1086). IPX-066 was about to enter Phase III clinical trials and Impax expected the product to launch in 2013. [redacted] (CX5003 at 033 (¶ 53) (Geltosky Report) (*in camera*) ("A lot would happen in the marketplace between the time that IPX-066 was approved and on the market versus when IPX-203 would be on the market, so that...shift in the timeline would have a big effect on the quality of that market research."); (Geltosky, Tr. 1086; CCF ¶¶ 1144, 1147-1148, 1153)).

RESPONSE TO FINDING NO. 1205:

Complaint Counsel's Proposed Finding No. 1205 should be disregarded because it violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." (*See* Court, Tr. 1859 ("[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.")). But Proposed Finding No. 1205 is also inaccurate. Impax also looked to assumptions about IPX-066 when forecasting IPX-203 costs and timing "[b]ecause basically it's coming into exactly the same market. It's coming in with a similar premise -- that is, an improvement, clinical improvement, over immediate-release carbidopa-levodopa -- except in this case a much greater improvement. But the basic structure of the clinical trial programs would be the same." (Nestor, Tr. 2944). Finally, Endo did account for the different stages of development. (CX2533-001 ("we can hold to the original forecast assumptions with a shift out in the sales line to reflect the 2017 launch versus the 2013 launch with IMPAX-066")).

1206. In addition, many of the assumptions related to IPX-066 were improper when applied to IPX-203. (Geltosky, Tr. 1084-85).

RESPONSE TO FINDING NO. 1206:

Complaint Counsel's Proposed Finding No. 1206 should be disregarded because it violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." (*See* Court, Tr. 1859 ("[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.")).

1207. [redacted] (Geltosky, Tr. at 1089 (*in camera*)). [redacted]

[redacted] (Geltosky, Tr. at 1090 (*in camera*); CX5003 at 033-34 (¶ 54) (Geltosky Report) (*in camera*)). [redacted] (Geltosky, Tr. at 1089-90 (*in camera*)). [redacted] (CX4031 (Bradley, Dep. at 116-17); Geltosky, Tr. at 1090 (*in camera*)).

RESPONSE TO FINDING NO. 1207:

Complaint Counsel's Proposed Finding No. 1207 should be disregarded because it violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." (*See* Court, Tr. 1859 ("[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.")). Proposed Finding No. 1207 is also inaccurate and inconsistent with the record to the extent it suggests IPX-203 could not match IPX-066's performance. Mr. Nestor testified that Impax expected IPX-203 to offer a real and significant clinical improvement compared to IPX-066. (Nestor, Tr. 2938-39 ("So we envision IPX-203 being a better product, a much better product than not only immediate-release carbidopa-levodopa but also Rytary")). Endo's diligence team similarly concluded that IPX-203 would be a "greater improvement in disease control and ease of use relative to" IPX-066. (RX-080.0011). That in turn would drive sales. [redacted] (Cobuzzi, Tr. 2536-37).

1208. [redacted] (*Compare* CX1208 at 014) (Endo's Opportunity Evaluation Worksheet for IPX-066) to CX1209 at 016 (Endo's Final Opportunity Evaluation Worksheet for IPX-203) [redacted]). [redacted] CX1209 at 012, 016 (Endo's Final Opportunity Evaluation Worksheet for IPX-203) (*in camera*)).

RESPONSE TO FINDING NO. 1208:

Respondent has no specific response.

1209. Mark Bradley, Endo's Senior Director of Finance, performed the valuation of IPX-203. (CX4031 (Bradley, Dep. at 64, 103). [redacted] (CX4031 (Bradley, Dep. at 84-85); Geltosky, Tr. 1091 [redacted] (*in camera*)). [redacted] (CX5003 at 034 (¶5 5) (Geltosky Report) (*in camera*)).

RESPONSE TO FINDING NO. 1209:

Respondent has no specific response to the first and second sentences of Complaint Counsel's Proposed Finding No. 1209. The third sentence Proposed Finding No. 1209 lacks foundation and is inaccurate. First, Dr. Geltosky did not conduct any valuation analysis of the DCA. (Geltosky, Tr. 1125). Nor has Dr. Geltosky ever performed a financial valuation of a pharmaceutical collaboration. (Geltosky, Tr. 1179-80). Second, Dr. Geltosky's hypothetical comparison of different pill burdens assumes that all else is equal, but the record reflects that all else was *not* equal between IPX-203 and IPX-066, as Impax and Endo expected IPX-203 to offer a real and significant clinical improvement compared to IPX-066. (Nestor, Tr. 2938-39 ("So we envision IPX-203 being a better product, a much better product than not only immediate-release carbidopa-levodopa but also Rytary"); RX-080.0011 (Endo's diligence team concluded that IPX-203 would be a "greater improvement in disease control and ease of use relative to" IPX-066)). That in turn would drive sales. [redacted] (Cobuzzi, Tr. 2536-37).

1210. [redacted]
(*Compare* CX1208 at 014 (Endo's Opportunity Evaluation Worksheet for IPX-066) to CX1209 at 016 (Endo's Final Opportunity Evaluation Worksheet for IPX-203) (*in camera*); Geltosky, Tr. 1091 (*in camera*). [redacted]
(CX2780 at 023 (Impax Powerpoint presentation on IPX-203 [redacted] (*in camera*)). [redacted] (CX5003 at 034 (¶ 54) (Geltosky Report) (*in camera*)).

RESPONSE TO FINDING NO. 1210:

Complaint Counsel's Proposed Finding No. 1210 should be disregarded because it violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." (*See* Court, Tr. 1859 ("[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.")). Proposed Finding No. 1210 is also speculative, lacks foundation, and is inaccurate. Both Endo and Impax appropriately looked to assumptions about IPX-066 when forecasting IPX-203 costs and timing "[b]ecause basically it's coming into exactly the same market. It's coming in with a similar premise -- that is, an improvement, clinical improvement, over immediate-release carbidopa-levodopa -- except in this case a much greater improvement. But the basic structure of the clinical trial programs would be the same." (Nestor, Tr. 2944).

1211. In addition to using inappropriate assumptions in its financial evaluation of IPX-203, Endo also did not account for the considerable scientific, regulatory, and legal risks particular to IPX-203. Failure to account for the risks associated with IPX-203 in the valuation is like "flying blind"--that is, entering into the deal without really understanding its expected value. (Geltosky, Tr. 1084).

RESPONSE TO FINDING NO. 1211:

Complaint Counsel's Proposed Finding No. 1211 should be disregarded because it violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." (*See* Court, Tr. 1859 ("[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert

witness for facts.")). Proposed Finding No. 1211 is also inaccurate. Dr. Cobuzzi, who was responsible for the overall evaluation of the IPX-203 opportunity, testified that Endo did understand the risks associated with IPX-203, and that those risks were accounted for and mitigated in the DCA deal structure. (Cobuzzi, Tr. 2523, 2543; *see also* Geltosky, Tr. 1136-37 (financial risk to Endo under the DCA was capped)). And Endo did perform valuation analyses, which Dr. Cobuzzi concluded were an "adequate and fair representation of what I would define as a good deal for Endo." (CX2748-001 (June 7, 2010 email from Robert Cobuzzi to Endo management); *see* Cobuzzi, Tr. 2563 (Endo had adequate time and "the information we needed" to evaluate IPX-203)).

1212. Similar to the standard practice in the industry, Mr. Bradley, stated that when performing valuations of other business opportunities at Endo, he attempted to account for uncertainty by using sensitivity analyses and probability adjustments. (CX4031 (Bradley, Dep. at 38-39). For these other opportunities, Mr. Bradley created multiple scenarios for the cash flows in the majority of the valuations he performed. (CX4031 (Bradley, Dep. at 39-40, 43). The number of variables would change in each scenario depending on the facts, circumstances, and nature of the particular opportunity. (CX4031 (Bradley, Dep. at 44)).

RESPONSE TO FINDING NO. 1212:

The first sentence of Complaint Counsel's Proposed Finding No. 1212 is not supported by the cited evidence. Mr. Bradley did not testify about sensitivity analyses, probability adjustments, or Endo acting similar to industry standard practice. In fact, he testified that "[j]ust about every" development opportunity contains uncertainty and that there are "[v]arious ways" one can attempt to account for that uncertainty. (CX4031 (Bradley, Dep. at 38-40)). Respondent has no specific response to the second and third sentences of Proposed Finding No. 1212.

1213. Mr. Bradley, however, did not take any steps to account for the risk that IPX-203 would face scientific, regulatory, or market obstacles, when preparing his financial analysis. [redacted]

[redacted] (CX5003 at 035 (¶ 57) (Geltosky Report) (*in camera*)). Although an earlier valuation of IPX-066 included a sensitivity analysis around the discount rate and terminal growth rate to assess the risk that revenues might be lower than anticipated, Mr. Bradley did not include any sensitivity analysis in his final valuation of IPX-203. (CX4031 (Bradley, Dep. at 86-89, 157-58)).

RESPONSE TO FINDING NO. 1213:

The first sentence of Complaint Counsel's Proposed Finding No. 1213 should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2).

The second sentence of Proposed Finding No. 1213 should be disregarded because it violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." (*See* Court, Tr. 1859 ("[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.")).

The third sentence of Proposed Finding No. 1213 is inaccurate and misleading in its attempt to suggest that Endo did not account for risk when assessing the DCA. Mr. Bradley testified that there are "[v]arious ways" one can attempt to account for that uncertainty and that he would only "sometimes" conducts sensitivity analyses. (CX4031 (Bradley, Dep. at 38, 41); *see* Cobuzzi, Tr. 2620 ([redacted])). Dr. Cobuzzi, who was responsible for the overall evaluation of the IPX-203 opportunity, testified that Endo did understand the risks associated with IPX-203, and that those risks were accounted for in the DCA deal structure. (Cobuzzi, Tr. 2523, 2543; *see also* Geltosky, Tr. 1136-37 (financial risk to Endo under the DCA was capped)).

1214. The only variable that Endo considered in its financial analysis of IPX-203 was the length of exclusivity that IPX-203 would enjoy: seven years of exclusivity as the base case; five years of exclusivity in the conservative case; and thirteen years in the optimistic case. (CX4031 (Bradley, Dep. at 159)). But, Endo never accounted for IPX-203 receiving less than five years of exclusivity, meaning that Endo never accounted for a scenario in which Endo did not receive NCE status. (CX4031 (Bradley, Dep. at 121)).

RESPONSE TO FINDING NO. 1214:

Complaint Counsel's Proposed Finding No. 1214 is inaccurate and misleading in its attempt to suggest that Endo did not account for risk when assessing the DCA. Mr. Bradley testified that there are "[v]arious ways" one can attempt to account for that uncertainty. (CX4031 (Bradley, Dep. at 38); *see* Cobuzzi, Tr. 2620 ([redacted])). Dr. Cobuzzi, who was responsible for the overall evaluation of the IPX-203 opportunity, testified that Endo did understand the risks associated with IPX-203, and that those risks were accounted for in the DCA deal structure. (Cobuzzi, Tr. 2523, 2543; *see also* Geltosky, Tr. 1136-37 (financial risk to Endo under the DCA was capped)).

1215. Although he did not take any steps to risk-adjust the IPX-203 opportunity, Mr. Bradley speculated that risks related to the IPX-203 investment could have been accounted for in the assumptions that were provided to him by others. (CX4031 (Bradley, Dep. at 47, 53, 54). But, he could not identify whether any such risk had been included in the assumptions used to evaluate IPX-203. (CX4031 (Bradley, Dep. at 158, 163, 165, 166)). [redacted] (Cobuzzi, Tr. 2620 (*in camera*)). In reviewing the case materials, Dr. Geltosky, an expert in pharmaceutical business development, could not identify how these assumptions were previously adjusted for risk. (CX5003 at 036 (¶ 59) (Geltosky Report)).

RESPONSE TO FINDING NO. 1215:

Complaint Counsel's Proposed Finding No. 1215 is inaccurate and misleading in its attempt to suggest that Endo did not account for risk when assessing the DCA. Mr. Bradley

testified only that he may not have included all risks in one aspect of Endo's valuation modelling. But Dr. Cobuzzi testified [redacted] (Cobuzzi, Tr. 2620). Dr. Cobuzzi, who was responsible for the overall evaluation of the IPX-203 opportunity, also explained that Endo did understand the risks associated with IPX-203, and that those risks were accounted for in the DCA deal structure. (Cobuzzi, Tr. 2523, 2543; *see also* Geltosky, Tr. 1136-37 (financial risk to Endo under the DCA was capped)).

> 1216. Even if the assumptions were previously risk adjusted, these values were pegged to the risks inherent to the IPX-066 opportunity. (CX5003 at 036 (¶ 59) (Geltosky Report)). As the same assumptions for IPX-066 were used for IPX-203, those values did not account for any additional risk associated with IPX-203, a product at a much earlier stage of development. (CX5003 at 036 (¶ 59) (Geltosky Report)).

RESPONSE TO FINDING NO. 1216:

Complaint Counsel's Proposed Finding No. 1216 should be disregarded because it violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." (*See* Court, Tr. 1859 ("[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.")). Proposed Finding No. 1216 is also at odds with the record. Dr. Cobuzzi, who was responsible for the overall evaluation of the IPX-203 opportunity, testified that Endo did understand the risks associated with IPX-203, and that those risks were accounted for in the DCA deal structure. (Cobuzzi, Tr. 2523, 2543; *see also* Geltosky, Tr. 1136-37 (financial risk to Endo under the DCA was capped)).

> 1217. A comprehensive financial analysis of the IPX-203 investment would rely on assumptions particular to the product in question in determining cash flow projections and NPV and IRR values. It would include sensitivity analyses to account for the

uncertainties and risks associated with the early stage IPX-203 opportunity. Using these analyses would help to develop probability adjusted NPV an IRR values to accurately reflect the significant risks associated with IPX-203. (CX5003 at 037 (¶¶ 60-61) (Geltosky Report)).

RESPONSE TO FINDING NO. 1217:

Complaint Counsel's Proposed Finding No. 1217 is inaccurate and based on improper and unreliable expert opinion. Dr. Geltosky has no expertise in financial analyses, nor was he tendered as an expert in this topic. (*See* Geltosky, Tr. 1058). Dr. Geltosky has never personally performed a financial analysis, (Geltosky, Tr. 1146, 1179-80), nor does he hold any degrees in finance, accounting, or business, (Geltosky, Tr. 1149). Moreover, Dr. Geltosky admitted that there are numerous approaches to calculating a risk-adjusted internal rate of return, calculating a net present value, and performing financial valuation analyses. (Geltosky, Tr. 1149; CX4042 (Geltosky, Dep. at 135-36)).

1218. In stark contrast, Endo's financial analysis of the DCA was based on inappropriate assumptions and was not adjusted for the risks associated with an early stage pharmaceutical product like IPX-203. (Geltosky, Tr. 1082-84). Endo's financial analysis was not a credible way to assess $40 million business deal. (CX5003 at 038 (¶ 62) (Geltosky Report)).

RESPONSE TO FINDING NO. 1218:

Complaint Counsel's Proposed Finding No. 1218 should be disregarded because it violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." (*See* Court, Tr. 1859 ("[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts."). Proposed Finding No. 1218 is also at odds with the record and lacks foundation. Dr. Geltosky did not perform any valuation analysis of the DCA or otherwise perform any empirical analysis. (Geltosky, Tr. 1125, 1133). In fact, Dr. Geltosky has never actually performed a financial valuation of any pharmaceutical collaboration. (Geltosky, Tr.

1179-80). Dr. Geltosky consequently has no basis to opine about the accuracy of Endo's valuation analyses, and his opinions are pure speculation. By contrast, Endo did perform valuation analyses and concluded that they were an "adequate and fair representation of what I would define as a good deal for Endo." (CX2748-001 (June 7, 2010 email from Robert Cobuzzi to Endo management); *see* Cobuzzi, Tr. 2563 (Endo had adequate time and "the information we needed" to evaluate IPX-203)).

7. In light of the high risks and uncertainty associated with an early development stage product like IPX-203, the terms of the DCA are not consistent with the usual and expected practice in the industry

1219. Given the high risks and uncertainties associated with an early stage development product such as IPX-203, the terms of the DCA are not consistent with industry standards. (CX5003 at 042 (¶ 71) (Geltosky Report)). The $10 million in upfront payments by Endo to Impax is unusually large and the contingency milestones decrease as development progresses. (*See* CCF ¶¶ 1220-1228**;** CX5003 at 042 (¶ 71) (Geltosky Report)). Some deal terms are ambiguous and do not precisely state the parties' rights. (*See* CCF ¶¶ 1229-1232**;** CX5003 at 042 (¶ 71) (Geltosky Report)). Other terms heavily favor Impax and leave Endo with little opportunity for input despite making a $10 million investment in the project. (*See* CCF ¶¶1233-1245**;** CX5003 at 042 (¶ 71) (Geltosky Report)).

RESPONSE TO FINDING NO. 1219:

Complaint Counsel's Proposed Finding No. 1219 is inaccurate. Dr. Cobuzzi, Endo's head of corporate development and the individual in charge of assessing every collaboration agreement at Endo, testified that the $10 million investment to buy into IPX-203 was not a lot of money for Endo, and that he did not view the payment as unusual, particularly in light of the profit-sharing rights Endo received in return. (Cobuzzi, Tr. 2543, 2559, 2564). The DCA, moreover, is a bundle of rights and burdens. Endo believed several terms were favorable to it and mitigated its risks, including that Endo received profit-sharing rights, did not have to perform any development work, was required to contribute a capped, pre-determined amount to Impax's development work, and was only obligated to pay anything beyond the initial payment

if Impax made demonstrable progress. (Cobuzzi, Tr. 2543, 2558-59, 2627-28). This left Endo "comfortable" with the collaboration. (Cobuzzi, Tr. 2543-44). Dr. Geltosky, for his part, did not offer any opinion on whether the DCA's bundle of rights and burdens favored Impax or Endo, (Geltosky, Tr. 1137-38), or whether Endo exercised sound business judgment in entering into the DCA, (Geltosky, Tr. 1126).

a) The payment terms of the DCA are unusual

1220. Endo's $10 million upfront payment was unusually large given the early stage of development of IPX-203 and the fairly small market the product was intended to address. (Geltosky, Tr. 1073, 1100 [redacted] (*in camera*); CX5003 at 043 (¶ 72) (Geltosky Report)). Upfront payments typically reflect the value of work done on the project to date. CX5003 at 43 (¶ 72) (Geltosky Report). [redacted] (CX5003 at 027-28 (¶¶ 41-42) (Geltosky Report)).

RESPONSE TO FINDING NO. 1220:

Complaint Counsel's Proposed Finding No. 1220 should be disregarded because it violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." (*See* Court, Tr. 1859 ("[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.")). But Proposed Finding No. 1220 is also inaccurate. Dr. Cobuzzi, Endo's head of corporate development and the individual in charge of assessing every collaboration agreement at Endo, testified that the $10 million investment to buy into IPX-203 was not a lot of money for Endo. (Cobuzzi, Tr. 2543, 2559, 2564). Compared to other collaboration agreements, Endo's $10 million payment was "not an uncharacteristically large amount of money." (Cobuzzi, Tr. 2559; *see also* Nestor, Tr. 3052-53 (had Impax waited until it had

performed additional development work on IPX-203 to seek a partner, Impax likely would not have been able to fund the development of IPX-203)).

Dr. Geltosky did not conduct any valuation analysis of the DCA or estimate the net present value of the DCA at the time it was executed. (Geltosky, Tr. 1125). And he did not address whether Endo's profit-sharing rights justified its DCA payment obligations. (Geltosky, Tr. 1124). Endo's diligence team, by comparison, concluded that IPX-203 would be a "greater improvement in disease control and ease of use relative to" other drugs. (RX-080.0011). It also determined that the DCA and IPX-203 had a "good" and "very reasonable rate of return" [redacted] (Cobuzzi, Tr. 2560). [redacted] (Cobuzzi, Tr. 2536-37). For this reason, Endo viewed the DCA payment obligations as justified. (Cobuzzi, Tr. 2564).

> 1221. Endo's $10 million upfront payment to Impax represented 25% of the deal's $40 million precommercialization milestones, a very high percentage for an early stage molecule. (Geltosky, Tr. 1073). Based on Dr. Geltosky's 35 plus years of experience in the pharmaceutical industry, he would expect to see upfront payments reflecting 5% to 10% of the total deal value for an early stage compound like IPX-203. (Geltosky, Tr. 1073).

RESPONSE TO FINDING NO. 1221:

Complaint Counsel's Proposed Finding No. 1221 is inaccurate and is based on unreliable expert testimony. Dr. Geltosky points to the risk associated with discovery-stage development as the primary reason he believes the DCA payment structure was unusual. (Geltosky, Tr. 1073). But Dr. Geltosky has virtually no experience with discovery-stage development deals like the DCA. (Geltosky, Tr. 1144-45 (only a "handful" of deals involving a discovery-stage asset)). And Dr. Geltosky did not compare the DCA with any other discovery-stage development

agreements, or quantify any purported risk. (Geltosky, Tr. 1140-41, 1147). Moreover, Dr. Geltosky's report hardly mentions Impax at all, and he offers no opinions about Impax's practices, procedures, or intent. (*See generally* CX5003 (Geltosky Rep.); Geltosky, Tr. 1129 (noting Dr. Geltosky had not met or spoken to any Impax employees); Geltosky, Tr. 1183 (testifying that his criticisms do not apply "to anything that Impax did")). The Proposed Finding is also inconsistent with Dr. Cobuzzi's testimony that Endo's $10 million payment was "not an uncharacteristically large amount of money." (Cobuzzi, Tr. 2543).

> 1222. Ten million dollars is a meaningful amount of money for a large or small size pharmaceutical company. (Geltosky, Tr. 1073-74). In addition to coming out of the company's budget, the $10 million represents an opportunity cost that firms must consider. (Geltosky, Tr. 1073-75). The $10 million could be spent or invested in a number of ways. (Geltosky, Tr. 1075).

RESPONSE TO FINDING NO. 1222:

Respondent has no specific response other than to note that Endo did not believe $10 million was a lot of money. (Cobuzzi, Tr. 2559, 2564). Compared to other collaboration agreements, Endo's $10 million payment was "not an uncharacteristically large amount of money." (Cobuzzi, Tr. 2559).

> 1223. The basic structure of the DCA is not consistent with industry norms for an early stage development deal, because the payment terms are "front-loaded." (Geltosky, Tr. 1072) (stating that structuring of the milestone payments in the DCA is "the exact opposite of the way agreements like this are structured."). In a front-loaded deal, a significant amount of money is put at risk at the very earliest stages of the development program. (Geltosky, Tr. 1072). Endo front-loaded its payments to Impax, providing $10 million in nonrefundable upfront payments. (Geltosky, Tr. 1072).

RESPONSE TO FINDING NO. 1223:

Complaint Counsel's Proposed Finding No. 1223 is inaccurate and is based on unreliable expert testimony. Dr. Geltosky points to the risk associated with discovery-stage development as the primary reason he believes the DCA payment structure was unusual. (Geltosky, Tr. 1073).

But Dr. Geltosky has virtually no experience with discovery-stage development deals like the DCA. (Geltosky, Tr. 1144-45 (only a "handful" of deals involving a discovery-stage asset)). And Dr. Geltosky did not compare the DCA with any other discovery-stage development agreements, or quantify any purported risk. (Geltosky, Tr. 1140-41, 1147). Moreover, Dr. Geltosky's report hardly mentions Impax at all, and he offers no opinions about Impax's practices, procedures, or intent. (*See generally* CX5003 (Geltosky Rep.); Geltosky, Tr. 1129 (noting Dr. Geltosky had not met or spoken to any Impax employees); Geltosky, Tr. 1183 (testifying that his criticisms do not apply "to anything that Impax did")). The Proposed Finding is also inconsistent with Dr. Cobuzzi's testimony that Endo's $10 million payment was not usual or an "uncharacteristically large amount of money." (Cobuzzi, Tr. 2543-44).

> 1224. Typically, firms looking to acquire an early stage asset would much prefer to "backload" payments because of the unpredictability inherent in an early stage program. (CX5003 at 043-44 (¶ 74) (Geltosky Report); (Geltosky, Tr. 1075-76). Contingency milestone payments are a way for firms in the pharmaceutical industry to achieve this goal. (CX5003 at 043-44 (¶ 74) (Geltosky Report). Contingency milestone payments assure that payments are tied to achieving tangible and identifiable goals on the project. (CX5003 at 043-44 (¶ 74) (Geltosky Report); Geltosky, Tr. 1074).
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> **RESPONSE TO FINDING NO. 1224:**

Complaint Counsel's Proposed Finding No. 1224 is inaccurate and is based on unreliable expert testimony. Dr. Geltosky has virtually no experience with discovery-stage development deals like the DCA. (Geltosky, Tr. 1144-45 (only a "handful" of deals involving a discovery-stage asset)). And Dr. Geltosky acknowledged that he cannot speak to how the universe of mid-sized pharmaceutical companies approach partnerships for discovery-stage products. (Geltosky, Tr. 1177). Dr. Geltosky did not even compare the DCA with any other discovery-stage development agreements. (Geltosky, Tr. 1140-41, 1147). By contrast, Endo regularly enters "very early, very speculative agreements" for promising drugs. (Cobuzzi, Tr. 2516). Dr.

Cobuzzi testified that Endo's $10 million payment was not usual or an "uncharacteristically large amount of money." (Cobuzzi, Tr. 2543-44). And Endo viewed the DCA payment structure as mitigating the risks associated with IPX-203's early stage of development, with Impax bearing most of the risk. (CX1209-003 ([redacted] (emphasis added)); Cobuzzi, Tr. 2543-44).

1225. Contingency milestone payments typically increase as development of the product proceeds. (CX5003 at 045 (¶ 76) (Geltosky Report); Geltosky, Tr. 1074-75). Increasing contingent payments reflects the idea that every step forward in development reduces the overall risk and therefore creates value, which is reflected in the magnitude of the milestone. (CX5003 at 045 (¶ 76) (Geltosky Report); Geltosky, Tr. 1072 ("[T]he milestone payments actually, in every agreement that I've ever seen, increase as risk is taken out of the program. Value is created. The originator then is sort of rewarded with a larger milestone payment reflecting that increased value by taking risk out.")).

RESPONSE TO FINDING NO. 1225:

Complaint Counsel's Proposed Finding No. 1225 is inaccurate and is based on unreliable expert testimony. Dr. Geltosky has virtually no experience with discovery-stage development deals like the DCA. (Geltosky, Tr. 1144-45 (only a "handful" of deals involving a discovery-stage asset)). And Dr. Geltosky acknowledged that he cannot speak to how the universe of mid-sized pharmaceutical companies approach partnerships for discovery-stage products. (Geltosky, Tr. 1177). Dr. Geltosky did not even compare the DCA with any other discovery-stage development agreements. (Geltosky, Tr. 1140-41, 1147). By contrast, Endo regularly enters "very early, very speculative agreements" for promising drugs. (Cobuzzi, Tr. 2516). And Endo viewed the DCA payment structure as mitigating the risks associated with IPX-203's early stage of development, with Impax bearing most of the risk. (CX1209-003 ([redacted] (emphasis added)); Cobuzzi, Tr. 2543-44).

1226. The DCA contained up to $30 million in milestone payments contingent upon the development and forecasted sales of IPX-203. (RX-365 at 0009 (DCA, §§3.2, 3.3 ("Milestone Fees," "Forecast Net Sales")). But, the magnitude of the development contingent milestone payments in the DCA decreased as IPX-203 moved closer to FDA approval: $10 million for successful completion of Phase II, $5 million for successful completion of Phase III, $2.5 million for NDA acceptance, $2.5 million for FDA approval. (RX-365 at 0009 (DCA, §3.2 ("Milestone Fees"). Structuring the contingency milestone payments in the DCA to decrease as development of IPX-203 progresses is unusual and does not reflect industry standards. (CX5003 at 045 (¶ 77) (Geltosky Report)).

RESPONSE TO FINDING NO. 1226:

Respondent has no specific response to the first and second sentences of Complaint Counsel's Proposed Finding No. 1226. The third sentence of Proposed Finding No. 1226 is inaccurate and is based on unreliable expert testimony. Dr. Geltosky has virtually no experience with discovery-stage development deals like the DCA. (Geltosky, Tr. 1144-45 (only a "handful" of deals involving a discovery-stage asset)). And Dr. Geltosky acknowledged that he cannot speak to how the universe of mid-sized pharmaceutical companies approach partnerships for discovery-stage products. (Geltosky, Tr. 1177). Dr. Geltosky did not even compare the DCA with any other discovery-stage development agreements. (Geltosky, Tr. 1140-41, 1147). By contrast, Endo regularly enters "very early, very speculative agreements" for promising drugs. (Cobuzzi, Tr. 2516). And Endo viewed the DCA payment structure as mitigating the risks associated with IPX-203's early stage of development, with Impax bearing most of the risk. (CX1209-003 ([redacted] (emphasis added)); Cobuzzi, Tr. 2543-44).

1227. Firms frequently mitigate the risks inherent in a particular transaction by structuring the deal as an option agreement. (CX5003 at 044 (¶ 75) (Geltosky Report); Geltosky, Tr. 1076 (stating that option agreements are "a great risk mitigator. You're not putting a lot of money at risk until you see something that convinces you it has a higher probability of success")). An exclusive option agreement is one where the potential licensee or partner usually pays the other party a nominal sum to hold the asset (not shop it to other potential acquirers) for a given period of time while the licensee decides on

whether or not to proceed with a full licensing or a co-development/co-promotion transaction. (CX5003 at 044 (¶ 75) (Geltosky Report); Geltosky, Tr. 1076).

RESPONSE TO FINDING NO. 1227:

Respondent has no specific response.

1228. Endo was aware of specific risks posed by the IPX-203 opportunity. CX1209 at 007-009 (Endo's Final Opportunity Evaluation Worksheet for IPX-203) (noting possible development, manufacturing, toxicology, and regulatory issues associated with IPX-203). Under an option agreement arrangement, Endo could have negotiated the right to pursue IPX-203 at some time in the future, after Impax collected more data on the drug without giving Impax $10 million upfront. (CX5003 at 044 (¶ 75) (Geltosky Report). Endo specifically recognized the use of an option agreement in other early-phase deals. (CX3170 at 003, 04 (May 28, 2008 Rasty/Bingol email attaching OEW for Project Nevada)). [redacted] (Nestor, Tr. 2974-75 (*in camera*)). However, Endo took no steps to structure the DCA in a way that would mitigate the risks particular to the IPX-203, instead guaranteeing Impax $10 million on unconditional terms. (CX5003 at 044-45 (¶ 75) (Geltosky Report).

RESPONSE TO FINDING NO. 1228:

The first sentence of Proposed Finding No. 1228 is incomplete and misleading. Dr. Cobuzzi testified that while "every drug that is developed has inherent risk in the development program," IPX-203 had a "risk profile that [Endo] understood, which I think is the best that we could ask for a drug in development." (Cobuzzi, Tr. 2553). For this reason Endo actually thought IPX-203 "had the opportunity to move very quickly through development," (CX4017 (Levin, Dep. at 166-67)), and that there was [redacted] (Cobuzzi, Tr. 2537-38).

The second and fifth sentences of Proposed Finding No. 1228 lack foundation and are not supported by the record. Dr. Geltosky was not tendered to offer opinions on possible alternative DCA structures Endo could have pursued. (*See* Geltosky, Tr. 1058). An option structure,

moreover, was not viable for Impax given its difficulty funding IPX-203; had it waited until later in development to receive funding, it likely would not have been able to pursue IPX-203 at all. (Nestor, Tr. 3052-53).

Respondent has no specific response to the third sentence of Proposed Finding No. 1228. The fourth sentence of Proposed Finding No. 1228 is incomplete and misleading to the extent it attempts to draw a comparison between the payment terms in the DCA and those in Impax's agreement with Glaxo. [redacted] (Nestor, Tr. 2974-76; CX3441-009-10). By comparison, the DCA did not require Endo to perform any development work, or provide any funding beyond the specific amounts listed. (Cobuzzi, Tr. 2543; Geltosky, Tr. 1136-37). Deals in which Endo must perform development work itself and does not know its maximum development costs up front "hurt [Endo] from an accounting standpoint as well as from a risk standpoint." (Cobuzzi, Tr. 2629).

b) The DCA contains ambiguous terms

1229. The DCA contains a number of ambiguous terms. (*See* CCF ¶¶ 1230-1232).

RESPONSE TO FINDING NO. 1229:

The proposed summary finding should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Moreover, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondent's replies to those findings.

1230. The language defining "Successful Completion" in relation to Phase II clinical trials allows Impax to proceed into Phase III testing even if there is disagreement among the parties around the outcome of the Phase II study. (RX-365 at 0007 (DCA, §1) (definition of "Successful Completion" with respect to Phase II clinical trials). The DCA is unclear as to whether Endo would be required to make the $10 million milestone payment in that case and the subsequent milestones if development were to continue only at Impax's discretion. (CX5003 at 046 (¶ 78) (Geltosky Report)).

RESPONSE TO FINDING NO. 1230:

Respondent has no specific response to the first sentence of Complaint Counsel's Proposed Finding No. 1230. The second sentence of Proposed Finding No. 1230 is based on improper expert opinion. Dr. Geltosky has no expertise in contract interpretation, nor has he been tendered to offer opinions regarding the interpretation of pharmaceutical agreement terms or the DCA's terms specifically. (*See* Geltosky, Tr. 1058).

1231. Under the DCA, Impax was responsible for development of IPX-203, but Endo would be involved in this effort through participation in quarterly Joint Development Committee ("JDC") meetings. (RX-365 at 0016 (DCA §§ 7.2, 7.3 ("Meetings," "Responsibilities")). It is typical for a partnership of this type to attach a "development plan" to the agreement, carefully laying out steps required to secure FDA approval, a timeline of events, and expectations and standards for developing the product. (CX5003 at 046 (¶ 79) (Geltosky Report)). Carefully defined performance criteria would be established at the outset of the program to guide decisions on whether or not to continue development. (CX5003 at 046 (¶ 79) (Geltosky Report)). The DCA fails to outline future product development activities and it does not appear that Impax and Endo discussed the details of, or a timeline for, the development of IPX-203 either before or after signing the Agreement. (CX5003 at 046 (¶ 79) (Geltosky Report); (CX3165 at 001 (Nov. 17, 2014 Paterson/Gupta email chain) (noting that no JDC meetings were held between the parties)).

RESPONSE TO FINDING NO. 1231:

Complaint Counsel's Proposed Finding No. 1231 is misleading, incomplete, and based on unreliable expert testimony. Dr. Geltosky has virtually no experience with discovery-stage development deals like the DCA. (Geltosky, Tr. 1144-45 (only a "handful" of deals involving a discovery-stage asset)). And Dr. Geltosky acknowledged that he cannot speak to how the universe of mid-sized pharmaceutical companies approach partnerships for discovery-stage

products. (Geltosky, Tr. 1177). Dr. Geltosky did not even compare the DCA with any other discovery-stage development agreements. (Geltosky, Tr. 1140-41, 1147).

The record, moreover, reflects that the DCA joint development committee meetings were intended to be "[e]ssentially a progress report on clinical development by Impax." (CX3345-006). Michael Nestor, the president of Impax's brand division, testified that [redacted] (Nestor, Tr. 2967-69). Indeed, Impax "had to make sure we had a formulation first and that we were ready to go into the clinic" before meetings of the joint development committee "would be relevant." (CX4033 (Nestor, Dep. at 164); *see* Nestor, Tr. 2967-68). Once Impax's formulation work had reached that point, it did in fact meet with Endo regarding the status of Impax's IPX-203 development work. (Nestor, Tr. 2963-64, 2967; CX4033 (Nestor, Dep. at 164)).

> 1232. The DCA also does not refer to "IPX-203", Impax's code name for the subject product of the deal. In the DCA, the product is defined as "an extended release, orally administered product containing a combination of levodopa-ester and carbidopa, as described in the first investigational new drug application and, after submission, the NDA for such product filed by Impax in the Territory after the Effective Date." (RX-365 at 0006 (DCA, § 1) (definition of "Product"). Most development agreements of this type would clearly identify the code name of the product in question in the actual agreement to avoid any confusion. (CX5003 at 046 (¶ 77) (Geltosky Report)).

RESPONSE TO FINDING NO. 1232:

Respondent has no specific response to the first and second sentences of Complaint Counsel's Proposed Finding No. 1232. The third sentence of Proposed Finding No. 1232 is based on unreliable expert testimony. Dr. Geltosky has virtually no experience with discovery-stage development deals like the DCA. (Geltosky, Tr. 1144-45 (only a "handful" of deals involving a discovery-stage asset)). And Dr. Geltosky acknowledged that he cannot speak to how the universe of mid-sized pharmaceutical companies approach partnerships for discovery-

stage products. (Geltosky, Tr. 1177). Dr. Geltosky did not even compare the DCA with any other discovery-stage development agreements. (Geltosky, Tr. 1140-41, 1147).

c) The Sales Milestone trigger, non-compete term, and termination term limit Endo's rights and are more favorable to Impax

1233. In addition to some terms being ambiguous, other terms of the DCA favor Impax, leaving Endo with little opportunity for input, despite making a $10 million upfront investment in the project. (*See* CCF ¶¶ 1234-1245).

RESPONSE TO FINDING NO. 1233:

The proposed summary finding should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Moreover, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondent's replies to those findings.

1234. The DCA contains a "Sales Milestone" trigger, based on a sales forecast created by an outside group. (RX-365 at 0009 (DCA §3.3 ("Forecast Net Sales"))). Should the sales forecast exceed $175 million for any of the first seven years after launch, then Endo would pay Impax an additional $10 million. (RX-365 at 0009 (DCA §3.3 ("Forecast Net Sales"))). The sales forecast would be made available to the parties within thirty days of FDA approval of IPX-203. (RX-365 at 0009 (DCA §3.3 ("Forecast Net Sales"))). The use of a forecast rather than actual sales figures is an atypical way to establish a milestone in this context. (CX5003 at 047 (¶ 80) (Geltosky Report). The typical way to structure this section of the agreement is to tie the payments to actual sales, either through royalty payments or sales-based milestone payments. (CX5003 at 047 (¶ 80) (Geltosky Report).

RESPONSE TO FINDING NO. 1234:

Respondent has no specific response to the first, second, and third sentences of Complaint Counsel's Proposed Finding No. 1234. The fourth and fifth sentences of Proposed Finding No. 1234 are inaccurate and based on unreliable expert testimony. Dr. Geltosky has virtually no experience with discovery-stage development deals like the DCA. (Geltosky, Tr.

1144-45 (only a "handful" of deals involving a discovery-stage asset)). And Dr. Geltosky acknowledged that he cannot speak to how the universe of mid-sized pharmaceutical companies approach partnerships for discovery-stage products. (Geltosky, Tr. 1177). Dr. Geltosky did not even compare the DCA with any other discovery-stage development agreements. (Geltosky, Tr. 1140-41, 1147).

> 1235. The DCA also does not expressly state whether Endo has the right to co-promote IPX-203 if the sales forecast is less than $175 million or how much time after receiving the forecast Endo would have to decide whether to co-promote IPX-203. (CX5003 at 47 (¶ 81) (Geltosky Report); RX-365 at 0009 (DCA §3.3 ("Forecast Net Sales"))). The DCA does not contain any language addressing Endo's right to appeal the forecast. (CX5003 at 047 (¶ 81) (Geltosky Report); RX-365 at 0009 (DCA §3.3 ("Forecast Net Sales"))). The sales forecast term disfavors Endo because it gives very little time to prepare to promote IPX-203. (CX5003 at 047 (¶ 81) (Geltosky Report)). Considerable time is required to prepare marketing materials for and train a sales force for launch. (CX5003 at 047 (¶ 81) (Geltosky Report)). As pre-launch activities are expensive and labor intensive, Endo is at a further disadvantage, as it may not wish to engage in these activities until it sees and evaluates the forecast. (CX5003 at 047-48 (¶ 81) (Geltosky Report)).
>
> **RESPONSE TO FINDING NO. 1235:**

Complaint Counsel's Proposed Finding No. 1235 should be disregarded because it violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." Proposed Finding No. 1239 is also based on improper expert opinion. Dr. Geltosky has no expertise in contract interpretation, nor has he been tendered to offer opinions regarding the interpretation of pharmaceutical agreement terms generally or the DCA's terms specifically. (*See* Geltosky, Tr. 1058). Moreover, the DCA is a bundle of rights and burdens that must be considered together as a whole. (Noll, Tr. 1645-46). Yet Dr. Geltosky did not offer any opinion on whether the DCA's bundle of rights and burdens favored Impax or Endo, (Geltosky, Tr. 1137-38), or whether Endo exercised sound business judgment in entering into the DCA, (Geltosky, Tr. 1126).

1236. Other unusual terms of the DCA relate to Impax's marketing of competing products. (RX-365 at 0023 (DCA § 12 ("Noncompete"))). Under the agreement, Impax and Endo are intended to be partners in co-promoting IPX-203. (RX-365 at X (DCA § 2.1 "Co-Promotion Rights")). But the agreement does not prohibit Impax from competing with IPX-066. (RX-365 at 0023 (DCA § 12.1 ("Noncompete"))). [redacted] (RX-365 at 0023 (DCA § 12 ("Noncompete")); CX5003 at 048-49 (¶ 82) (Geltosky Report)); (Geltosky, Tr. 1113-14) (*in camera*).

RESPONSE TO FINDING NO. 1236:

While Respondent does not dispute that Impax and Endo intended to co-promote IPX-203, the remainder of Complaint Counsel's Proposed Finding No. 1236 is an improper legal conclusion. The Proposed Finding, moreover, ignores the fact that Impax planned to limit the ability of IPX-066 to compete with IPX-203 by "pull[ing] all promotion, all sampling from Rytary" and "devot[ing] all of our sales force attention, all of our marketing attention, all of our sampling attention to IPX-203, to build the demand for IPX-203 *and allow Rytary to have its natural decline*." (Nestor, Tr. 2937 (emphasis added)). Mr. Nestor explained IPX-203's commercial success was "very important in terms of ensuring that [Impax's brand division] had a longer term business foundation established." (Nestor, Tr. 2939; *see* Cobuzzi, Tr. 2536-37, 2622-23 ([redacted])).

1237. [redacted] (Nestor, Tr. 2935-36; *Compare* CX1208 at 003 (Opportunity Evaluation Worksheet for IPX-066) to CX1209 at 003 (Endo's Final Opportunity Evaluation Worksheet for IPX-203) (*in camera*)). Endo knew Impax was planning to launch IPX-066 well before IPX-203, in 2012. (CX1208 at 007-08 (Opportunity Evaluation Worksheet for IPX-066)). [redacted] (Geltosky, Tr. 1114 (*in camera*)).

RESPONSE TO FINDING NO. 1237:

While Respondent does not dispute that IPX-066 and IPX-203 would both treat Parkinson's disease, or that Endo knew IPX-066 would likely launch before IPX-203, the

remainder of Complaint Counsel's Proposed Finding No. 1237 is incomplete, inaccurate, and misleading. Mr. Nestor testified that Impax expected IPX-203 to offer a real and significant clinical improvement compared to IPX-066. (Nestor, Tr. 2938-39 ("So we envision IPX-203 being a better product, a much better product than not only immediate-release carbidopa-levodopa but also Rytary")). For that reason, Impax planned to limit the ability of IPX-066 to compete with IPX-203 by "pulling all promotion, all sampling from Rytary" and "devot[ing] all of our sales force attention, all of our marketing attention, all of our sampling attention to IPX-203, to build the demand for IPX-203 *and allow Rytary to have its natural decline*." (Nestor, Tr. 2937 (emphasis added)). Mr. Nestor explained IPX-203's commercial success was "very important in terms of ensuring that [Impax's brand division] had a longer term business foundation established." (Nestor, Tr. 2939; *see* Cobuzzi, Tr. 2536-37, 2622-23 ([redacted])).

1238. The DCA limited Impax to promoting IPX-203 to neurologists. (RX-365 at 0005 (DCA § 1) (definition of "Impax Audience")). However, there was no apparent restriction on Impax's ability to promote IPX-066 to Endo's target audience (non-neurologists). (RX-365 at 0023 (DCA § 12.1 ("Noncompete"))). In the event that issues over supply, distribution, or pricing of IPX-203 arise, Impax could have favored its own wholly-owned product, IPX-066. (CX5003 at 048 (¶ 82) (Geltosky Report)).

RESPONSE TO FINDING NO. 1238:

Respondent has no specific response to the first sentence of Proposed Finding No. 1238. The second sentence of Proposed Finding No. 1238 is an improper legal conclusion, not a fact. The third sentence of Proposed Finding No. 1238 should be disregarded because it violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." The third sentence also ignores the record, which is clear that Impax planned to limit the ability of IPX-066 to compete with IPX-203 by "pulling all promotion, all sampling from Rytary" and "devot[ing] all of our sales force

attention, all of our marketing attention, all of our sampling attention to IPX-203, to build the demand for IPX-203 *and allow Rytary to have its natural decline*." (Nestor, Tr. 2937 (emphasis added)). Mr. Nestor explained IPX-203's commercial success was "very important in terms of ensuring that [Impax's brand division] had a longer term business foundation established." (Nestor, Tr. 2939; *see* Cobuzzi, Tr. 2536-37, 2622-23 ([redacted])).

> 1239. Under the DCA, Impax held control over all aspects of the development and commercialization of IPX-203. (RX-365 at 0002 (DCA, "Recitals") ("Impax has the exclusive right to develop, market, promote and sell the Product"). Acceding this degree of control to Impax, without any other obligations to develop IPX-203, put Endo at a competitive disadvantage. (CX5003 at 048 (¶ 82) (Geltosky Report)).

RESPONSE TO FINDING NO. 1239:

Respondent has no specific response to the first sentence of Complaint Counsel's Proposed Finding No. 1239. The second sentence of Proposed Finding No. 1239 should be disregarded because it violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." Proposed Finding No. 1239 is also based on improper expert opinion. Dr. Geltosky has no expertise in contract interpretation, nor has he been tendered to offer opinions regarding the interpretation of pharmaceutical agreement terms generally or the DCA's terms specifically. (*See* Geltosky, Tr. 1058). Finally, Proposed Finding No. 1239 ignores the record, which reflects that it has long been Impax's "strategy to continue to grow and extend the duration of our Parkinson's franchise." (Reasons, Tr. 1238 (noting also that IPX-203 is Impax's "lead compound on the brand side"); *see* Nestor, Tr. 2935-37 (Impax long planned to withdraw promotion and sampling of IPX-066 once IPX-203 reached the market to ensure Impax's sales force could focus on IPX-203 and extend Impax's Parkinson's franchise)).

1240. Endo should have included terms in the DCA giving it some control over the development and production of IPX-203 or terms that provided some assurance against Impax favoring IPX-066. (CX5003 at 048-49 (¶ 82) (Geltosky Report)). Endo could have demanded that Impax refrain from detailing IPX-066 to non-neurologists when IPX-203 was approved, or after a 6–12 month period to allow Impax to wind down IPX-066 promotional activities to that audience. (CX5003 at 048-49 (¶ 82) (Geltosky Report)). Such a provision could have helped pave the way for a successful IPX-203 launch. (CX5003 at 048-49 (¶ 82) (Geltosky Report)). Alternatively, because IPX-203 appears to have been conceived as a follow-on to IPX-066, the Agreement could have specified that Impax withdraw IPX-066 after launching IPX-203. (CX5003 at 048-49 (¶ 82) (Geltosky Report)).

RESPONSE TO FINDING NO. 1240:

Complaint Counsel's Proposed Finding No. 1240 should be disregarded because it violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." Proposed Finding No. 1240 is also based on improper expert opinion. Dr. Geltosky has not been tendered to offer opinions on possible alternative DCA terms Endo could have pursued. (*See* Geltosky, Tr. 1058). (*See* Geltosky, Tr. 1058). Finally, Proposed Finding No. 1240 ignores the record, which reflects that it has long been Impax's "strategy to continue to grow and extend the duration of our Parkinson's franchise," (Reasons, Tr. 1238 (noting also that IPX-203 is Impax's "lead compound on the brand side")), in part by withdrawing promotion and sampling of IPX-066 once IPX-203 reached the market, ensuring Impax's sales force could focus on IPX-203, (Nestor, Tr. 2935-37).

1241. The termination language used in the DCA was unusual and appears to have favored Impax. (RX-365 at 0023 (DCA §13 ("Term and Termination"))). The DCA states that Endo cannot terminate the Agreement before the completion of Phase III studies, unless Impax breaches any representations, warranties, and obligations set forth in the agreement. (RX-365 at 0023 (DCA §13.2(c) ("Termination by Endo"))). But, the DCA does not contain any "reasonable commercial efforts" or "best efforts" language in this section or in the entire Agreement as applied to Impax's development of the product. (RX-365 at 0023 (DCA §13.2(c) ("Termination by Endo"))); (CX5003 at 049 (¶ 83) (Geltosky Report)).

RESPONSE TO FINDING NO. 1241:

While Respondent does not dispute that certain terms are included (or not) in the DCA—the agreement speaks for itself—the cited evidence does not support the proposition that any term favored any party. Dr. Geltosky has no expertise in contract interpretation, nor has he been tendered to offer opinions regarding the interpretation of pharmaceutical agreement terms generally or the DCA's terms specifically. (*See* Geltosky, Tr. 1058).

Moreover, the DCA is a bundle of rights and burdens that must be considered together as a whole. (Noll, Tr. 1645-46). Yet Dr. Geltosky did not offer any opinion on whether the DCA's bundle of rights and burdens favored Impax or Endo, (Geltosky, Tr. 1137-38), or whether Endo exercised sound business judgment in entering into the DCA, (Geltosky, Tr. 1126).

1242. Absent "reasonable commercial efforts" or "best efforts" language, Impax was not committed to take any steps towards developing IPX-203. (CX5003 at 049 (¶ 83) (Geltosky Report)). Impax could accept the $10 million from Endo and decide not to invest any more resources into IPX-203. (CX5003 at 049 (¶ 83) (Geltosky Report)).

RESPONSE TO FINDING NO. 1242:

Complaint Counsel's Proposed Finding No. 1242 should be disregarded because it violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." Proposed Finding No. 1242 is also based on improper expert opinion. Dr. Geltosky has no expertise in contract interpretation, nor has he been tendered to offer opinions regarding the interpretation of pharmaceutical agreement terms generally or the DCA's terms specifically. (*See* Geltosky, Tr. 1058). Finally, Proposed Finding No. 1242 ignores the record, which reflects that it has long been Impax's "strategy to continue to grow and extend the duration of our Parkinson's franchise." (Reasons, Tr. 1238 (noting also that IPX-203 is Impax's "lead compound on the brand side"); *see* Nestor, Tr. 2935-37).

1243. Language regarding "reasonable commercial efforts" or "best efforts" is standard in most pharmaceutical agreements and is important to have in the event of a breach in responsibilities. (CX5003 at 049 (¶ 83) (Geltosky Report)).

RESPONSE TO FINDING NO. 1243:

Respondent has no specific response.

1244. Without such language, Endo had no ability to terminate the DCA if the data derived from Phase I and Phase II studies did not meet Endo's expectations. (CX5003 at 049 (¶ 83) (Geltosky Report)). The ability to terminate was particularly relevant in the case of IPX-203, as the pharmacokinetic data derived from Phase I human trials would indicate whether or not IPX-203 would likely meet expectations for a superior product. (CX5003 at 049 (¶ 83) (Geltosky Report)). If these data showed no improvement over IPX-066, there would be no reason to continue developing IPX-203. (CX5003 at 049 (¶ 83) (Geltosky Report)).

RESPONSE TO FINDING NO. 1244:

Complaint Counsel's Proposed Finding No. 1244 should be disregarded because it violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." Proposed Finding No. 1244 is also based on improper expert opinion. Dr. Geltosky has no expertise in contract interpretation, nor has he been tendered to offer opinions regarding the interpretation of pharmaceutical agreement terms generally or the DCA's terms specifically. (*See* Geltosky, Tr. 1058).

1245. The provision of the DCA covering Endo's right to terminate after Phase III trials are completed is also overly punitive to Endo. (CX5003 at 049 (¶ 84) (Geltosky Report)). Endo is subject to a $5 million penalty if it terminates the DCA after the completion of Phase III trials but prior to FDA acceptance of the NDA. (RX-365 at 0024 (DCA §13.2(d) ("Termination by Endo"))). The $5 million penalty is the same amount of money that Endo would have to pay Impax if the deal continued and Impax met the remaining two milestones. (RX-365 at 0009, 0023 (DCA §§3.2, 13.2(d) ("Milestone Fees," "Termination by Endo"))). Such financial penalties are rare in the pharmaceutical industry. (CX5003 at 050 (¶ 84) (Geltosky Report)).

RESPONSE TO FINDING NO. 1245:

Complaint Counsel's Proposed Finding No. 1245 is misleading and inaccurate in its claim that certain aspects of the DCA are "overly punitive" to Endo. The DCA is a bundle of rights and burdens that must be considered together as a whole. (Noll, Tr. 1645-46). Yet Dr. Geltosky did not offer any opinion on whether the DCA's bundle of rights and burdens favored Impax or Endo, (Geltosky, Tr. 1137-38), or whether Endo exercised sound business judgment in entering into the DCA, (Geltosky, Tr. 1126). Proposed Finding No. 1245 is also based on unreliable expert testimony. Dr. Geltosky has virtually no experience with discovery-stage development deals like the DCA. (Geltosky, Tr. 1144-45 (only a "handful" of deals involving a discovery-stage asset)). And Dr. Geltosky acknowledged that he cannot speak to how the universe of mid-sized pharmaceutical companies approach partnerships for discovery-stage products. (Geltosky, Tr. 1177). Dr. Geltosky did not even compare the DCA with any other discovery-stage development agreements. (Geltosky, Tr. 1140-41, 1147).

8. Post-agreement information confirms that Endo would not have entered into the DCA absent Impax's willingness to accept the January 2013 entry date

1246. Post agreement information confirms that Endo would not have entered the DCA absent Impax's willingness to accept the January 2013 entry date: the parties did not appear interested in moving quickly to develop IPX-203; and in 2015, Endo terminated the DCA when Impax attempted to modify the agreement, despite already paying $10 million in upfront payment to Impax. (*See* CCF ¶¶ 1247-1267).

RESPONSE TO FINDING NO. 1246:

The proposed summary finding should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Moreover, the

individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondent's replies to those findings.

a) Impax and Endo did not appear interested in moving quickly to develop IPX-203

1247. In stark contrast to the timeline of deal negotiations, the parties did not appear interested in moving quickly to develop IPX-203. Impax was slow to conduct the necessary studies to develop IPX-203 and the parties never established a Joint Development Committee as required by the DCA. (*See* CCF ¶¶ 1248-1255).

RESPONSE TO FINDING NO. 1247:

The proposed summary finding should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Moreover, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondent's replies to those findings.

1248. [redacted] (CX2928 at 011; (Impax Response to Interrogatory No. 17) (*in camera*)). [redacted] (CX2928 at 011 (Impax Response to Interrogatory No. 17) (*in camera*)). [redacted] (CX2928 at 011 (Impax Response to Interrogatory No. 17) (*in camera*)).

RESPONSE TO FINDING NO. 1248:

Respondent has no specific response.

1249. [redacted] (Geltosky, Tr. 1103 (*in camera*)).

RESPONSE TO FINDING NO. 1249:

Complaint Counsel's Proposed Finding No. 1249 is misleading and based on unreliable expert opinion. Dr. Geltosky's "35 plus years of experience" involve only a "handful" of deals related to discovery-stage development assets. (Geltosky, Tr. 1144-45). Dr. Geltosky also has very little experience with deals in which the net buyer is a mid-sized pharmaceutical company like Endo, as opposed to a big pharmaceutical company like Bristol-Meyers Squibb or SmithKline Beecham. (Geltosky, Tr. 1141, 1143, 1177). Indeed, Dr. Geltosky acknowledged that he cannot speak to how the universe of mid-sized pharmaceutical companies approach partnerships for discovery-stage products. (Geltosky, Tr. 1177). By contrast, Endo regularly enters "very early, very speculative agreements" for promising drugs. (Cobuzzi, Tr. 2516).

[redacted] (Cobuzzi, Tr. 2532-33).

1250. When the DCA was signed in June of 2010, IPX-203 was in the "feasibility study" phase of development. (Nestor, Tr. 3034). The feasibility study phase refers to a phase of development that is prior to locking in a final formulation of the drug product. (Nestor, Tr. 3033).

RESPONSE TO FINDING NO. 1250:

Respondent has no specific response.

1251. Pharmacokinetic studies are part of the feasibility study phase of development. (Nestor, Tr. 3034). [redacted] (CX3167 at 048 (Aug. 2010 Impax Brand R&D presentation) (*in camera*)). However, as of April 2013, nearly three years after entering into the DCA, Impax had still not conducted a pharmacokinetic study of IPX-203, and the product was still in the feasibility study phase of development. (Nestor, Tr. 3034).

RESPONSE TO FINDING NO. 1251:

Respondent has no specific response to the first and second sentences of Complaint Counsel's Proposed Finding No. 1251. And while Respondent does not dispute that IPX-203 was still in the feasibility stage of development in April 2013, the remainder of the third sentence of Proposed Finding No. 1251 is inaccurate, inconsistent with record evidence, and not supported by the testimony cited. Impax's internal documents, specifically R&D presentations and detailed time entry records, reflect that Impax [redacted] and spent a substantial amount of time working on them in 2011 as well. (*See* CX3166-039-42 [redacted]; RX-242 (IPX-203 Hours Spreadsheet) (Tab 2012 Project Detail reflecting results from IPX-203 pharmacokinetic studies—for example, "IPX203-B12-01 PK results"—and work on additional pharmacokinetic studies involving different IPX-203 formulations—for example "IPX203-B12-03 study"); RX-242 (IPX-203 Hours Spreadsheet) (Tab 2011 Project Detail entries showing work regarding IPX-203 pharmacokinetic studies in 2011, including "IPX203 new study," "IPX203 next PK," "study design formulation," "IPX203-B12-01 protocol," and "IPX203-B12-01 draft protocol"); *see also* CX0310-026-27 (Impax Narrative Responses to CID) (listing various IPX-203 pharmacokinetic studies completed by Impax as of the date of the response, as well as the IPX-203 formulation numbers tested)).

These documents reflect several rounds of pharmacokinetic studies on IPX-203 formulations. The testimony of Michael Nestor, on which the Proposed Finding attempts to rely, reflects only that, as of April 2013, Impax was "still planning on doing a PK study of IPX-203,"

not that it had never completed one. (Nestor, Tr. 3034). In this respect, the Proposed Finding misunderstands the role of pharmacokinetic studies in pharmaceutical development generally, and the development work on IPX-203 specifically. [redacted] (Nestor, Tr. 2962-61; CX0310-026-27; RX-242 (reflecting pharmacokinetic study work on various formulations in 2011, 2012, and 2013); CX3166-039-42 ([redacted])).

The third sentence of Proposed Finding No. 1251 is also misleading in its description of the timeline for Impax's development work on IPX-203, because it ignores the fact that some work was temporarily delayed after Impax experienced delays in the development of IPX-066, the brand drug IPX-203 was intended to extend and improve upon. (Reasons, Tr. 1237-38; CX4021 (Ben-Maimon, Dep. at 145) (IPX-066 development was delayed for a "[c]ouple years"); CX4033 (Nestor, Dep. at 135-36)). Bryan Reasons, Impax's current Chief Financial Officer, explained that when IPX-066 was delayed, "resources were put to focus on the approval of Rytary [IPX-066] so that we could get that to market, grow that . . . commercially, and it would also be beneficial to [] when we launched the next generation of [IPX-]203." (Reasons, Tr. 1237-38).

> 1252. As per the terms of the DCA, "[p]romptly following the Effective Date [of the DCA], each party shall appoint its initial representatives to the JDC." (RX365 at 0016 (DCA § 7.1 ("Membership"))). Impax did not reach out to Endo to discuss the Join Development Committee for the IPX-203 opportunity until September 2010, nearly four months after the DCA was signed. (CX3179 at 001 (Sep. 15, 2010 Pong/Donatiello email)).

RESPONSE TO FINDING NO. 1252:

Respondent has no specific response.

1253. Typically, the project management group at a pharmaceutical company is intimately involved with the technical due diligence process for a particular opportunity, as it ultimately bears some degree of responsibility in driving the program forward. (CX5003 at 050 (¶ 85) (Geltosky Report)). Yet in this case, when asked to assemble the JDC for Endo in September 2010, Endo's head of Project Management, Charlie Gombar, indicated that he had no idea what IPX-203 was and did not have a contact person at Impax. (CX3180 at 001 (Sep. 14, 2010 Pong/Cobuzzi email)).

RESPONSE TO FINDING NO. 1253:

The first sentence of Complaint Counsel's Proposed Finding No. 1253 is misleading and based on unreliable expert testimony. Dr. Geltosky's opinions regarding "typical" diligence practices are based on his experience. (Geltosky, Tr. 1063, 1128-29, 1140). But Dr. Geltosky has virtually no experience with discovery-stage development deals like the DCA. (Geltosky, Tr. 1144-45 (only a "handful" of deals involving a discovery-stage asset)). Dr. Geltosky acknowledged that he cannot speak to how the universe of small or mid-sized pharmaceutical companies approach partnerships for discovery-stage products. (Geltosky, Tr. 1143). Dr. Cobuzzi, who himself has over two decades of pharmaceutical industry experience, (CX4016 (Cobuzzi, IHT at 12-13)), testified that there is no typical, one-size-fits-all process for performing due diligence on a pharmaceutical collaboration, particularly at Endo. (Cobuzzi, Tr. 2543). Respondent has no specific response to the second sentence of Proposed Finding No. 1253.

1254. Under the terms of the DCA, while Impax was developing IPX-203, the JDC was to meet a minimum of four times a year. (RX-365 at 0016 (DCA § 7.2 ("Meetings"))). Yet, Impax's Brand Research & Development group never held any of the quarterly JDC meetings with Endo as contemplated in the Agreement. (Nestor, Tr. 3035; 3036-37; CX3165 at 001 (Nov. 17, 2014 Paterson/Gupta email) (stating that Impax Brand R&D had not had any JDC meetings with Endo and that there is "no active involvement" between Endo and Impax on the project)).

RESPONSE TO FINDING NO. 1254:

Complaint Counsel's Proposed Finding No. 1254 is misleading and incomplete. The record reflects that the DCA joint development committee meetings were intended to be "[e]ssentially a progress report on clinical development by Impax." (CX3345-006). Michael Nestor, the president of Impax's brand division, testified that [redacted] (Nestor, Tr. 2967-69). Indeed, Impax "had to make sure we had a formulation first and that we were ready to go into the clinic" before meetings of the joint development committee "would be relevant." (CX4033 (Nestor, Dep. at 164); *see* Nestor, Tr. 2967-68). Once Impax's formulation work had reached that point, it updated Endo regarding the status of Impax's IPX-203 development work, [redacted] (Nestor, Tr. 2963-64, 2967; CX4033 (Nestor, Dep. at 164)).

1255. [redacted] (Nestor, Tr. 3035; *see also* Nestor, Tr. 2966-67 [redacted] (*in camera*)). The post-deal delay in establishing a JDC is highly unusual given the time pressures imposed on finalizing the DCA. (CX5003 at 050 (¶ 85) (Geltosky Report)).

RESPONSE TO FINDING NO. 1255:

While Respondent does not dispute that the joint development committee never met, [redacted] (Nestor, Tr. 2963-64, 2967; CX4033 (Nestor, Dep. at 164)). The second sentence of Proposed Finding No. 1255 is misleading and based on unreliable expert testimony. Dr. Geltosky's opinions regarding "usual" behavior is based on his experience. (Geltosky, Tr. 1063, 1128-29, 1140). But Dr. Geltosky has virtually no

experience with discovery-stage development deals like the DCA. (Geltosky, Tr. 1144-45 (only a "handful" of deals involving a discovery-stage asset)). And Dr. Geltosky acknowledged that he cannot speak to how the universe of small or mid-sized pharmaceutical companies approach partnerships for discovery-stage products. (Geltosky, Tr. 1141, 1143, 1177).

b) Despite having already paid Impax $10 million upfront, Endo terminated the agreement in 2015 when Impax attempted to modify the DCA

1256. [redacted] (CX3166 at 038 (Jan. 2013 Impax Pharmaceutical R&D presentation) (*in camera*)).

RESPONSE TO FINDING NO. 1256:

Respondent has no specific response.

1257. [redacted] (CX2928 at 012) (Impax Response to Interrogatory No. 18) (*in camera*)). A target product profile categorizes key performance parameters of a drug, such as effectiveness, safety, dosage and stability. (CX5003 at 037 (¶ 61) (Geltosky Report). [redacted] (Nestor, Tr. 2960-61 (*in camera*)).

RESPONSE TO FINDING NO. 1257:

Respondent has no specific response.

1258. Eventually, Impax discontinued the levodopa-ester/carbidopa program because it did not meet the target product profile to be categorized as a competitive product. (CX2747 at 001 (Oct. 29, 2014 Macpherson/Ailinger email)).

RESPONSE TO FINDING NO. 1258:

Complaint Counsel's Proposed Finding No. 1258 is inaccurate and misleading in its suggestion that Impax had a "levodopa-ester/carbidopa program" or that IPX-203 was discontinued. [redacted]

[redacted] (Nestor, Tr. 2962 ([redacted]); Nestor, Tr. 2935 ("IPX-203, the whole idea behind this product . . . is to be able to even extend more the effective time that a patient is on IPX-203, meaning that they have a longer period of time when their motor control symptoms are under control.")).

1259. [redacted] (Nestor, Tr. 3050 (*in camera*)).

RESPONSE TO FINDING NO. 1259:

Respondent has no specific response.

1260. [redacted] (Nestor, Tr. 2961 (*in camera*); CX2928 at 012 (Impax Response to Interrogatory No. 18) (*in camera*)).

RESPONSE TO FINDING NO. 1260:

Respondent has no specific response.

1261. [redacted] (Nestor, Tr. 3045 (*in camera*)). The new microencapsulated formulation was not covered by the DCA. (RX-365 at 0006 (DCA, § 1) (definition of "Product").

RESPONSE TO FINDING NO. 1261:

Respondent has no specific response.

1262. [redacted]

[redacted] (Nestor, Tr. 2963 (*in camera*); CX2747 at 001 (Oct. 29, 2015 Macpherson/Ailinger email)).

RESPONSE TO FINDING NO. 1262:

While Respondent does not dispute that the [redacted] formulation for IPX-203 was not covered by the definition of the product in the DCA, or that Impax approached Endo about amending the agreement, Proposed Finding No. 1262 is inaccurate in its claim that discussions about an amendment first occurred in the fall of 2015. [redacted] (Nestor, Tr. 2963-64; RX-208). During that conversation, Impax offered to amend the DCA [redacted] (Nestor, Tr. 3057; CX2928-013).

1263. [redacted] (CX2747 at 001 (Oct. 29, 2015 Macpherson/Ailinger email); Nestor, Tr. 3049) (*in camera*).

RESPONSE TO FINDING NO. 1263:

While Respondent does not dispute that Endo ultimately declined to amend the DCA, Complaint Counsel's Proposed Finding No. 1263 is misleading and incomplete because it ignores the fact that, in April 2015, Endo agreed to amend the DCA, noting that it "would like to maintain or even increase [its] involvement with the development program . . . as [it] remain[ed] optimistic this will be a successfully differentiated product, which Endo looks forward to the opportunity to co-promote it with Impax." (RX-218.0001; *see* Snowden, Tr. 460-61). Impax consequently prepared an amendment to the DCA and expected the parties to continue collaborating. (Snowden, Tr. 458-59; *see* CX2747-001). Endo subsequently reversed course and informed Impax that Endo had "decided not to amend the existing agreement" and would no longer "participat[e] in [the] program," but did not provide any explanation. (CX2747-001).

1264. In passing on the new microencapsulated formulation of IPX-203, Endo raised a number of issues. [redacted] (CX3181 at 006, 010 (Oct. 28, 2015 Evaluation of IPX-203 (*in camera*)). [redacted] (CX3181 at 010 (Oct. 28, 2015 Evaluation of IPX-203) (*in camera*)).

RESPONSE TO FINDING NO. 1264:

Respondent has no specific response.

1265. [redacted] (CX5003 at 53 (¶89) (Geltosky Report) (*in camera*)).

RESPONSE TO FINDING NO. 1265:

Complaint Counsel's Proposed Finding No. 1265 should be disregarded because it violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." (*See* Court, Tr. 1859 ("[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.")).

1266. When the DCA was signed, Endo had not seen any data demonstrating IPX-203's superior clinical benefit over competitor products. (Nestor, Tr. 3026-28; Cobuzzi, Tr. 2634-35). [redacted] (Geltosky, Tr. 1098) (*in camera*)). Endo was aware that there could be development challenges with IPX-203 that would impact the "development timelines and increase overall development risk." (CX1209 at 008 (Endo Final Opportunity Evaluation Worksheet for IPX-203)). Endo also knew that the carbidopa/levodopa market was "heavily genericized" and that IPX-203 would ultimate compete with IPX-066 (now known as Rytary). (CX1209 at 012 (Endo Final Opportunity Evaluation Worksheet for IPX-203)).

RESPONSE TO FINDING NO. 1266:

Complaint Counsel's Proposed Finding No. 1266 is inaccurate and misleading in its suggestion that Endo did not assess information regarding the likelihood that IPX-203 would offer a superior clinical benefit compared to IPX-066. [redacted] (Cobuzzi, Tr. 2532-37 ([redacted]); RX-080.0011 (Endo diligence team concluding that IPX-203 would be a "greater improvement in disease control and ease of use relative to" IPX-066)).

Proposed Finding No. 1266 is also incorrect and unsupported by the cited evidence with respect to Endo's purported views about competition. The cited portion of the Endo Opportunity Evaluation Worksheet describes Endo's belief that it would successfully capture market share *despite* the presence of other products: "The pharmaceutical characteristics of IPX-203 represent a still greater improvement in disease control and ease of use relative to IPX-066, so although it will come to market later than IPX-066 we anticipate that it will achieve comparable market share albeit at a later market entry point." (CX1209-012; *see* Cobuzzi, Tr. 2536-37, 2622-23 ([redacted])).

1267. [redacted]

[redacted]
(CX2747 at 001 (Oct. 29, 2015 Macpherson/Ailinger email stating that Endo declined to amend the DCA because the existing program does not meet the definition of product in the DCA); Nestor, Tr. 3049 (*in camera*)). Despite the fact that Endo had already paid $10 million to Impax, and would not need to make further payments unless certain developmental milestones were met, Endo chose to terminate the agreement on December 23, 2015. (RX-198 at 0005-07 (Termination Agreement); CX2928 at 012 (Impax Response to Interrogatory No. 18); CX3165 at 001 (Nov. 17, 2014, Paterson/Gupta email chain noting that as per the DCA, Endo only pays Impax additional milestones after Phase II and Phase III are complete); CX1819 at 001 (June 24, 2010 Cooper/Mollichella email confirming $10 million payment)).

RESPONSE TO FINDING NO. 1267:

The first sentence of Complaint Counsel's Proposed Finding No. 1267 is not supported by the cited evidence to the extent that it suggests Endo was not interested in continuing to participate in the DCA because "the DCA was no longer tied to the SLA and Impax's entry date on its generic oxymorphone product." Nothing in the documents or testimony cited speaks to the connection, or lack thereof, between the DCA, the SLA, and/or Impax's entry date for generic Opana ER. These documents and testimony reflect only that Endo chose not to amend the DCA and do not mention the SLA or generic Opana ER at all. (CX2747-001; Nestor, Tr. 3049 ([redacted])). In fact, in April 2015, Endo told Impax that Endo "would like to maintain or even increase [its] involvement with the development program . . . as [it] remain[ed] optimistic this will be a successfully differentiated product, which Endo looks forward to the opportunity to co-promote it with Impax." (RX-218.0001).

Respondent has no specific response to the second sentence of Proposed Finding No. 1267.

XIII. The other justifications offered by Impax for the payment are not cognizable and do not undermine the conclusion that Endo's payment to eliminate the risk of competition is anticompetitive

A. The reverse-payment settlement did not result in a better outcome for consumers

1268. Impax has offered the purported justification that the settlement with Endo resulted in a better outcome for consumers than continued patent litigation because the litigation was likely to take years to conclude, and Impax was likely to lose. (RX-548 at 0058 (¶ 136) (Figg Report)).

RESPONSE TO FINDING NO. 1268:

Respondent has no specific response.

1. The outcome of the underlying patent litigation was highly uncertain

1269. The outcome of patent litigation generally is uncertain. (Snowden, Tr. 483 ("patent litigation is uncertain"); Snowden, Tr. 563 ("Patent challenges are inherently risky because they involve uncertain outcomes with court decisions"); Figg, Tr. 2006-07; CX5007 at 025 (¶ 51) (Hoxie Report); Noll, Tr. 1644, 1645). It is not possible to assign a percentage to the likely outcome of patent litigation. (CX4045 (Figg, Dep. at 152)).

RESPONSE TO FINDING NO. 1269:

Respondent has no specific response.

1270. The ultimate outcome of the underlying patent litigation on the '456 and '933 patents was uncertain. (Figg, Tr. 1905, 2007; Hoxie, Tr. 2665; Noll, Tr. 1644).

RESPONSE TO FINDING NO. 1270:

Respondent has no specific response.

1271. In January 2008, Endo sued Impax, alleging that Impax's ANDA for the 5, 10, 20, 30, & 40 mg dosages of generic oxymorphone ER infringed the '456 and '933 patents. (JX-001 at 007 (¶¶ 13, 15)). Impax raised a number of counterclaims and defenses, including that Endo's patents were invalid and that Impax's product did not infringe the patents. (RX-454 at 0004-07 (answer, affirmative defenses, and counterclaims of defendant Impax Labs, Inc., in Endo v. Impax) (admitted for the fact of the assertion, not for truth of the matter asserted)).

RESPONSE TO FINDING NO. 1271:

Respondent has no specific response.

1272. Among the issues contested in the patent litigation was the construction of certain claims found in the '456 and '933 patents. (RX-484 at 0001-03 (amended order on claim construction, in Endo v. Impax) (admitted for the fact of the statement, not for truth of the matter asserted); CX5007 at 029 (¶ 55) (Hoxie Report); RX-548 at 0013-14 (¶¶ 27-28) (Figg Report)).

RESPONSE TO FINDING NO. 1272:

Respondent has no specific response.

1273. Patent claims define the scope of the patent holder's right to exclude, and inform the public on what they are precluded from doing by this patent. Patent claims often contain technical terms, and the parties may dispute the meanings of some or all of the claims in a particular patent. One of the roles the court undertakes is to rule on what various terms in the claims mean. (Figg, Tr. 1861-62).

RESPONSE TO FINDING NO. 1273:

Respondent has no specific response.

1274. In claim construction proceedings, often referred to as Markman proceedings, the court typically sets a schedule and puts forth a procedure for the parties to exchange the list of claims they think require interpretation and explain each party's proffered interpretation of those claims. These interpretations will be explained in briefing, which is sometimes supported by expert testimony. (Figg, Tr. 1862).

RESPONSE TO FINDING NO. 1274:

Respondent has no specific response.

1275. Once the parties have completed briefing on their claim constructions, the court typically holds a hearing, called the claim construction hearing or Markman hearing. (Figg, Tr. 1862-63).

RESPONSE TO FINDING NO. 1275:

Respondent has no specific response.

1276. After the claim construction hearing, the court issues a claim construction order or Markman order, which defines the terms of the claims for purposes of determining infringement or invalidity. (Hoxie, Tr. 2671). The claim construction order lays the groundwork for the attorneys on both sides to determine whether the accused product infringes the claims and also whether the claims are invalid. (Hoxie, Tr. 2671). In some circumstances, the claim construction order can be dispositive. (Hoxie, Tr. 2671-72; Figg, Tr. 1863).

RESPONSE TO FINDING NO. 1276:

Respondent has no specific response.

1277. In the '456 and '933 patent litigation, the parties contested the proper construction of the terms "hydrophobic material" and "sustained release" as used in the claims of the '456 and '933 patents. (RX-484 at 0003 (amended order on claim construction, in Endo v. Impax) (admitted for the fact of the assertion, not for truth of the matter asserted); CX5007 at 029 (¶ 55) (Hoxie Report); RX-548 at 0016 (¶ 36) (Figg Report)).

RESPONSE TO FINDING NO. 1277:

Respondent has no specific response.

1278. The district court held Markman hearings in the '456 and '933 patent litigation on December 21, 2009 and March 19, 2010. (JX-003 at 004 (¶ 18)). The court issued its claim construction order on March 30, 2010 (RX-483 (order on claim construction, in Endo v. Impax) (admitted for the fact of the statement, not for truth of the matter asserted); RX-548 at 0013-14 (¶ 28) (Figg Report)), and issued a slightly modified claim construction order on April 5, 2010 (RX-484 (amended order on claim construction, in Endo v. Impax) (admitted for the fact of the statement, not for truth of the matter asserted); CX5007 at 029 (¶ 55) (Hoxie Report); RX-548 at 0013-14 (¶ 28) (Figg Report)).

RESPONSE TO FINDING NO. 1278:

Respondent has no specific response.

1279. The district court adopted the claim constructions advocated by Endo for the terms "hydrophobic material" and "sustained release". (Hoxie, Tr. 2670-71; Figg, Tr. 1867, 1868).

RESPONSE TO FINDING NO. 1279:

Respondent has no specific response.

1280. The district court construed "hydrophobic material" to mean "a material which is effective to slow the hydration of the gelling agent without disrupting the hydrophilic matrix." (RX-484 at 0003 (amended order on claim construction, in Endo v. Impax) (admitted for the fact of the statement, not for truth of the matter asserted); Hoxie, Tr. 2672; Figg, Tr. 1865, 1867).

RESPONSE TO FINDING NO. 1280:

Respondent has no specific response.

1281. The district court construed "sustained release" to mean "the active medicament is released at a controlled rate such that therapeutically beneficial blood levels of the medicament are maintained over a period of at least 12 hours." (RX-484 at 0003 (amended order on claim construction, in Endo v. Impax) (admitted for the fact of the statement, not for truth of the matter asserted); Hoxie, Tr. 2673-74; Figg, Tr. 1867-68).

RESPONSE TO FINDING NO. 1281:

Respondent has no specific response.

1282. The district court's claim construction in favor of Endo was not dispositive—even after the court's claim construction, the outcome of the '456 and '933 patent litigation remained uncertain. (Hoxie, Tr. 2693-94 (testifying that the outcome of the patent litigation could not be predicted after the claim construction); Figg, Tr. 2008). Despite having its claim construction adopted by the court, the claim construction order posed potential problems for Endo's case. (Hoxie, Tr. 2668; *see* CCF ¶¶ 1301-17, below).

RESPONSE TO FINDING NO. 1282:

Respondent has no specific response to the first sentence of Complaint Counsel's Proposed Finding No. 1282.

The second sentence of Proposed Finding No. 1282 is inaccurate and based on unreliable expert testimony. The Court adopted Endo's proposed claim constructions verbatim, which was a "significant setback for Impax," and made it "less likely . . . [for Impax] to prevail ultimately in the patent trial." (Figg, Tr. 1870-71).

1283. Mr. Thomas Hoxie is an expert in pharmaceutical patent licensing, pharmaceutical patent litigation, and pharmaceutical patent prosecution with over 30 years of experience. Mr. Hoxie has worked for and advised pharmaceutical companies on

a variety of patent licensing, prosecution, and litigation issues for both branded and generic products. Mr. Hoxie was with Novartis Group from 1992 to 2004, where he held a number of positions, including Head of Intellectual Property for North America, and Head of Global IP Litigation/Head of Patents, Global Pharma Markets. His responsibilities included negotiating patent license agreements, including patent litigation settlements, reviewing all major patent licenses for Novartis worldwide, and managing all intellectual property litigation for Novartis globally. Mr. Hoxie also served on committees including the executive committee and the portfolio review committee, where he was involved in decisionmaking related to product development and commercialization, as well as other global business decisions. (Hoxie, Tr. 2645-46). Since 2004, Mr. Hoxie has led his own firm, now Hoxie & Associates LLC, which specializes in in patent matters relating to pharmaceuticals, chemicals and biotechnology, including patent licensing in these areas. (CX5007 at 003-05 (¶¶ 2-6) (Hoxie Report)).

RESPONSE TO FINDING NO. 1283:

Complaint Counsel's Proposed Finding No. 1283 is incomplete and misleading. While Respondent does not oppose Mr. Hoxie as an expert in patent licensing and patent prosecution, Mr. Hoxie does not have sufficient background to act as an expert in Hatch-Waxman patent litigation. (Hoxie, Tr. 2663-64 (Mr. Hassi objecting to proffer of Mr. Hoxie as an expert in patent litigation)). Mr. Hoxie has never represented ANDA filers in court. (Hoxie, Tr. 2743). In fact, in the last thirteen years, Mr. Hoxie has never set foot in a courtroom on behalf of a generic pharmaceutical company in Hatch-Waxman litigation. (Hoxie, Tr. 2757). Mr. Hoxie has never argued in a claim construction hearing. (Hoxie, Tr. 2744). And Mr. Hoxie has no experience litigating in front of the judge who presided over the Endo-Impax patent litigation. (Hoxie, Tr. 2871). Indeed, Mr. Hoxie conceded his only role in patent infringement trials has been to sit at counsel's table as "the corporate representative" and "try by mind control to convince the jury to rule our way." (Hoxie, Tr. 2650). Finally, Mr. Hoxie has only been involved with a single at-risk launch in any capacity. (Hoxie, Tr. 2761-63).

1284. Based on Mr. Hoxie's more than 30 years of experience in pharmaceutical patent licensing, pharmaceutical patent litigation, and pharmaceutical patent prosecution, the claim construction adopted by the court for "hydrophobic material" posed potential problems for Endo's infringement case. (Hoxie, Tr. 2669). Specifically, the claim

construction was a functional definition, which means that the claim was defined by what function the material or ingredient is performing in the formulation, as opposed to a definition based on its chemical and physical properties. (CX5007 at 029 (¶ 56, n.69) (Hoxie Report)).

RESPONSE TO FINDING NO. 1284:

Complaint Counsel's Proposed Finding No. 1284 is inaccurate and is based on unreliable expert testimony. The court's claim construction of "hydrophobic material" was the *verbatim* construction *advocated by Endo*. (Figg, Tr. 1868; Hoxie, Tr. 2836).

Respondent has no specific response to the second sentence of Proposed Finding No. 1284, but notes that the "functional definition" of hydrophobic material did not "pose[] potential problems for Endo's infringement case" because Endo had testing designed to meet this definition. (Figg, Tr. 1874 ("Endo had its experts supervise tests where the water uptake was actually measured."); Hoxie, Tr. 2836 ("Endo's attorneys commissioned certain tests.")). Impax had no such testing supporting its position. (Figg, Tr. 1874 ("Impax did not do any tests of its own."); Hoxie, Tr. 2839).

1285. Because the claim construction adopted a functional definition, Endo would have to prove that a specific component of Impax's formulation of its generic Opana ER product worked as a hydrophobic material, to slow the hydration of the gelling agent. The normal way to tell if something had the effect required by the patent is to test it. But, the experimental data Endo put forth did not show that the specific component of Impax's formulation functioned as a hydrophobic material. Endo's infringement expert, Dr. Lowman admitted that the experimental evidence did not support Endo's claims. (CX5007 at 029-31 (¶¶ 57-58) (Hoxie Report); Hoxie, Tr. 2672-73).

RESPONSE TO FINDING NO. 1285:

The first three sentences of Complaint Counsel's Proposed Finding No. 1285 should be disregarded because they violate the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2).

The third sentence is also false and misleading. Endo, through the expert report of Dr. Lowman, submitted experimental data supporting its infringement claims. As Mr. Figg explained, "Endo had its expert supervise tests where the water uptake was actually measured. . . . And they had a company manufacture various versions of the Impax tablet with different percentages of the material that Endo was arguing was a hydrophobic material. And these tests demonstrated that [] material inhibited water uptake." (Figg, Tr. 1874).

The final sentence of Proposed Finding No. 1285 is false, misleading, and based on unreliable expert testimony. In his report, Mr. Hoxie cites a footnote in one of Endo's scientific expert's (Dr. Lowman) reports that discusses a *second set* of studies. (*See* RX-469.0022 ("Emerson also conducted dissolution tests on each set of the above-describe Sample Tablets using standard USP protocols.")). In that footnote, Dr. Lowman states that in these tests "[t]here is little difference in the dissolution rates," but explicitly notes that "[t]his data does *not* change my conclusion that, as demonstrated by the direct testing of water uptake, the Avicil PH-101 MCC in the Accused Impax Tablets is acting to slow hydration of the gelling agent." (RX-469.0022 (emphasis added)). Thus, Mr. Hoxie's conclusion that Dr. Lowman "admitted that the experimental evidence did not support Endo's claims" is based on a statement cherry-picked out of context and should be disregarded in its entirety. Finally, it is telling that despite the purported criticisms in Proposed Finding No. 1285, Complaint Counsel's patent expert, Mr. Hoxie, did not opine that Impax would have prevailed on the infringement issue. (Hoxie, Tr. 2841). Indeed, Mr. Hoxie offers no opinions on the likely outcome of the Endo-Impax litigation. (Hoxie, Tr. 2751-52).

1286. The claim construction the court adopted for "sustained release" also posed potential problems for Endo's infringement case. (Hoxie, Tr. 2673-76). The claims of the '933 and '456 patents are directed to a controlled release solid dosage form and, as explained in the patents, the solid dosage form is a single tablet. (RX-452 at 0016-17

('933 Patent) (admitted for the fact of the statement, not for the truth of the matter asserted); RX-453 at 0016 ('456 Patent) (admitted for the fact of the statement, not for the truth of the matter asserted); RX-260 at 0017 (Impax's pre-trial brief, in Endo v. Impax) (admitted for the fact of the assertion, not for the truth of the matter asserted); CX5007 at 032 (¶ 61) (Hoxie Report)). Endo's expert in the patent litigation, Dr. Lowman, admitted the solid dosage form recited in the claims of the '933 and '456 patents refers to a single tablet. (RX-260 at 0017 (Impax's pre-trial brief, in Endo v. Impax) (admitted for the fact of the statement, not for the truth of the matter asserted); CX5007 at 032 (¶ 61) (Hoxie Report)). The claims are not related to a method of administering many tablets over many twelve-hour periods to reach a steady-state blood level that would provide a therapeutic effective amount. (Hoxie, Tr. 2674-75). This means that the sustained release element of maintaining therapeutically effective blood levels for over twelve hours needed to be achieved by administration of one tablet of Impax's product. (CX5007 at 032 (¶ 61) (Hoxie Report)).

RESPONSE TO FINDING NO. 1286:

Complaint Counsel's Proposed Finding No. 1286 is inaccurate, misleading, and not based on reliable expert testimony. The court's claim construction of "sustained release" did not pose problems for Endo; indeed the construction adopted by the court was the *verbatim* construction *advocated by Endo*. (Figg, Tr. 1868; Hoxie, Tr. 2836).

The rest of Proposed Finding No. 1286 is irrelevant because even if "sustained release" required only a "single tablet," Impax offered no expert testimony in support of that position, and therefore the issue likely would not have been available for Impax to argue at trial. (RX-548.0017 (Figg Rep. ¶ 38 n.3)). Indeed, Impax did not even contest "sustained release" infringement in its non-infringement contentions. (*See* RX-261.0013 (Endo's pre-trial brief, in Endo v. Impax) (admitted for the fact of the assertion, not for the truth of the matter asserted)). Furthermore, even if this line of argument theoretically would have been allowed at trial, Endo had significant evidence that Impax's product infringed this claim. Indeed, any such contention by Impax would likely have been inconsistent with representations Impax had made to the FDA regarding bioequivalence. (Figg, Tr. 1876-77).

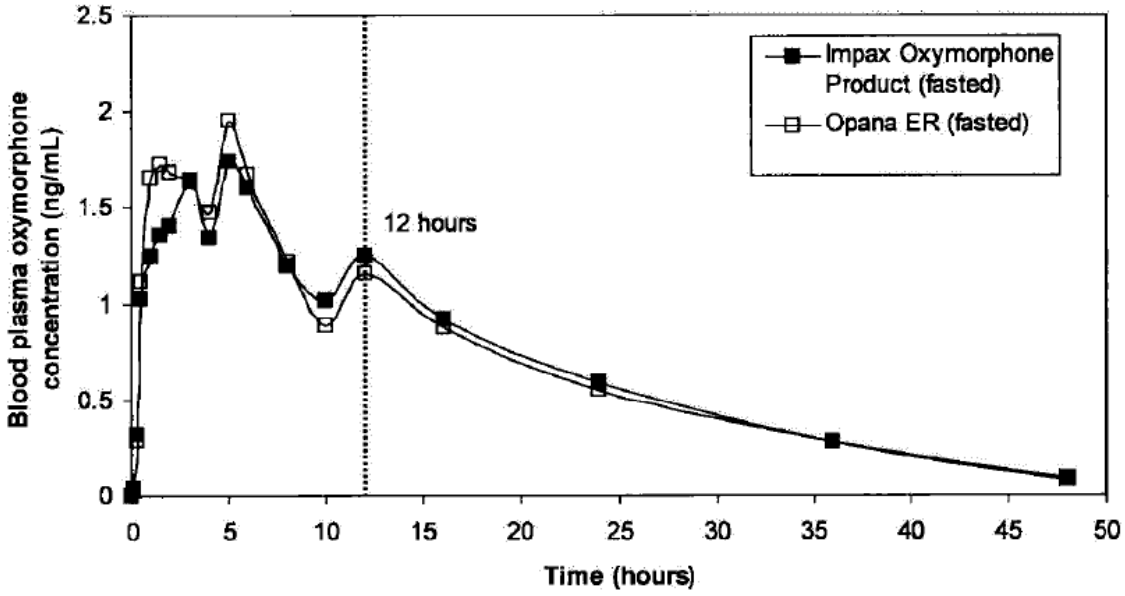
1287. Impax's generic Opana ER product, however, was designed to be used in a twice-daily dosage regimen, not as a single daily dose. (RX-230 at 0001 (Oxymorphone ER label)). When Impax pointed out that there was no evidence that a single tablet of its product would provide therapeutically beneficial blood levels of the medicament over a period of at least twelve hours, Endo responded by arguing that Impax had not provided expert evidence to the contrary. (RX-260 at 0017-18 (Impax's pre-trial brief, in Endo v. Impax) (admitted for the fact of the assertion, not for the truth of the matter asserted); RX-261 at 0013 (Endo's trial brief, in Endo v. Impax) (admitted for the fact of the assertion, not for the truth of the matter asserted)). But the burden of proving infringement rested on Endo: Endo needed to show that a single tablet of Impax's product met this limitation. (CX5007 at 033 (¶ 62) (Hoxie Report)). Endo did not have any experimental data to prove that a single tablet of Impax's product would provide a therapeutically effective blood level over twelve hours, as required by the claims. (Hoxie, Tr. 2674; CX5007 at 032-033 (¶¶ 61-63) (Hoxie Report)). In fact, Endo's expert Dr. Lowman testified in deposition that if a patient were to ingest a single tablet of Opana ER, after twelve hours the patient's blood levels of the drug would be close to zero. (RX-260 at 0018 (Impax's pre-trial brief, in Endo v. Impax) (admitted for the fact of the statement, not for the truth of the matter asserted); CX5007 at 033-34 (¶ 63) (Hoxie Report); Hoxie, Tr. 2674).

RESPONSE TO FINDING NO. 1287:

Complaint Counsel's Proposed Finding No. 1287 is inaccurate and based on unreliable expert testimony. The first sentence is irrelevant because Opana ER was also designed to be used in a twice-daily dosage regimen, not as a single daily dose. (*See* Savage, Tr. 723-24 (testifying Opana ER has "true twelve-hour dosing")).

Respondent has no specific response to the second and third sentences of Proposed Finding No. 1287, but points out that Endo's burden is only to show infringement by a "preponderance of the evidence." (Hoxie, Tr. 2831; Figg, Tr. 1884). The fourth sentence of Proposed Finding No. 1287 is wrong. Endo submitted evidence regarding admissions that Impax made to the FDA certifying that its product had "the same dosage form, strength and administration 'Twice-A-Day (*every 12 hours*)'" as Opana ER. (*See* RX-261.0013 (Endo's pre-trial brief, in *Endo v. Impax*) (emphasis added) (admitted for the fact of the assertion, not for the truth of the matter asserted)). Indeed, to get its ANDA approved Impax had to prove to the FDA through clinical trials that its product was bioequivalent and therefore as effective over a 12-hour

period as Endo's product. (*See* RX-261.0013-14 (Endo's pre-trial brief, in *Endo v. Impax*) (admitted for the fact of the assertion, not for the truth of the matter asserted)). Endo even submitted a chart showing that Impax's product had slightly more blood plasma concentration after twelve hours with the administration of *only a single tablet* than Opana ER did as part of its pre-trial briefing.



(*See* RX-261.0014 (Endo's pre-trial brief, in *Endo v. Impax*) (admitted for the fact of the assertion, not for the truth of the matter asserted)). Thus, even under a new "single tablet" theory, Endo had significant clinical evidence to support its infringement case with regard to the "sustained release" construction, including pharmacokinetic data submitted to the FDA *by Impax*. Furthermore, this evidence was cited by Endo's expert, Dr. Lowman, in Paragraph 48 of his expert report, contrary to the assertion in Proposed Finding 1287. (RX-469.0016 (¶48) (admitted for the fact of the assertion, not for the truth of the matter asserted)).

The last sentence of Proposed Finding No. 1287 should be disregarded because it relies on a quotation of three words from Dr. Lowman's deposition cherry-picked entirely out of

context. Mr. Hoxie did not even review Dr. Lowman's deposition transcript before relying on this phrase. (*See* CX4043 (Hoxie, Dep. at 291) (noting he only reviewed "that particular quote" from the briefing); *see also* CX5007-050-53 (Hoxie Rep., Ex. B) (not listing Dr. Lowman's deposition transcript as a material considered)). Without knowing the context or how Dr. Lowman clarified the testimony at his deposition, Mr. Hoxie's assertion that Dr. Lowman admitted that Impax's product did not infringe lacks foundation, is unreliable, and should be disregarded. To the contrary, Mr. Figg, relying on his 30-years of experience in Hatch-Waxman litigation, opined that "Endo would have prevailed on proving infringement based on the construction[] of . . . 'sustained release.'" (Figg, Tr. 1884).

Finally, it is telling that despite the purported criticisms in Proposed Finding No. 1287, Complaint Counsel's patent expert, Mr. Hoxie, stopped short of opining that Impax would have prevailed on the infringement issue. (Hoxie, Tr. 2841). Indeed, Mr. Hoxie offers no opinions on the likely outcome of the Endo-Impax litigation. (Hoxie, Tr. 2751-52).

> 1288. Moreover, a therapeutically effective dosage of oxymorphone varies very much from patient to patient. (Hoxie, Tr. 2675) The blood levels a patient would be expected to have twelve hours after a single dose of a sustained release drug would depend on the dosage, the drug, the specific release characteristics of the formulation, food effects, and on the patient's weight and individual absorption and metabolism. (CX5007 at 034-35 (¶ 64) (Hoxie Report); Hoxie, Tr. 2675)). Under the court's claim construction of "sustained release," one could not tell whether the claim is infringed until someone has taken the tablet, and his or her blood levels are measured. (Hoxie, Tr. 2676); (RX-260 at 0017-18 (Impax's pre-trial brief, in Endo v. Impax) (admitted for the fact of the statement, not for the truth of the matter asserted); CX5007 at 034 (¶ 63) (Hoxie Report) (Blood levels thus could not be predicted from the levels achieved in a continuous dosing regimen, without human clinical data, which Endo did not have for Impax's product). Thus, even under Endo's own claim construction, Endo would have had difficulty meeting its burden to prove infringement. (Hoxie, Tr. 2674-76; CX5007 at 033-35 (¶¶ 63, 64) (Hoxie Report)).

RESPONSE TO FINDING NO. 1288:

Complaint Counsel's Proposed Finding No. 1288 is irrelevant to the issue of infringement. In an infringement case, the plaintiff need not prove that the defendant's product infringes its patents in every conceivable instance (*i.e.*, in every patient no matter the patient's weight or diet). Indeed, contrary to Complaint Counsel's suggestion, Impax did not even make this argument, and therefore it would likely not have been at issue during the trial. (*See* RX-260 (not admitted or cited for the truth of the matters therein)). Moreover, the fact remains that Endo submitted significant evidence of infringement of the "sustained release" claim. For example, Endo submitted evidence regarding admissions that Impax made to the FDA certifying that its product had "the same dosage form, strength and administration 'Twice-A-Day (*every 12 hours*)'" as Opana ER. (*See* RX-261.0013 (Endo's pre-trial brief, in *Endo v. Impax*) (emphasis added) (admitted for the fact of the assertion, not for the truth of the matter asserted)). Endo even submitted a chart showing that Impax's product had slightly more blood plasma concentration after twelve hours with the administration of *only a single tablet* than Opana ER did. (*See* RX-261.0014 (Endo's pre-trial brief, in *Endo v. Impax*) (admitted for the fact of the assertion, not for the truth of the matter asserted) (pictured in Respondent's Response to Complaint Counsel's Proposed Finding No. 1287)). Furthermore, this evidence was cited by Endo's expert, Dr. Lowman, in Paragraph 48 of his expert report, contrary to the assertion in Complaint Counsel's Proposed Finding. (RX-469.0016 (¶48) (admitted for the fact of the assertion, not for the truth of the matter asserted)). Mr. Figg, relying on his 30-years of experience in Hatch-Waxman litigation, opined that "Endo would have prevailed on proving infringement based on the construction[] of . . . 'sustained release.'" (Figg, Tr. 1884).

1289. Impax raised invalidity claims based on anticipation, obviousness, and inadequate written description. (Hoxie, Tr. 2676; CX5007 at 035 (¶ 65) (Hoxie Report); RX-548 at

0020, 022, 025 (¶¶ 45, 49, 56) (Figg Report)). The court's claim construction order also raised issues for Endo's defense against Impax's invalidity case on each of these grounds. (Hoxie, Tr. 2679-93; CX5007 at 035 (¶ 65) (Hoxie Report)).

RESPONSE TO FINDING NO. 1289:

Respondent has no specific response to the first sentence of Complaint Counsel's Proposed Finding No. 1289.

The second sentence of Proposed Finding No. 1289 is inaccurate because Endo prevailed on the claim construction issues by convincing the court to adopt is constructions of "sustained release" and "hydrophobic material" verbatim. (Hoxie, Tr. 2836; Figg, Tr. 1868).

1290. "'Anticipation' requires that a single prior art reference disclose (explicitly, implicitly, or inherently) every element of the claim, arranged as in the claim. A claim that is anticipated is invalid under 35 U.S.C. § 102 because the claimed subject matter is not novel—it was identically disclosed in the prior art." (RX-548 at 0019-20 (¶ 44) (Figg Report); Hoxie, Tr. 2677; Figg, Tr. 1889-90). Impax argued that some of the asserted claims were invalid as anticipated by prior art references. (RX-548 at 0020 (¶ 45) (Figg Report); Figg, Tr. 1894-95).

RESPONSE TO FINDING NO. 1290:

Respondent has no specific response.

1291. The court's claim construction order raised issues for Endo's defense against Impax's invalidity case on the basis of anticipation. Endo argued that a particular component of Impax's Opana ER product, known as microcrystalline cellulose (MCC), served as the hydrophobic material required by the patent claims. (Hoxie, Tr. 2672-73; CX5007 at 03536 (¶ 66) (Hoxie Report)).

RESPONSE TO FINDING NO. 1291:

The first sentence of Complaint Counsel's Proposed Finding No. 1291 should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Respondent has no specific response to the second sentence of Proposed Finding No. 1291.

1292. Endo's arguments that MCC served as the hydrophobic material in Impax's product opened the door to a number of prior art references that could have invalidated the '933 and '456 patents. MCC is a very commonly used excipient, and is present in many drug formulations and patents. (Hoxie, Tr. 2679-80; CX5007 at 035-36 (¶¶ 66-67) (Hoxie Report)). There is a significant amount of literature, patents, and other information that could serve as prior art regarding its use. A patent can be invalidated by as little as one prior art reference. (Hoxie, Tr. 2681). By opening the door to more prior art, Endo was faced with the added difficulty of having to distinguish even more prior art references to avoid invalidation of the '933 and '456 patents. (Hoxie, Tr. 2681).

RESPONSE TO FINDING NO. 1292:

The first sentence of Complaint Counsel's Proposed Finding No. 1292 should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Further, expert discovery had closed prior to the court's claim construction decision, meaning that even if Endo's arguments "opened the door to a number of prior art references," Impax could not have submitted additional expert testimony related to new prior art references. (Hoxie, Tr. 2846-49 ("Q. And you agree that after the claim construction decision, it was too late in the case for Impax to conduct those studies and offer them as evidence in the case; correct? A. That's correct. Q. and the same would be true for introducing new prior art; correct? Expert discovery had closed by then. A. That's correct.")). Therefore, whether or not the claim construction "opened the door to a number of prior art references" is irrelevant given the procedural posture of the patent infringement litigation. Finally, Impax did not assert that Endo's patents were invalid by means of anticipation for each claim in the case, which means that even if Impax had prevailed on its anticipation claims, it would not have prevailed on all issues of validity and Impax would still need to prove those claims invalid by other means. (Figg, Tr. 1894-95).

1293. To distinguish the claims of the patents over the numerous prior art references disclosing MCC, Endo argued that in the prior art, there was no experimental evidence to

prove that MCC was hydrophobic. (RX-261 at 0027 (Endo's trial brief, in Endo v. Impax) (admitted for the fact of the assertion, not for truth of the matter asserted); Hoxie, Tr. 2679-80; CX5007 at 036-37 (¶ 68) (Hoxie Report)). This argument created inconsistencies in Endo's case. Thus, for purposes of assessing validity, Endo argued that the prior art did not show that MCC was hydrophobic. But for purposes of proving infringement, Endo insisted that that the MCC in Impax's product was hydrophobic. (RX-261 at 0027 (Endo's trial brief, in Endo v. Impax) (admitted for the fact of the assertion, not for the truth of the matter asserted); *see also* Hoxie, Tr. 2679-81; CX5007 at 036-37 (¶¶ 67-68) (Hoxie Report)).

RESPONSE TO FINDING NO. 1293:

Respondent has no specific response to the first sentence of Complaint Counsel's Proposed Finding No. 1293.

Complaint Counsel's assertion in the second sentence of Proposed Finding No. 1293 that Endo's arguments "created inconsistencies in Endo's case" is false and based on unreliable expert testimony. Both patent experts agree that the court's claim construction of "hydrophobic material" was a "functional" construction, and thus required testing. (Figg, Tr. 1873-75; Hoxie, Tr. 2836). Further, the burdens of proof differ between infringement and invalidity: Endo needed only to prove infringement by a preponderance of the evidence, whereas Impax needed to show that prior art anticipated the claim by clear and convincing evidence. (Hoxie, Tr. 2850; Figg, Tr. 1872, 1885). Endo provided tests in support of its infringement case, (Figg, Tr. 1874; Hoxie, Tr. 2836 ("Endo's attorneys commissioned certain tests.")), but Impax did not offer any tests related to the prior art, (Figg, Tr. 1874 ("Impax did not do any tests of its own."); Hoxie, Tr. 2839), and therefore Impax could not meet the clear and convincing standard to show the prior art anticipated the patents. Tellingly, Mr. Hoxie did not opine that he believed Impax would have prevailed on the validity arguments, including anticipation. (Hoxie, Tr. 2845). Indeed, Mr. Hoxie did not offer any opinion on the outcome of the Endo-Impax litigation. (Hoxie, Tr. 2751-52).

1294. Impax's second grounds for invalidity—obviousness—requires demonstration that "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person of ordinary skill in the art to which the subject matter pertains." (RX-548 at 0022 (¶ 49) (Figg Report); Hoxie, Tr. 2677; Figg, Tr. 1897). Impax argued that the asserted claims of the '933 patent were invalid under 35 U.S.C. §103 as obvious. (RX-468 at 0029-39 (¶¶ 110-133) (Expert Report of Edmund J. Elder from Endo v. Impax) (admitted for the fact of the assertion, not for truth of the matter asserted); RX-548 at 0022 (¶ 49) (Figg Report)).

RESPONSE TO FINDING NO. 1294:

Respondent has no specific response.

1295. The court's claim construction order raised issues for Endo's defense against Impax's invalidity case on the basis of obviousness. Impax argued that MCC is a well-known excipient and therefore, there was a large volume of prior art references that could have potentially invalidated Endo's patents under an obviousness theory. (RX-260 at 0009-10, 0027-28 (Impax's pre-trial brief, in Endo v. Impax) (admitted for the fact of the assertion, not for truth of the matter asserted)).

RESPONSE TO FINDING NO. 1295:

Complaint Counsel's Proposed Finding No. 1295 is misleading and inaccurate. The first sentence of Proposed Finding No. 1295 should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). In any event, the Court's claim construction order did not "raise[] issues for Endo's defense against Impax's invalidity case on the basis of obviousness." Instead, the claim construction—adopting a functional claim that required testing—made it very difficult for Impax to meet its burden of showing that the prior art references could have invalidated Endo's patents under an obviousness theory because Endo had submitted to testing the function of the MCC in the referenced prior art. Accordingly, Impax was not likely to meet its burden under the "clear and convincing evidence" standard. Tellingly, Mr. Hoxie did not opine that Impax would have prevailed on the validity arguments, including obviousness. (Hoxie, Tr. 2845).

1296. To overcome Impax's obviousness claims, Endo argued that secondary indicia of nonobviousness (also known as 'secondary considerations') supported the non-obviousness of the claimed formulations. (Hoxie, Tr. 2683-84; Figg, Tr. 1899; RX-548 at 0023 (¶ 51) (Figg Report); CX5007 at 037 (¶ 69) (Hoxie Report)). In particular, Endo relied on secondary considerations that included commercial success of the invention and findings that the invention satisfied a long-felt but unmet need. (Hoxie, Tr. 2683-84; Figg, Tr. 1899; RX-548 at 0023 (¶ 51) (Figg Report); CX5007 at 037 (¶ 69) (Hoxie Report)).

RESPONSE TO FINDING NO. 1296:

Respondent has no specific response to Complaint Counsel's Proposed Finding No. 1296, except to clarify that the secondary indicia were not Endo's only arguments regarding obviousness. (RX-261.0030-32 (Endo's trial brief, in *Endo v. Impax*) (admitted for the fact of the assertion, not for truth of the matter asserted)).

1297. For secondary considerations to be relevant, there needs to be a nexus between proven success of the product and the patented invention. But the patents do not mention oxymorphone, the active ingredient of Opana ER, and the patents do not address any special problems or long-felt, unmet needs with regard to the administration of oxymorphone. (Hoxie, Tr. 2684; CX5007 at 038-39 (¶ 71) (Hoxie Report)). The examples in the patent are directed to formulations of albuterol, a bronchodilator, which is chemically and therapeutically unrelated to oxymorphone, the active ingredient of Opana ER. (Hoxie, Tr. 2684-86; CX5007 at 038-39 (¶ 71) (Hoxie Report)).

RESPONSE TO FINDING NO. 1297:

Respondent has no specific response.

1298. As a result, Endo may have encountered problems trying to "successfully rely on secondary considerations or objective indicia of non-obviousness based on purported advantages and success of its Opana ER formulation because, as Impax argued, the Opana ER formulation was not the invention of the asserted patents." (CX5007 at 037 (¶ 69) (Hoxie Report); Hoxie, Tr. 2684-86; RX-260 at 0035-36 (Impax's pre-trial brief, in Endo v. Impax) (admitted for the fact of the assertion, not for the truth of the matter asserted)). In fact, when Endo filed the original NDA for Opana ER, and again when the product was approved, Endo was required under 21 U.S.C. §355(a)(1) and 21 C.F.R. §314.53 to identify to the FDA all patents covering the product. (CX5007 at 039 (¶ 72) (Hoxie Report)). But Endo did not identify the '933 and '456 patents in the original Orange Book listing for Opana ER. (CX2967 at 017 (June 25, 2007 ANDA for Oxymorphone HCl extended release tablets); Hoxie, Tr. 2684; CX5007 at 039 (¶ 72) (Hoxie Report)). Endo did not list the '933 and '456 patents in the Orange Book until

after Impax's initial ANDA filing in June 2007. (JX-001 at 006-07 (¶¶ 9, 11); CX5007 at 039 (¶ 72) (Hoxie Report)).

RESPONSE TO FINDING NO. 1298:

Complaint Counsel's Proposed Finding No. 1298 is incomplete and inaccurate. Endo was more likely than not to prevail on the obviousness issue. (Figg, Tr. 1897-98).

The final two sentences of Proposed Finding No. 1298, moreover, do not accurately reflect Impax's obviousness arguments. Impax never once mentioned the Orange Book or the timing in which Endo listed the '933 and '456 patents in its pre-trial briefing. (RX-260.0027-36 (Impax's pre-trial brief, in Endo v. Impax) (admitted for the fact of the statement, not for the truth of the matter asserted)). Thus, this argument is a post-hoc rationalization created by Complaint Counsel's expert for purposes of this Part III proceeding, and it would not have been raised or considered during the actual Endo-Impax patent trial. Further, Proposed Finding No. 1298 ignores significant evidence that secondary factors supported Endo's argument of non-obviousness, including (1) the fact Endo's product was commercially successful with hundreds of millions of dollars of sales; and (2) that Opana ER was the only extended-release version of oxymorphone on the market despite the fact oxymorphone IR had been available for many years. (Figg, Tr. 1899). Moreover Endo would have enjoyed a presumption of a nexus between the inventions and the commercial success of Opana ER. (Figg, Tr. 1901). Finally, it is telling that Mr. Hoxie did not opine that Impax would prevail on the issue of invalidity under obviousness. (Hoxie, Tr. 2845). Indeed, Mr. Hoxie did not offer any opinion on the likely outcome of the Endo-Impax litigation. (Hoxie, Tr. 2751-52).

1299. Under Impax's third grounds for invalidity—inadequate written description—a patent is invalid "if a person of skill in the art would not conclude from reading the patent specification that the inventors had possession of the claimed invention as of the filing date." (RX-548 at 0025 (¶ 55) (Figg Report); Hoxie, Tr. 2677-78; Figg, Tr. 1902).

RESPONSE TO FINDING NO. 1299:

Respondent has no specific response.

1300. Endo may have faced difficulty in defending against Impax's invalidity case on the basis of lack of written description. Impax asserted that the '456 and '933 patents only disclose a single study regarding the use of albuterol in the formulation. (RX-260 at 0036-38 (Impax's pre-trial brief, in Endo v. Impax) (admitted for the fact of the assertion, not for truth of the matter asserted); CX5007 at 040 (¶ 75) (Hoxie Report); Hoxie, Tr. 2688-89). They do not discuss other active ingredients. Because pharmacokinetics of active ingredients depend on many properties, there is no guarantee that non-albuterol active ingredients, including oxymorphone, would work in the same way. (CX5007 at 040-41 (¶ 75) (Hoxie Report); Hoxie, Tr. 2688-89).

RESPONSE TO FINDING NO. 1300:

Complaint Counsel's Proposed Finding No. 1300 is incomplete and misleading. First, Proposed Finding No. 1300 fails to mention that Impax only alleged a lack of written description on three claims (claims 41, 42, and 43). (Figg, Tr. 1902). Therefore, even if Impax had prevailed on this issue, it would have needed to also prevail on the issue of obviousness or anticipation to prevail on invalidity. (Figg, Tr. 1902-03). As described in Proposed Finding No. 1300, the written description related to albuterol, but Mr. Figg opined that because Endo disclosed the precise numerical values for the T-max (time after a tablet is swallowed until a blood plasma level reaches a certain level), the written description was likely sufficient. (Figg, Tr. 1903). Therefore, Mr. Figg opined that Endo had "an edge on that issue." (Figg, Tr. 1904). Mr. Hoxie, to the contrary, did not opine that Impax would have prevailed. (Hoxie, Tr. 2845). Indeed, Mr. Hoxie did not opine on the likely outcome of the Endo-Impax litigation. (Hoxie, Tr. 2751-52).

1301. Following the court's issuing its amended claim construction order, on May 19, 2010, the court scheduled the *Endo v. Impax* patent infringement trial on the '456 and '933 patents to begin on June 3, 2010 and continue through June 17, 2010. (JX-003 at 004 (¶ 22); (CX2759 at 020 (Docket of the '456 and '933 *Endo v. Impax* patent litigation)).

RESPONSE TO FINDING NO. 1301:

Respondent has no specific response.

1302. On June 3, 2010, the *Endo v. Impax* patent infringement trial on the '456 and '933 patents began. (JX-001 at 007 (¶ 18)). In a face-to-face negotiation, Guy Donatiello of Endo told Meg Snowden of Impax that Endo wanted to settle the litigation by June 8 to avoid having its expert witness cross-examined during the trial. (Snowden, Tr. 400-01). Impax and Endo settled the litigation on June 8, 2010. (JX-001 at 007-08 (¶¶ 18-19)).

RESPONSE TO FINDING NO. 1302:

Respondent has no specific response.

1303. At the time of the settlement, the outcome of the litigation was uncertain. (JX-001 at 008 (¶ 20); Figg, Tr. 2008). While the court adopted Endo's claim construction, the claim construction order did not provide more certainty, as it introduced more potential issues for Endo's infringement case and invalidity defenses. (Hoxie, Tr. 2692-93; *see* CCF ¶¶ 1282-1300, above).

RESPONSE TO FINDING NO. 1303:

Respondent has no specific response to the first sentence of Complaint Counsel's Proposed Finding No. 1303.

The second sentence, however, is inaccurate, misleading, and based on unreliable expert testimony. The court's claim construction created additional certainty in the patent infringement litigation because after the order the parties knew that they would be litigating under Endo's proposed constructions of "hydrophobic material" and "sustained release." (Figg, Tr. 2836). Therefore, the claim construction ruling removed the uncertainty of which constructions would apply to the claims at issue in the case. While Endo's victory was not a "sure thing" under its preferred claim construction (Figg, Tr. 1870), the claim construction made it more likely than not that Endo would ultimately prevail in the patent infringement trial (Figg, Tr. 1870). Complaint Counsel's assertion that Endo's total victory in the claim construction phase would "introduce[] more potential issues for Endo's infringement case and invalidity defenses" defies logic. Any

rational party would advocate for claim constructions that most favor their position and disfavor the positions of the opposing party. (*See* Hoxie, Tr. 2833 (Q. And you agree that each party would advocate for a claim construction that would be most advantageous for their case going forward; correct? A. Yes.")).

> 1304. If Endo and Impax had not entered into a settlement, the trial on the '933 and '456 patents would have continued. If litigation continued, Impax may have "obtained a favorable judgment" at the district court. (CX5007 at 044 (¶ 82) (Hoxie Report); Figg, Tr. 2017).

RESPONSE TO FINDING NO. 1304:

Respondent has no specific response to Complaint Counsel's Proposed Finding No. 1304, except to note that Complaint Counsel offers no evidence regarding the likelihood that Impax would have obtained a favorable judgment or the strength of either party's litigation positions. (Hoxie, Tr. 2693, 2752-53, 2835).

> 1305. If litigation continued, Impax lost at the district court, and appealed that decision, the outcome of any such appeal was uncertain. (Figg, Tr. 2007-08; Hoxie, Tr. 2694; CX5007 at 041-42 (¶¶ 76-79) (Hoxie Report)). Endo faced a significant risk of loss on appeal. (CX5007 at 041-42 (¶ 76) (Hoxie Report)).

RESPONSE TO FINDING NO. 1305:

Respondent has no specific response to the first sentence of Complaint Counsel's Proposed Finding No. 1305.

The assertion in the second sentence of Proposed Finding No. 1305 is based on unreliable expert testimony. Mr. Figg explained that even though there was a theoretical risk that Endo's victory could be reversed and remanded, Mr. Figg would give the edge to Endo on appeal because Impax would have to "convince the appeals court that that judge made a mistake even though it's de novo review." (Figg, Tr. 2019).

1306. The district court's claim construction was susceptible to reversal by the Federal Circuit, in part because that construction was contrary to the ordinary meaning of the terms. (CX5007 at 041-43 (¶¶ 76-79) (Hoxie Report)).

RESPONSE TO FINDING NO. 1306:

Complaint Counsel's Proposed Finding No. 1306 should be disregarded because it violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." (*See* Court, Tr. 1859 ("[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.")). The phrase "ordinary meaning" is also vague and ambiguous. The court adopted a functional definition of "hydrophobic material," namely "a material which is effective to slow the hydration of the gelling agent without disrupting the hydrophilic matrix." (RX-548.0018 (Figg Rep. ¶ 39)).

1307. The district court's construction of the term "hydrophobic material" is contrary to the word's ordinary meaning. (CX5007 at 042-43 (¶¶ 77-78) (Hoxie Report)). The ordinary meaning of the term "hydrophobic material" is one having a lack of affinity for water. Nothing in the patents or the prosecution history suggest that "hydrophobic" is intended to mean something different. The patents do not suggest that MCC, a material that absorbs water and is universally described in the art as hydrophilic, is considered hydrophobic. (CX5007 at 042 (¶ 77) (Hoxie Report)).

RESPONSE TO FINDING NO. 1307:

Complaint Counsel's Proposed Finding No. 1307 should be disregarded because it violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." (*See* Court, Tr. 1859 ("[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.")). The phrase "ordinary meaning" is also vague and ambiguous. Further, despite Mr. Hoxie's opinions to the contrary, the district court adopted a functional definition of "hydrophobic material," namely "a material which is effective to slow the hydration of the

gelling agent without disrupting the hydrophilic matrix," (RX-484 (Amended Order on Claim Construction)), after reviewing numerous briefs and conducting two days of hearings, (*see* RX-462; RX-464; RX-465 (claim construction briefing)). Accordingly, the court disagreed with Mr. Hoxie's conclusion as advanced in the last sentence of Proposed Finding No. 1307, and Mr. Hoxie offers no basis for why his opinion should be accepted over that of a federal judge who heard similar arguments to those offered by Mr. Hoxie.

> 1308. The construction of the term "sustained release" as correlating to blood levels of over twelve hours is also contrary to the ordinary meaning of the words and to the specification of the patents. (CX5007 at 043 (¶ 79) (Hoxie Report)). Taking a single pill in isolation would not provide the same blood levels as taking a pill on a twice-daily basis, over a period of time. Achieving therapeutic blood levels in a dosage regimen takes into account the fraction of drug that is not yet metabolized from the prior dose. It also takes into account the rate of metabolism of the drug when there is continuous exposure to the drug. Thus, therapeutic blood levels are not the same as the rate of release from a tablet, as described in the in vitro experiments in the patents. (CX5007 at 033-34 (¶ 63) (Hoxie Report)). The examples in the specifications of the patents do not address how to measure and achieve specific blood levels. Moreover, the specification only shows release up to twelve hours. (CX5007 at 043 (¶ 79 n.126) (Hoxie Report)). It does not address release (let alone blood levels) beyond twelve hours. There is nothing about the term "sustained release" that would indicate it means "at least 12 hours," as opposed to three or six hours or any period significantly longer than "immediate release." (CX5007 at 043 (¶ 79) (Hoxie Report)). Impax's patent litigation expert testified that the issue of claim construction "would have been an issue that was fairly litigable and it would have been a fairly close call." (Figg, Tr. 2019-20).

RESPONSE TO FINDING NO. 1308:

Complaint Counsel's Proposed Finding No. 1308 should be disregarded because it violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." (*See* Court, Tr. 1859 ("[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.")). The phrase "ordinary meaning" is also vague and ambiguous. Further, despite Mr. Hoxie's opinions to the contrary, the district court adopted a functional definition of "sustained release," namely "the active medicament is released at a controlled rate such that

therapeutically beneficial blood levels of the medicament are maintained over a period of at least 12 hours," (RX-484 (Amended Order on Claim Construction)), after reviewing numerous briefs and conducting two days of hearings, (*see* RX-462; RX-464; RX-465 (claim construction briefing)). Accordingly, the court disagreed with Mr. Hoxie's conclusions as advanced in Proposed Finding No. 1308, and Mr. Hoxie offers no basis for why his opinion should be accepted over that of a federal judge who heard similar arguments to those offered by Mr. Hoxie.

Respondent has no specific response to the final sentence of Proposed Finding No. 1308 other than to clarify that Mr. Figg testified he would give the edge to Endo on appeal because Impax would have to "convince the appeals court that that judge made a mistake even though it's de novo review." (Figg, Tr. 2019). Further, Complaint Counsel's Proposed Finding No. 1308 is based on unreliable expert testimony.

2. The elephant in the room: Endo did not pay Impax to accelerate the expected date of generic oxymorphone ER entry

1309. Impax has proffered as an alleged procompetitive benefit of the settlement that the SLA allowed it to enter earlier than it could have under continued litigation. In particular, Impax asserts that absent the settlement, it not only would have lost the '933 and '456 patent litigation, but it would have faced additional patent infringement litigations on later-issued patents that it would have lost as well. (Figg, Tr. 1904-05, 1963-64, 1971-72).

RESPONSE TO FINDING NO. 1309:

Complaint Counsel's Proposed Finding No. 1309 is misleading. Impax does not assert that absent the settlement it "would have" lost the '933 and '456 patent litigation. (RX-548.0005, 28-31 (Figg Rep. ¶¶ 4(a),.63-71); *see also* Figg, Tr. 1870, 1904).

1310. This justification is implausible because it means that "Endo made a charitable contribution to Impax by paying Impax over $100 million AND allowing Impax to enter earlier than otherwise would have been likely." (CX5004 at 059-60 (¶ 125) (Noll Report); Noll, Tr. 1487-88). The purported justification is also inconsistent with the facts. *See* CCF ¶¶ 1311-27.

RESPONSE TO FINDING NO. 1310:

Complaint Counsel's Proposed Finding No. 1310 should be disregarded because it is based on nothing but unreliable expert testimony. What is more, the SLA did not require Endo to pay anything to Impax at the time it was executed. And the evidence is clear that Endo had no expectation that it would make a payment under the Endo Credit anytime thereafter, until a supply disruption forced it to launch reformulated Opana ER sooner than planned and to withdraw original Opana ER at the request of the FDA. (CX4017 (Levin, Dep. at 99-100, 131); Cuca, Tr. 677; RX-094.0003-06 ("Prior to March [2012], it would have been reasonable to assume that prescriptions of old formulation [Opana ER] would have occurred in Q4 2012"); RX-100.0001 ("Several of [Endo's] strategies envisioned [Endo] selling both [original and reformulated Opana ER] products at the same time. It was only upon [Endo's] discussions with the FDA in February [2012] that they told [Endo] not to do this in order to avoid patient confusion.")).

The second sentence of Proposed Finding No. 1310 should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Moreover, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondent's replies to those findings.

a) Outcomes of the settlement for Endo and Impax

1311. The settlement agreement produced the following outcomes for Endo and Impax. For Endo, the settlement guaranteed that generic entry on the five dosages of Opana ER that accounted for more than 90% of sales would not occur until about eight months before the expiration of the patents that were at issue in the Endo/Impax patent infringement litigation. (RX-364 at 0010-11 (SLA §§ 4.1(c), 4.2 ("License; Covenant Not to Sue" and "License Term")); CX0203 (Nov. 11, 2009 Mengler/Smolenski email); Noll, Tr. 1456-57; CX5000 at 146-47, 163 (¶¶ 335, 366) (Noll Report); CX5004 at 060 (¶ 127) (Noll Rebuttal Report)).

RESPONSE TO FINDING NO. 1311:

Respondent has no specific response.

1312. Because of Impax's 180-day exclusivity period as a first filer, the settlement agreement also guaranteed Endo that no other generic entry would occur until, at the earliest, only ten weeks before these patents expired. (*See* CCF ¶¶ 378-87, above; CX5004 at 060 (¶ 127) (Noll Rebuttal Report)). This agreement preserved Impax's 180-day exclusivity period, but guaranteed that entry would not occur for two and a half years after Impax received FDA approval to enter. (*See* CCF ¶¶ 332-87, above; CX5004 at 060 (Noll Rebuttal Report)). Thus, the earliest possible date of entry was substantially delayed by the agreement. (*See* CCF ¶¶ 332-87, above; CX5004 at 060 (Noll Rebuttal Report)).

RESPONSE TO FINDING NO. 1312:

Complaint Counsel's Proposed Finding No. 1312 should be disregarded because it violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." (*See* Court, Tr. 1859 ("[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.")). Moreover, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondent's replies to those findings.

1313. Impax received three benefits to compensate for agreeing that it would not enter until January 2013. (*See* CCF ¶¶ 1314-27, below).

RESPONSE TO FINDING NO. 1313:

The proposed summary finding should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Additionally, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondent's replies to those findings.

1314. One benefit to Impax was the value of Endo's commitment not to produce an authorized generic version of Original Opana ER, thereby guaranteeing that Impax would face no competition from another generic during the 180-day exclusivity period. (RX-364 at 0010-11 (SLA § 4.1(c) ("License; Covenant Not to Sue")); Noll, Tr. 1453-54; CX5000 at 152-53 (¶ 345) (Noll Report); CX5001 at 015 (¶ 32) (Bazerman Report)).

RESPONSE TO FINDING NO. 1314:

Complaint Counsel's Proposed Finding No. 1314 is incomplete and misleading. Endo's "commitment not to produce an authorized generic version of Opana ER" was not a "benefit to Impax" because Endo never intended to launch an authorized generic. (CX4019 (Lortie, Dep. at 117-18) (testifying it would be "morally very difficult to justify at the same time having a crushable authorized generic product" and a non-crushable branded product); Bingol, Tr. 1337-39 (testifying that an authorized generic "was never, to my knowledge . . . fully realized as a plan or an idea"); CX4019 (Lortie, Dep. at 118-19) ("we never seriously considered taking any further steps to prepare for or to do [an authorized generic] because we really didn't want to.")). Accordingly, Endo did not stand to lose any potential sales while earning a 28.5 percent royalty. (RX-364.0012 (SLA § 4.3)).

Moreover, the record is replete with evidence that generic oxymorphone ER would still compete with generic and branded versions of many different long-acting opioids, even if there was no authorized generic of oxymorphone ER. (Savage, Tr. 732 (when a patient seeks treatment for chronic pain in the first instance, doctors can prescribe any long-acting opioid); RX-083.0003 at 35 (highlighting real-world switching patterns between oxymorphone-based products and drugs including fentanyl, oxycodone, and morphine)). Demir Bingol, Endo's Senior Director of Marketing and the Endo employee responsible for knowing with whom oxymorphone-based products compete, testified that "all long-acting opioid formulations," including generics that are not actively marketed, are direct competitors. (Bingol, Tr. 1271, 1313).

1315. In fact, Endo intended to launch an authorized generic and was prepared to do so. In late 2009 Endo began preparing to launch an AG if Impax launched generic oxymorphone ER. Endo knew that Impax was likely to receive final approval for its generic by June 2010, and so began to prepare for an AG launch in the summer of 2010. (CX2576 at 001, 003 (Feb. 2010 Endo email)). Endo's latest estimate of the date that Impax would launch was mid-2011, when Endo expected that the appellate decision on the infringement case would be issued. (CX3001 at 001 (Endo Launch scenario); CX2576 at 001 (Feb. 2010 Endo email); CX2573 at 004 (Feb. 2010 EN3288 Commercial Update Presentation); *see* CCF ¶¶ 58, 64, above).

RESPONSE TO FINDING NO. 1315:

The first sentence of Complaint Counsel's Proposed Finding No. 1315 should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). The documents cited in support of Proposed Finding No. 1315 indicate only that Endo forecast the possibility of an authorized generic in the 2010 through 2011 time frame, and do not indicate that Endo would actually have launched an authorized generic. Indeed, Endo looked at an authorized generic as "another scenario that you go through, just like when you're making an assumption around potential launch dates." (CX4025 (Bingol, Dep. at 180)). Finally, Complaint Counsel's failure to cite any testimony from any Endo witnesses is telling, especially since all Endo witnesses testified that Endo had no intention of launching an authorized generic. (*See* Bingol, Tr. 1337-39 (testifying that an authorized generic "was never, to my knowledge . . . fully realized as a plan or an idea"); CX4019 (Lortie, Dep. at 118-19) ("we never seriously considered taking any further steps to prepare for or to do [an authorized generic] because we really didn't want to."); CX4031 (Bradley, Dep. at 198) ("I don't recall having any conversation with any colleagues regarding the launch of an authorized generic.")).

1316. To prepare for an AG launch, Endo took a number of steps, including designing tablets, receiving labels, and creating SKUs for its AG oxymorphone ER product. Endo made one batch of each strength of its AG product, and had manufactured enough to support a June 2010 launch, if necessary. Endo also informed drug wholesalers about its

intentions to launch an AG, [redacted] (*See* CCF ¶¶ 86-90, above) (*in camera*).

RESPONSE TO FINDING NO. 1316:

The proposed summary finding should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Additionally, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondent's replies to those findings.

1317. Endo's financial analyses estimated that an Impax launch in mid-2010 would cause Endo to lose $45.6 million in "Product Contribution" in 2010, but that Endo could recoup $17.7 million by launching an AG. (CX3009 at 003 (June 2010 Endo email attaching P&L scenarios)); *see* CCF ¶ 84, above)).

RESPONSE TO FINDING NO. 1317:

Respondent has no specific response.

1318. Endo and Impax settled the infringement case on June 8, 2010. (JX-001 at 009 (¶ 33)). Three days later Endo employees concluded that Endo could make arrangements to destroy its generic oxymorphone ER inventory. (CX3000 (June 2010 Endo email)).

RESPONSE TO FINDING NO. 1318:

Respondent has no specific response.

1319. The value to Impax of Endo's agreement not to launch an authorized generic is reflected in Impax's documents. Impax executives estimated that if Original Opana ER were still on the market and Endo launched an AG when Impax entered, Endo's AG would capture roughly half of sales and cause substantially lower generic prices during the exclusivity period than would be the case if Impax sold the only generic. (CX0202 at 001 (July 2009 Impax email); CX2825 at 008 (Feb. 2010 Impax email attaching 5-year forecast); CX4037 (Smolenski, Dep. at 52-54, 149-50); CX4002 (Smolenski, IHT at 80-81, 94-95)).

RESPONSE TO FINDING NO. 1319:

Complaint Counsel's Proposed Finding No. 1319 is incomplete and misleading because it ignores the testimony of Mr. Smolenski, who explained that the figure was simply "what I was assuming in this particular email," not a detailed analysis of the marketplace. (CX4037 (Smolenski, Dep. at 53) (discussing CX0202)). Further, whether a No-Authorized Generic provision had any value depends entirely on whether Endo intended to launch an authorized generic but-for the term, and Endo employee testimony demonstrates Endo did not. (CX4019 (Lortie, Dep. at 117-18) (testifying it would be "morally very difficult to justify at the same time having a crushable authorized generic product" and a non-crushable branded product); Bingol, Tr. 1337-39 (testifying that an authorized generic "was never, to my knowledge . . . fully realized as a plan or an idea"); CX4019 (Lortie, Dep. at 118-19) ("we never seriously considered taking any further steps to prepare for or to do [an authorized generic] because we really didn't want to.")). Finally, Professor Noll did not calculate the expected value of any provision in the Settlement and License Agreement, or the overall expected value of the Settlement and License Agreement. (Noll, Tr. 1613, 1651-52).

1320. Analysts at Impax produced several analyses of the effect of an AG on the success of Impax's generic version of oxymorphone ER. For example, in the last analysis of the prospects for generic entry before settlement talks were reopened in May 2010, two cases were examined: an "Upside" case assuming Impax entry in June 2010 followed by entry of an AG on August 1, and a "Base" case assuming Impax entry in July 2011 that was simultaneous with AG entry. (CX0222 at 004-05 (May 2010 Impax email attaching 5-year forecast).

RESPONSE TO FINDING NO. 1320:

Complaint Counsel's Proposed Finding No. 1320 lacks foundation and is misleading. The Proposed Finding asserts there are "several analyses," but the Proposed Finding only cites

one document. That document (CX0222) was never shown to any fact witness and there is no explanation regarding the meaning of the document.

> 1321. In the Upside case, after AG entry Impax's share of generic sales is estimated to fall to 60% and average price to fall by 36%. (CX0222 at 004 (May 2010 Impax email attaching 5-year forecast)). As a result, AG entry during the exclusivity period causes Impax's revenues to fall by 61.6%, amounting to $5 million per month or a reduction of about $23 million in the four and a half months after AG entry. (CX5000 at 155 (¶ 350) (Noll Report)). In the Base case, Endo's AG enters simultaneously with Impax and captures half of the market while causing prices to fall by the same 36%. (CX0222 at 005 (May 2010 Impax email attaching 5-year forecast)). These estimates imply that simultaneous AG entry would reduce Impax's revenues by 68.0% during the exclusivity period, or about $33 million for a launch on June 14, 2010. (CX5000 at 155-56 (¶ 350) (Noll Report)).
>
> **RESPONSE TO FINDING NO. 1321:**
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> Complaint Counsel's Proposed Finding No. 1321 is lacks foundation and is misleading. The cited document (CX0222) was never shown to any fact witness and there is no explanation regarding the meaning of the document, despite Complaint Counsel's efforts to use their economic expert to testify about the purpose and nature of figures within the document, which violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." (*See* Court, Tr. 1859 ("[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.")). Moreover, any purported estimates of how much an authorized generic would reduce Impax's revenues is based on the false premise that Endo would launch an authorized generic, which Endo did not intend. (*See* CX4019 (Lortie, Dep. at 117-18) (testifying it would be "morally very difficult to justify at the same time having a crushable authorized generic product" and a non-crushable branded product); Bingol, Tr. 1337-39 (testifying that an authorized generic "was never, to my knowledge . . . fully realized as a plan or an idea");

CX4019 (Lortie, Dep. at 118-19) ("we never seriously considered taking any further steps to prepare for or to do [an authorized generic] because we really didn't want to.")).

1322. The value of the "No AG Provision" would be higher in the future if the revenues from Original Opana ER continued to increase. Sales of Original Opana ER grew from $240 million in 2010 to $384 million in 2011 and, after the switch to Reformulated Opana ER in 2012, Opana ER revenues remained at $299 million. (CX3215 at 010 (Mar. 1, 2013 SEC Form 10-K, Endo Health Solutions, Inc.); CX5000 at 156 (¶ 351) (Noll Report)). These data imply that the value of the "No AG Provision" for entry would have been approximately 60% greater (over $50 million) in 2011 and at least 25% greater (over $40 million) in 2012. (CX5000 at 156 (¶ 351) (Noll Report)).

RESPONSE TO FINDING NO. 1322:

Complaint Counsel's Proposed Finding No. 1322 lacks foundation and is misleading. Professor Noll calculated neither the expected value of any provision in the Settlement and License Agreement, nor the overall expected value of the Settlement and License Agreement. (Noll, Tr. 1613, 1651-52). Moreover, any speculation about how much the absence of an authorized generic would be worth is based on the false premise that Endo would launch an authorized generic, which Endo did not intend. (*See* CX4019 (Lortie, Dep. at 117-18) (testifying it would be "morally very difficult to justify at the same time having a crushable authorized generic product" and a non-crushable branded product); Bingol, Tr. 1337-39 (testifying that an authorized generic "was never, to my knowledge . . . fully realized as a plan or an idea"); CX4019 (Lortie, Dep. at 118-19) ("we never seriously considered taking any further steps to prepare for or to do [an authorized generic] because we really didn't want to.")).

1323. Another benefit of the settlement to Impax was the "Endo Credit" provision which led to a payment of $102 million in compensation for Endo's withdrawal of Original Opana ER before the date that Impax was permitted to enter. (RX-364 at 0012; Noll, Tr. 1454-56; CX5000 at 158-59, 161-62 (¶¶ 354, 362) (Noll Report); CX5004 at 060-61 (¶ 128) (Noll Rebuttal Report)).

RESPONSE TO FINDING NO. 1323:

Complaint Counsel's Proposed Finding No. 1323 should be disregarded because it only cites expert testimony for propositions of fact. (*See* Court, Tr. 1859 ("[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.")). Further, Proposed Finding No. 1323 is based on unreliable expert testimony. In any event, there is nothing in the record to support the proposition that the Endo Credit had any value at the time of settlement. Professor Noll did not calculate the expected value of any provision in the Settlement and License Agreement, or the overall expected value of the Settlement and License Agreement. (Noll, Tr. 1613, 1651-52). Impax never analyzed or forecasted whether it would receive a payment under the Endo Credit at the time of settlement and knew that the Endo Credit could result in zero value. (Reasons, Tr. 1219; Mengler, Tr. 582; CX4038 (Engle, Dep. at 187-88)). Endo similarly had no "expectation that a payment would have to be made." (CX4017 (Levin, Dep. at 99-100) ("at the time the transaction was inked I did not expect that Endo would have to make a payment under this provision"); Cuca, Tr. 664-65 (Endo did not book a reserve because no Endo Credit payment was "probable and estimable" at settlement); *see* Noll, Tr. 1611, 1649 (neither party estimated value of Endo Credit at the time of settlement)).

The Endo Credit was instead designed to encourage Endo to support original Opana ER and deter the introduction of reformulated Opana ER. (Koch, Tr. 241; Snowden, Tr. 386; CX4021 (Ben-Maimon, Dep. at 118, 122) (the Endo Credit was designed to act as "a deterrent to prevent [Endo] from switching the market."); CX4037 (Smolenski, Dep. at 244-45) (Endo Credit "intended to disincentivize Endo from" introducing a reformulated product)).

1324. The Settlement and License Agreement includes a provision referred to as the "Endo Credit," under which Endo agreed to compensate Impax if sales of Original Opana ER fell by more than 50% before Impax was allowed to enter. (RX-364 at 0003, 0005, 0006, 0012; Cuca, Tr. 617-18).

RESPONSE TO FINDING NO. 1324:

Respondent has no specific response.

1325. The "Endo Credit" provision was designed to insulate Impax against a substantial decrease in sales of Opana ER. (Cuca, Tr. 617). At the time the parties were negotiating the terms of the "Endo Credit" provision, Endo was developing a reformulated version of Opana ER, the introduction of which could lead to such a decrease in the sales of Original Opana ER. (Cuca, Tr. 618-19; *see also* CCF ¶¶ 246-50, 253-75, above).

RESPONSE TO FINDING NO. 1325:

Complaint Counsel's Proposed Finding No. 1325 is incomplete and misleading. The Endo Credit was designed to deter Endo from introducing a reformulated product. (Koch, Tr. 241; Snowden, Tr. 386; CX4021 (Ben-Maimon, Dep. at 118, 122) (the Endo Credit was designed to act as "a deterrent to prevent [Endo] from switching the market."); CX4037 (Smolenski, Dep. at 244-45) (Endo Credit "intended to disincentivize Endo from" introducing a reformulated product)). Respondent has no specific response to the second sentence of Proposed Finding No. 1325.

1326. Endo later introduced Reformulated Opana ER and discontinued selling Original Opana ER. (JX-001 at 011-12 (¶¶ 48-50)). As a result, sales of Original Opana ER did decrease substantially—falling to zero—which triggered the payment of the "Endo Credit". Ultimately, Endo paid Impax $102 million under the "Endo Credit." (JX-001 at 011 (¶ 45); CX1216 (Apr. 2013 email requesting payment); CX5000 at 161-62 (¶ 362) (Noll Report)).

RESPONSE TO FINDING NO. 1326:

Respondent has no specific response other than to note that to the extent Complaint Counsel's Proposed Finding No. 1326 attempts to suggest that a substantial decrease in original Opana ER sales was planned or anticipated, it is inaccurate and misleading. Indeed, the first time that Endo knew its sales would be zero was in the last quarter of 2012, after the Novartis plant shutdown and resulting supply interruption. (Cuca, Tr. 615, 617, 677 ("I don't know that

anyone was anticipating a change in the marketplace"); RX-094.0003-06 (supply chain disruption for original Opana ER resulted in Endo Credit liability)). Until that point, Endo expected to sell Opana ER through the fourth quarter of 2012. (CX4017 (Levin, Dep. at 131); RX-094.0006 ("Prior to March [2012], it would have been reasonable to assume that prescriptions of old formulation [Opana ER] would have occurred in Q4 2012"); RX-108.0002 at 10).

1327. Another benefit of the settlement to Impax was an upfront payment of $10 million dollars for a co-development and co-promotion agreement that was then terminated. (RX-365 at 0009 (DCA § 3.1); *see also* CCF ¶¶ 320, 1246, above; CX5003 at 052 (¶ 87) (Geltosky Report); CX5000 at 162 (¶ 363) (Noll Report); CX5004 at 060 (¶ 128) (Noll Rebuttal Report)).

RESPONSE TO FINDING NO. 1327:

Complaint Counsel's Proposed Finding No. 1327 is inaccurate and misleading. While Endo paid Impax $10 million as part of the Development and Co-Promotion agreement for IPX-203, this was not a "benefit of the settlement." The Development and Co-Promotion Agreement was a "stand-alone legal document[]." (CX4017 (Levin, Dep. at 157-58); *see* Koch, Tr. 313-14 (Impax assessed and considered DCA and SLA as standalone agreements "all the time"); CX4036 (Fatholahi, Dep. at 138-39)). Accordingly, both Endo and Impax assessed the Development and Co-Promotion Agreement independently from the Settlement and License Agreement. (Koch, Tr. 313 (Impax's CEO "was very clear that each agreement should be evaluated on their own merits as a standalone agreement"); CX4001 (Koch, IHT at 41) (DCA was "a separate negotiation that came up during settlement negotiations")). The ultimate payment under the DCA was for rights to IPX-203, which included profit-sharing rights that Endo believed justified the investment. (Cobuzzi, Tr. 2564).

b) The question not answered by Dr. Addanki and Mr. Figg

1328. Dr. Addanki and Mr. Figg have offered the opinion that, if Impax had not entered into this settlement with Endo, it would have been prevented from entering the market until at least mid-2013, and possibly still would not be on the market today. (Figg, Tr. 1971-72; Addanki, Tr. 2376-77 *see, also* CCF ¶¶ 1021, above).

RESPONSE TO FINDING NO. 1328:

Respondent has no specific response.

1329. According to their opinions, therefore, Impax's entry date under continued litigation was not likely to occur until a number of months later than the January 2013 generic entry date in the SLA, and possibly still would not have occurred at all. (RX-548 at 0038 (¶ 83) (Figg Report); Figg Tr. 1971-72).

RESPONSE TO FINDING NO. 1329:

Respondent has no specific response.

1330. Neither Dr. Addanki nor Mr. Figg explains why, if the settlement accelerated entry of generic oxymorphone ER, Endo paid so much to reach an agreement that reduced the duration of the period in which they could have profited from a continued patent monopoly. Neither Dr. Addanki nor Mr. Figg addresses why Endo agreed to such a bad deal when it could have achieved a better outcome by spending a few million dollars more on litigating patent infringement claims against Impax. (CX5004 at 066-67 (¶ 141) (Noll Rebuttal Report)).

RESPONSE TO FINDING NO. 1330:

Complaint Counsel's Proposed Finding No. 1330 is inaccurate and based on unreliable expert testimony. The first sentence is false, lacks foundation that Endo made any payment at the time of settlement, and should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Still, Mr. Figg answered this exact question at trial, where he explained litigation is uncertain and that "things could have gone the other direction as well." (Figg, Tr. 2046). Yet even under the Settlement and License Agreement, whether and how much Endo would pay was uncertain and outside of Endo's

control. (*See* Bazerman, Tr. 923 (testifying Endo did not have control over the events leading to the Endo Credit payment)). And the record is clear that Endo did not expect to make any payment, and did not book a reserve for any payment. (Cuca, Tr. 664-65; CX4017 (Levin, Dep. at 125-26)). Brian Lortie, Endo's Senior Vice President for Pain Solutions at the time of settlement, explained that Endo "intended to replace one product with the other, and that would be the only product that we had on the market," (CX4019 (Lortie, Dep. at 117-18)), but still "did not expect to make a payment to Impax," (CX4017 (Levin, Dep. at 126)).

> 1331. Dr. Addanki and Mr. Figg have no answer to the question why Endo paid so much to settle an infringement case on worse terms than Dr. Addanki and Mr. Figg claim that Endo could have expected to achieve had they just continued to litigate the infringement case to conclusion. The answer is that the only plausible explanation for why Endo entered into a reverse-payment settlement that cost Endo over $100 million dollars is that the agreement enabled Endo to eliminate the possibility of generic entry until eight months before the expiration of the patents at issue in the infringement case. (CX5004 at 066-67 (¶ 141) (Noll Rebuttal Report)).
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> **RESPONSE TO FINDING NO. 1331:**

Complaint Counsel's Proposed Finding No. 1331 is inaccurate. Mr. Figg answered this exact question at trial, where he explained litigation is uncertain and that "things could have gone the other direction as well." (Figg, Tr. 2046). Yet even under the Settlement and License Agreement, whether and how much Endo would pay was uncertain and outside of Endo's control. (*See* Bazerman, Tr. 923 (testifying Endo did not have control over the events leading to the Endo Credit payment)). And the record is clear that Endo did not expect to make any payment, and did not book a reserve for any payment. (Cuca, Tr. 664-65; CX4017 (Levin, Dep. at 125-26)). Brian Lortie, Endo's Senior Vice President for Pain Solutions at the time of settlement, explained that Endo "intended to replace one product with the other, and that would be the only product that we had on the market," (CX4019 (Lortie, Dep. at 117-18)), but Endo still "did not expect to make a payment to Impax," (CX4017 (Levin, Dep. at 126)).

The first sentence of Proposed Finding No. 1331, moreover, should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings shall be supported by specific references to the evidentiary record," and prohibits citations "to expert testimony to support factual propositions that should be established by fact witnesses or documents." (*See* Court, Tr. 1859 ("[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.")).

> 1332. Rather than answer the question of why Endo paid so much to settle with Impax, Respondent asserts that a finding that a settlement is anticompetitive depends on addressing two considerations. One is whether an alternative no-payment settlement is feasible. (RX-547 at 0009-10 (Addanki Report)). The other is the probability that Endo would prevail in the patent infringement litigation. (RX-547 at 0009-10 (Addanki Report)).

RESPONSE TO FINDING NO. 1332:

Complaint Counsel's Proposed Finding No. 1332 is misleading and inaccurate. Mr. Figg answered this exact question at trial, where he explained litigation is uncertain and that "things could have gone the other direction as well." (Figg, Tr. 2046). Yet even under the Settlement and License Agreement, whether and how much Endo would pay was uncertain and outside of Endo's control. (*See* Bazerman, Tr. 923 (testifying Endo did not have control over the events leading to the Endo Credit payment)). And the record is clear that Endo did not expect to make any payment, and did not book a reserve for any payment. (Cuca, Tr. 664-65; CX4017 (Levin, Dep. at 125-26)). Brian Lortie, Endo's Senior Vice President for Pain Solutions at the time of settlement, explained that Endo "intended to replace one product with the other, and that would be the only product that we had on the market," (CX4019 (Lortie, Dep. at 117-18)), but Endo still "did not expect to make a payment to Impax," (CX4017 (Levin, Dep. at 126)). Further, "[t]he test of whether the agreement at issue is anticompetitive [] is a test of whether consumers would have been better off had the parties eschewed settlement and proceeded with litigation,"

(RX-547.0021 (Addanki Rep. ¶ 36)). That test involves more than two considerations, but is not something that Complaint Counsel considered because they offer no evidence regarding the but-for world.

> 1333. Economic analysis of reverse-payment settlements shows that, by definition, the very existence of a large reverse-payment settlement rules out the possibility that the settlement benefits consumers. (CX5000 at 120 (¶ 271) (Noll Report); CX5004 at 061-62 (¶ 130) (Noll Rebuttal Report)). This conclusion is derived from a comparison between the settlement agreement that would maximize expected consumer welfare, regardless of whether such a settlement is feasible, and the expected consumer welfare arising from a settlement. (CX5000 at 120 (¶ 271) (Noll Report); CX5004 at 061-62 (¶ 130) (Noll Rebuttal Report)). The settlement that maximizes expected consumer welfare is one in which the expected profits of the brand-name and generic firms are the same as the expected profits from litigating the case to conclusion, which is why a settlement in which the brand-name firm pays more than saved litigation cost is anticompetitive. (CX5000 at 120 (¶ 271) (Noll Report); CX5004 at 061-62 (¶ 130) (Noll Rebuttal Report)).
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> **RESPONSE TO FINDING NO. 1333:**
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> Complaint Counsel's Proposed Finding No. 1333 is an improper legal conclusion, not a fact, and is based on unreliable expert testimony. In any event, Proposed Finding No. 1333 is inaccurate because it deliberately ignores real-world considerations. Indeed, Professor Noll admitted that he "do[es] not measure the actual anticompetitive harm in the market." (Noll, Tr. 1665). Instead, Professor Noll believes that "one can infer whether a settlement is anticompetitive from the terms of the agreement," (Noll, Tr. 1663), and that he need not "actually model what's going to actually happen in the market," (Noll, Tr. 1661). Professor Noll's purported test has never been published or peer-reviewed, and has never been accepted or utilized by any court. (Noll, Tr. 1642). Actually assessing impact on consumers requires economists to ask "whether consumers would have been better off had the parties eschewed settlement and proceeded with litigation." (RX-547.0021 (Addanki Rep. ¶ 36)). Professor Noll's purported test ignores actual consumers entirely.

1334. As explained in Section XI above, the conclusion that large, unexplained reverse-payment settlements are anticompetitive does not depend on the feasibility of a no-payment settlement or the probability that the brand-name firm will win the infringement litigation because both the brand-name and generic firms take these factors into account. (*See* CCF ¶¶ 983-89, 1021-30, above; Noll, Tr. 1437-38, 1597; CX5004 at 062, 065-66 (¶¶ 131, 139) (Noll Rebuttal Report)).

RESPONSE TO FINDING NO. 1334:

Complaint Counsel's Proposed Finding No. 1334 should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Moreover, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondent's replies to those findings. Finally, Proposed Finding No. 1334 should be disregarded because Complaint Counsel cites only expert testimony for issues of fact. (*See* Court, Tr. 1859 ("[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.")).

3. The conclusion that the reverse-payment agreement harmed consumers does not hinge on proving that Impax would have entered at risk or that Impax would have won the infringement suit

a) The harm is eliminating the potential for competition before January 2013

1335. Dr. Addanki offers the opinion that whether the generic firm was likely to enter prior to the negotiated entry date, either through an at risk launch or after winning the patent infringement case, must be considered in determining whether a settlement agreement is anticompetitive. (RX-547 at 0010 (¶ 11(h-i)) (Addanki Report)).

RESPONSE TO FINDING NO. 1335:

Respondent has no specific response.

1336. Dr. Addanki's method require assessing the likely outcome of the '456 and '933 patent litigation as well as any later litigation over the later-issued patents, plus further evidence to determine whether at-risk entry was more likely than not and, if not, how long all of the infringement trials would last. (CX5004 at 008 (¶ 12) (Noll Rebuttal Report)).

RESPONSE TO FINDING NO. 1336:

Complaint Counsel's Proposed Finding No. 1336 is inaccurate. Complaint Counsel should cite Dr. Addanki to describe Dr. Addanki's "method." Dr. Addanki's test is a simple one: "whether consumers would have been better off had the parties eschewed settlement and proceeded with litigation." (RX-547.0021 (Addanki Rep. ¶ 36)). "Such a comparison would involve evaluating likely consumer benefits in light of the various events that may have transpired had the parties continued litigating the patent case instead of reaching the settlement at issue." (RX-547.0010 (Addanki Rep. ¶ 11(h))). Further, Dr. Addanki testified that his ultimate conclusion was not based on the outcome of the '456 and '933 patent litigation. (Addanki, Tr. 2383 ("Q. [D]oes your opinion in any way depend on how the patent suits between Endo and Impax would ultimately been resolved? A. No."); Addanki, Tr. 2418).

> 1337. Dr. Addanki ignores, however, the underlying economics of settlements of patent infringement cases in the pharmaceutical industry. A small probability that the generic firm will win the infringement litigation is inconsistent with a large reverse-payment settlement because a brand-name firm has nothing to gain by paying off a generic firm that is highly likely to lose the infringement case. Thus, the very existence of a large reverse-payment settlement rules out the possibility that the settlement benefits consumers, making assessing the merits of the infringement case unnecessary in determining whether a reverse-payment settlement causes anticompetitive harm to consumers. (CX5000 at 120 (¶ 271) (Noll Report)).

RESPONSE TO FINDING NO. 1337:

Complaint Counsel's Proposed Finding No. 1337 is misleading because it prioritizes an untested and never-accepted mathematical theory of harm over real-world evidence of consumer welfare. (Noll, Tr. 1642). With regard to the "probability that the generic firm will win the infringement litigation," Professor Noll admitted that this is an economic *assumption*, not a real-world fact. (Noll, Tr. 1634 ("Q. But you don't calculate, for example, the net probability of winning the Endo-Impax patent litigation[?] A. No. I'm entering assumptions in the model.")).

Indeed, Professor Noll admits that his model does not "actually model what's going to actually happen in the market." (Noll, Tr. 1661). Thus, Professor Noll's theoretical approach fails to consider a number of scenarios that could have left consumers worse off but for the settlement. (*See* Noll, Tr. 1667 ("If [Impax] continued litigating and lost, that would make consumers worse off.")). Professor Noll instead contends that the "very existence of a large reverse-payment" is sufficient to condemn the agreement, even though he cannot say whether or not consumers are better off with the settlement. (Noll, Tr. 1669 ("Q. Is it fair to say you believe consumers are better off today because Impax is selling oxymorphone? A. I think that's an extremely difficult question to answer.")). To the contrary, Dr. Addanki explained that "there are all kinds of reasons that firms may enter into agreements that include payments that are nevertheless procompetitive in the effect they have on consumers." (Addanki, Tr. 2353).

> 1338. The harm caused by the Impax-Endo Settlement Agreement is the elimination of the potential for competition before January 2013. (*See* CCF ¶¶ 966-71, above). The validity of this conclusion does not depend on a finding of which side will win the '456 and '933 patent litigation or any later infringement litigation over the later-issued patents, and whether Impax would launch at risk if it did not settle. (CX5004 at 009 (¶ 15) (Noll Rebuttal Report)).

RESPONSE TO FINDING NO. 1338:

The first sentence of Complaint Counsel's Proposed Finding No. 1338 should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Moreover, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondent's replies to those findings. Proposed Finding No. 1338 is also misleading, inaccurate, and based on unreliable expert testimony. The relevant question is "whether consumers would have been better off had the parties eschewed settlement and proceeded with litigation." (RX-547.0021

(Addanki Rep. ¶ 36)). Proposed Finding No. 1338 consequently is incorrect because if Endo had won the underlying patent litigation, Impax would have been enjoined from selling oxymorphone ER until September 2013 at the earliest, resulting in significant consumer harm. (*See* Noll, Tr. 1667 ("If [Impax] continued litigating and lost, that would make consumers worse off."); Savage, Tr. 818, 821; Hoxie, Tr. 2834; Figg, Tr. 1972-76).

> 1339. The fundamental underlying fact is that no brand-name firm would pay a generic firm to settle a patent infringement case unless the brand-name firm expected to recover at least the cost of the settlement in increased profits from the brand-name drug. (CX5004 at 009 (¶ 14) (Noll Rebuttal Report)).

RESPONSE TO FINDING NO. 1339:

Complaint Counsel's Proposed Finding No. 1339 lacks foundation that there was any payment at the time of settlement and is not supported by any record evidence. (Addanki, Tr. 2353 ("there are all kinds of reasons that firms may enter into agreements that include payments that are nevertheless procompetitive in the effect they have on consumers")). Professor Noll did not calculate an expected value of the challenged terms of the settlement. (Noll, Tr. 1651). Indeed, the parties knew that the settlement could have no value to Impax. (Cuca, Tr. 628-29; CX4017 (Levin, Dep. at 143-44)). In fact, "it was not [Endo's] expectation that a payment would have to be made." (CX4017 (Levin, Dep. at 99-100) ("at the time the transaction was inked I did not expect that Endo would have to make a payment under this provision")). Even Professor Noll agrees that the payment pursuant to the SLA could have been zero. (Noll, Tr. 1479-80). Finally, Proposed Finding No. 1339 should be disregarded because Complaint Counsel cites only expert testimony for issues of "fundamental underlying fact." (*See* Court, Tr. 1859 ("[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.")).

1340. As long as entry prior to the entry date in the SLA was possible, one does not need to assess the likelihood of contingent events to conclude that the settlement was anticompetitive. (CX5004 at 058-59 (¶ 123) (Noll Rebuttal Report)).

RESPONSE TO FINDING NO. 1340:

Complaint Counsel's Proposed Finding No. 1340 is an improper and inaccurate conclusion of law, not a fact. Further, whether "entry prior to the entry date in the SLA was possible" tells one nothing about actual effects without assessing the likelihood of contingent events. Because Endo obtained additional patents, even if Impax had entered "prior to the entry date in the SLA" it would have very likely been enjoined by those patents but for the license Impax secured in the Settlement and License Agreement, just as every other ANDA filer is now enjoined. (Figg, Tr. 1972 (testifying Impax would likely be enjoined from selling oxymorphone ER until 2029 without the SLA)).

1341. The very existence of a reverse payment indicates that the brand-name firm expects that the duration of the patent monopoly will be longer under the settlement than under continuing the infringement litigation to conclusion. Hence, the expected entry date in the settlement agreement must be later than the entry date that the brand-name firm expects to occur without a settlement. Thus, the agreement is anticompetitive because it eliminates the risk to the brand-name firm of entry occurring before the agreed date. (CX5004 at 009 (¶ 14) (Noll Report)).

RESPONSE TO FINDING NO. 1341:

Complaint Counsels' Proposed Finding No. 1341 is an improper conclusion of law, not a fact. Proposed Finding No. 1341 is also wrong because it relies solely on economic assumptions instead of real-world evidence. Professor Noll admits that his model does not "actually model what's going to actually happen in the market." (Noll, Tr. 1661). Professor Noll's proposed framework "might be something that would trigger an inquiry as to whether a settlement was anticompetitive in its effect, *but it couldn't possibly substitute for that factual inquiry*. [That] inquiry is a factual one, was monopoly power less effectively dissipated through the settlement

that you're analyzing than it would have been otherwise in the but-for world but for the settlement." (Addanki, Tr. 2352-53 (emphasis added)). Professor Noll and Complaint Counsel ignore that factual inquiry completely.

b) The payment logically pushes back the expected entry date

1342. The entry date in the Impax-Endo Settlement Agreement was linked to the reverse payment from Endo to Impax. (*See* CCF ¶¶ 1034-54, above). Adding a payment to the negotiation of the settlement increases the range of acceptable outcomes for the generic company, including entry dates later than what the generic would have accepted without the payment. In such a situation, the expected result is that the generic company is willing to accept an entry date later than what it would have accepted without the payment. (CX5001 at 009 (¶ 17) (Bazerman Report); Addanki, Tr. 2392-93; CX4044 (Addanki, Dep. at 26-27)). The logical result of linking the payment from Endo to Impax and the entry date is that the payment resulted in a later entry date than would be expected absent the payment. (CX5001 at 022 (¶ 44) (Bazerman Report)).

RESPONSE TO FINDING NO. 1342:

The first sentence of Complaint Counsel's Proposed Finding No. 1342 should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Moreover, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondent's replies to those findings.

Proposed Finding No. 1342 also misrepresents Dr. Addanki's testimony. He did not state that "the generic company is willing to accept an entry date later than what it would have accepted without the payment." Rather, Dr. Addanki agreed with a hypothetical in which that was an underlying assumption he was told to accept. (Addanki, Tr. 2393 ("[B]ecause you told me to assume that the brand would settle for nothing earlier than June 1, I would have to agree that it would be June 1.")). Furthermore, there is no evidence in the record that the Endo Credit or No-Authorized Generic provision resulted in a later licensed-entry date. Endo consistently

refused to contemplate any licensed entry date before January 1, 2013. (Koch, Tr. 239 ("met complete resistance to the concept of an earlier launch date"); Mengler, Tr. 565-67; *see* Noll, Tr. 1599-1600 ("Impax's attempt to get an earlier date met with complete resistance.")). This resistance was the same whether or not the Endo Credit and No-AG terms were included. (Snowden, Tr. 371-73, 423 (explaining Endo refused a July 2011 licensed entry date without the Endo Credit or No-AG provision)). Indeed, at no point during settlement discussions did Endo and Impax discuss Impax accepting a later entry date in exchange for something of value. (Mengler, Tr. 567-68; CX4012 (Donatiello, IHT at 172-73) (no provisions in SLA linked to commencement date)). Tellingly, the two cited paragraphs of Professor Bazerman's report cite no record evidence.

> 1343. Impax's and Endo's documents are consistent with the logic that linking the entry date to the payment would result in a later entry date. The evidence shows that: (1) Endo and Impax had the financial incentives to reach such an agreement; (2) the branded-to-generic payments did not make sense from Endo's perspective absent the ability to avoid the risk of competition; (3) Impax presented a risk to competition and was, in fact, preparing to be ready for a possible at-risk launch significantly before January 2013; and (4) settlements with other generic Opana ER manufacturers did not include branded-to-generic payments and had earlier entry dates (which would become effective as soon as Impax used its first-filer exclusivity). (CX5001 at 22 (¶ 45) (Bazerman Report)).

RESPONSE TO FINDING NO. 1343:

Complaint Counsel's Proposed Finding No. 1343 should be disregarded because it violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." (*See* Court, Tr. 1859 ("[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.")). The cited paragraph of Professor Bazerman's report also fails to cite any record evidence in support of the proposition. And witnesses from both Endo and Impax confirm that at no point during settlement discussions did Endo and Impax discuss Impax

accepting a later entry date in exchange for something of value from Endo. (Mengler, Tr. 567-68; CX4012 (Donatiello, IHT at 172-73) (no provisions in SLA linked to commencement date)).

(1) Impax and Endo's financial incentives

1344. The amount that Endo could expect to gain from not facing generic competition until January 2013 was significantly greater than the costs to Impax of agreeing not to sell generic Opana ER until January 2013. Endo could use the profits it would generate from sales before January 2013 to compensate Impax for agreeing to abandon its patent litigation and not sell generic Opana ER until 2013. (CX5001 at 023-24 (¶¶ 46-48) (Bazerman Report)).

RESPONSE TO FINDING NO. 1344:

Complaint Counsel's Proposed Finding No. 1344 should be disregarded because it violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." (*See* Court, Tr. 1859 ("[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.")). Professor Bazerman calculated neither "[t]he amount that Endo could expect to gain" from the settlement nor the "costs to Impax of agreeing not to sell generic Opana ER until January 2013." (Bazerman, Tr. 903 (testifying he did not calculate expected values for various scenarios)).

1345. This is a common pattern in brand-generic entry discussions and consistent with the parties' financial planning documents. (CX5001 at 23 (¶ 46) (Bazerman Report)).

RESPONSE TO FINDING NO. 1345:

Complaint Counsel's Proposed Finding No. 1345 should be disregarded because it violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." (*See* Court, Tr. 1859 ("[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.")). In any event, there is no indication that this so-called "pattern" occurred in

the Endo-Impax negotiations. In fact, witnesses from both Endo and Impax confirm that at no point during settlement discussions did Endo and Impax discuss Impax accepting a later entry date in exchange for something of value. (Mengler, Tr. 567-68; CX4012 (Donatiello, IHT at 172-73) (no provisions in SLA linked to commencement date)).

> 1346. For example, Endo's 3-year plan for 2010, circulated a few months prior to the settlement with Impax, assumes generic entry in July 2011 and estimates that Endo's net sales will be $184.5 million lower in the four quarters after July 2011 than its net sales in the four quarters before July 2011. (CX1320 at 007 (email from Nancy Santilli to Alan Levin, et al. re: Updated Three Year Forecast 2010-2012) (sum of Net Sales for Q3'10-Q2'11 minus sum of Net Sales for Q3'11-Q2'12)). In another document, Endo indicates that it could gain hundreds of millions of dollars from not facing generic competition until January 2013. (CX1314 at 001 (June 1, 2010 Endo Cuca/Levin email) (forecasting that, in 2010 Endo "would lose $71.2M in branded ER sales assuming a generic launch on July 1")).

RESPONSE TO FINDING NO. 1346:

Complaint Counsel's Proposed Finding No. 1346 is incomplete and misleading. The first cited document (CX1320-007) simply assumes lost sales for purposes of the particular forecasts. (CX1320-007 (describing "assumptions")). It was Endo's practice to forecast different scenarios regarding the future of its Opana ER product to "analyze the full range of potential outcomes." (Cuca, Tr. 663-64). Endo did not know if any of the many different assumptions contained in its forecasts would come true. (Cuca, Tr. 662-63). Endo simply forecasted "a number of different potential outcomes over the course of years," the accuracy of which were "always debatable." (Bingol, Tr. 1292, 1303).

Similarly, Mr. Cuca, the author of the second cited document (CX1314), testified that the figures came from "assuming some specified erosion assumption." (CX4035 (Cuca, Dep. at 66) (discussing CX1314)). Mr. Cuca also testified that under those assumptions, "the bottom-line effect" of a theoretical Impax launch—Endo's income before taxes, which considers revenues and expenses together—would only be $2 million at the "more aggressive end of the range of

cost savings" and $13.5 million if Endo was "less aggressive about cost savings." (CX4035 (Cuca, Dep. at 67) (discussing CX1314)).

1347. Impax stood to lose a much smaller amount by agreeing not to enter until January 2013 than Endo would gain from additional sales of its branded product without generic competition. For example, in Impax's 5-year plan for 2010, which was finalized shortly before the settlement with Endo, Impax forecasted two scenarios: (1) a launch in June 2010; and (2) a launch in July 2011. (CX0514 at 004 (Impax 5-Year Plan)). Under the first scenario, Impax estimated that it would have net sales of approximately $53.2 million between June 2010 and December 2012 from the five dosage strengths on which Impax was first filer, with the majority of sales coming during Impax's first-filer exclusivity period. (CX0514 at 004-07 (Impax 5-Year Plan)). Under the second scenario, Impax estimated its net sales from launch through December 2012 at approximately $25.6 million. (CX0514 at 004-07 (Impax 5-Year Plan)). Based on either scenario, Impax's projected revenues from entry until January 2013, which would be lost under the settlement, were less than a third of what Endo would gain in a single year of additional sales of branded product without generic competition. (CX0514 at 004-07 (Impax 5-Year Plan); CX5001 at 023 (¶ 47) (Bazerman Report)).

RESPONSE TO FINDING NO. 1347:

Complaint Counsel's Proposed Finding No. 1347 is inaccurate, misleading, and lacks foundation. Impax used assumptions of sales price as a "milestone or marker that I generally default to *as a first step*" for purposes of forecasting possible outcomes. (Engle, Tr. 1711 (emphasis added)). Five year plans, moreover, utilize "many, many assumptions" as a means to understand possible outcomes. (Engle, Tr. 1710, 1719-20 (they "give a good range of possibilities")). Finally, the cited document makes clear that an Impax launch of generic oxymorphone ER is an "obvious[] controversial element" in the forecast and says nothing about Endo's sales. (CX0514-001).

(2) The Payments from Endo to Impax would make no sense to Endo unless the Payments were connected to a later entry date

1348. Endo's commitment to the No-AG agreement and the Endo Credit, make no sense for Endo other than as an inducement for Impax to accept the entry date in 2013. There are costs to Endo in the form of foregone authorized generic sales or a cash payment.

(See CCF ¶¶ 1040-42, above). The only benefit to Endo, however, flows from Impax's agreement not to enter until January 2013. (*See* CCF ¶ 1043, above).

RESPONSE TO FINDING NO. 1348:

The proposed summary finding should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Additionally, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondent's replies to those findings.

1349. Endo had strong financial incentives, absent the Impax-Endo Settlement Agreement, to launch an AG if Impax entered with its own generic. Once generic entry occurs, a brand company's sales quickly erode as pharmacies automatically substitute prescriptions to a generic equivalent. Brand companies launch authorized generics to recoup some of the lost branded sales by taking a share of generic sales. (CX6052 at 080-83 (FTC Authorized Generics Report)). Absent reformulation, Endo would have these incentives to launch an authorized generic, and in 2010 Endo was preparing to launch an AG for Opana ER. (*See* CCF ¶¶ 84-92, 399-403, above).

RESPONSE TO FINDING NO. 1349:

The first and fourth sentences of Complaint Counsel's Proposed Finding No. 1349 should be disregarded because they violate the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Moreover, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondent's replies to those findings.

The only document cited to support the propositions in the second and third sentences of Proposed Finding No. 1349 is a report from the FTC itself, which was drafted in part by members of Complaint Counsel. (CX6052-002). The evidence at trial indicated that brand companies launch authorized generics "from time to time," but do not always utilize authorized

generics. (Koch, Tr. 233). Moreover, whatever brand companies typically do says nothing about Endo. And the only sentence in Proposed Finding No. 1349 that references Endo has no citation to the record. This is because Endo "never seriously considered taking any further steps to prepare for or to do [an authorized generic of Opana ER] because we really didn't want to." (CX4019 (Lortie, Dep. at 118-19); *see also* Bingol, Tr. 1337 ("I don't recall specific forecasts about an authorized generic."); Bingol, Tr. 1338-39 (an authorized generic "was never, to my knowledge . . . fully realized as a plan or an idea"); CX4031 (Bradley, Dep. at 198) ("I don't recall having any conversation with any colleagues regarding the launch of an authorized generic.")).

1350. Endo has made the decision to launch authorized generics of other drugs. For example, Endo launched an authorized generic of immediate-release Opana in the third quarter of 2010, shortly after the Opana ER settlement with Impax. (CX3188 (Endo press release) ("Endo Pharmaceuticals launches generic version of immediate release OPANA.")). Endo also launched authorized generic versions of Lidoderm and Fortesta gel in 2014 and Voltaren gel in 2016. (CX4019 (Lortie, Dep. at 120 (Lidoderm), 122 (Fortesta), 129-30 (Voltaren gel))).

RESPONSE TO FINDING NO. 1350:

Respondent has no specific response except to point out that Complaint Counsel's Proposed Finding No. 1350 shows that Endo had never launched an authorized generic at the time of settlement. Indeed, Mr. Lortie explained that Endo did not even have a general practice regarding launching authorized generics. (CX4019 (Lortie, Dep. at 112)).

1351. Absent the settlement with Impax, Endo may have had a contractual commitment to Penwest to sell an authorized generic. (CX4019 (Lortie, Dep. at 19 ("To the best of my recollection, there were requirements that Endo perform commercially reasonable efforts in support of Original Opana ER, which is the product that we were partnered with Penwest, and those commercially reasonable efforts typically include active promotion and investment in the product.")).

RESPONSE TO FINDING NO. 1351:

Complaint Counsel's Proposed Finding No. 1351 should be disregarded because it lacks foundation, is not supported by record evidence, and is base speculation. Mr. Lortie said nothing about a "contractual commitment to Penwest to sell an authorized generic." Mr. Lortie said only "to the best of my recollection" there were requirements to "perform commercially reasonable efforts in support of Original Opana ER." (CX4019 (Lortie, Dep. at 19)).

1352. By agreeing to not launch an AG, Endo incurred a potential cost in the form of foregone sales of its AG. By launching an AG, Endo projected it could recoup a significant portion of the branded Opana ER sales it would expect to lose if Impax entered. (*See* CCF ¶ 84, above).

RESPONSE TO FINDING NO. 1352:

The proposed summary finding should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Additionally, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondent's replies to those findings.

1353. The cost of the Endo Credit to Endo is clear—a cash payment to Impax. (RX-364 at 0003, 0012 (SLA §§1.1, 4.4) (defining "Endo Credit" and "Endo Credit")); JX-001 at 011 (¶ 46)).

RESPONSE TO FINDING NO. 1353:

Complaint Counsel's Proposed Finding No. 1353 is inaccurate and not supported by the record. When it was signed, the SLA did not require Endo to actually pay anything to Impax. (RX-364.0012 (SLA § 4.4) (no payment until 90 days after documentation that Endo Credit was triggered is provided)). Nor did Endo expect to make a payment at any point in the future. (CX4017 (Levin, Dep. at 99-100) ("at the time the transaction was inked I did not expect that

Endo would have to make a payment under this provision")). Whether Endo would eventually have to make a payment under the Endo Credit provision depended on factors outside either party's control that would not be known until years after the parties executed the SLA. (Cuca, Tr. 625-30). In fact, both Complaint Counsel and its economic expert admitted it was possible that the Endo Credit (and the No-Authorized Generic provision) would have zero value. (Court, Tr. 71, 75 ("JUDGE CHAPPELL: Are you going to stand there and tell me that the lowest possible outcome was not going to be zero? You're going to stand there and tell me that because some paid expert tells you that it had to be $62 million floor that it couldn't have been zero? MR. LOUGHLIN: No, Your Honor. There was a theoretical possibility of zero."); Noll, Tr. 1654 ("Q. And that example where you get zero of both, you didn't include that on your demonstrative of scenarios, did you? A. No, I didn't.")).

> 1354. The cost to Endo imposed by the Impax-Endo Settlement Agreement must be considered in whole. If one looks at the No-AG provision and Endo Credit provision separately, one might not see a cost to Endo. But, this can be achieved only by ignoring other facts. For example, if Endo reformulated to a new version of Opana ER and moved customers to that product before generic entry on the Original Opana ER, there would be no cost to Endo from the No-AG provision, because Endo would not have sold an AG. But this ignores that Endo would then need to make a payment under the Endo Credit provision— as it ultimately did. Alternatively, if Endo did not reformulate and move customers, then it would not have to pay the Endo Credit. But it would then be forgoing valuable AG sales that could be realized absent the No-AG agreement. (CX5001 at 028-29 (¶ 54) (Bazerman Report); (*see also* CCF ¶¶ 322-28, 395, 399, above).

RESPONSE TO FINDING NO. 1354:

Complaint Counsel's Proposed Finding No. 1354 is an improper and inaccurate conclusion of law, not a fact. Complaint Counsel's Proposed Finding No. 1354 should also be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Moreover, the individual findings cited do not support the

proposed summary finding and are unreliable for the reasons set out in Respondent's replies to those findings. Further, Proposed Finding No. 1354 ignores the possibility that Impax would have received no value from *both* the Endo Credit and No-AG provision. (RX-547.0067-68 (Addanki Rep. ¶ 126); Court, Tr. 71, 75 ("JUDGE CHAPPELL: Are you going to stand there and tell me that the lowest possible outcome was not going to be zero? You're going to stand there and tell me that because some paid expert tells you that it had to be $62 million floor that it couldn't have been zero? MR. LOUGHLIN: No, Your Honor. There was a theoretical possibility of zero."); Noll, Tr. 1654 ("Q. And that example where you get zero of both, you didn't include that on your demonstrative of scenarios, did you? A. No, I didn't."); Noll, Tr. 1479).

(3) Impax Was Preparing for an At-Risk Launch Significantly Earlier Than January 2013

1355. The focus of the Impax-Endo settlement negotiations was primarily on the branded-to-generic payments, rather than the generic entry date. This is consistent with Impax's unwillingness to accept a January 2013 entry date without a payment, because Impax expected to sell generic Opana ER earlier without the payments in the settlement. (CX5001 at 031 (¶ 58) (Bazerman Report)).

RESPONSE TO FINDING NO. 1355:

Complaint Counsel's Proposed Finding No. 1355 should be disregarded because it violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." (*See* Court, Tr. 1859 ("[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.")). Proposed Finding No. 1355 also lacks support in the record. Impax and Endo negotiated a license date extensively, with the date moving from March 2010 to February 2010 to January 2010. (Mengler, Tr. 566; *see* Noll, Tr. 1598). But once Impax obtained the January 1, 2013 date, Endo dug in its heels and refused to entertain anything earlier. (Mengler,

Tr. 565-67 (Endo was "adamant about 2013 and not getting anything into 2012" and "was certainly digging in their heels with that date"); *see* Noll, Tr. 1599-1600 ("Impax's attempt to get an earlier date met with complete resistance.")).

1356. As discussed in greater detail above, both Impax and Endo forecasted generic entry by Impax in 2010 or 2011. (*See* CCF ¶¶ 58-64, 148-66, above). And Impax was taking steps to plan and prepare for an at-risk launch. (*See* CCF ¶¶ 168-213, above).

RESPONSE TO FINDING NO. 1356:

The proposed summary finding should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Additionally, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondent's replies to those findings.

1357. Impax's preparations for a possible at-risk launch show that it was targeting making money from generic Opana ER in 2010 or 2011. By agreeing not to market generic Opana ER until January 2013, Impax was sacrificing any potential for those profits, plus potential future profits if Endo reformulated to a new version of Opana ER before Impax's generic entry. The branded-to-generic payments provide a bridge to compensate Impax for sacrificing those potential near-term and future profits. (CX5001 at 034 (¶ 63) (Bazerman Report)).

RESPONSE TO FINDING NO. 1357:

Complaint Counsel's Proposed Finding No. 1357 should be disregarded because it violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." (*See* Court, Tr. 1859 ("[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.")). In any event, the first sentence of Proposed Finding No. 1357 is factually incorrect. Impax's regular-course preparations did not indicate it was "targeting making money"; the preparations simply indicated that Impax sought to be launch ready at the earliest

date allowed by the Hatch-Waxman Act, as it does with every product. (CX4023 (Hildenbrand, Dep. at 60-61, 140); CX4030 (Hsu, Dep. at 85-86)).

The second sentence of Proposed Finding No. 1357 assumes that Impax could have sold generic oxymorphone ER before January 1, 2013, but that was uncertain given the patent litigation and unlikely given Endo's ability to obtain additional future patents. (Addanki, Tr. 2360; Figg, Tr. 1971-72). Finally, the alleged payment terms were not compensation, but a means "to prevent [Endo] from switching the market." (Mengler, Tr. 582-83 (Endo Credit was not intended to generate income, it was meant to ensure Impax had a generic opportunity); CX4021 (Ben-Maimon, Dep. at 118, 122); CX4037 (Smolenski, Dep. at 244-45) ("intended to disincentivize Endo from" introducing a reformulated product); CX4026 (Nguyen, Dep. at 163-64) (Endo Credit was used to "put [Endo] to [its] word" with respect to reformulation)).

> 1358. The existence of the branded-to-generic payments implies a concern within Endo that Impax was a threat to launch at risk. If Endo believed there was no chance for Impax to launch at risk, then Endo could have converted the marketplace to Reformulated Opana ER without needing to pay Impax. It was the combination of Endo planning on launching a Reformulated Opana ER and the significant risk of Impax launching without a license in advance of the Reformulated Opana ER launch that created a strong incentive for Endo to pay Impax to agree not to enter until 2013, thereby avoiding a risk of competition to Endo's branded product. (CX5001 at 034 (¶ 64) (Bazerman Report)).

RESPONSE TO FINDING NO. 1358:

Complaint Counsel's Proposed Finding No. 1358 should be disregarded because it violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." (*See* Court, Tr. 1859 ("[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.")). In fact, the cited paragraph of Professor Bazerman's report does not cite to anything in the evidentiary record. Furthermore, record evidence indicates that Endo was not concerned with an at-risk launch. When Impax suggested during settlement negotiations that it

might launch at risk at the end of the Hatch-Waxman Act's thirty-month stay, Endo's lawyer laughed at the suggestion. (Snowden, Tr. 424; CX4032 (Snowden, Dep. at 26)). Endo's lawyer responded that "Impax never launches at risk. . . . That's not a realistic date." (Snowden, Tr. 424). Endo's internal documents make the same point, stating that at the time of settlement Impax was "not likely to launch at risk" because it had never done so before. (RX-086 at 9-10 (third-party market intelligence firm noted that "Impax tends not to launch at risk")). Indeed, Endo surveyed doctors, drug wholesalers, pharmacists, academics, and financial analysts and reported that each "doubt[s] Impax would launch at risk." (RX-086 at 9).

(4) Opana ER Settlements with No Payments Had Earlier Entry Dates

1359. [redacted] (CX3383 at 002, 003 (Actavis Settlement) (admitted for fact of the settlement and its terms, not truth of the matter asserted) (*in camera*); *see* CCF ¶¶ 222, 384, above). Actavis was the first generic company to file an ANDA on two dosage strengths of Opana ER (the 7.5 and 15 mg) and was not blocked from selling these by any Impax first-filer exclusivity. (JX-003 at 003 (¶ 12)). [redacted] (CX3383 (Actavis Settlement) (admitted for fact of the settlement and its terms, not truth of the matter asserted) (*in camera*); *see* CCF ¶ 1009, above).

RESPONSE TO FINDING NO. 1359:

Complaint Counsel's Proposed Finding No. 1359 is incomplete and misleading. The settlements referenced in Proposed Finding No. 1359 are simply not probative of the settlement between Endo and Impax. "Endo would have had strong incentives to settle with Actavis and to give Actavis a relatively early entry date for the 7.5 mg and 15 mg dosages because those dosages accounted for such a small percentage of Opana ER sales. For Endo, the risk in litigating its patents is that one or more claims could be invalidated." (RX-548.0046-47 (Figg

Rep. ¶ 101); *see also* Figg, Tr. 1946-47; Bazerman, Tr. 877 (admitting that one of the reasons Endo settled with Actavis was because the two dosages did not represent meaningful portion of Endo's Opana ER sales)). Professor Bazerman explained that Endo's willingness to accept a comparable settlement with Impax would have been impacted by the psychological precedent created by Endo's settlement with Actavis, requiring a later date for Impax. (Bazerman, Tr. 918). And Professor Bazerman admits that the negotiations and settlement agreement with Impax were likely more important to Endo than the negotiations and settlement with Actavis. (Bazerman, Tr. 917-18).

As for the other settlements, they are not comparable because none of the ANDA filers had "first to file" status, and therefore the entry dates had little meaning since those companies could not launch until after the first-filer. (Koch, Tr. 232; Figg, Tr. 1854 ("[T]he FDA is not allowed to approve a subsequent ANDA until 180 days after the first applicant launches its product.")). Finally, none of the other ANDA filers, including Actavis, secured broad rights to later-acquired patents. (RX-548.0044 (Figg Rep. ¶ 95)).

4. Mr. Figg's opinions do not undermine the conclusion that the reverse-payment agreement harmed consumers

1360. Mr. Figg is not being proffered as an expert in antitrust economics. (Figg, Tr. 1977). Mr. Figg does not hold himself out as a specialist in antitrust law. (Figg, Tr. 2054).

RESPONSE TO FINDING NO. 1360:

Respondent has no specific response.

1361. Mr. Figg is not offering any opinion as to whether the settlement between Endo and Impax violated the antitrust laws. (Figg, Tr. 2057).

RESPONSE TO FINDING NO. 1361:

Respondent has no specific response.

a) Mr. Figg offers no opinions about whether Endo made any payments to Impax or whether any entry date other than January 1, 2013 would have been reasonable

1362. Mr. Figg has no opinions about any Endo payments to Impax and no opinion about the reasonableness of any other potential entry dates on which Endo and Impax could have agreed. (Figg, Tr. 1998 ("I was not asked to and I have not looked at whether there was a payment . . . ."); Figg, Tr. 2006 (not offering any opinion about the reasonableness of any other potential entry date for Impax other than January 1, 2013)).

RESPONSE TO FINDING NO. 1362:

Complaint Counsel's Proposed Finding No. 1362 is incomplete. Mr. Figg opined that entering the Settlement and License Agreement with the January 1, 2013, licensed entry date was "the most reasonable and prudent course of action at the time and likely provided Impax the earliest opportunity to sell generic Opana ER to the benefit of consumers." (RX-548.0005 (Figg Rep. ¶ 3); *see* Figg, Tr. 1976).

1363. Mr. Figg offers no opinions about the amount of litigation costs saved by Endo or Impax as a result of having settled their patent litigation. (Figg, Tr. 1998-99).

RESPONSE TO FINDING NO. 1363:

Respondent has no specific response.

1364. Mr. Figg is not offering any opinions regarding the contents of the DCA. (Figg, Tr. 1997-98).

RESPONSE TO FINDING NO. 1364:

Respondent has no specific response.

b) Mr. Figg offers no opinions about whether Impax would have launched at risk

1365. Mr. Figg offers no opinion regarding whether Impax would have launched its generic oxymorphone ER product at risk and has no experience making decisions regarding at-risk launches. Mr. Figg has never been the decision maker at a pharmaceutical company with respect to decisions about whether to launch a pharmaceutical at risk. (Figg, Tr. 1979-80). He has never been in a meeting where the ultimate decision whether to launch at risk was made. (Figg, Tr. 1980).

RESPONSE TO FINDING NO. 1365:

Complaint Counsel's Proposed Finding No. 1365 is inaccurate and misleading. First, Mr. Figg did offer an opinion about an at-risk launch by Impax, noting that "Impax could not have launched before a favorable decision of the Court of Appeals for the Federal Circuit without facing significant risks" and that "it would have been prudent to wait for final resolution by the Federal Circuit to avoid the potential for lost-profit damages." (RX-548.0042-43 (Figg Rep. ¶¶ 90-91)). Second, the first sentence of Proposed Finding No. 1365 should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Third, Mr. Figg testified that the decision to launch at-risk was a business decision, and that he had not been involved in the particular business decision, (Figg, Tr. 1979), but that Mr. Figg has been involved in Hatch-Waxman litigation in which an at-risk launch was considered, (Figg, Tr. 1828).

1366. Mr. Figg did not undertake his own quantitative analysis of how often at-risk launches occur. (Figg, Tr. 2026; *see also* Figg, Tr. 2060 (agreeing that he is not offering any empirical claim or numerical analysis to support his opinion that at-risk launches were "rare")). None of his opinions rely on an analysis of Impax's financial statements, which he did not look at. (Figg, Tr. 2060). He did not consider Impax's financial condition as of June 2010. (Figg, Tr. 2060).

RESPONSE TO FINDING NO. 1366:

Respondent has no specific response.

1367. Mr. Figg avoids advising his clients whether they should launch at risk or not, because that is not his decision to make, and that is not the type of advice he provides to his clients. (Figg, Tr. 2061, 2063-64). Mr. Figg conceded that his opinion in his report—that, if he were counseling Impax in June 2010, he would not have recommended that Impax launch at risk—is an "overgeneralization." (Figg, Tr. 2061-62).

RESPONSE TO FINDING NO. 1367:

Complaint Counsel's Proposed Finding No. 1367 is incomplete and misleading. Mr. Figg testified that "[w]hat I try to do is advise them of what I perceive the patent risks to be, and then whether they decide to accept that risk or whether there are business considerations that influence, that's their decision." (Figg, Tr. 2061). Mr. Figg testified that a specific line in his report was an "overgeneralization," but explained that "[m]y advice in that situation would have been that there are substantial risks if you proceed with this litigation that you will lose, and if you launch at risk, you run the risk of losing and being liable for lost profit damages to Endo." (Figg, Tr. 2062).

1368. Mr. Figg has no experience as an executive or businessperson in a management role at a pharmaceutical company. (Figg, Tr. 1978; *see also* Figg, Tr. 1978 (never served on a board of directors of a pharmaceutical company)). He has never been the decision maker at a pharmaceutical company with respect to decisions about settling Hatch-Waxman litigation. (Figg, Tr. 1979).

RESPONSE TO FINDING NO. 1368:

Respondent has no specific response.

1369. Mr. Figg has never worked at Impax and never represented Impax as counsel. (Figg, Tr. 1980).

RESPONSE TO FINDING NO. 1369:

Respondent has no specific response.

c) Mr. Figg's opinions do not rest on a reliable or valid methodology

1370. Mr. Figg's opinions are not based on a cognizable methodology. (CX4045 (Figg, Dep. at 108) (stating that he cannot summarize the methodology he applied in reaching his opinions)).

RESPONSE TO FINDING NO. 1370:

Complaint Counsel's Proposed Finding No. 1370 is an incomplete and inaccurate summary of Mr. Figg's testimony. The cited testimony states that Mr. Figg cannot summarize the methodology because Mr. Figg "doesn't know what [Counsel] mean[s] by that," and that "everything I did here was from the perspective of someone who litigates patent cases or advises clients about issues." (CX4045 (Figg, Dep. at 108-09)). Mr. Figg further clarified that "my methodology of analyzing the facts of the case were clear from my report. And if -- therefore, I don't really understand what you're asking when you ask that." (Figg, Tr. 2003-04). Indeed, Judge Chappell noted that Complaint Counsel's questioning was "assuming that a method is required rather than honesty and hard work." (Figg, Tr. 2004). Mr. Figg agreed that "I think honesty and hard work and applying the knowledge that I've gained over a few decades as a patent attorney and a litigator were all part of the methodology I applied here, a careful analysis. They were all part of it." (Figg, Tr. 2005).

> 1371. Mr. Figg's opinions are not reliable because his process in developing his opinions in this case deviated from his usual process as a litigator of Hatch-Waxman cases. Mr. Figg cannot remember ever litigating a Hatch-Waxman case in which he did not discuss the merits of the case with in-house counsel, but he did not talk to anyone at Impax about the merits of the patent case between Endo and Impax that settled in June 2010. (Figg, Tr. 1992).

RESPONSE TO FINDING NO. 1371:

Complaint Counsel's Proposed Finding No. 1371 is incomplete and misleading. The first sentence of Proposed Finding No. 1371 should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). While the second sentence is factually correct, it is irrelevant to Mr. Figg's opinions because Mr. Figg was not asked to litigate the case.

1372. Mr. Figg did not review any of the actual prior art referenced in the underlying patent litigation between Endo and Impax. (Figg, Tr. 1987). Mr. Figg did not review the discovery record in the patent case between Impax and Endo that settled in June 2010. (Figg, Tr. 1991-92). Mr. Figg has never in his career provided advice in a Hatch-Waxman case in which he was not involved until after a claim construction opinion had issued. (Figg, Tr. 1982).

RESPONSE TO FINDING NO. 1372:

Complaint Counsel's Proposed Finding No. 1372 is incomplete and inaccurate. Mr. Figg reviewed the extensive discussions of the prior art in the expert reports, including direct quotations for the prior art itself. (Figg, Tr. 1890). Mr. Figg explained that it would not have been "particularly relevant or helpful for me to go back and maybe come up with prior art arguments that the experts for the parties had not come up with, because that would not have been something that would have informed a party in Impax'[s] position of how it viewed the case." (Figg, Tr. 1891).

The second sentence is similarly misleading because litigating a case start to finish is "different from providing advice based on the record that has already been established in a case that's ready for trial and actually has gone to trial." (Figg, Tr. 1988).

1373. In the course of litigating a Hatch-Waxman case, Mr. Figg would talk to executives of the company he was representing, but he did not talk to anyone at Impax about the merits of the patent case between Endo and Impax. (Figg, Tr. 1992-93). Nor did Mr. Figg talk to Impax's outside counsel that represented Impax in the underlying patent case. (Figg, Tr. 1993). He did not talk to anyone affiliated with Endo about the merits of the patent case. (Figg, Tr. 1993). He did not consider or have access to the privileged materials or communications of Endo or Impax when he was forming his opinions. (Figg, Tr. 1994).

RESPONSE TO FINDING NO. 1373:

Complaint Counsel's Proposed Finding No. 1373 is incomplete and misleading. The assertions about steps Mr. Figg would take "[i]n the course of litigating a Hatch-Waxman case" are "different from providing advice based on the record that has already been established in a case that's ready for trial and actually has gone to trial." (Figg, Tr. 1988).

1374. For some of the materials that Mr. Figg considered in forming his opinions, he reviewed excerpts, but he did not indicate anywhere in his report which documents he reviewed solely in excerpted form. (Figg, Tr. 1994).

RESPONSE TO FINDING NO. 1374:

Complaint Counsel's Proposed Finding No. 1374 is incomplete. Mr. Figg testified that he reviewed excerpts of some "lengthy" documents like deposition transcripts. (Figg, Tr. 1994).

d) Mr. Figg's opinions about the timing of the patent litigation and any appeals are not reliable

1375. Mr. Figg's opinion that a district court judgment in the patent case would not issue until November 2010 is not reliable. Mr. Figg concedes that it is possible that the judge presiding over the Impax-Endo patent litigation could have ruled from the bench at the end of the trial in mid-June 2010. (Figg, Tr. 2030). Mr. Figg's opinion that the district court decision would come in November 2010 is based on a review of a report of five district court trials in Hatch-Waxman cases in the District of New Jersey, but he did not review the underlying facts or legal issues of any of those cases, and none of those cases were presided over by the judge who presided over the Impax-Endo patent litigation that settled in June 2010. (Figg, Tr. 2028-29). Mr. Figg did not conduct any research into how long it takes Judge Hayden—who presided over the Impax-Endo patent litigation that settled in June 2010—to decide Hatch-Waxman cases and did not review Judge Hayden's case load in 2010. (Figg, Tr. 2029-30). Mr. Figg has never litigated a Hatch-Waxman case through trial to judgment in the District of New Jersey. (Figg, Tr. 2031-32).

RESPONSE TO FINDING NO. 1375:

Complaint Counsel's Proposed Finding No. 1375 is inaccurate. Mr. Figg's opinion that a district court judgment would not likely issue until November 2010 is a reliable opinion because it is based on decades of experience litigating patent infringement cases through trial.

The second sentence of Proposed Finding No. 1375 leaves out Mr. Figg's testimony that rulings from the bench are "rare." (Figg, Tr. 2030).

The third sentence is similarly misleading because the five district court trials in Hatch-Waxman cases in the District of New Jersey represent all relevant cases from January 1, 2008, through January 1, 2010. (RX-548.0035 (Figg Rep. ¶ 78)). Further, while Mr. Figg did not review the "underlying facts or legal issues," they were all cases with similar claims, being tried

under the same regulatory framework, and therefore represented the most relevant cases for an objective review. Finally, while Mr. Figg has never taken a case to trial in the District of New Jersey, Mr. Figg has tried between 25 and 50 Hatch-Waxman cases around the country, and Mr. Figg's extensive experience with patent trials has been recognized by his induction into the American College of Trial Lawyers. (Figg, Tr. 1821, 1832). Finally, Complaint Counsel, through an expert or otherwise, did not challenge the average times suggested by Mr. Figg. In fact, Mr. Hoxie agreed that "the times that Mr. Figg puts out for each of those individual steps are, you know, fair, reasonable, conservative estimates." (Hoxie, Tr. 2861).

> 1376. Mr. Figg's opinion that Impax's hypothetical appeal of a loss in the district court would not likely have been decided until at least the fourth quarter of 2011 is not reliable. He cannot exclude the possibility that the Federal Circuit decision could have been sooner than the fourth quarter of 2011. (Figg, Tr. 2034).

RESPONSE TO FINDING NO. 1376:

Complaint Counsel's Proposed Finding No. 1376 is misleading and in accurate. It does not follow that because Mr. Figg "cannot exclude *the possibility* that that the Federal Circuit decision could have been sooner than the fourth quarter of 2011" that Mr. Figg's opinion that the appeal was not *likely* to be decided until the fourth quarter of 2011 is unreliable. Mr. Figg's opinion is reliable. First, Mr. Figg's opinion is based on nearly 45 years of experience litigating patent cases, (Figg, Tr. 1810), as well as objective statistics from the Federal Circuit, which indicate that the median time for the Federal Circuit Court of Appeals to resolve a case is roughly 11 months, (Figg, Tr. 1908-09). Indeed, Mr. Figg testified that these statistics were "conservative" because they include cases that are not fully litigated, including rule 36 affirmances. (Figg, Tr. 1909). Finally, Complaint Counsel's own patent expert agreed that "the times that Mr. Figg puts out for each of those individual steps are, you know, fair, reasonable, conservative estimates." (Hoxie, Tr. 2861).

1377. Mr. Figg's opinion that a win for Impax in its hypothetical appeal of the district court decision would have likely resulted in a remand rather than a reversal is not reliable. He did not conduct any analysis in his report of the rate at which the Federal Circuit reverses claim construction proceedings and then remands. (Figg, Tr. 2035). For this opinion, Mr. Figg relied on the fact that a colleague at his law firm could not find a case in which the Federal Circuit reversed a claim construction decision and proceeded to decide the issues without a remand. (Figg, Tr. 2035-37). There are examples of cases in which the Federal Circuit reversed a claim construction ruling and ordered entry of judgment without a remand for further proceedings. (Figg, Tr. 2037-42). Mr. Figg concedes that if there had been no remand, then there could have been a final decision in the patent litigation between Impax and Endo by November 2011. (Figg, Tr. 2044-45).

RESPONSE TO FINDING NO. 1377:

Complaint Counsel's Proposed Finding No. 1377 is incomplete and inaccurate. Mr. Figg's opinion regarding remand is reliable. First, Mr. Figg's opinion is based on nearly 45 years of experience litigating patent cases, (Figg, Tr. 1810), including before the Federal Circuit, (Figg, Tr. 1820). Indeed, Mr. Figg carefully reviewed the issues likely to be appealed and determined that the claim construction ruling was the most likely issue that Impax would press on an appeal. (Figg, Tr. 1911-12). Mr. Hoxie agreed. (Hoxie, Tr. 2699). If the Federal Circuit altered the claim construction, a new trial would be required because the original trial would not have addressed the newly-adopted constructions. (Figg, Tr. 1912-13).

The third sentence of Proposed Finding No. 1377 is especially misleading because while Mr. Figg did research remand cases, this was one factor in his analysis. (Figg, Tr. 2035-37). Mr. Figg also relied on his decades-long experience as a litigator, including involvement in numerous cases before the Federal Circuit Court of Appeals. (Figg, Tr. 1820). That said, the "examples of cases in which the Federal Circuit reversed a claim construction ruling and ordered entry of judgment without a remand for further proceedings" were not analogous to the Impax-Endo case because the litigant in those "examples" either stipulated that they lost under the alternative claim construction, (Figg, Tr. 2080), or the claim construction did not make a difference in the case, (Figg, Tr. 2075).

1378. Mr. Figg opines that if Impax had lost in the District Court, appealed to the Federal Circuit, won its appeal, had the case remanded back to District Court, and went all the way to a new final judgment in the District Court, then a final judgment in the patent litigation could have occurred as early as May 2012. (Figg, Tr. 2045). He has no opinion about the likelihood of Impax winning its case at the end of this new trial. (Figg, Tr. 2045).

RESPONSE TO FINDING NO. 1378:

Complaint Counsel's Proposed Finding No. 1378 is incomplete. While Mr. Figg said that completing a remand by May 2012 was theoretically "possible," he clarified: "I think that is extremely unlikely." (Figg, Tr. 2044-45). Mr. Figg explained that if the Federal Circuit remanded the case it was more likely that the case would not conclude until May 2013. Mr. Figg testified that "that remand would likely take somewhere between 6 months and 18 months. *And I tend to think more toward the latter*, because . . . the trial judge would have to schedule a new trial." (Figg, Tr. 1914-15 (emphasis added)).

e) Mr. Figg is not offering an opinion that Endo's patents were valid or invalid or whether Impax would have ultimately won or lost the patent case

1379. Mr. Figg is not offering any opinions as to whether, in 2010, Endo's patents were valid or invalid. (Figg, Tr. 1995).

RESPONSE TO FINDING NO. 1379:

Complaint Counsel's Proposed Finding No. 1379 is inaccurate and misleading. Mr. Figg opined that Impax would likely fail to meet its burden of proof with regard to its invalidity arguments at trial. (Figg, Tr. 1904 ("I think it was likely that Endo was going to prevail on these validity issues)).

1380. Mr. Figg does not offer an opinion on whether Impax was going to win or lose the patent case with Endo. (CX4045 (Figg, Dep. at 147)).

RESPONSE TO FINDING NO. 1380:

Complaint Counsel's Proposed Finding No. 1380 is inaccurate and misleading. The cited deposition testimony states, "What you're assessing here is not was Impax going to win or was it going to lose. What you're assessing is what -- what is it reasonable to think Impax's perception of its chances would have been at that time." (CX4045 (Figg, Dep. at 147)). Further, Mr. Figg offers clear opinions about the likelihood that Impax would have lost the patent case with Endo. (RX-548.0058 (Figg Rep. ¶ 136) ("I conclude that Impax was more likely than not to lose the '933 and '456 patent litigation with Endo")).

1381. Mr. Figg is not offering any opinion about how Endo or Impax actually understood their positions in the patent litigation at the time of the patent litigation. (Figg, Tr. 1997). He is not opining about Endo or Impax's actual state of mind during the patent litigation. (Figg, Tr. 1997). Mr. Figg concedes that a rational litigant in Endo's position would understand that it could have lost the patent case against Impax. (Figg, Tr. 2045-46).

RESPONSE TO FINDING NO. 1381:

Complaint Counsel's Proposed Finding No. 1381 is incomplete and misleading. Mr. Figg did not offer opinions about the subjective beliefs or attitudes of Endo or Impax, but Mr. Figg explained that he evaluated the claims from the perspective of "a reasonable litigant in Impax's position," (RX-548.0017 (Figg Rep. ¶ 37), and that "reasonable persons experienced in these kind of cases would have viewed it the same way at that time," (CX4045 (Figg, Dep. at 147)).

1382. Mr. Figg is not offering any opinion that Impax had a percentage probability of losing the patent litigation with Endo. Mr. Figg uses terms like "likely" and "more likely than not" in his expert report, but he does not assign any probability percentage to those words and did not have a specific percentage of probability in mind. (Figg, Tr. 2011-12).

RESPONSE TO FINDING NO. 1382:

The first sentence of Complaint Counsel's Proposed Finding No. 1382 should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Further, the phrase "percentage probability" is ambiguous and unclear.

The second sentence of Proposed Finding No. 1382 is incomplete. While Mr. Figg does not have a "specific percentage probability in mind," he clarified that his report does convey his "level of confidence" in each opinion and that "you would be able to ascertain [his level of confidence] from the context and the explanation in my report for how I arrived at that opinion." (Figg, Tr. 2011).

> 1383. Mr. Figg offers no opinion as to how the patent litigation ultimately would have turned out. He does not opine that Impax had a zero percent chance of overcoming the issues raised by the District Court's claim construction opinion. (Figg, Tr. 2012). There are some scenarios in which things could have gone badly for Endo in the patent litigation. (Figg, Tr. 2017-18).

RESPONSE TO FINDING NO. 1383:

The first sentence of Complaint Counsel's Proposed Finding No. 1383 should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Further, Mr. Figg offers clear opinions about the likelihood that Impax would have lost the patent case with Endo. (RX-548.0058 (Figg Rep. ¶ 136) ("I conclude that Impax was more likely than not to lose the '933 and '456 patent litigation with Endo")).

Respondent has no specific response to the second and third sentences of Proposed Finding No. 1383.

1384. Mr. Figg is not offering an opinion about whether the claim construction opinion by the district court was correctly decided. (Figg, Tr. 2018). If Impax had appealed that decision, it would have been a fair issue to litigate at the appellate level. (Figg, Tr. 2018). He does not offer in his report any opinion about whether the Federal Circuit would have affirmed or reversed the claim construction opinion of the district court. (Figg, Tr. 2020-21).

RESPONSE TO FINDING NO. 1384:

While Respondent has no specific response to the first two sentences of Complaint Counsel's Proposed Finding No. 1384, the third sentence misrepresents Mr. Figg's report and testimony. Mr. Figg testified that his report "make[s] it clear that [he] thought the overall outcome of the litigation was likely to be in Endo's favor, and [he] would include in the litigation the appeal." (Figg, Tr. 2020). Mr. Figg reiterated that "my opinion was that Endo was likely to prevail in the litigation, and in my mind that would *include the appellate process*." (Figg, Tr. 2021) (emphasis added)).

1385. With respect to the patent case between Impax and Endo that settled in June 2010, Mr. Figg opined that Impax's position that its product did not infringe Endo's patents was well-founded and made in good faith. (Figg, Tr. 2014-15; *see also* Figg, Tr. 2014 (concluding that no one would think that Impax made its non-infringement arguments in bad faith)).

RESPONSE TO FINDING NO. 1385:

Complaint Counsel's Proposed Finding No. 1385 is incomplete and misleading. Mr. Figg testified that he believed that Impax's infringement positions were well-founded and made in good faith *based on Impax's proposed claim constructions*, which the court ultimately *rejected*. (Figg, Tr. 2014 ("Q. My question, sir, was, it's your opinion that Impax' position on noninfringement appears to have been well-founded. A. Based on its claim construction. Q. Okay. And Impax had good-faith arguments that its product did not infringe Endo's patents? A. Based on its claim construction.")).

1386. Mr. Figg would not characterize any of Impax's arguments in the district court as being frivolous. (Figg, Tr. 2014-15).

RESPONSE TO FINDING NO. 1386:

Respondent has no specific response.

1387. Mr. Figg admits that he has been wrong about his prediction about litigation outcomes in the past. (CX4045 (Figg, Dep. at 180 ("There are cases I lost that I thought I should have won . . . .")).

RESPONSE TO FINDING NO. 1387:

Respondent has no specific response.

f) Mr. Figg's opinions about the scope of the license in the SLA and Endo's later-obtained patents are not reliable

1388. In his report, Mr. Figg opined that Impax received a license in the SLA "ensuring" it would not be sued on Endo's later obtained patents. (RX-548 at 0006 (¶ 4.c.) (Figg Report)).

RESPONSE TO FINDING NO. 1388:

Respondent has no specific response.

1389. Mr. Figg acknowledged that opinion was not accurate. (Figg, Tr. 2046-47 (acknowledging the opinion as a "poor choice of words" and admitting that "[o]ne can never ensure that their competitor is not going to sue them")).

RESPONSE TO FINDING NO. 1389:

Complaint Counsel's Proposed Finding No. 1389 is incomplete. While Mr. Figg acknowledged that using the term "ensuring" was a "poor choice of words," Mr. Figg explained that this was because "[i]t's pretty easy to bring a lawsuit in this country. . . . Impax could not ensure that Endo wouldn't sue it, but what Impax did do was it negotiated the terms of an agreement that gave it rights and freedom to operate under patents that Endo would obtain in the future." (Figg, Tr. 2047). Mr. Figg further explained that Impax secured a license that allowed it to come to market "without the risk of another infringement lawsuit," but that "[y]ou can't

control another person filing a lawsuit. It cost you 100 bucks or something to file a complaint." (CX4045 (Figg, Dep. at 262-63)).

1390. Mr. Figg did not quote or interpret the language of the license granted to Impax in the SLA in his report. (Figg, Tr. 2048; CX4045 (Figg, Dep. at 265)).

RESPONSE TO FINDING NO. 1390:

Complaint Counsel's Proposed Finding. No. 1390 misrepresents Mr. Figg's testimony. Mr. Figg never testified that he did not "interpret the language of the license granted to Impax in the SLA in his report." Mr. Figg clearly testified that he interpreted the language to mean that Impax was "able to negotiate a broad license and covenant not to sue under later-acquired patents." (CX4045 (Figg, Dep. at 265); *see* Figg, Tr. 1934, 1945, 2092). Mr. Figg explained that the language of the SLA granted Impax the freedom to operate "[u]nder both the litigated patents as well as future patents that Endo might obtain in this area." (Figg, Tr. 1936-37). That Mr. Figg did not directly quote the language of the SLA in his report is irrelevant.

1391. When he submitted his expert report in this case, Mr. Figg was unaware of the subsequent litigation between Endo and Impax regarding the license to Impax in the SLA. (Figg, Tr. 2051). As a result, his opinions in this case do not take into account the subsequent litigation between Endo and Impax regarding the license to Impax in the SLA. (Figg, Tr. 2051). Mr. Figg first saw the complaint that Endo had filed against Impax alleging breach of the license and infringement of some of Endo's later-obtained patents after he had served his expert report in this matter. (Figg, Tr. 2051). He did not review any pleadings that had to do with the subsequent litigation against Impax until after he had served his expert report. (Figg, Tr. 2052).

RESPONSE TO FINDING NO. 1391:

Complaint Counsel's Proposed Finding No. 1391 is inaccurate. First, Mr. Figg was aware of the subsequent litigation between Endo and Impax, and testified as much during his deposition. (Figg, Tr. 2048; CX4045 (Figg, Dep. at 247)). When asked whether he was "aware" of the litigation at trial, Complaint Counsel withdrew the question. (Figg, Tr. 2051). Second,

while Mr. Figg did not review materials from the litigation until after Mr. Hoxie raised it in his rebuttal report, Mr. Figg explained that the existence of the litigation "didn't alter [his] opinion that the license agreement that Impax entered gave it a license and a covenant not to sue under patents that would subsequently issue to Endo." (Figg, Tr. 2052; *see also* Figg, Tr. 2092). Mr. Figg further explained: "The way I viewed all of this and the way it played out was, this was simply an effort by Endo to get additional money in the form of royalty payments from Impax. And the fact . . . that when Endo brought suits on the later patents against a number of other generic companies based on the original Opana ER generic product, they did not sue Impax, and the only rational reason that they would not have sued Impax was they recognized that Impax was licensed under those patents." (Figg, Tr. 2093-94).

1392. The District of Delaware has found one of Endo's later obtained patents invalid, and that court's ruling that the '779 patent had not been shown to be invalid is on appeal. (Figg, Tr. 2049). Mr. Figg offers no opinion as to how the appeal regarding the '779 patent will turn out. (Figg, Tr. 2050).

RESPONSE TO FINDING NO. 1392:

Respondent has no specific response.

B. The subsequent patent litigations do not demonstrate the reasonableness of the reverse-payment settlement

1393. Impax has offered the purported justification that the outcomes of the litigations concerning Endo's later-issued patents demonstrate the reasonableness of the Impax-Endo Settlement Agreement. Specifically, Impax argues that because other ANDA filers were enjoined from selling generic Opana ER by Endo's later-issued patents, it was reasonable for Impax to agree to the Impax-Endo Settlement Agreement. (RX-548 at 0058 (¶ 136) (Figg Report)).

RESPONSE TO FINDING NO. 1393:

Complaint Counsel's Proposed Finding No. 1393 is misleading. The cited paragraph of Mr. Figg's report states that "Impax's decision to enter into the SLA was not only reasonable

under the circumstances but the SLA provided Impax and the public with a better outcome than could have reasonably been expected through litigation, namely, generic entry that occurred months—and likely many years—earlier than what likely would have occurred without the settlement." (RX-548.0058 (Figg Rep. ¶ 136)). The import of the injunctions covering the other ANDA filers, therefore, is as real-world proof that but for the settlement, Impax would have been enjoined from selling oxymorphone ER in later infringement cases. (Figg, Tr. 1972).

1. The anticompetitive harm occurred between June 2010 and January 2013; subsequent decisions from other patent litigations cannot change that

1394. The Impax-Endo Settlement Agreement guaranteed that Impax would not launch its generic Opana ER product until January 2013. (RX-364 at 0001-02, 0009 (SLA §§ 1.1 (defining "Commencement Date"), 4.1(a) ("License; Covenant Not to Sue")). The harm to consumers, therefore occurred during the period of time Impax agreed to not enter the market to compete by the settlement. (CX5004 at 010 (¶ 17) (Noll Rebuttal Report)). This period of time fell between June 2010, when Impax received final approval of its ANDA, and January 2013, the entry date it agreed to with Endo. (CX6060 at 001 (Impax Press Release re Final Approval for Generic Opana ER Tablets); RX-364 at 0001-02, 0009 (SLA §§ 1.1 (defining "Commencement Date"), 4.1(a) ("License; Covenant Not to Sue")).

RESPONSE TO FINDING NO. 1394:

Respondent has no specific response to the first and third sentences of Complaint Counsel's Proposed Finding No. 1394.

The second sentence of Proposed Finding No. 1394 is an improper legal conclusion, not a fact. It is also inaccurate. There can be no "harm to consumers" if Impax otherwise would not have (or could not have) launched generic oxymorphone ER prior to January 1, 2013. The record indicates that had Impax not settled and obtained a license to Endo's future-obtained patents, Impax would not have launched generic oxymorphone ER prior to January 1, 2013. (Figg, Tr. 1904, 1971; Addanki, Tr. 2360, 2374-82). Further, Proposed Finding No. 1394 is based on unreliable expert testimony because Dr. Noll did not seek to measure consumer harm.

(Noll, Tr. 1665 ("Q. You did not measure what the actual anticompetitive effects are[?] A. That's correct.")).

> 1395. The later-issued patents that were the subject of patent infringement litigation were all issued after Impax and Endo agreed to the Impax-Endo Settlement Agreement in June 2010. The patents that were issued to or acquired by Endo were the 8,309,122, 8,329,216, and 7,851,482 patents in 2012, and the 8,808,737 and 8,871,779 patents in 2014. (*see* CCF ¶¶ 1397-1401, below).

RESPONSE TO FINDING NO. 1395:

The proposed summary finding should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Additionally, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondent's replies to those findings.

> 1396. At the time of the Impax-Endo Settlement Agreement, it was uncertain whether any new patents would issue that Endo might claim would cover Impax's generic Opana ER product. (CX3455 at 022-23 (Sep. 19, 2013 *Endo v. Actavis* transcript) ("Nobody knew for sure whether these patents were going to issue . . . . [T]he '122 and the '216 patent were in the Patent Office at the time that the prior case was settled. The Patent Office may never have issued the patents; the Patent Office may have issued it.")).

RESPONSE TO FINDING NO. 1396:

Complaint Counsel's Proposed Finding No. 1396 should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). The only citation provided by Complaint Counsel is to attorney argument at a preliminary injunction hearing, and therefore should not be admitted for the truth of the matter asserted. Further, the citation makes clear that the statement only applies to two of the relevant patents.

1397. The 8,309,122 patent was issued to Endo on November 13, 2012. (JX-001 at 012 (¶ 56)).

RESPONSE TO FINDING NO. 1397:

Respondent has no specific response.

1398. The 8,329,216 patent was issued to Endo on December 11, 2012. (JX-001 at 012 (¶ 57)).

RESPONSE TO FINDING NO. 1398:

Respondent has no specific response.

1399. In 2012, Endo acquired the 7,851,482 patent from Johnson Matthey. (JX-003 at 006 (¶ 36); Snowden Tr. 444). The '482 patent was issued in December 2010 to Johnson Matthey. (CX3329 at 006 (May-June 2011 emails from Johnson Matthey)). Johnson Matthey did not inform Impax that it believed the '482 patent covered Impax's generic Opana ER product until 2011. (CX3329 at 003-006 (May-June 2011 emails from Johnson Matthey)). The '482 patent was partially invalidated in 2013 following interference proceedings with the '779 patent, owned by Mallinckrodt. (Snowden, Tr. 444).

RESPONSE TO FINDING NO. 1399:

Respondent has no specific response.

1400. The 8,808,737 patent was issued to Endo on August 19, 2014. (JX-001 at 013 (¶ 59)).

RESPONSE TO FINDING NO. 1400:

Respondent has no specific response.

1401. The '779 patent was issued on October 28, 2014. (JX-001 at 013 (¶ 60); JX-003 at 007 (¶ 46)). Endo acquired an exclusive field-of-use license to the 8,871,779 patent from Mallinckrodt. (JX-001 at 013 (¶ 61); JX-003 at 007 (¶ 46)).

RESPONSE TO FINDING NO. 1401:

Respondent has no specific response.

1402. The litigations concerning infringement of Endo's later-issued patents covering Opana ER all occurred after Impax and Endo agreed to the Impax-Endo Settlement

Agreement in June 2010. The first litigation was filed December 11, 2012 against Actavis for infringement of the newly-issued '122, '216, and '482 patents. (RX-495 (*Endo v. Actavis* complaint) (admitted for the fact of the complaint, not the truth of the matter asserted).

RESPONSE TO FINDING NO. 1402:

Respondent has no specific response.

1403. Endo filed infringement suits against Teva, Sandoz, and Roxane on the '122 and '216 patents on May 15, 2013 (RX-501 (*Endo v. Teva* complaint) (admitted for the fact of the complaint, not the truth of the matter asserted); RX-500 (*Endo v. Sandoz* complaint) (admitted for the fact of the complaint, not the truth of the matter asserted); RX-499 (*Endo v. Roxane Labs* complaint) (admitted for the fact of the complaint, not the truth of the matter asserted)).

RESPONSE TO FINDING NO. 1403:

Respondent has no specific response except to note that a number of the cited infringement cases also included claims related to the '482 patent. (*See* RX-500; RX-501 (not admitted or cited for the truth of the matters asserted therein)).

1404. In 2014, Endo filed infringement suits against Opana ER ANDA filers including Actavis on the '737 and '779 patents. (RX-507 (*Endo v. Actavis* complaint) (admitted for the fact of the complaint, not the truth of the matter asserted)).

RESPONSE TO FINDING NO. 1404:

Respondent has no specific response.

2. There is no link between the "broad patent" license and the reverse payment

1405. There is no connection between the scope of the patent license and the payment under the SLA. (CX5001 at 030 (¶ 56) (Bazerman Report)).

RESPONSE TO FINDING NO. 1405:

Complaint Counsel's Proposed Finding No. 1405 should be disregarded because it violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." (*See* Court, Tr. 1859

("[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.")). Tellingly, the cited paragraph in Professor Bazerman's report cites no record evidence for his opinion.

> 1406. As discussed in greater detail above, the issue of including in the SLA a license to future Endo patents arose in the last few days of negotiation of the SLA. Endo and Impax had reached an agreement on the form and substance of the payments from Endo to Impax before Impax requested that a license to patents that may issue from Endo's pending patent applications be included in the SLA. There is no indication that the payments from Endo to Impax changed in any way as a result of adding the license to potential future patents. (*See* CCF ¶¶ 279-84, above).

RESPONSE TO FINDING NO. 1406:

The proposed summary finding should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Additionally, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondent's replies to those findings.

> 1407. There is no indication that the payments to Impax were necessary to induce Impax to accept the license to any future patents. Like the payments, the license itself benefitted Impax. (Figg, Tr. 1934).

RESPONSE TO FINDING NO. 1407:

The first sentence to Complaint Counsel's Proposed Finding No. 1407 should be disregarded because it is not supported by any record evidence and violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2).

Respondent has no specific response to the second sentence of Proposed Finding No. 1407 other than to clarify that the cited testimony says nothing of "the payments," as suggested in Proposed Finding No. 1407. (Figg, Tr. 1934).

3. The license Impax obtained was fairly typical

1408. The license Impax obtained under Section 4.1(a) of the SLA is fairly typical in the pharmaceutical industry. (CX5007 at 011-12 (¶ 20) (Hoxie Report)).

RESPONSE TO FINDING NO. 1408:

Respondent has no specific response.

1409. Section 4.1(a) of the SLA provided Impax with a license to current patents and patents that may issue in the future from pending patent applications covering Endo's Opana ER. (RX-364 at 0009 (SLA § 4.1(a) ("License; Covenant Not to Sue")).

RESPONSE TO FINDING NO. 1409:

Respondent has no specific response, except to note that Section 4.1(a) also covers patents Endo acquires by other means, not only "from pending patent applications." (RX-364.0009 (SLA § 4.1(a))).

1410. A freedom to operate license is a license that provides the licensee with the rights necessary to engage in a particular commercial activity free from the threat of a valid patent claim. (Figg, Tr. 1936).

RESPONSE TO FINDING NO. 1410:

Respondent has no specific response.

1411. It is common for a licensee seeking freedom to operate for a product to seek a license to all potentially relevant patents and patents issuing from pending applications owned or controlled by the licensor. Licensing some patents while still blocking the licensee's product with other patents frustrates the underlying purpose of the license, which is ordinarily to give the licensee freedom to operate. (CX5007 at 011-12 (¶ 20) (Hoxie Report)).

RESPONSE TO FINDING NO. 1411:

Respondent has no specific response.

1412. Consistent with the general practice in the pharmaceutical industry, Impax understood that in order to successfully launch a product and keep it on the market, it was important to obtain freedom to operate under any patents that Endo might later acquire. (RX-548 at 0044 (¶ 95) (Figg Report)); CX4014 (Hsu, IHT at 117) ("[T]his is very

important for us to have what I call risk-free launch because otherwise if you only in-license certain patents but not all the patents then you still have to launch at risk which we try to avoid.")). Generally, ANDA filers can monitor the status of pending patent applications at the PTO that may pertain to their product. (CX4043 (Hoxie, Dep. at 94)). Indeed, prior to entering into settlement negotiations with Endo, Impax was aware that Endo had patent applications pending that might cover Impax's generic oxymorphone ER product. (RX-396 (Feb. 2010 Impax email re Analyst Reports)).

RESPONSE TO FINDING NO. 1412:

Respondent has no specific response.

1413. The license in Section 4.1(a) of the SLA was typical of licenses Impax itself sought. It was Impax's general practice to seek a license broad enough to ensure it will have freedom to operate for the product at issue. The license Impax obtained from Endo was consistent with the types of licenses it typically seeks from licensors. (CX4026 (Nguyen, Dep. at 155-56 (taking her "cues from what sort of the business wants, and, if the business wants to launch and continue to sell the product, even after a launch indefinitely, then I would have to craft the license in such a way as to allow for that to happen without -- without later on a patent popping up and -- and us being pulled off the market")).

RESPONSE TO FINDING NO. 1413:

Complaint Counsel's Proposed Finding No. 1413 is not supported by the cited evidence. Ms. Nguyen testified that "I can't say normally" when asked if Impax had a "normal approach[] to seek that broad of a license in any generic settlement agreement." (CX4026 (Nguyen, Dep. at 156)).

1414. Impax was not unique among Opana ER ANDA filers in asserting that it had a license that covered later-issued patents. Other ANDA filers, including Actavis, argued in litigation that they had received an express or implied license to future patents in the settlements they reached with Endo over their generic Opana ER products. In a subsequent patent infringement lawsuit that Endo filed against Actavis on the '122 and '216 patents, Actavis successfully asserted at the district court level that the license it obtained from Endo extended to pending patent applications as well. (CX3455 at 049 (Sep. 19, 2013 *Endo v. Actavis* transcript). Another ANDA filer, Sandoz, obtained an option to license Orange Book patents that Endo might obtain in the future relating to Opana ER. (CX3378 at 100 (Sandoz settlement, § 4.4)).

RESPONSE TO FINDING NO. 1414:

The first two sentences of Complaint Counsel's Proposed Finding No. 1414 should be disregarded because they violate the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2).

The third sentence of Proposed Finding No. 1414 is incomplete and misleading because it fails to note that Actavis's argument "arose in the context of a motion for preliminary injunction," and therefore the district court judge was not determining whether or not Actavis actually had the license they claimed. (Figg, Tr. 1953). Instead, the judge "appl[ied] the equities that are required in the context of a preliminary injunction proceeding and concluded it would be unfair to subject Actavis and Roxane to these later issued patents given that Endo had licensed them under the first patents." (Figg, Tr. 1953). Furthermore, the Federal Circuit reversed the district court's decision. (Figg, Tr. 1954; *see also* RX-504 (not admitted or cited for the truth of the matters asserted)). Finally, Actavis never argued that its settlement contained an express license, only that it should be interpreted to include an implied license. (Figg, Tr. 1954 ("Actavis didn't argue there was an express license. They argued that there was an implied license.")).

Respondent has no specific response to the fourth sentence of Proposed Finding No. 1414.

4. The license did not eliminate all uncertainty

1415. The license Impax received did not ensure freedom to operate. It left Impax exposed to considerable risk, uncertainty, and expense. (CX5007 at 015-16 (¶ 27) (Hoxie Report)).

RESPONSE TO FINDING NO. 1415:

Complaint Counsel's Proposed Finding No. 1415 is inaccurate. The record shows that the Settlement and License Agreement guaranteed Impax the freedom to operate. (Figg, Tr.

1936). Endo admitted as much. In a subsequent breach of contract action between Endo and Impax, Endo asserted that Endo would have sued Impax for infringing subsequently acquired patents but for the fact that the Endo-Impax settlement included a license to future patents. (Hoxie, Tr. 2892-93). Mr. Figg similarly testified that "if Impax had not had the license to future patents in its settlement agreement, there's little doubt in my mind that Endo would have included claims of infringement against Impax for the original generic Opana ER." (Figg, Tr. 1951). Indeed, Endo *did* sue Impax for infringement of its later-acquired patents with regard to Impax's generic version of *reformulated* Opana ER because the license in the SLA did not cover a reformulated product. (Figg, Tr. 1951-52, 1964). There is no reason why Endo would have sued Impax on the reformulated version but not the original version in later cases except for the license covering the original version.

> 1416. The license Impax received in the SLA was open to contradictory interpretations. The primary section outlining the scope of the license (Section 4.1(a)) referred to a "royalty-free" license to current and future patents. (RX-364 at 0009 (SLA (§4.1(a)))). An additional section (Section 4.1(d)) provided that the parties agreed "to negotiate in good faith an amendment to the terms of the License to any [later-issued] patents." (RX-364 at 0011 SLA (§4.1(d))).

RESPONSE TO FINDING NO. 1416:

The first sentence of Complaint Counsel's Proposed Finding No. 1416 should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). In any event, the proposition is inaccurate. Both Mr. Figg and Mr. Hoxie agree that the language of Section 4.1(a) of the SLA provided Impax the freedom to operate. (Figg, Tr. 1936-37; Hoxie, Tr. 2718 (testifying § 4.1 gives a license that "includes any patents that . . . would potentially block the Impax product")). Moreover, Section 4.1(d) does not deal with the scope of the license, but only requires "good faith" negotiations regarding potential

royalties. (RX-364.0011 (SLA § 4.1(d))). This requirement does not affect the scope of the license in Section 4.1(a), which is why Endo never sued Impax for infringement regarding the generic version of original Opana ER under later-acquired patents. (Figg, Tr. 1951-52, 1964). Indeed, Complaint Counsel's own expert states that Section 4.1(d) is only "arguably in conflict with § 4.1(a)." (Hoxie, Tr. 2720).

> 1417. A term such as the one in Section 4.1(d) of the SLA that requires the parties to negotiate in good faith "the terms of the License to any patents which issue from any Pending Applications" is uncommon and problematic. (CX5007 at 016 (¶ 28) (Hoxie Report)).

RESPONSE TO FINDING NO. 1417:

Complaint Counsel's Proposed Finding No. 1417 should be disregarded because it violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." (*See* Court, Tr. 1859 ("[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.")). Further, even Mr. Hoxie acknowledges that Sections 4.1(a) and 4.1(d) can be interpreted to cover *other* products not already covered by the SLA's license and, thus, any substantive negotiation would be limited to those *other* products. (CX5007-016 (Hoxie Rep. ¶ 28)).

> 1418. There are multiple plausible interpretations of the interplay between Section 4.1(a) and 4.1(d). One possible interpretation is that Section 4.1(d) undercuts the grant in Section 4.1(a), so that if additional applications issue, the license and payment structure for the existing products might be renegotiated. If that is the case, it puts the entire agreement up for grabs. Another interpretation is that the additional applications could result in coverage for other products not already covered by the license, and any substantive negotiation would be with respect to those other products. (CX5007 at 016 (¶ 28) (Hoxie Report)).

RESPONSE TO FINDING NO. 1418:

Complaint Counsel's Proposed Finding No. 1418 should be disregarded because it violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." (*See* Court, Tr. 1859 ("[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.")). Proposed Finding No. 1418 is also an improper legal conclusion, not a fact. In any event, Endo's litigation decisions with respect to its later-acquired patents indicate that Endo believed Impax had a license to those patents. (Figg, Tr. 1951-52, 1964; Hoxie, Tr. 2892-93). There is simply no explanation for why Endo would sue every other ANDA filer and not Impax if it believed Impax's license did not give Impax freedom to operate. (Figg, Tr. 1951-52).

1419. In January 2013, in accordance with the SLA, Impax began to sell its generic version of the Original Opana ER product. (JX-003 at 006 (¶ 40)). In October 2015, Endo reached out to Impax to negotiate a license fee for the patents that issued after the execution of the SLA and proposed a royalty of 85% of Impax's gross profits. (CX2938 at 004 (email chain between Impax and Endo re: Impax License Agreement); CX2942 at 003 (Oct. 1, 2015 email from Endo to Impax attaching Draft Non-Binding Term Sheet)).

RESPONSE TO FINDING NO. 1419:

Respondent has no specific response.

1420. The parties disagreed over the interpretation of 4.1(a) and 4.1(d). Impax's position was that the SLA did not require the parties to negotiate a license fee for the later-issued patents because the SLA granted Impax a royalty-free license that includes patents or patents issued from pending patent applications that could cover or potentially cover Impax's ANDA product. (CX2938 at 002 (email chain between Impax and Endo re: Impax License Agreement) (asserting that "the patent applications (*and any patents issued thereunder*) being the 'Pending Applications,'" and that accordingly "Endo knows that the '122, the '216, the '779 and the '737 patents all issued from the Pending Applications, and, therefore are included in Impax's existing license regarding its ANDA for generic original Opana ER.")).

RESPONSE TO FINDING NO. 1420:

Respondent has no specific response.

1421. On May 4, 2016, Endo filed a suit against Impax in New Jersey, alleging that Impax was in breach of the SLA for failing to negotiate with Endo in good faith a royalty for the three new patents – the '122, the '216 and the '737 – which were pending applications at the time Endo and Impax entered into the SLA. (CX2976 at 001 (*Endo v. Impax*, complaint) (admitted for the fact the complaint was filed, not truth of the matter asserted)). Endo claimed that Impax's refusal to negotiate a royalty under the new patents was a breach of Section 4.1(d)'s requirement that they negotiate in good faith an amendment to the terms of the License to any patents which issue from any Pending Applications for the time period following the Exclusivity Period." (CX2976 at 011-012 (*Endo v. Impax*, complaint) (admitted for the fact that the allegation was made, not truth of the matter asserted); RX-364 at 0011 (SLA § 4.1(d)). Endo simultaneously sued Impax for infringement of the same patents. (CX2976 at 014-18 (*Endo v. Impax*, complaint) (admitted for the fact of the allegations, not truth of the matter asserted)).

RESPONSE TO FINDING NO. 1421:

Complaint Counsel's Proposed Finding No. 1421 is incomplete. While Endo included claims for patent infringement in its complaint, (CX2976-014-18 (admitted for the fact of the allegations, not truth of the matter asserted)), those claims were predicated on the alleged breach and termination of the contract, which purportedly would have terminated the license, (Figg, Tr. 2050-51). Whether the contract was terminated was an issue in the litigation. Endo did not seek an injunction to prevent Impax from selling oxymorphone ER. (Hoxie, Tr. 2891).

1422. Endo indicated to Impax that it hoped the patent infringement suit would lead Impax to come to terms with Endo over royalties for the newly-issued patents. (CX2944 at 001-02 (Oct. 31, 2016 email chain attaching letter from Endo to Impax re: notice of termination of the license agreement ("had hoped the lawsuit would prompt Impax to honor the promises it made to Endo and come to the negotiation table"))).

RESPONSE TO FINDING NO. 1422:

Respondent has no specific response.

1423. Impax moved to dismiss for failure to state a claim upon which relief could be granted, arguing that the plain language of Section 4.1(a) of the SLA granted it a royalty-free license under the Pending Applications. (CX3356 at 011-12 (Impax's Motion to Dismiss) (admitted for the fact of allegation, not truth of the matter asserted)).

RESPONSE TO FINDING NO. 1423:

Complaint Counsel's Proposed Finding No. 1424 is inaccurate and misstates the arguments that Impax made in its motion to dismiss. Impax moved to dismiss on a number of grounds described in CX3356, which speaks for itself.

1424. On October 25, 2016, the judge denied the motion to dismiss except as to the '737 patent. (CX3361 at 014 (*Endo v. Impax*, opinion) (admitted for the fact the court issued the opinion, not truth of the matter asserted)).

RESPONSE TO FINDING NO. 1424:

Respondent has no specific response.

1425. On October 31, 2016, Endo provided Impax notice of termination of the SLA due to what Endo characterized as Impax's material breach of the agreement. (CX2944 at 002 (email chain attaching letter from Endo to Impax re: notice of termination of the license agreement)). Endo requested that Impax immediately cease sales of what it characterized as Impax's infringing generic Opana ER product. (CX2944 at 003 (Oct. 31, 2016 email chain attaching letter from Endo to Impax re: notice of termination of the license agreement) (notifying Impax that "there is no legitimate dispute that Impax's current Opana ER generic tablets infringe Endo's patents" and demanding that "Impax should therefore honor Endo's patent rights and immediately cease all sales of those infringing tablets")). Impax continued to disagree with Endo's interpretation of the SLA as it applied to the later-issued patents, as well as Endo's interpretation of what constituted a material breach. (CX2939 at 003-04 (Nov. 2, 2016 email chain attaching letter from Impax to Endo)).

RESPONSE TO FINDING NO. 1425:

Respondent has no specific response.

1426. [redacted] (CX3275 at 001 [redacted] (*in camera*)).

RESPONSE TO FINDING NO. 1426:

Respondent has no specific response.

1427. The 2017 Contract Settlement Agreement included [redacted]

[redacted] (CX3275 at 011, 013-14 [redacted] (*in camera*)). [redacted] (CX3275 at 014-15 [redacted] (*in camera*))).

RESPONSE TO FINDING NO. 1427:

Respondent has no specific response.

1428. [redacted] (CX3275 at 012, 014 [redacted] (*in camera*)). [redacted] (CX3275 at 013 [redacted] (*in camera*)). [redacted] (CX3275 at 002 [redacted] (*in camera*)).

RESPONSE TO FINDING NO. 1428:

Respondent has no specific response.

1429. By the time of the 2017 Contract Settlement Agreement, Endo had withdrawn its Original Opana ER and announced its intention to cease selling its Reformulated Opana ER as of September 2017. (JX-001 at 012 (¶ 49); CX6035 (July 6, 2017 news release)).

RESPONSE TO FINDING NO. 1429:

Respondent has no specific response.

1430. If the parties had not settled, Impax could have been liable for damages and possibly even required to withdraw its Original Opana ER generic product from the market. (CX5007 at 020 (¶ 36) (Hoxie Report)).

RESPONSE TO FINDING NO. 1430:

Complaint Counsel's Proposed Finding No. 1430 should be disregarded because it violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." (*See* Court, Tr. 1859 ("[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.")). Tellingly, the cited paragraph from Mr. Hoxie's report cites no record evidence. (CX5007-020 (Hoxie Rep. ¶ 36)). Finally, Proposed Finding No. 1430 is inaccurate. Endo did not seek an injunction to prevent Impax from selling oxymorphone ER. (Hoxie, Tr. 2891).

5. There are sound reasons to expect an oxymorphone ER product be on the market today, even in the absence of the Impax-Endo Settlement Agreement

1431. At the time Impax and Endo entered into the Impax-Endo Settlement Agreement, there were myriad future outcomes. Impax may have launched at risk. (*See* CCF ¶¶ 127-213, above). Impax may have proceeded with the litigation, won, and entered the market. (*See* CCF ¶¶ 361-77, above). Endo may have faced different incentives in pursuing patent approvals and acquiring patents. It is not possible to know what the market would look like today if Impax and Endo had not settled. (Noll, Tr. 1578-79 ("If there had been no settlement agreement, we do not know -- it is incorrect to assert they would never have been on the market"); CX4039 (Noll, Dep. at 263-64)).

RESPONSE TO FINDING NO. 1431:

The first three sentences of Complaint Counsel's Proposed Finding No. 1431 should be disregarded because they violate the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Moreover, the individual findings cited do not support the Proposed Finding and are unreliable for the reasons set out in Respondent's replies to those findings.

With respect to the fourth sentence of Proposed Finding No. 1431, while it may not be possible "to know what the market would look like today if Impax and Endo had not settled," there is significant real-world evidence that indicates that if Impax had not secured a broad license from Endo, oxymorphone ER may not be on the market today, especially in generic form. First, given the court's claim construction in the underlying infringement case, it was more likely than not that Impax would have lost the infringement case and therefore been enjoined from selling the product. (RX-548.0058 (Figg Rep. ¶ 136); Figg, Tr. 1870). Second, Endo has aggressively and successfully asserted its patents covering oxymorphone ER and enjoined all other ANDA filers from marketing oxymorphone ER. (Figg, Tr. 1958-59, 1965-66). Third, Endo has ceased selling any oxymorphone ER product because it switched its original product to a reformulated product—claiming the original formulation posed safety risks, (Snowden, Tr. 480)—and then was later asked to remove the reformulated product from the market, (Snowden, Tr. 446). Finally, Impax is the only seller of oxymorphone ER on the market today. (JX-003-008 (¶ 59) (Second Set of Joint Stipulations); Addanki, Tr. 2383 ("today Impax is the only seller of that product")).

1432. Even today, the outcome of the litigation regarding the later-issued patents, like all patent litigation, is uncertain. If Endo had brought additional suits against Impax based on these later-issued patent, the outcome of such litigation cannot be predicted. (CX4039 (Noll, Dep. at 265-66)). To know the outcome of such a litigation would require making many assumptions about a series of events, including the date of acquisition of certain later-issued patents, Impax's infringement case, and the outcome of Endo's infringement cases against other ANDA filers. (CX4039 (Noll, Dep. at 265-66).

RESPONSE TO FINDING NO. 1432:

Complaint Counsel's Proposed Finding No. 1432 is inaccurate and misleading. It is a near certainty that if Impax had not secured the license in the Settlement and License Agreement, Endo would have sued Impax on the later-acquired patents and prevailed. In fact, in a

subsequent breach of contract action between Endo and Impax, Endo asserted that it would have sued Impax for infringing subsequently acquired patents but for the fact that the Endo-Impax settlement included a license to future patents. (Hoxie, Tr. 2892-93). Mr. Figg testified that "if Impax had not had the license to future patents in its settlement agreement, there's little doubt in my mind that Endo would have included claims of infringement against Impax for the original generic Opana ER." (Figg, Tr. 1951). Indeed, Endo *did* sue Impax for infringement of its later-acquired patents with respect to Impax's generic version of *reformulated* Opana ER because the license in the Settlement and License Agreement did not cover a reformulated product. (Figg, Tr. 1951-52, 1964). Endo *won* that case and has successfully *enjoined* Impax's reformulated product pursuant to the later-acquired patents. (*See* Figg, Tr. 1951-52; Koch, Tr. 440; RX-525).

> 1433. In the world where Impax and Endo had not entered into the Impax-Endo Settlement Agreement, and Impax and no other generics had entered with an oxymorphone ER product market, Endo may have had different incentives following its withdrawal of Reformulated Opana ER. Endo would have strong financial incentives to realize value from its Opana ER franchise and its patent portfolio relating to Opana ER. If Impax had never come on the market, Endo would have had an incentive to introduce a version of the original formulation of Opana ER when Endo knew that the FDA was considering requesting it to withdraw Reformulated Opana ER from the market. (Noll, Tr. 1575-76). In that situation, Endo might be selling its own original formulation of Opana ER.

RESPONSE TO FINDING NO. 1433:

Complaint Counsel's Proposed Finding No. 1433 should be disregarded because it violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." (*See* Court, Tr. 1859 ("[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.")). Further, Proposed Finding No. 1433 ignores significant real-world evidence that Endo would not have relaunched its original oxymorphone ER after the FDA asked it to withdraw its reformulated product. (Snowden, Tr. 446). Indeed, Endo argued that it

removed the original formulation for safety reasons. (Snowden, Tr. 480). And Endo recognized that there would be significant "moral" issues with bringing back a product it claimed it removed for safety reasons. (CX4019 (Lortie, Dep. at 117-18)). Accordingly, Complaint Counsel's unsupported assertion that "Endo might be selling its own original formulation of Opana ER" is base speculation and contrary to the weight of the record.

1434. Even if Endo does not introduce a version of the original formulation of Opana ER, Endo has the financial incentive to maximize profits from its Opana ER franchise and its patent portfolio relating to Opana ER. (Addanki, Tr. 2462 (would expect Endo to try to maximize its overall profits)). When Endo is selling an Opana ER product, it makes financial sense to use the patents to exclude other competitors and protect its market position. (RX-547 at 0072, 81, 82-83 (¶¶ 134, 150, 153) (Addanki Report) (Endo would have every incentive to obtain additional patents to assert them and protect its Opana ER product)).

RESPONSE TO FINDING NO. 1434:

Respondent has no specific response.

1435. If, however, Endo is forced to withdraw its Opana ER product and decides not to reintroduce Original Opana ER, then Endo no longer has a market position to protect. At that point, Endo has the financial incentive to license its patents to at least one generic company so it can receive a royalty and earn some money in the oxymorphone market. (Snowden, Tr. 393 (a "patent holder can obtain value by seeking a royalty for the use of its patents"); Addanki, Tr. 2462)). Indeed, this is exactly what Endo did [redacted] (CX3275 at 014-15 [redacted] (*in camera*)). Even if Impax had not entered the market under the Impax-Endo Settlement Agreement, Endo would have had the financial incentive to enter into a similar type of license with Impax or another generic company if Endo found itself not on the market.

RESPONSE TO FINDING NO. 1435:

Complaint Counsel's Proposed Finding No. 1435 should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial

Briefs at 2). Proposed Finding No. 1435 also lacks foundation and is not supported by the record. The documents cited do not say anything about the propositions advanced. It is especially telling that Complaint Counsel does not cite a single Endo witnesses or document, despite discussing Endo's actions, incentives, and potential plans. Proposed Finding No. 1435 is an improper attempt by Complaint Counsel to insert a new issue into the litigation that was not addressed at trial or during discovery, and it is entirely speculative.

C. The reverse payment was not necessary to achieve any of the purported procompetitive benefits of the agreement

1436. The reverse payment from Endo to Impax was not necessary to achieve either entry before patent expiration or a license to patents that had not yet issued. (*See* CCF ¶¶ 1437-59).

RESPONSE TO FINDING NO. 1436:

The proposed summary finding should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Additionally, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondent's replies to those findings.

1. The reverse payment was not necessary for Impax to achieve entry prior to patent expiration in September 2013

1437. The SLA restricted Impax from selling generic Opana ER for more than 30 months— from mid-June 2010 until the end of December 2012—and licensed Impax to enter approximately eight months before expiration of the last patent on which Impax was sued. (RX-364 at 007 (SLA § 3.2); CX0301 (Orange Book patent data)).

RESPONSE TO FINDING NO. 1437:

While Respondent does not dispute that the Settlement and License Agreement allowed Impax to launch its generic product risk-free roughly eight months before the patents-in-suit

expired, the remainder of Complaint Counsel's Proposed Finding No. 1437 is incomplete and misleading. Impax could sell certain dosages of generic Opana ER as soon as "a Third Party commences commercial sale of an FDA approved generic extended release oxymorphone product that is AB rated to Opana ER Product." (RX-364.0002 (SLA § 1.1)). With respect to the rest of the dosages, the agreement allowed Impax to market and offer to sell its generic product "thirty days prior to the anticipated applicable Commencement Date," which would be no later than January 1, 2013. (RX-364.0001-02, 07 (SLA § 3.2)).

1438. A pure term-split settlement between Impax and Endo was feasible. Removing the reverse payments would logically result in an entry date earlier than January 2013. (*See* CCF ¶¶ 1439-55).

RESPONSE TO FINDING NO. 1438:

The proposed summary finding should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Additionally, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondent's replies to those findings.

1439. Settlements of Hatch-Waxman litigation can be, and typically are, based on the merits of the patent, reduced litigation costs, and risk aversion. (CX5001 at 011-012 (¶ 22) (Bazerman Report)).

RESPONSE TO FINDING NO. 1439:

Respondent has no specific response.

1440. Parties regularly settle pharmaceutical patent litigation without reverse payments. (CX5001 at 010-011 (¶¶ 20-21) (Bazerman Report)). Indeed, in the decade after 2004 when Congress required pharmaceutical companies to file final patent settlements, nearly 77% of pharmaceutical patent litigations settled without a reverse payment and a restriction on generic entry. (CX6140 at 004 (FY2014 MMA Report showing that,

between FY2004 and FY2014, 719 of 934 final settlements were without reverse payment and a restriction on generic entry)).

RESPONSE TO FINDING NO. 1440:

The first sentence of Complaint Counsel's Proposed Finding No. 1440 should be disregarded because it violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." (*See* Court, Tr. 1859 ("[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.")). The document cited in support of the second sentence of Proposed Finding No. 1440 was prepared by the Federal Trade Commission's Bureau of Competition, which includes Complaint Counsel, and therefore is self-serving and should be disregarded.

1441. In this case, a settlement with an earlier entry date and no reverse payment was possible. It is simple negotiation logic that, rather than including a reverse payment such as the combined No-AG provision/Endo Credit payment—which actually resulted in a $102 million payment from Endo to Impax—Endo would have agreed to an earlier date without that amount of money being paid. (Bazerman, Tr. 873-74).

RESPONSE TO FINDING NO. 1441:

Complaint Counsel's Proposed Finding No. 1441 should be disregarded because it violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." (*See* Court, Tr. 1859 ("[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.")). Further, there is no support in the record for the assertion that "a settlement with an earlier entry date and no reverse payment was possible." Impax met complete resistance from Endo when trying to negotiate a license date prior to January 1, 2013. (Koch, Tr. 239 ("met complete resistance to the concept of an earlier launch date"); Mengler, Tr. 565-67; *see* Noll, Tr. 1599-1600 ("Impax's attempt to get an earlier date met with complete resistance.")). Endo even

resisted an earlier licensed-entry date when Impax approached Endo with an entry-date only proposal. (Snowden, Tr. 371-73, 423).

Professor Bazerman conceded that he has not seen any evidence in the record that Endo offered an earlier entry date. (Bazerman, Tr. 907). Professor Bazerman did not identify a possible reservation date for Endo. (Bazerman, Tr. 913). And Professor Bazerman cannot say with any certainty that an alternative settlement was possible. (Bazerman, Tr. 914). Dr. Addanki confirms that "[f]rom an economic standpoint, there's no basis" to assume an alternative settlement was possible. (Addanki, Tr. 2359). Therefore, "the only real alternative we have to the settlement that we have before us is that the parties continue to litigate." (Addanki, Tr. 2374).

1442. Although Impax's economic expert, Dr. Addanki, outlines "selected reasons" why settlement with no reverse payments might not have been negotiated by Impax and Endo, he never concludes that such an agreement was impossible. (RX-547 at 0061-66 (¶¶ 115-24) (Addanki Rebuttal Report)). In fact, Dr. Addanki does not know whether or not there were any settlements that Endo and Impax were willing to accept absent any payments. (Addanki, Tr. 2467).

RESPONSE TO FINDING NO. 1442:

Respondent has no specific response.

1443. Dr. Addanki concedes that he lacks information to determine the earliest date of generic entry that Endo was willing to accept, also known as Endo's reservation date. (Addanki, Tr. 2466-67 ("I do not know what the true reservation date was for Endo or anyone negotiating on behalf of Endo")).

RESPONSE TO FINDING NO. 1443:

Complaint Counsel's Proposed Finding No. 1443 is incomplete and misleading. While Dr. Addanki said he did not know the "true reservation date" for Endo, he states that he is "not aware of any evidence that Endo would have agreed to an earlier entry date, and, as an economic matter, there is no reason to expect that the parties could have agreed upon an earlier entry date."

(RX-547.0060 (Addanki Rep. ¶ 114)). Indeed, Professor Bazerman did not identify a possible reservation date for Endo. (Bazerman, Tr. 913). In any event, the record is clear: Endo would not accept an earlier licensed-entry date regardless of the terms of the agreement. (Koch, Tr. 239 ("met complete resistance to the concept of an earlier launch date"); Mengler, Tr. 565-67; Noll, Tr. 1599-1600 ("Impax's attempt to get an earlier date met with complete resistance.")).

> 1444. Nor can Dr. Addanki determine Endo's true reservation value from examining the negotiations that occurred between Impax and Endo. (Addanki, Tr. 2391, 2466). Thus, even though Endo may have insisted in negotiations that it would not offer Impax an entry date earlier than 2013, that negotiating position provides no insight into Endo's true reservation date. (Addanki, Tr. 2390-91 ("I don't think you can infer what someone's true reservation date was from a negotiation posture in a settlement negotiation.")).

RESPONSE TO FINDING NO. 1444:

Complaint Counsel's Proposed Finding No. 1444 is inaccurate and misleading. While Dr. Addanki recognizes that he does not know Endo's true reservation date because "[i]t's not possible to divine what's in someone's head," (Addanki, Tr. 2466), that does not lead to the conclusion in Proposed Finding No. 1444 that "negotiating position provides no insight into Endo's true reservation date." The evidence is clear that Impax attempted to obtain a date earlier than January 2013, but Endo refused outright. (*See* Koch, Tr. 239 ("met complete resistance to the concept of an earlier launch date")). In any event, Professor Bazerman, who claims an early entry date was possible, offers no evidence of a possible reservation date for Endo. (Bazerman, Tr. 913).

> 1445. Dr. Addanki also concedes that he lacks information to determine the latest entry date that Impax was willing to accept, also known as Impax's reservation date. (Addanki, Tr. 2467).

RESPONSE TO FINDING NO. 1445:

Respondent has no specific response.

1446. Consequently, Dr. Addanki does not know whether, absent any payments, the earliest entry date Endo was willing to offer overlapped with the latest entry date Impax was willing to accept. (Addanki, Tr. 2467).

RESPONSE TO FINDING NO. 1446:

Respondent has no specific response.

1447. Moreover, between February 2009 and May 2011, Endo settled patent litigation relating to generic Opana ER with five companies other than Impax. None of these five settlement and license agreements contained reverse payments to the relevant generic company. (*See* CCF ¶¶ 1448-52). Dr. Addanki failed to consider that fact. For example, Dr. Addanki provides no explanation for why Endo would not have accepted a settlement agreement with Impax with no reverse payments and an entry date in September 2012, which Endo granted to four other generics. (CX5005 at 009 (¶ 15) (Bazerman Rebuttal Report); CCF ¶¶ 1449-52).

RESPONSE TO FINDING NO. 1447:

The first three sentences of Complaint Counsel's Proposed Finding No. 1447 should be disregarded because they violate the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Moreover, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondent's replies to those findings.

With respect to the settlements with "four other generics" referenced in the fourth sentence of Proposed Finding No. 1447, those settlements are not comparable to the Impax-Endo settlement because none had "first to file" status, and therefore the entry dates had little meaning since those ANDA filers could not enter until after the first-filer. (Koch, Tr. 232; Figg, Tr. 1854 ("[T]he FDA is not allowed to approve a subsequent ANDA until 180 days after the first applicant launches its product.")). Moreover, none of the other ANDA filers, including Actavis, secured broad rights to later-acquired patents. (RX-548.0044 (Figg Rep. ¶ 95)). This Proposed Finding should be disregarded because it is based on unreliable expert testimony.

1448. [redacted] (CX3383 (Actavis settlement) (admitted for fact of the settlement and its terms, not truth of the matter asserted) (*in camera*)).

RESPONSE TO FINDING NO. 1448:

Respondent has no specific response.

1449. Effective April 12, 2010, Barr Laboratories, Inc. settled litigation relating to generic Opana ER with Endo and received a license to the litigated patents starting no later than September 15, 2012. The Barr-Endo settlement did not include a reverse payment. (CX3378 at 070-071 (Barr settlement, definitions of "Commencement Date" and "Effective Date")).

RESPONSE TO FINDING NO. 1449:

Respondent has no specific response.

1450. Effective June 7, 2010, Sandoz Inc. settled litigation relating to generic Opana ER with Endo and received a license to the litigated patents starting no later than September 15, 2012. The Sandoz-Endo settlement did not include a reverse payment. (CX3378 at 092-93 (Sandoz settlement, definitions of "Commencement Date" and "Effective Date")).

RESPONSE TO FINDING NO. 1450:

Respondent has no specific response.

1451. Effective October 4, 2010, Watson Laboratories, Inc. settled litigation relating to generic Opana ER with Endo and received a license to the litigated patents starting no later than September 15, 2012. The Watson-Endo settlement did not include a reverse payment. (CX3378 at 031 (Watson settlement, definitions of "Commencement Date" and "Effective Date")).

RESPONSE TO FINDING NO. 1451:

Respondent has no specific response.

1452. Effective May 4, 2011, Roxane Laboratories, Inc. settled litigation relating to generic Opana ER with Endo and received a license to the litigated patents starting no later than September 15, 2012. The Roxane-Endo settlement did not include a reverse payment. (CX3452 at 115-17 (Roxane settlement, definitions of "Commencement Date" and "Effective Date")).

RESPONSE TO FINDING NO. 1452:

Respondent has no specific response.

1453. Dr. Addanki's failure to consider a September 2012 entry date similar to what other generics received cannot be attributed to Endo's goal to introduce a reformulated version of Opana ER before generic entry. Around the time of settlement with Impax, Endo expected that it would get approval for and launch a reformulated oxymorphone extended-release product between December 2010 and June 2011. (CX3038 at 001 (Hogan email dated 4/2/2010 entitled "FW: EN3288 Core Commercial Launch Team (CCLT) Update")). Dr. Addanki offers no analysis supporting a conclusion that paying the Endo Credit—which was ultimately more than $102 million—was preferable to Endo than offering Impax an entry date in September 2012 without any reverse payments. (RX-547 at 0060 (Addanki Rebuttal Report) (¶ 114) ("I am not aware of any evidence that Endo would have agreed to an earlier entry date, and, as an economic matter, there is no reason to expect that the parties could have agreed upon an earlier entry date")).

RESPONSE TO FINDING NO. 1453:

Complaint Counsel's Proposed Finding No. 1453 is inaccurate and misleading because there is no evidence in the record that a "September 2012 entry date" was possible. First, Complaint Counsel cites no evidence indicating that Endo would have agreed to a September 2012 entry date. Second, while a number of other ANDA filers obtained a September 2012 entry date in settlements with Endo, that date had little meaning since the other ANDA filers could not enter before Impax given the 180-day exclusivity provided to Impax as the first-filer. (Koch, Tr. 232; Figg, Tr. 1854 ("[T]he FDA is not allowed to approve a subsequent ANDA until 180 days after the first applicant launches its product.")). Third, none of the other ANDA filers, including Actavis, secured broad rights to later-acquired patents. (RX-548.0044 (Figg Rep. ¶ 95)). Thus, as Dr. Addanki testified, "to hypothesize a settlement and say they would have agreed to it would be pure speculation, and so the only real alternative we have to the settlement that we have before us is that the parties continue to litigate." (Addanki, Tr. 2374). Indeed, the only real-world evidence actually in the record is clear: Endo resisted an earlier license date when Impax sought a pure term-split settlement. (Snowden, Tr. 371-73, 423).

1454. Further, the only "simple settlement" without any payment and a 2011 entry date was proposed late in the negotiations and immediately rejected by Endo. (*See* CCF ¶¶ 276-78).

RESPONSE TO FINDING NO. 1454:

The proposed summary finding should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Additionally, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondent's replies to those findings.

1455. Endo's ability to settle five separate Opana ER patent infringement litigations with sophisticated pharmaceutical companies for generic entry dates prior to January 2013 and without payments supports the feasibility of a pure term-split settlement with Impax. (CX5005 at 007 (¶ 10) (Bazerman Rebuttal Report)).

RESPONSE TO FINDING NO. 1455:

Complaint Counsel's Proposed Finding No. 1455 is inaccurate, not supported by the record, and based on unreliable expert testimony. The entry dates in other settlement agreements were illusory because the other ANDA filers could not enter before Impax given the 180-day exclusivity provided to Impax as first-filer. (Koch, Tr. 232; Figg, Tr. 1854 ("[T]he FDA is not allowed to approve a subsequent ANDA until 180 days after the first applicant launches its product.")). Accordingly, the dates do not reflect a marketplace reality, and offer no support for the proposition in Proposed Finding No. 1455. Indeed, the only real-world evidence actually in the record is clear: Endo resisted an earlier license date when Impax sought a pure term-split settlement. (Snowden, Tr. 371-73, 423). Finally, none of the other ANDA filers, including Actavis, secured broad rights to later-acquired patents. (RX-548.0044 (Figg Rep. ¶ 95)).

2. The reverse payment was not necessary for Impax to obtain a license to additional patents

1456. Under the SLA, Impax received a license to patent applications that had not issued at the time of settlement, but might issue in the future. (RX-364 at 0009 (SLA § 4.1(a))).

RESPONSE TO FINDING NO. 1456:

Respondent has no specific response.

1457. The reverse payment was not necessary for Impax to receive such a license to patents that had not yet issued. This license was requested by and had value for Impax. (CX0324 at 030 (draft SLA § 4.1(a) (showing Impax's edits to the June 5, 2010 draft version to include patent applications)). It would make no sense that the reverse payment was necessary to induce Impax to accept the license that it wanted and that would benefit Impax. (CX5001 at 030 (¶ 56) (Bazerman Report)). Indeed, Sandoz obtained an option to license Orange Book patents that Endo might obtain in the future relating to Opana ER, and the Sandoz settlement—signed the same day as Impax—did not include a reverse payment. (CX3378 at 092-93 (Sandoz settlement, definitions of "Commencement Date" and "Effective Date"), 100 (Sandoz settlement, § 4.4)).

RESPONSE TO FINDING NO. 1457:

The first and third sentences of Complaint Counsel's Proposed Finding No. 1457 should be disregarded because they violate the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). These sentences are also improper argument, not facts. Indeed, the cited paragraph of Professor Bazerman's report includes no citations to record evidence to support his argument, and therefore Mr. Bazerman's opinions are based on unreliable expert testimony.

Respondent has no specific response to the second sentence of Proposed Finding No. 1457 other than to clarify that the cited evidence says nothing about whether any term had "value" to any party. Finally, the last sentence of Proposed Finding No. 1457 is incomplete and misleading. Endo never granted Sandoz a license to future patents covering generic

oxymorphone ER, which is why Endo sued Sandoz for infringement of the '482, '122, and '216 patents in 2013. (RX-500 (*Endo v. Sandoz* complaint) (admitted for the fact of the complaint, not the truth of the matters asserted therein)).

> 1458. Moreover, the reverse payment was part of the settlement agreement substantially before the license to additional patents was even suggested. Impax first raised that license on June 5, 2010, whereas Impax and Endo had been discussing the reverse payment since the previous month and had even reached an agreement in principle on June 3, 2010, two days before Impax raised the license to patents not yet issued. (CX0320 at 003, 009-010 (draft terms sheets circulated on May 26, 2010, which incorporated the No-AG provision and payments under a co-promotion/licensing agreement for IPX-066, including a $10 million option fee due at signing); *see also* CCF ¶¶ 279-84 (discussing agreement in principle on June 3, 2010 and Ms. Nguyen of Impax first raising license scope on June 5, 2010)).

RESPONSE TO FINDING NO. 1458:

The first sentence of Complaint Counsel's Proposed Finding No. 1458 should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2).

The second sentence of the Proposed Finding is incomplete and misleading. Ms. Nguyen testified that "I don't have exact dates" and that the date of June 5 may only be "approximately right for when [she] became involved." (CX4026 (Nguyen, Dep. at 142-43)). While Respondent does not dispute the content of Impax's counterproposal on June 5, 2010, the cited evidence does not support the proposition that "Impax first raised that license on June 5, 2010." Moreover, the individual findings in the cited paragraphs do not support the proposed summary finding and are unreliable for the reasons set out in Respondent's replies to those findings.

> 1459. The license is immaterial to any discussion of the reverse payment that Endo made to Impax. (CX5001 at 030 (¶ 56) (Bazerman Report); *see also* CCF ¶¶ 1405-07).

RESPONSE TO FINDING NO. 1459:

Complaint Counsel's Proposed Finding No. 1459 should be disregarded because it violates this Court's Order on Post-Trial Briefs by citing "to expert testimony to support factual propositions that should be established by fact witnesses or documents." (*See* Court, Tr. 1859 ("[W]hen it comes time for posttrial briefing, [] neither side is allowed to cite to an expert witness for facts.")). Tellingly, the cited paragraph in Professor Bazerman's report cites no evidence for the proposition. Moreover, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondent's replies to those findings.

XIV. Remedy

A. Injunctive relief is necessary to prevent Impax from entering similar reverse-payment settlement agreements in the future

1. Impax remains in the business of manufacturing and marketing both generic and branded pharmaceutical products

1460. Impax "is an integrated specialty pharmaceutical company focused on developing, manufacturing and marketing generic and brand pharmaceutical products." (JX-001 at 001 (¶ 3); CX3271 at 002 (Impax 2015 Annual Report); CX3163 at 002 (¶ 5) (Impax Answer) (Impax "engages in the business of, among other things, developing, manufacturing, and marketing generic drugs.")).

RESPONSE TO FINDING NO. 1460:

Respondent has no specific response.

1461. Impax applies its "formulation and development expertise" and "drug delivery technology" to develop, manufacture, and market both generic and branded drug products. (CX3271 at 011 (Impax 2015 Annual Report)).

RESPONSE TO FINDING NO. 1461:

Respondent has no specific response.

1462. As of February 2016, Impax's generics business had more than 60 products on the market and more than 40 ANDAs either in regulatory review or in development. (CX3271 at 003 (Impax 2015 Annual Report)).

RESPONSE TO FINDING NO. 1462:

Respondent has no specific response.

1463. As of February 2016, Impax had 112 ANDAs approved by the FDA (including one with tentative approval) and the right to market and/or share in the profits of 14 approved ANDAs held by third parties. (CX3271 at 012 (Impax 2015 Annual Report)).

RESPONSE TO FINDING NO. 1463:

Respondent has no specific response.

1464. As of February 2016, Impax had 25 applications pending at the FDA representing approximately $7.9 billion in 2015 U.S. product sales. (CX3271 at 012 (Impax 2015 Annual Report)).

RESPONSE TO FINDING NO. 1464:

Respondent has no specific response.

1465. [redacted]
(RX-246 at 0024 (July 2015 Impax Portfolio Executive Committee (PEC) Meeting Presentation) (*in camera*); CX3271 at 011 (Impax 2015 Annual Report)).

RESPONSE TO FINDING NO. 1465:

Respondent has no specific response.

1466. Impax's "products and product candidates are generally difficult to formulate and manufacture, providing certain competitive advantages." (CX3271 at 011 (Impax 2015 Annual Report)).

RESPONSE TO FINDING NO. 1466:

Respondent has no specific response.

1467. Impax's Specialty Pharma division primarily focuses on the development and promotion of "proprietary branded pharmaceutical products for the treatment of central

nervous system (CNS) disorders and other specialty segments." (CX3271 at 002 (Impax 2015 Annual Report)).

RESPONSE TO FINDING NO. 1467:

Respondent has no specific response.

1468. CNS disorders "include migraine, multiple sclerosis, Parkinson's disease and postherpetic neuralgia." (CX3271 at 013 (Impax 2015 Annual Report)).

RESPONSE TO FINDING NO. 1468:

Respondent has no specific response.

1469. As of February 2016, Impax's specialty portfolio was "comprised of six commercialized products, one in regulatory review and one in development." (CX3271 at 003 (Impax 2015 Annual Report)).

RESPONSE TO FINDING NO. 1469:

Respondent has no specific response.

1470. In January 2015, Impax's branded drug Rytary was approved by the FDA for the treatment of Parkinson's disease. In April 2015, Impax began marketing the product in the U.S. (CX3271 at 013 (Impax 2015 Annual Report)).

RESPONSE TO FINDING NO. 1470:

Respondent has no specific response.

1471. Impax also has "a couple of product candidates that are in varying stages of development." (CX3271 at 013 (Impax 2015 Annual Report)).

RESPONSE TO FINDING NO. 1471:

Respondent has no specific response.

1472. Impax continues to invest in its branded development pipeline, "both internally and through acquisitions and partnerships primarily focused on late-stage and next generation product opportunities." (CX3271 at 002 (Impax 2015 Annual Report)).

RESPONSE TO FINDING NO. 1472:

Respondent has no specific response.

2. Impax regularly engages in patent litigation

1473. As a manufacturer and marketer of both generic and branded pharmaceutical products, Impax regularly engages in patent litigation. (CX3163 at 020 (¶ 100) (Impax Answer) (Impax "is sometimes involved in patent litigation related to various drugs."); *see also* CCF ¶¶ 1474-1478).

RESPONSE TO FINDING NO. 1473:

Complaint Counsel's Proposed Finding No. 1473 is not supported by the cited evidence. The cited document states that "Impax admits that it continues to develop and manufacturer pharmaceutical products, and that—like virtually all pharmaceutical companies—it is *sometimes* involved in patent litigation related to various drugs." (CX3163-020 (emphasis added)).

1474. Impax is "involved in numerous patent litigations" in which Impax "challenge[s] the validity or enforceability of innovator companies' listed patents and/or their applicability to" Impax's generic products. (CX3271 at 030 (Impax 2015 Annual Report)).

RESPONSE TO FINDING NO. 1474:

Respondent has no specific response.

1475. Impax's generic products division "is routinely subject to patent infringement litigation brought by branded pharmaceutical manufacturers seeking to delay FDA approval to manufacture and market generic forms of their branded products." (CX3271 at 030 (Impax 2015 Annual Report)).

RESPONSE TO FINDING NO. 1475:

Respondent has no specific response.

1476. Impax is "[a]lmost always" sued any time Impax files an ANDA with a Paragraph IV certification. (CX4003 at 005 (Snowden, IHT at 15)).

RESPONSE TO FINDING NO. 1476:

Respondent has no specific response other than to clarify that Ms. Snowden was testifying about a brand suing Impax for patent infringement after Impax filed a Paragraph IV certification, not the FTC or any other party suing on the basis of antirust (or any other type of) allegations. (CX4003 (Snowden, IHT at 15)).

1477. Impax also is involved in patent infringement litigation "in which generic companies challenge the validity or enforceability of [Impax's] patents and/or their applicability to their generic pharmaceutical products." (CX3271 at 030 (Impax 2015 Annual Report)).

RESPONSE TO FINDING NO. 1477:

Respondent has no specific response.

1478. Thus, "settling patent litigations has been and is likely to continue to be an important part of [Impax's] business." (CX3271 at 030 (Impax 2015 Annual Report)).

RESPONSE TO FINDING NO. 1478:

While Respondent does not dispute that the quoted language appears in the cited document, Complaint Counsel's Proposed Finding No. 1478 is speculative, misleading, and lacks foundation in its attempt to suggest that such settlements, or any terms therein, would violate the law.

3. Impax may seek to enter additional reverse-payment settlements in the future

1479. In an SEC filing, Impax has cited the Supreme Court's ruling in *FTC v. Actavis* and the FTC's position on reverse-payment settlements as "Risks Related to Our Business." (CX3271 at 025, 30 (Impax 2015 Annual Report)).

RESPONSE TO FINDING NO. 1479:

Complaint Counsel's Proposed Finding No. 1479 is incomplete and misleading. Impax did not state that *Actavis* itself was a risk. Rather, Impax's Annual Report explained to investors

that uncertainty existed: "In June 2013, the U.S. Supreme Court in its decision in *FTC v. Actavis* determined that 'reverse payment' settlement agreements between brand and generic companies could violate antitrust laws. The Supreme Court held that such settlement agreements are neither immune from antitrust attack nor presumptively illegal but rather should be analyzed under the 'Rule of Reason.' It is currently uncertain the effect the Supreme Court's decision will have on our existing settlement agreements or its impact on our ability to enter into such settlement agreements in the future or the terms thereof." (CX3271-030).

1480. Impax believes that such "agreements with brand pharmaceutical companies . . . are important to [its] business." (CX3271 at 030 (Impax 2015 Annual Report)).

RESPONSE TO FINDING NO. 1480:

Complaint Counsel's Proposed Finding No. 1480 is not supported by the cited evidence and is misleading because it selectively quotes the cited document. Impax stated in its Annual Report that, "Our agreements with brand pharmaceutical companies, which are important to our business, are facing increased government scrutiny in the United States, which may result in increased government actions and private litigation suits." (CX3271-030). Impax did not state that so-called "reverse-payment" settlements are important.

1481. Impax prefers to include No-AG clauses in its settlements with branded companies. (*See* CCF ¶¶ 1482-1484).

RESPONSE TO FINDING NO. 1481:

The proposed summary finding should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Additionally, the individual findings cited do not support the proposed summary finding and are unreliable for the reasons set out in Respondent's replies to those findings.

1482. Impax's current CEO and former head of several pharmaceutical companies, Paul Bisaro, has testified under oath that he "would like to always try to maintain" a No-AG clause "wherever possible." (CX4000 at 004 (Bisaro, IHT at 33-34); Nestor, Tr. 2928 (identifying Mr. Bisaro as CEO of Impax)).

RESPONSE TO FINDING NO. 1482:

Complaint Counsel's Proposed Finding No. 1482 is inaccurate and misleading. First, Mr. Bisaro testified at an investigational hearing in 2014, when he was an employee of Actavis, another pharmaceutical company, and at which Impax was not present and had no rights. (CX4000 (Bisaro, IHT at 7)). Second, Mr. Bisaro actually testified, "having grown up in the industry and knowing when the law [Hatch-Waxman] was passed, it was not supposed to have an AG, I would like to always try to maintain that, wherever possible. . . . So, I mean, they weren't contemplated at the time the law was passed, for sure. Otherwise somebody would have said something." (CX4000 (Bisaro, IHT at 33-34)). Third, Mr. Bisaro stated that a No-Authorized Generic Provision is not an "essential term," but rather "we look at the whole situation and say this is -- this is a good deal for us. And it's a good deal for our shareholders, and it's a good deal for consumers. And that's what we do." (CX4000 (Bisaro, IHT at 127)). Fourth, there is no evidence to suggest Mr. Bisaro, in his role at Impax, attempted to maintain a No-Authorized Generic clause. Fifth, it bears noting that at the time Mr. Bisaro gave his testimony, no Court of Appeals had ruled on the legality of a "No AG" provision, and multiple district courts had held that they were *lawful*. *See, e.g.*, *In re Loestrin 24 Fe Antitrust Litig.*, 45 F. Supp. 3d 180, 190–95 (D.R.I. 2014), *vacated*, 814 F.3d 538 (1st Cir. 2016); *In re Lamictal Dir. Purchaser Antitrust Litig.*, 18 F. Supp. 3d 560, 567–69 (D.N.J. 2014), *vacated*, 791 F.3d 388 (3d Cir. 2015).

1483. Impax's former CEO, Larry Hsu, testified under oath that, "obviously, if you have a choice, with AG, without AG, you prefer to get the no AG." (CX4014 at 018 (Hsu, IHT at 68)).

RESPONSE TO FINDING NO. 1483:

Complaint Counsel's Proposed Finding No. 1483 is inaccurate, incomplete, and misleading. Dr. Hsu's full answer is unequivocal: "[W]hat I'm trying to say here is important in the sense if everything else equal, okay, of course, no AG is better than having AG. But when you start talking about . . . no AG means you can delay the launch, delay the entry date, that's a different story. That's a different story. Because there is a very important factor here, which is . . . to have an entry date, have a launch as soon as possible." (CX4014 (Hsu, IHT at 68-69)). Mr. Hsu made the same point at his deposition, at which he explained that Impax did not value the absence of an authorized generic if it meant delaying its own product. (CX4030 (Hsu, Dep. at 76-77)). Finally, the Proposed Finding cites a *former* Impax employee about his views. The Proposed Finding does not support the suggestion that current Impax employees view other theoretical No-Authorized Generic provisions as important in any theoretical future settlements.

1484. Impax's former president of its generics division, Chris Mengler, testified that it was important to Impax to negotiate a No-AG provision with Endo. (CX4010 at 007 (Mengler, IHT at 24)).

RESPONSE TO FINDING NO. 1484:

Complaint Counsel's Proposed Finding No. 1484 is incomplete and misleading. Mr. Mengler testified at trial that Impax did not view the No-Authorized Generic provision as particularly valuable because Impax derives value "by selling the drug [] with or without an" authorized generic. (Mengler, Tr. 528-29; *see* Mengler, Tr. 529-30 ("The value I get is selling my drug with whatever market conditions exist, so if there's no market, then an AG is not a relevant issue")). The Proposed Finding, moreover, cites a *former* Impax employee about a *single* settlement agreement executed nearly *eight years ago*. The Proposed Finding does not

support the suggestion that current Impax employees view other theoretical No-Authorized Generic provisions as important in any theoretical future settlements.

B. Injunctive relief is necessary to prevent anticompetitive conduct in the oxymorphone ER market

1485. [redacted] (CX3275 at 001 (2017 Contract Settlement Agreement) (*in camera*)).

RESPONSE TO FINDING NO. 1485:

The first sentence of Complaint Counsel's Proposed Finding No. 1485 is an improper legal conclusion, not a fact. The first sentence is also unsupported by any record evidence and should be disregarded because it violates the Court's Order on Post-Trial Briefs, which requires that "[a]ll proposed findings of fact shall be supported by specific references to the evidentiary record." (Order on Post-trial Briefs at 2). Respondent has no specific response to the second sentence of Proposed Finding No. 1485. Finally, Proposed Finding No. 1485 is an improper attempt by Complaint Counsel to insert a new issue into the litigation that was not addressed at trial or during discovery, and it is entirely speculative.

1486. [redacted] (CX3275 at 011 (2017 Contract Settlement Agreement) (*in camera*)).

RESPONSE TO FINDING NO. 1486:

Respondent has no specific response.

1487. [redacted]

[redacted] (CX3275 at 013-14 (2017 Contract Settlement Agreement § 1(i)) (*in camera*))).

RESPONSE TO FINDING NO. 1487:

Respondent has no specific response.

1488. [redacted] (CX3275 at 013 (2017 Contract Settlement Agreement §§ 1(h), (i)) (*in camera*))).

RESPONSE TO FINDING NO. 1488:

Respondent has no specific response.

1489. Endo ceased selling Reformulated Opana ER on September 1, 2017. (JX-001 at 012 (¶ 54)).

RESPONSE TO FINDING NO. 1489:

While Respondent does not dispute that Endo ceased selling reformulated Opana ER on September 1, 2017, there is no evidence to suggest it was related to any Endo-Impax settlement agreement. Indeed, the record is clear that on June 8, 2017, the United States Food and Drug Administration publicly requested that Endo voluntarily withdraw its Reformulated Opana ER product (NDA No. 201655) from the market. (JX-001-012 (¶ 52) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity); Snowden, Tr. 446). The FDA made its request following an investigation that uncovered "a significant shift in the route of abuse of Opana ER from nasal to injection following the product's reformulation." (CX6048-001). The FDA concluded that "the benefits of reformulated Opana ER no longer outweigh its risks" because the "injection abuse of reformulated Opana ER has been associated with a serious outbreak of HIV and hepatitis C, as well as cases of serious blood disorder (thrombotic microangiopathy)."

(CX6048-001). In July 2017, Endo announced that it would cease shipping Reformulated Opana ER. (JX-001-012 (¶ 53) (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity)).

1490. [redacted] (CX3275 at 013 (2017 Contract Settlement Agreement § 1(i)) (*in camera*))).

RESPONSE TO FINDING NO. 1490:

Complaint Counsel's Proposed Finding No. 1490 is not supported by the cited evidence or any other record evidence. The cited document [redacted]. Moreover, [redacted]. Proposed Finding No. 1490 is an improper attempt by Complaint Counsel to insert a new issue into the litigation that was not addressed at trial or during discovery, and it is entirely speculative.

1491. Endo has not reintroduced a branded or authorized generic version of Original Opana ER. (JX-001 at 012 (¶¶ 49-50) (Endo stopped selling Original Opana ER in 2012; the FDA moved Original Opana ER to the Orange Book Discontinued List); *see generally* CX6044 at 057 (June 2017 FDA Listing of Authorized Generics) (showing Endo's Opana IR as the only AG from the Opana franchise)).

RESPONSE TO FINDING NO. 1491:

Respondent has no specific response.

1492. [redacted] (CX3275 at 004 (§ 10(c)) (2017 Contract Settlement Agreement) (*in camera*)).

RESPONSE TO FINDING NO. 1492:

While Respondent does not dispute [redacted] as Proposed Finding No. 1492 attempts to suggest. Moreover, Proposed Finding No. 1492 is an improper attempt by Complaint Counsel to insert a new issue into the litigation that was not addressed at trial or during discovery, and it is entirely speculative.

IMPAX'S REPLIES TO COMPLAINT COUNSEL'S PROPOSED CONCLUSIONS OF LAW

1. Impax Laboratories, Inc., is a "corporation" within the meaning of Section 4 of the Federal Trade Commission Act., 15 U.S.C. § 44. JX-001 at 001 (¶ 4).

RESPONSE TO CONCLUSION NO. 1:

Respondent has no specific response.

2. Impax has engaged, and continues to engage, in commerce and activities affecting commerce in each of the fifty states in the United States and the District of Columbia, as the term "commerce" is defined by Section 1 of the Federal Trade Commission Act, 15 U.S.C. § 44. JX-001 at 001-02 (¶ 5-6).

RESPONSE TO CONCLUSION NO. 2:

Respondent has no specific response.

3. The Federal Trade Commission has jurisdiction over Impax Laboratories, Inc., and over the subject matter of this proceeding, pursuant to Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45. JX-001 at 002 (¶ 7).

RESPONSE TO CONCLUSION NO. 3:

Respondent has no specific response.

4. Conduct that violates Section 1 or 2 of the Sherman Act is deemed to constitute an unfair method of competition and hence a violation of Section 5 of the FTC Act as well. *FTC v. Cement Inst.*, 333 U.S. 683, 694 (1948); JX-001 at 002 (¶ 9).

RESPONSE TO CONCLUSION NO. 4:

Respondent has no specific response.

5. Reverse-payment patent settlements are subject to antitrust scrutiny under the rule of reason. JX-001 at 002 (¶ 11). Application of the rule of reason follows a well-established three-step burden shifting framework: (1) the plaintiff bears the initial burden to make a *prima facie* showing of an anticompetitive effect; (2) if the plaintiff makes that showing, the burden shifts to the defendant to demonstrate a procompetitive justification for the restraint; and (3) if the defendant establishes such a justification, the burden shifts back to the plaintiff to show that the restraint is not reasonably necessary to achieve the procompetitive objective. *Sullivan v. Nat'l Football League*, 34 F.3d 1091, 1096 (1st Cir. 1994); *1-800 Contacts*, FTC File No. 141-0200, Doc. No. 9372, at 120 (Oct. 27, 2017). *See also* VII P. Areeda & H. Hovenkamp, *Antitrust Law: An Analysis of Antitrust Principles and Their Application* ¶ 1504b, at 358 (2d ed. 2003) ("Areeda").

RESPONSE TO CONCLUSION NO. 5:

Complaint Counsel's Proposed Conclusion No. 5 is incomplete.

To begin with, it is not the case that *all* alleged reverse-payment settlements are automatically subject to antitrust scrutiny under the rule of reason. As the Supreme Court stated in *FTC v. Actavis Inc.*, 133 S. Ct. 2223 (2013), a reverse-payment settlement "can bring with it the risk of significant anticompetitive effects" warranting the application of antitrust scrutiny only where the reverse payment is "large and unjustified." *Id.* at 2237.

Numerous courts have affirmed that proof of a settlement with a "large and unjustified" reverse payment is required to trigger antitrust scrutiny in the first place. *See, e.g.*, *In re Lipitor Antitrust Litig.*, 868 F.3d 231, 251-52 (3d Cir. 2017), *petition for cert. filed*, No. 17-771 (U.S. Nov. 20, 2017) (only after plaintiffs have "'allege[d] facts sufficient to support the legal conclusion that the settlement at issue involves a large and unjustified reverse payment under *Actavis*'" may plaintiffs "proceed to prove their allegations under the traditional rule-of-reason analysis") (quoting *In re Loestrin 24 Fe Antitrust Litig.* ("*Loestrin I*"), 814 F.3d 538, 552 (1st Cir. 2016)); *Sergeants Benevolent Ass'n Health & Welfare Fund v. Actavis, PLC*, No. 15-cv-6549 (CM), 2016 WL 4992690, at *13 (S.D.N.Y. Sept. 13, 2016) (large, unjustified reverse payment "trigger[s] antitrust concern" under *Actavis*); *In re Actos End Payor Antitrust Litig.*, No. 13-CV-9244 (RA), 2015 WL 5610752, at *11, *14 (S.D.N.Y. Sept. 22, 2015), *aff'd in part and vacated in part on other grounds*, 848 F.3d 89 (2d Cir. 2017) (same); *United Food & Comm. Workers Local 1776 & Participating Emp'rs Health & Welfare Fund v. Teikoku Pharma USA, Inc.*, 74 F. Supp. 3d 1052, 1065-66 (N.D. Cal. 2014) (large and unjustified reverse payment required to "raise antitrust concerns"; "only after finding such a payment in the settlement may courts engage in the traditional rule of reason analysis"); *In re Nexium (Esomeprazole) Antitrust*

Litig., 42 F. Supp. 3d 231, 262 (D. Mass. 2014), *aff'd*, 842 F.3d 34 (1st Cir. 2016) ("'large and unjustified' reverse payments must be analyzed under the rule of reason"). To hold otherwise "would compel antitrust scrutiny of a settlement regardless of whether its terms could reasonably be construed as a large and unjustified reverse payment[, . . .] ignore the limiting principles set forth in the [*Actavis*] decision, and subject virtually *any* settlement to antitrust scrutiny—a result the [Supreme] Court could not have intended." *Actos*, 2015 WL 5610752, at *14.

Once a plaintiff proves the existence of a settlement with a "large and unjustified" reverse payment, the analysis proceeds under the rule of reason. *Actavis*, 133 S. Ct. at 2237-38. It is true that the rule of reason follows a well-established three-step burden shifting framework, under which (1) the plaintiff bears the initial burden of showing an actual anticompetitive effect; (2) if the plaintiff makes that showing, the burden shifts to the defendant to demonstrate a procompetitive justification for the restraint; and (3) if the defendant offers a procompetitive justification, the burden shifts back to the plaintiff to show that the restraint is not reasonably necessary to achieve the procompetitive objective. *See Buccaneer Energy (USA) Inc. v. Gunnison Energy Corp.*, 846 F.3d 1297, 1310 (10th Cir. 2017) (quoting *Gregory v. Ft. Bridger Rendezvous Ass'n*, 448 F.3d 1195, 1205 (10th Cir. 2006)).

Complaint Counsel neglects to mention that the plaintiff must also prove that the defendants possessed monopoly power (or "market power") in a properly defined relevant market. "Substantial market power is an indispensable ingredient of every claim under the full Rule of Reason." *Chi. Prof'l Sports Ltd. P'ship v. Nat'l Basketball Ass'n*, 95 F.3d 593, 600 (7th Cir. 1996); *see, e.g.*, *PSKS, Inc. v. Leegin Creative Leather Prods., Inc.*, 615 F.3d 412, 418-19 (5th Cir. 2010) (applying monopoly power screen). As Complaint Counsel concedes in its post-trial brief, "[a] firm without market power will not be able to harm competition successfully."

(Compl. Counsel Post-trial Br. at 47, *In re Impax Labs., Inc.*, Dkt. 9373 (F.T.C. Dec. 20, 2017) [hereinafter "CC PTB"].)

Proving monopoly power invariably requires the plaintiff to identify and establish the existence of a cognizable relevant market. "Without a well-defined relevant market, a court cannot determine the effect that an allegedly illegal act has on competition." Initial Decision at 123, *In re 1-800 Contacts, Inc.*, No. 9372 (F.T.C. Oct. 27, 2017) [hereinafter "*1-800 Contacts*"].

> 6. Under *Actavis*, a plaintiff can satisfy its "initial burden" under the rule of reason by "establishing anticompetitive effects through market power and evidence of a large reverse payment." *King Drug Co. of Florence v. Cephalon, Inc.*, 88 F. Supp. 3d 402, 416 (E.D. Pa. 2015).

RESPONSE TO CONCLUSION NO. 6:

Complaint Counsel's Proposed Conclusion No. 6 is wrong.

This Proposed Conclusion wholly relies on a single district court decision that may not even be good law in that district. In *King Drug Co. of Florence v. Cephalon, Inc.* ("*Cephalon*"), 88 F. Supp. 3d 402 (E.D. Pa. 2015), the court began with the observation that "[t]he specific contours of the rule of reason analysis to be applied under *Actavis* are not . . . well-defined," and from there, fashioned its own framework. *See* 88 F. Supp. 3d at 412-21. Later that year, however, the Third Circuit made clear in *King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp.* ("*Lamictal*"), 791 F.3d 388 (3d Cir. 2015), that the "traditional," "full-fledged," "well-established," "well-mapped" rule of reason applies. *Id.* at 398 n.15, 399, 411, 412.

As noted in Impax's response to Complaint Counsel's Proposed Conclusion No. 5, proof of monopoly power in a properly defined relevant market is an essential element of every rule of reason claim. *Chi. Prof'l Sports*, 95 F.3d at 600. But that does not relieve Complaint Counsel of the burden of showing actual anticompetitive effects. *See In re Wellbutrin XL Antitrust Litig.*, 133 F. Supp. 3d 734, 755 (E.D. Pa. 2015), *aff'd*, 868 F.3d 132 (3d Cir. 2017) ("In the context of

reverse payment patent settlement lawsuits, . . . market power alone cannot be sufficient to demonstrate anticompetitive effects under the rule of reason. . . . The plaintiffs, therefore, must show actual anticompetitive effects of the Wellbutrin Settlement."); *In re Schering-Plough Corp.* ("*Schering I*"), No. 9297, 2002 WL 1488085, at *88 (F.T.C. June 27, 2002) ("In a rule of reason case, Complaint Counsel must prove that the challenged agreements had the effect of injuring competition."). "It is well established that proof of anticompetitive effect is essential to a rule of reason case." *E.W. French & Sons, Inc. v. Gen. Portland Inc.*, 885 F.2d 1392, 1402 (9th Cir. 1989); *see Lektro-Vend Corp. v. Vendo Co.*, 660 F.2d 255, 268 (7th Cir. 1981) ("any rule of reason analysis requires a showing of anticompetitive market effect"). As the D.C. Circuit stated in *United States v. Microsoft Corp.*, 253 F.3d 34 (D.C. Cir. 2001), "[m]eeting [the government's] burden 'involves an inquiry into the actual effect' of [the defendants'] conduct on competition." *Id.* at 95 (quoting *Jefferson Par. Hosp. Dist. No. 2 v. Hyde*, 466 U.S. 2, 29 (1984)).

Contrary to Complaint Counsel's suggestion, this Court may not infer anticompetitive effects merely from the existence of a "large reverse payment." As the Commission held in denying Complaint Counsel's Motion for Partial Summary Decision, "anticompetitive effects should not be presumed from the mere presence of a reverse payment." Opinion and Order of the Commission at 8, *In re Impax Labs., Inc.*, Dkt. 9373 (F.T.C. Oct. 27, 2017) [hereinafter "Comm'n Decision"] (citing *Actavis*, 133 S. Ct. at 2237). *That* is tantamount to a "quick look" analysis, which places the onus on the defendant to offer procompetitive justifications for its conduct before any evidence of anticompetitive effects has been proffered. *See Deutscher Tennis Bund v. ATP Tour, Inc.*, 610 F.3d 820, 831 (3d Cir. 2010) ("Under 'quick look' analysis, the competitive harm is presumed, and the defendant must promulgate some competitive justification for the restraint.") (quotation omitted); *Major League Baseball Props., Inc. v.*

Salvino, Inc., 420 F. Supp. 2d 212, 220 (S.D.N.Y. 2005), *aff'd*, 542 F.3d 290 (2d Cir. 2008) ("Under a quick look analysis, the plaintiff is relieved of its initial burden of showing that the challenged restraints have an adverse effect on competition.") (quotation omitted). This is exactly what the FTC advocated for in *Actavis*—unsuccessfully.[1]

Moreover, Complaint Counsel's Proposed Conclusion No. 6 conflates two distinct analytical questions: **(1)** whether the defendants entered into a settlement containing a "large and unjustified" reverse payment, warranting antitrust scrutiny in the first place; and **(2)** whether the settlement is anticompetitive, as determined by the rule of reason. While proof of a settlement with a "large and unjustified" reverse payment may be necessary to subject a challenged agreement to rule of reason scrutiny under *Actavis*, it does not substitute for proof of actual anticompetitive effects under the rule of reason. *See Sergeants Benevolent Ass'n*, 2016 WL 4992690, at *13; *Wellbutrin*, 133 F. Supp. 3d at 754-55; *Actos*, 2015 WL 5610752, at *11, *14; *United Food*, 74 F. Supp. 3d at 1065-66. As the Supreme Court stated in *Actavis*, while a "large and unjustified" reverse payment carries "*risk* of significant anticompetitive effects," the "basic question" posed by the rule of reason remains "that of the *presence* of significant unjustified anticompetitive consequences." 133 S. Ct. at 2237-38 (emphasis added).

> 7. The relevant anticompetitive effect *under Actavis* is that the reverse payment agreement interferes with the competitive process. The reverse payment agreement prevents "the risk of competition," allowing the parties "to maintain and share patent-generated monopoly profits" rather than "face what might have been a competitive market—the very anticompetitive consequence that underlies the claim of antitrust unlawfulness." *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2236-37 (2013). Thus, "in the

[1] (*See* Reply Br. of FTC at 2-3, *FTC v. Actavis Inc.*, No. 12-416 (U.S. Mar. 18, 2013) (asserting that a "large cash payment" warrants 'a confident conclusion' that 'the principal tendency' . . . of a reverse-payment agreement is anticompetitive, so that the burden of identifying a procompetitive justification is properly placed on the agreeing parties"; advocating for "quick look" analysis) (quoting *Cal. Dental Ass'n v. FTC*, 526 U.S. 756, 781 (1999)).)

absence of some other justification, the antitrust laws are likely to forbid the arrangement." *Id.* at 2237.

RESPONSE TO CONCLUSION NO. 7:

Complaint Counsel's Proposed Conclusion No. 7 is wrong. Though Complaint Counsel couches its arguments in cherry-picked snippets from *Actavis*, it mischaracterizes that decision and misstates the law.

To begin with, nowhere in *Actavis* did the Supreme Court mention the "competitive process," much less hold that the "relevant anticompetitive effect" is "interfer[ing] with the competitive process." Rather, the Court made clear that Complaint Counsel must "prove its case as in other rule-of-reason cases," and that the "basic question" posed by the rule of reason remains unchanged: "that of the *presence* of significant unjustified anticompetitive consequences." *Actavis*, 133 S. Ct. at 2237-38 (emphasis added).

Other decisions, not cited in Complaint Counsel's Proposed Conclusion No. 7, explain that proving harm to the "competitive process" does not lighten or obviate the need to show actual anticompetitive effects. As the D.C. Circuit stated in *Microsoft*, for example, to be deemed anticompetitive, a defendant's conduct "must harm the competitive *process* and thereby *harm consumers*." 253 F.3d at 58 (latter emphasis added); *see also id.* at 59 ("no less in a case brought by the Government, [the government] must demonstrate that the monopolist's conduct harmed competition").

To the extent Complaint Counsel suggests that the *Actavis* Court's reference to avoiding the "risk of competition" amounts to a redefinition of the term "anticompetitive effect," it is incorrect. The Commission has held that where Complaint Counsel alleges an agreement "*eliminate[d] the risk of competition*," it must prove that the allegedly excluded competitor's "entry was reasonably probable in the absence of the [challenged agreement]." *In re McWane,*

Inc., No. 9351, 2014 WL 556261, at *32-37 (F.T.C. Jan. 30, 2014), *aff'd*, 783 F.3d 814 (11th Cir. 2015) (emphasis added). This is in keeping with standard antitrust principles in cases where defendants allegedly excluded or avoided potential competition. *See, e.g.*, *Meijer, Inc. v. Biovail Corp.*, 533 F.3d 857, 862 (D.C. Cir. 2008) (in suit alleging that defendants restrained generic drug competition, plaintiff must prove that "the excluded firm was willing and able to supply [the generic drug] but for the incumbent firm's exclusionary conduct"); *Engine Specialties, Inc. v. Bombardier Ltd.*, 605 F.2d 1, 7-11 (1st Cir. 1979) ("It must be shown . . . that the potential competitor . . . had the necessary desire, intent, and capability to enter the market.").

As in "other rule-of-reason cases," *Actavis*, 133 S. Ct. at 2237, Complaint Counsel must prove anticompetitive effects—in particular, actual delay—as an element of liability. *Microsoft*, 253 F.3d at 95; *Schering I*, 2002 WL 1488085, at *88; *see also Lamictal*, 791 F.3d at 404 ("prevention of th[e] risk of competition" means "'paying the challenger to stay out' of the market . . . for longer than the patent's strength would otherwise allow") (quoting *Actavis*, 133 S. Ct. at 2236-37); *Wellbutrin*, 133 F. Supp. 3d at 756 ("It is in keeping with the traditional rule of reason analysis to require the plaintiffs to show that the Wellbutrin Settlement actually resulted in the delayed entry of Wellbutrin XL—that absent the Wellbutrin Settlement, generic competition would have occurred earlier."); *In re Cipro Cases I & II*, 348 P.3d 845, 864 (Cal. 2015) (relevant "anticompetitive harm" is "delay[ing] entry" for longer than "the expected level of competition" absent settlement).

8. An antitrust market is comprised of a relevant geographic market and a relevant product market.

RESPONSE TO CONCLUSION NO. 8:

Respondent has no specific response.

9. The relevant geographic market for purposes of this litigation is the United States. JX 001 at 002 (¶ 10).

RESPONSE TO CONCLUSION NO. 9:

Respondent has no specific response.

10. For market definition, the relevant antitrust question is whether products are economic substitutes, not just whether they are functional substitutes. A product is a close economic substitute for another only if there is high cross-elasticity of demand between the products—i.e., an increase in price on one product would cause a large number of consumers to switch to the other. *Queen City Pizza, Inc. v. Domino's Pizza, Inc.*, 124 F.3d 430, 437-38 (3rd Cir. 1997).

RESPONSE TO CONCLUSION NO. 10:

Complaint Counsel's Proposed Conclusion No. 10 is incomplete and partially incorrect.

For purposes of identifying the relevant product market, the question is not whether products are "close" substitutes, as Complaint Counsel contends. The question, rather, is whether the products are "*reasonable* substitutes." *FTC v. Sysco Corp.*, 113 F. Supp. 3d 1, 25 (D.D.C. 2015) (emphasis added) (citing *FTC v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 46 (D.D.C. 1998); *FTC v. Staples, Inc.*, 970 F. Supp. 1066, 1074 (D.D.C. 1997)). Or as the Supreme Court has put it, products that are "reasonably interchangeable by consumers for the same purposes" belong to the same relevant market. *United States v. E.I. Du Pont de Nemours & Co. v. United States*, 351 U.S. 377, 395 (1956); *see In re N.C. Bd. of Dental Examiners*, 152 F.T.C. 75, 161, *aff'd*, 152 F.T.C. 640 (2011) ("Relying on *du Pont*, courts have found the 'reasonable interchangeability' standard to be the essential test for ascertaining the relevant product market.").

Reasonable interchangeability requires only that "one product [be] roughly equivalent to another for the use to which it is put; while there may be some degree of preference for the one over the other, either would work effectively." *Queen City Pizza, Inc. v. Domino's Pizza, Inc.*, 124 F.3d 430, 436-37 (3d Cir. 1997); *see Mylan Pharm. Inc. v. Warner Chilcott Pub. Ltd. Co.*,

838 F.3d 421, 436 (3d Cir. 2016) ("products need not be perfectly fungible to be considered reasonably interchangeable for market-definition purposes").

It is indeed true that mere functional substitutes do not necessarily compete in the same relevant market, though Complaint Counsel does not cite any authority for that proposition. *See FTC v. Swedish Match N. Am., Inc.*, 131 F. Supp. 2d 151, 156-65 (D.D.C. 2000). And while cross-elasticity of demand is part of the relevant market inquiry, Complaint Counsel's explanation is not complete. The Supreme Court has held that "[t]he outer boundaries of a product market are determined by the reasonable interchangeability of use or the cross-elasticity of demand between the product itself and substitutes for it." *Brown Shoe v. United States*, 370 U.S. 294, 325 (1962).

In addition to economic constructs like cross-elasticity and "SSNIP" tests, courts routinely look to "practical indicia" in discerning the relevant product market—especially where statistical or econometric analyses are lacking or cannot be performed. *See Brown Shoe*, 370 U.S. at 325 (endorsing "practical indicia"); *United States v. H&R Block, Inc.*, 833 F. Supp. 2d 36, 51 (D.D.C. 2011) ("These 'practical indicia' of market boundaries may be viewed as evidentiary proxies for proof of substitutability and cross-elasticities of supply and demand"); *Sterling Merch., Inc. v. Nestle, S.A.*, 724 F. Supp. 2d 245, 257-58 (D.P.R. June 23, 2010), *aff'd*, 656 F.3d 112 (1st Cir. 2011) (applying "practical, fact-driven, approach" to relevant market inquiry; relying on parties' "internal business communications"); *Swedish Match*, 131 F. Supp. 2d at 161-62 (rejecting both parties' expert econometric analyses as "not persuasive," and instead relying on "[t]he views of Swedish Match and National competitors, statements by loose leaf distributors, and internal documents of Swedish Match and National" to determine the relevant market).

"[T]he determination of the relevant market in the end is 'a matter of business reality—[] of how the market is perceived by those who strive for profit in it.'" *Cardinal Health*, 12 F. Supp. 2d at 46 (quoting *FTC v. Coca-Cola Co.*, 641 F. Supp. 1128, 1132 (D.D.C. 1986), *vacated as moot*, 829 F.2d 191 (D.D. Cir. 1987)). As this Court has recently emphasized, "[o]rdinary course business documents reveal the contours of competition from the perspective of the parties, who may be presumed to 'have accurate perceptions of economic realities.'" *1-800 Contacts*, at 124-25 (quoting *FTC v. Whole Foods Mkt, Inc.*, 548 F.3d 1028, 1045 (D.C. Cir. 2008) (Tatel, J., concurring)). Because of this, "courts often pay close attention to the defendants' ordinary course of business documents" when "determining the relevant product market." *H&R Block, Inc.*, 833 F. Supp. 2d at 52.

11. The relevant antitrust product market in which to analyze the effects of Impax's reverse payment agreement with Endo is extended-release oxymorphone products.

RESPONSE TO CONCLUSION NO. 11:

Complaint Counsel's Proposed Conclusion No. 11 is wrong for the reasons stated in Paragraphs 693-1009 of Impax's Proposed Findings of Fact and Paragraphs 498-965 of Impax's Replies to Complaint Counsel's Proposed Findings of Fact.

The relevant product market in this case no narrower than the market for long-acting opioids ("LAOs"). This is so for the following reasons, at minimum:

- LAOs, including Opana ER, are "reasonably interchangeable by consumers for the same purposes"—namely, to treat chronic pain. *E.I. du Pont*, 951 U.S. at 395; *see Mylan*, 838 F.3d at 436-37 (oral tetracyclines were interchangeable for the treatment of acne, and belonged to same product market); *HDC Med., Inc. v. Minntech Corp.*, 474 F.3d 543, 547-49 (8th Cir. 2007) (medical products that had "identical uses" belonged to same relevant market); *Schering I*, 2002 WL 1488085, at *7-10, *73-78 (relevant market consisted of "all oral potassium supplements," which were reasonably interchangeable).

- There is no identifiable population of patients and no medical condition for which Opana ER is the only treatment, or for which Opana ER is the superior treatment option. *See* U.S. Dep't of Justice & Fed. Trade Comm'n, *Horizontal Merger*

Guidelines §§ 3, 4.1.4 (2010) (markets defined by "targeted customers" must be based on "observable characteristics"); *In re R.R. Donnelly & Sons Co.*, 120 F.T.C. 36, 51 (1995) ("[A] profitable discriminatory price increase is possible, and therefore sufficient to define a relevant market," only if, *inter alia*, "the hypothetical monopolist can identify . . . customers with sufficiently inelastic demand for [the relevant product].").

- Endo's and other LAO manufacturers' ordinary course business documents reflect that LAOs compete in the same market, including on the basis of price. *See 1-800 Contacts*, at 124-25 ("Ordinary course business documents reveal the contours of competition from the perspective of the parties, who may be presumed to 'have accurate perceptions of economic realities.'") (quoting *Whole Foods*, 548 F.3d at 1045); *id.* at 132 ("Analysis of the market is a matter of business reality—a matter of how the market is perceived by those who strive for profit in it.") (quoting *Coca-Cola*, 641 F. Supp. at 1132); *see also Town Sound & Custom Tops, Inc. v. Chrysler Motors Corp.*, 959 F.2d 468, 497 (3d Cir. 1992) (evidence that "Chrysler dealers perceive[d] themselves as competing with dealers handling other cars" indicated that the relevant market was not limited to Chrysler cars); *Mylan Pharm., Inc. v. Warner Chilcott Pub. Ltd. Co.*, Civ. No. 12-3824, 2015 WL 1736957, at *9 (E.D. Pa. Apr. 16, 2015), *aff'd*, 838 F.3d 421 (3d Cir. 2016) ("Years of internal marketing documents further confirm that tetracyclines are reasonable substitutes for one another. Defendants consistently defined the market in which Doryx competed as including other tetracyclines."); *Staples*, 970 F. Supp. at 1080 (relying on evidence that Staples and Office Depot "price check[ed] the other office superstores" in defining relevant market as sale of consumable office suppliers through office superstores).

- "It is imperative that the Court, in determining the relevant market, take into account the economic and commercial realities of the pharmaceutical industry." *Cardinal Health*, 12 F. Supp. 2d at 46. LAOs compete on the basis of price at every level of competition in the pharmaceutical industry—at the payor level, at the patient level, and at the prescriber level. *See United States v. Phillipsburg Nat'l Bank & Trust Co.*, 399 U.S. 350, 360 (1970) ("the relevant product market is determined by the nature of the commercial entities involved and by the nature of the competition that they face"); *United States v. Continental Can Co.*, 378 U.S. 441, 457 (1964) (relevant market's "contours must, as nearly as possible, conform to competitive reality"); *Whole Foods*, 548 F.3d at 1039 ("As always in defining a market, we must 'take into account the realities of competition.'") (quoting *Weiss v. York Hosp.*, 745 F.2d 786, 826 (3d Cir. 1984)).

- Patients can and regularly do switch between LAOs, including in response to changes in relative price—direct evidence of cross-elasticity of demand. *See Apple, Inc. v. Psystar Corp.*, 586 F. Supp. 2d 1190, 1196 (N.D. Cal. 2008) ("Whether products are part of the same or different markets under antitrust law depends on whether consumers view those products as reasonable substitutes for each other and would switch among them in response to changes in relative prices."); *see also Mylan*, 838 F.3d at 437 (evidence of price-related switching

was the "[m]ost convincing[]" proof that Doryx competed in the same market as other oral tetracyclines). The antitrust agencies recognize that real-world evidence of price-induced switching is probative of market definition. *See Horizontal Merger Guidelines* § 4.1.3 (evidence of "how customers have shifted purchases in the past in response to relative changes in price or other terms and conditions" is probative of relevant market).

- The Federal Trade Commission itself has recognized that Opana ER competes against other LAOs. In the *King Pharmaceuticals* matter, the Commission identified a relevant market consisting of "the manufacture and sale of oral LAOs," which included "orally-administered extended-release formulations of . . . oxycodone, morphine sulfate and oxymorphone." (Compl. ¶¶ 1, 11, *In re King Pharm., Inc. & Alpharma Inc.*, No. C-4246 (F.T.C. Feb. 2, 2009).) In its analysis published in the Federal Register, the Commission stated that although "oral LAOs are based on distinct chemical compounds, . . . all of these products have the same mechanisms of action, similar indications, similar dosage forms and similar dosage frequency." King Pharm., Inc. and Alpharma Inc. Agreement Containing Consent Order to Aid Public Comment, 74 Fed. Reg. 295, 296 (Jan. 5, 2009). The Commission specifically noted that "*Endo Pharmaceutical's Opana ER . . . also competes in the market.*" *Id.* (emphasis added).

Complaint Counsel has not borne its burden of proving a single-product market consisting solely of branded and generic Opana ER. *See Planetarium Travel, Inc. v. Altour Int'l, Inc.*, 97 F. Supp. 3d 424, 429 (S.D.N.Y.), *aff'd*, 622 F. App'x 40 (2d Cir. 2015) ("courts routinely reject markets defined by a single product"). This is so for the following reasons, at minimum:

- Dr. Noll did not calculate cross-elasticity of demand, conduct a SSNIP test, or perform any other quantitative or statistical analysis of LAO sales. He merely inspected Opana ER sales trends for any "visible effect" of generic LAO entry—a metric he never bothered to define. This does not suffice. *See Ky. Speedway, LLC v. NASCAR, Inc.*, 588 F.3d 908, 918 (6th Cir. 2009) (upholding exclusion of plaintiff's expert's testimony where expert did not perform "standard SSNIP test," but merely looked at average prices and attendance figures for sporting event over an eight-year period; stating that expert's methodology "has not been tested; has not been subject to peer review and publication; there are no standards controlling it; and there is no showing that it enjoys general acceptance within the scientific community"); *Schering I*, 2002 WL 1488085, at *15, *69, *80 (rejecting proposed single-product market where Complaint Counsel's expert did not "calculate demand elasticities" and "presented no statistical pricing study").

- Complaint Counsel did not demonstrate that switching costs among LAOs are high, and has not identified any patients who wanted to but were unable to switch from Opana ER to another LAO. *See SMS Sys. Maint. Servs., Inc. v. Digital*

Equip. Corp., 188 F.3d 11, 20 (1st Cir. 1999) ("SMS has not proffered significantly probative evidence sufficient to create a fact question as to whether this alleged switching cost is material"); *Brokerage Concepts, Inc. v. U.S. Healthcare, Inc.*, 140 F.3d 494, 515 (3d Cir. 1998) ("we find no evidence suggesting that U.S. Healthcare members who wish to switch HMOs face switching costs significant enough to constitute a lock in"); *Comm. Data Servers, Inc. v. IBM Corp.*, 262 F. Supp. 2d 50, 68-69 (S.D.N.Y. 2003) (rejecting plaintiff's proposed relevant market where plaintiff's expert "did not try to identify any S/390 customers who wanted to leave the S/390 platform but were unable to migrate due to high switching costs, or to quantify how many such customers there might be").

- Complaint Counsel did not demonstrate that chemical differences between Opana ER and other LAOs were economically meaningful. *See Mylan*, 2015 WL 1736957, at *8-9 (testimony that Doryx had "unique characteristics that differentiate it from other antibiotics," such as its "side-effect profile," did not defeat conclusion that "all oral tetracyclines treat acne with similar effectiveness and so are interchangeable for that purpose"); *id.* at *10 (Doryx's "unique side effect profile" did not delineate a relevant market because "[i]nterchangeability is defined by rough equivalence, not perfect correspondence").

- Advertising and similar product differentiation efforts are consistent with competition in a relevant market consisting of multiple LAOs. *See* Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 520c (rev. ed. 2017) ("[N]onprice competition is too widespread to indicate power, for it accompanies virtually all product differentiation, and most product differentiation does not indicate substantial market power for anyone. Indeed, highly competitive firms advertise [and] vary products."); *Town Sound*, 959 F.2d at 478-81 (evidence that Chrysler's advertising compared the "features of its autos with other companies' [cars]" *supported* the conclusion that "Chrysler cars compete vigorously with many other companies' automobiles").

The relevant product market in this case no narrower than the market for LAOs.

12. Complaint Counsel has met its burden that Endo possessed market power in the extended-release oxymorphone market.

RESPONSE TO CONCLUSION NO. 12:

Complaint Counsel's Proposed Conclusion No. 12 is wrong for the reasons stated in Paragraphs 657-1009 of Impax's Proposed Findings of Fact and Paragraphs 498-965 of Impax's Replies to Complaint Counsel's Proposed Findings of Fact.

As explained in Impax's response to Complaint Counsel's Proposed Conclusion No. 11, the relevant market in this case is no narrower than the market for LAOs. Because Endo's share of the relevant market never even reached 10%, it did not possess monopoly power. *See Cohlmia v. St. John Med. Ctr.*, 693 F.3d 1269, 1283 (10th Cir. 2012) ("a market share of less than 20% is woefully short under any metric from which to infer market power"); *Vollrath Co. v. Sammi Corp.*, 9 F.3d 1455, 1461 (9th Cir. 1993) ("no danger of monopoly power" where defendant "controlled only 10% of the market"); *Ryko Mfg. Co. v. Eden Servs.*, 823 F.2d 1215, 1232 (8th Cir. 1987) ("clearly" defendant whose "share of the entire relevant market is at most between 8% and 10%" does not possess market power); *MHB Distribs., Inc. v. Parker Hannifin Corp.*, 800 F. Supp. 1265, 1270 (E.D. Pa. 1992) ("Even assuming Parker's market share were 10%, the percentage is insufficient to bestow market power upon Parker.").

Nor did Complaint Counsel succeed in proving monopoly power through direct evidence. To prove monopoly power directly, the plaintiff must present "direct evidence of supracompetitive prices *and* restricted output." *Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 307 (3d Cir. 2007) (emphasis added); *see Mylan*, 838 F.3d at 434 (same); *Rebel Oil Co. v. Atl. Richfield Co.*, 51 F.3d 1421, 1434 (9th Cir. 1995) (same). Complaint Counsel did not prove *either*.

In order to demonstrate supracompetitive prices, a plaintiff ordinarily must "provide an analysis of the defendant's costs, showing . . . that the defendant had an 'abnormally high price-cost margin.'" *Mylan*, 838 F.3d at 434 (quoting *Geneva Pharm. Tech. Corp. v. Barr Labs., Inc.*, 386 F.3d 485, 500 (2d Cir. 2004)). While Complaint Counsel asserts that Endo had a "high" price-cost margin—as measured by its Lerner Index—at no point did it show that Endo's margins were *abnormally* high for the industry. *See id.* at 434-35 (defendant's 83% margin was

not evidence of supracompetitive pricing or monopoly power, since plaintiffs did not show that the margin was "abnormally high"). High or not, Endo's Lerner Index says nothing about whether it was charging supracompetitive prices or otherwise exercising monopoly power. *See In re Wireless Tel. Servs. Antitrust Litig.*, 385 F. Supp. 2d 403, 422 & n.27 (S.D.N.Y. 2005) (testimony that defendants' Lerner Indices were 0.85 and 0.5 did not establish monopoly power).

Nor do any price differentials between Endo's branded Opana ER and Impax's generic Opana ER show that Endo possessed monopoly power. *See Twin City Sportservice, Inc. v. Charles O. Finley & Co.*, 512 F.2d 1264, 1274 (9th Cir. 1975) ("the scope of the relevant market is not governed by the presence of a price differential between competing products"); *In re Live Concert Antitrust Litig.*, 247 F.R.D. 98, 128 (C.D. Cal. 2007) ("[T]he difference in price between the two products is irrelevant."). To hold otherwise "would render most brand name pharmaceutical companies as *per se* monopolists prior to generic entry." *In re Remeron Direct Purchaser Antitrust Litig.*, 367 F. Supp. 2d 675, 683 (D.N.J. 2005) ("Clearly, there must be more proof [of monopoly power] than just a showing that a brand name drug costs more than a generic equivalent.").

Even if Complaint Counsel had met its burden of proving supracompetitive prices—and it has not—its "direct proof" of monopoly power would fall short because it did not show that Endo restricted output. *Mylan*, 838 F.3d at 434; *Broadcom*, 510 F.3d at 307; *Rebel Oil*, 51 F.3d at 1434.

Finally, Complaint Counsel's argument that Endo's ability to enforce its patents against other potential generic entrants supports a finding of monopoly power has been rejected by no less than the Supreme Court. *See Ill. Tool Works Inc. v. Indep. Ink, Inc.*, 547 U.S. 28, 44 (2006) (rejecting the "'patent equals market power' presumption"); *see also* U.S. Dep't of Justice &

Fed. Trade Comm'n, *Antitrust Guidelines for the Licensing of Intellectual Property* § 2.2 (2017) ("Although the intellectual property right confers the power to exclude with respect to the specific product, process, or work in question, there will often be sufficient actual or potential close substitutes for such product, process, or work to prevent the exercise of market power.").

13. Complaint Counsel has met its *prima facie* case burden to prove that Impax received a large reverse payment from Endo Pharmaceutical Inc. to stay off the market with its generic version of Original Opana ER until 2013.

RESPONSE TO CONCLUSION NO. 13:

Complaint Counsel's Proposed Conclusion No. 13 is wrong.

For the reasons stated in Impax's response to Complaint Counsel's Proposed Conclusion Nos. 5, 6, and 7, Complaint Counsel ***cannot*** satisfy its *prima facie* burden under the rule of reason by merely by proving that "Impax received a large reverse payment." This argument conflates the initial question of antitrust scrutiny (whether the generic company received a "large and unjustified" reverse payment) with the rule of reason question of whether the settlement caused anticompetitive effects. *See Actavis*, 133 S. Ct. at 2237-38; *Sergeants Benevolent Ass'n*, 2016 WL 4992690, at *13; *Actos*, 2015 WL 5610752, at *11, *14; *United Food*, 74 F. Supp. 3d at 1065-66. Moreover, Complaint Counsel's argument runs headlong into the Commission's ruling that "anticompetitive effects should not be presumed from the mere presence of a reverse payment." Comm'n Decision at 8.

In any event, for the reasons stated in Paragraphs 382-656 of Impax's Proposed Findings of Fact and Paragraphs 388-497 of Impax's Replies to Complaint Counsel's Proposed Findings of Fact, Complaint Counsel has not borne its burden of proving that Impax received a "large and unjustified" reverse payment from Endo.

Moreover, as Impax also stated in response to Complaint Counsel's Proposed Conclusion Nos. 6 and 7, to shoulder its *prima facie* burden under the rule of reason, Complaint Counsel was

required to prove that the challenged settlement agreement caused "actual anticompetitive effects." *Wellbutrin*, 133 F. Supp. 3d at 755; *see E.W. French*, 885 F.2d at 1402 ("It is well established that proof of anticompetitive effect is essential to a rule of reason case."); *Schering I*, 2002 WL 1488085, at *88 ("In a rule of reason case, Complaint Counsel must prove that the challenged agreements had the effect of injuring competition.").

For the reasons stated in Paragraphs 1010-1438 of Impax's Proposed Findings of Fact and Paragraphs 966-1459 of Impax's Replies to Complaint Counsel's Proposed Findings of Fact, Complaint Counsel has not presented evidence of *any* actual anticompetitive effects. Because of that, its claims necessarily fail. *See Procaps S.A. v. Patheon, Inc.*, 845 F.3d 1072, 1087 (11th Cir. 2016) (affirming summary judgment for defendant on rule of reason claim where plaintiffs "failed to adduce concrete evidence of actual anticompetitive effects"); *Eisai, Inc. v. Sanofi Aventis U.S., LLC*, 821 F.3d 394, 403 (3d Cir. 2016) (affirming summary judgment for defendant on rule of reason claim where plaintiff lacked evidence of anticompetitive effects).

> 14. If the plaintiff meets its initial burden to demonstrate likely anticompetitive effects, the burden shifts to the defendant to establish a legitimate, procompetitive justification for the challenged restraint. *United States v. Brown Univ.*, 5 F.3d 658, 669 (3d Cir. 1993). An antitrust defendant in a reverse payment case may show in the antitrust proceeding "that legitimate justifications are present, thereby explaining the presence of the challenged term and showing the lawfulness of that term under the rule of reason." *Actavis*, 133 S. Ct at 2236.

RESPONSE TO CONCLUSION NO. 14:

Complaint Counsel's Conclusion No. 14 is incomplete and partially incorrect.

As an initial matter, as stated in Impax's responses to Complaint Counsel's Proposed Conclusion Nos. 6, 7, and 13, a plaintiff must prove "*actual* anticompetitive effects" to discharge its initial burden under the rule of reason. *Wellbutrin*, 133 F. Supp. 3d at 755 (emphasis added); *see Microsoft Corp.*, 253 F.3d at 95 ("Meeting [the government's] burden 'involves an inquiry into the actual effect' of [the defendants'] conduct on competition.") (quoting *Jefferson Par.*, 466

U.S. at 29). If the plaintiff meets its initial burden, then "the burden shifts to the defendant to offer evidence of the procompetitive effects of its agreement." *Major League Baseball Props., Inc. v. Salvino, Inc.*, 542 F.3d 290, 308 (2d Cir. 2008); *see Wellbutrin*, 133 F. Supp. 3d at 753 (second step of rule of reason asks, "are there procompetitive justifications for the agreement[?]").

In a reverse-payment case, the defendant may show that the "challenged term" (whatever that may be[2]) is lawful under the rule of reason by demonstrating that "*the challenged settlement* is in fact procompetitive." *Cipro*, 348 P.3d at 869-70 (emphasis added). The competitive effects must be assessed with reference to the settlement *as a whole*, since the settlement is the challenged restraint. *Id.*; *see In re Loestrin 24 Fe Antitrust Litig.* ("*Loestrin II*"), 261 F. Supp. 3d 307, 330-31 (D.R.I. 2017); *Wellbutrin*, 133 F, Supp. 3d at 753-54; *In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735, 752 (E.D. Pa. 2014); *see also In re Androgel Antitrust Litig. (No. II)*, No. 1:09-MD-2084-TWT, 2014 WL 1600331, at *8 (N.D. Ga. Apr. 21, 2014) ("the 'source . . . of the anticompetitive restraint at issue' is the parties' reverse payment agreement itself") (quoting *Allied Tube & Conduit Corp. v. Indian Head, Inc.*, 486 U.S. 492, 499 (1988)).

> 15. "Cognizable justifications ordinarily explain how specific restrictions enable the defendants to increase output or improve product quality, service or innovation." *1-800 Contacts* at 166 (quotation omitted). "An allegedly legitimate objective is, of course, entirely immaterial unless it is served by the challenged restraint." Areeda, ¶ 1505a.
>
> **RESPONSE TO CONCLUSION NO. 15:**
>
> Complaint Counsel's Proposed Conclusion No. 15 is incomplete.
>
> As this Court has recognized, it is indeed true that cognizable procompetitive justifications include increasing output and improving product quality, service, or innovation. *1-*

[2] In *Actavis*, the Court does not specify whether the "challenged term" refers to the settlement's payment term, the allegedly delayed entry date term, or something else altogether.

800 Contacts, at 166. Procompetitive benefits also include "ensuring consistent supply of [a] product,"[3] *Wellbutrin*, 133 F. Supp. 3d at 760, and facilitating a potential entrant's "ability to compete," *FTC v. AbbVie, Inc.*, 107 F. Supp. 3d 428, 437 (E.D. Pa. 2015).

In *Wellbutrin*, for instance, the defendants raised as a procompetitive justification the fact that the generic companies (Anchen/Teva) procured, as part of a settlement with GlaxoSmithKline (GSK), a sublicense to a patent (owned by Andrx) that was not at issue in the original patent litigation. 133 F. Supp. 3d at 737, 747, 759. Teva had insisted on the sublicense, on the ground that it "needed 'the full freedom to operate' without concern over [a] patent infringement claim by Andrx." *Id.* at 747. The court held that the sublicense was a cognizable procompetitive justification for the settlement, since it "eliminat[ed] an independent and substantial hurdle to generic entry," and removed "the possibility that Andrx could prevent generic Wellbutrin XL from being marketed for the 15 years remaining on its patent." *Id.* at 758-59.

While Complaint Counsel's reference to the *Antitrust Law* treatise is accurate, Complaint Counsel gets the burden of proof wrong. Under standard rule of reason principles, the defendant need only come forward with evidence of procompetitive benefits, at which point it falls to the *plaintiff* to demonstrate a lack of connection between the challenged restraint and the stated benefits. *See Race Tires Am., Inc. v. Hoosier Racing Tire Corp.*, 614 F.3d 57, 75 (3d Cir. 2010) ("The *plaintiff* then must demonstrate that the restraint itself is not reasonably necessary to

[3] *See also Eisai*, 821 F.3d at 403 ("assuring [consumers] the availability of supply" is a cognizable procompetitive benefit).

achieve the stated objective.") (emphasis added). This is emphatically the plaintiff's burden. *See McWane*, 2014 WL 556261, at *36.[4]

This is evident from the *Antitrust Law* section quoted in Complaint Counsel's Proposed Conclusion No. 14. Complaint Counsel cites Paragraph 1505a, which addresses the *plaintiff's* rebuttal burden once the defendant's comes forward with procompetitive justifications. *See* Areeda & Hovenkamp, *Antitrust Law* ¶ 1505.

Typically, to discharge its rebuttal burden at this stage of the rule of reason analysis, the plaintiff must show that the "legitimate objectives can be achieved in a substantially less restrictive manner." *O'Bannon v. NCAA*, 802 F.3d 1049, 1070 (9th Cir. 2015) (quoting *Tanaka v. Univ. of S. Cal.*, 252 F.3d 1059, 1063 (9th Cir. 2001)).

> 16. Respondent failed to demonstrate that the challenged restraint, the large payment from Endo to stay off the market, is connected to any procompetitive objective or provides procompetitive benefits that justify the restraint's anticompetitive harm.

RESPONSE TO CONCLUSION NO. 16:

Complaint Counsel's Proposed Conclusion No. 16 is wrong.

To begin with, Complaint Counsel erroneously equates the "challenged restraint" to the "large payment." That is wrong. A payment is *not* a restraint. To "restrain" means to "bind." *Bd. of Trade of City of Chi. v. United States*, 246 U.S. 231, 244 (1918); *see also Standard Oil Co. of N.J. v. United States*, 221 U.S. 1, 55 (1911) (a restraint "imped[es] the due course . . . of trade"). A "restraint of trade" is something that restricts competition. *See* Areeda &

[4] Complaint Counsel seems to be confusing the traditional rule of reason with a "quick look" analysis, under which the burden of "articulat[ing] the specific link between the challenged restraint and the purported justification" *does* fall to the defendant. *In re Polygram Holding, Inc.*, 136 F.T.C. 310, 347 (2003), *aff'd*, 416 F.3d 29 (D.C. Cir. 2005).

Hovenkamp, *Antitrust Law* ¶ 1502. More precisely, an antitrust restraint refers to "an anticompetitive reduction in output." *Id.*

A payment does not, by itself, have *any* effect on competition—and certainly does not constitute an "anticompetitive reduction in output." *Id.* In the reverse-payment settlement context, the "restraint" is the *settlement*, since it is the settlement that "bind[s]" the settling parties, *Bd. of Trade*, 246 U.S. at 244, and "imped[es] the due course . . . of trade," *Standard Oil*, 221 U.S. at 55; *see also NCAA v. Bd. of Regents of Univ. of Okla.*, 468 U.S. 85, 98 (1984) (challenged practices were "restraint of trade" because they "limit[ed] members' freedom"); 15 U.S.C. § 1 (prohibiting *agreements* in restraint of trade). In economic terms, it is the parties' settlement upon a future entry date that may restrict the generic company's output between the date of settlement and the date of entry. *Cf.* Areeda & Hovenkamp, *Antitrust Law* ¶ 1502. Because of this, in reverse-payment cases, courts routinely treat the settlement, rather than the payment, as the challenged "restraint."[5] Indeed, the *Actavis* Court recognized that the concern with reverse-payment settlements is not the payment *per se*, but rather the *agreement to stay out of the market* that large and unjustified payments may procure.[6] Complaint Counsel's own Complaint reflects this exact view.[7]

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[5] *See, e.g.*, *Lipitor*, 868 F.3d at 245 (plaintiffs "challeng[ed] the settlement agreement as an unlawful restraint of trade."); *Loestrin I*, 814 F.3d at 542 ("They contend that these agreements constitute illegal restraints on trade."); *Wellbutrin*, 133 F. Supp. 3d at 752 (holding that "settlements . . . are without question agreements in restraint of trade"); *Androgel*, 2014 WL 1600331, at *8 ("This logic indicates that the 'source . . . of the anticompetitive restraint at issue' is the parties' reverse payment agreement itself.") (quoting *Allied Tube*, 486 U.S. at 499).

[6] *See, e.g.*, *Actavis*, 133 S. Ct. at 2227 (reverse-payment agreement is one that "require[s] . . . the claimed infringer, not to produce the patented product" in return for "many millions of dollars"); *id.* at 2229-30 (generics allegedly violated FTC Act by "agreeing 'to share in Solvay's monopoly profits, abandon their patent challenges, and refrain from launching their low-cost generic products to compete with AndroGel for nine years.'"); *id.* at 2231 ("the plaintiff agreed to pay the defendants many millions of dollars to stay out of its market"); *id.* at 2233 (under reverse-

Impax has presented substantial, unrebutted evidence that "the challenged settlement [was] in fact procompetitive." *Cipro*, 348 P.3d at 869-70. Specifically, as explained in Paragraphs 1439-1574 of Impax's Proposed Findings of Fact and Paragraphs 966-1459 of Impax's Replies to Complaint Counsel's Proposed Findings of Fact, the settlement permitted Impax to begin selling low-priced generic Opana ER on a sustained basis, free from patent risk, earlier than would have been possible absent the settlement. These are indisputably cognizable procompetitive effects. *See Bd. of Regents*, 468 U.S. at 102 (actions that "enable[] a product to be marketed which might otherwise be unavailable . . . widen consumer choice . . . and hence can be viewed as procompetitive."); *Law v. NCAA*, 134 F.3d 1020, 1023 (10th Cir. 1998) ("making a new product available" and "widening consumers choice" are procompetitive benefits); *AbbVie*, 107 F. Supp. 3d at 437 (agreement that "facilitat[ed] Teva's ability to compete in the cholesterol drug market [was] good for the consumer" and procompetitive under *Actavis*); *Wellbutrin*, 133 F. Supp. 3d at 760 ("ensuring consistent supply of product . . . to consumers" is a procompetitive justification).

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payment agreements, "a party with no claim for damages . . . walks away with money simply so it will stay away from the patentee's market"); *id.* at 2234 ("payment in return for staying out of the market [] simply keeps prices at patentee-set levels."); *id.* at 2237 ("paying the challenger to stay out [of the market]" risks antitrust liability).

[7] (*See, e.g.*, Compl. ¶ 1 ("This action challenges an anticompetitive reverse-payment *agreement* between Impax and Endo Pharmaceuticals Inc.") (emphasis added); *id.* ¶ 4 ("The purpose and effect of this anticompetitive *agreement* was to ensure that Endo would not face generic competition for Opana ER until at least January 2013.") (emphasis added); *id.* ¶ 48 ("Endo, therefore, decided to purchase the time it needed by paying Impax *not to compete* until January 2013.") (emphasis added); *id.* ¶ 74 ("The purpose and effect of Endo's Guaranteed No-AG Payment were to *induce Impax to abandon its patent challenge and agree not to compete* with a generic version of Original Opana ER until January 2013.") (emphasis added); *id.* ¶ 93 ("By impeding generic competition, Respondent's *agreement* with Endo denied consumers and other purchasers of Opana ER access to AB-rated generic versions of Opana ER that would offer the same therapeutic benefit as branded Opana ER but at a fraction of the price.") (emphasis added)).

The procompetitive benefits also flowed directly from the challenged "restraint"—the settlement—which "was negotiated as a whole, agreed to as a whole, and went into effect as a whole." *Wellbutrin*, 133 F. Supp. 3d at 754.

Impax more than satisfied its burden of demonstrating procompetitive justifications for the challenged settlement agreement.

17. Complaint Counsel has met its burden of proving that the Impax's agreement with Endo restrains competition in violation of Section 5(a) of the FTC Act, 15 U.S.0 §45(a).

RESPONSE TO CONCLUSION NO. 17:

Complaint Counsel's Proposed Conclusion No. 17 is wrong.

For the reasons stated in Impax's responses to Complaint Counsels Proposed Conclusion Nos. 11, 12, 13, and 16, **(1)** Complaint Counsel did not show that Impax received a "large and unjustified" reverse payment; **(2)** Complaint Counsel failed to demonstrate that Endo possessed monopoly power in a properly defined relevant market; **(3)** Complaint Counsel did not satisfy its *prima facie* burden of proving anticompetitive effects; and **(4)** Impax put on substantial, unrebutted evidence that the settlement agreement was procompetitive.

Further, Complaint Counsel has not even attempted to identify a "substantially less restrictive alternative" to the challenged settlement agreement. *O'Bannon*, 802 F.3d at 1074. Because of this, it has fallen far short of its burden of "mak[ing] a strong evidentiary showing" that a less restrictive alternative would not only be "viable," but "'virtually as effective' in serving the [settlement's] procompetitive purposes" and "'without significantly increased cost.'" *Id.* (quoting *Cty. of Tuolumne v. Sonora Cmty. Hosp.*, 236 F.3d 1148, 1159 (9th Cir. 2001)).

Because of this, Complaint Counsel has not shown that the settlement restrains competition in violation of the FTC Act. *See N. Am. Soccer League, LLC v. U.S. Soccer Fed'n, Inc.*, No. 17-CV-05495 (MKB), — F. Supp. 3d —, 2017 WL 5125771, at *15, *19-21 (E.D.N.Y.

Nov. 4, 2017) (plaintiffs failed to show likelihood of success where defendant adduced evidence of procompetitive benefits and plaintiffs failed to "provide some alternative to the [challenged restraint] that offer[ed] the same procompetitive benefits . . . 'without significantly increased cost'"; denying motion for preliminary injunction) (quoting *O'Bannon*, 802 F.3d at 1074).

> 18. Pursuant to Section 5 of the FTC Act, upon determination that the challenged practice is an unfair method of competition, the Commission shall issue an order requiring such person to cease and desist from using such method of competition or such act or practice. 15 U.S.C. § 45(b); *FTC v. Nat'l Lead Co.*, 352 U.S. 419, 428-29 (1957); *1-800 Contacts*, at 190.

RESPONSE TO CONCLUSION NO. 18:

Respondent has no specific response.

> 19. The FTC has considerable discretion in fashioning an appropriate remedial order, subject to the constraint that the order must bear a reasonable relationship to the unlawful acts or practices found to exist. *Nat'l Lead Co.*, 352 U.S. 419 at 428; *1-800 Contacts* at 190.

RESPONSE TO CONCLUSION NO. 19:

Complaint Counsel's Proposed Conclusion No. 19 is incomplete.

It is true that any remedy must bear a "reasonable relation to the unlawful practices found to exist." *FTC v. Nat'l Lead Co.*, 352 U.S. 419, 428 (1957) (quoting *Jacob Siegel Co. v. FTC*, 327 U.S. 608, 613 (1946)); *see* 15 U.S.C. § 45(b) (where violation is found, Commission may order respondent to "cease and desist from using *such method of competition or such act or practice*.") (emphasis added). But that is not all.

Antitrust remedies "should be tailored to fit the wrong creating the occasion for the remedy," *Microsoft*, 253 F.3d at 107, going "no further than is reasonably necessary to correct the evil and preserve the rights of competitors and public," *FTC v. Royal Milling Co.*, 288 U.S. 212, 217 (1933). Each remedy must also be "as specific as possible, not only in the core of its

relief, but in its outward limits, so that parties may know[ ] their duties and unintended contempts may not occur." *Int'l Salt Co. v. United States*, 332 U.S. 392, 400 (1947).

To justify prospective relief, Complaint Counsel must show that "there exists some cognizable danger of recurrent violation." *United States v. W.T. Grant Co.*, 345 U.S. 629, 633 (1953). This requires more than a "mere possibility"; the finding must be grounded in record fact. *See TRW, Inc. v. FTC*, 647 F.2d 942, 954 (9th Cir. 1981) (setting aside prospective remedy where record facts were "not enough" to demonstrate "cognizable danger" of repetition).

20. The Order entered herewith is necessary and appropriate to remedy the violations of law found to exist, is reasonably related to the proven violations, and is sufficiently clear and precise.

RESPONSE TO CONCLUSION NO. 20:

Complaint Counsel's Proposed Conclusion No. 20 is wrong.

As explained at length in Impax's Reply to Complaint Counsel's Post-trial Brief, Complaint Counsel's requested remedies suffer from a range of defects. These include the following, at minimum:

- Complaint Counsel has not shown a "cognizable danger" of recurrent violations, as is necessary to justify prospective remedies. *W.T. Grant*, 345 U.S. at 633; *TRW*, 647 F.2d at 954.
- Complaint Counsel's request for a prohibition on agreements under which any "transfer of value" flows from a branded company to Impax is overbroad and bears no reasonable relation to the violation alleged. *Nat'l Lead*, 352 U.S. at 428.
- Complaint Counsel's request for a prohibition on agreements that "disincentivize" competition for Opana ER is hopelessly vague and bears no reasonable relation to the violation alleged. *Nat'l Lead*, 352 U.S. at 428; *see Removatron Int'l Corp. v. FTC*, 884 F.2d 1489, 1499 (1st Cir. 1989) (where "the order's prohibitions are not sufficiently 'clear and precise in order that they may be understood by those against whom they are directed,'" it should be stricken) (quoting *FTC v. Colgate-Palmolive Co.*, 380 U.S. 374, 392 (1965)).
- Complaint Counsel's attack on Impax's 2017 settlement with Endo lacks any evidentiary basis and constitutes an improper violation of Impax's due process rights. *See Murphy Oil Corp. v. Fed. Power Comm'n*, 431 F.2d 805, 813 (8th Cir. 1970) ("The parties to a proceeding before an administrative agency such as the Commission are entitled to: first, due notice as to the nature and scope of the

> contemplated inquiry; second, an opportunity to be heard and present evidence; and third, a full hearing in conformity with the fundamental concepts of fairness. A departure from these minimal requirements is a denial of procedural due process.") (quoting *Shell Oil Co. v. Fed. Power Comm'n*, 334 F.2d 1002, 1012 (3rd Cir. 1964)).

Complaint Counsel has not justified its proposed remedies.

Dated: February 7, 2018

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CERTIFICATE OF SERVICE

I hereby certify that on February 7, 2018, I filed the foregoing document using the FTC's E-Filing System, which will send notification of such filing to:

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I also certify that I caused a copy of the foregoing to be served upon the following individuals by electronic mail:

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CERTIFICATE FOR ELECTRONIC FILING

I hereby certify that the electronic copy sent to the Secretary of the Commission is a true and correct copy of the paper original and that I possess a paper original of the signed document that is available for review by the parties and the adjudicator.

DATED: February 7, 2018

/s/ *Benjamin J. Hendricks*
Benjamin J. Hendricks

Notice of Electronic Service

I hereby certify that on February 13, 2018, I filed an electronic copy of the foregoing RESPONDENT IMPAX LABORATORIES, INC.'S REPLY TO COMPLAINT COUNSEL'S POST-TRIAL BRIEF, RESPONDENT IMPAX LABORATORIES, INC.'S REPLIES TO COMPLAINT COUNSEL'S PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW, with:

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I hereby certify that on February 13, 2018, I served via other means, as provided in 4.4(b) of the foregoing RESPONDENT IMPAX LABORATORIES, INC.'S REPLY TO COMPLAINT COUNSEL'S POST-TRIAL BRIEF, RESPONDENT IMPAX LABORATORIES, INC.'S REPLIES TO COMPLAINT COUNSEL'S PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW, upon:

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