PUBLIC

ORIGINAL

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

In the Matter of	)	
Impax Laboratories, Inc., a corporation,	)	**DOCKET NO. 9373**
Respondent	)	

COMPLAINT COUNSEL'S PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW

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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)).

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).

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)).

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)).

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

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).

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)).

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).

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)).

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).

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)).

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)).

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")).

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).

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).

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)).

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).

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).

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)).

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.")).

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)).

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)).

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.

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)).

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

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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).

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)).

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)).

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)).

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)).

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.)).

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).

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)).

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.)).

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.)).

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.)).

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)).

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.)).

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).

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 (s*ee* CCF ¶¶ 48-49, below), and the lack of meaningful patent protection (s*ee* CCF ¶¶ 50-57, below).

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).

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).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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).

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).

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)).

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)).

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).

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")).

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")).

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.")).

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).

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.

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).

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)).

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)).

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.)).

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.

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.")).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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.)).

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)).

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 . . . .")).

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)).

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.")).

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.")).

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.")).

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)).

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)).

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.").

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)).

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)).

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)).

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).

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)).

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)).

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)).

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)).

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)).

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).

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).

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.)).

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)).

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)).

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)).

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)).

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)).

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).

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).

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).

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)).

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

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)).

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

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")).

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)).

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).

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)).

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)).

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)).

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).

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)).

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)).

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).

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).

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)).

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)).

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)).

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")).

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)).

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).

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)).

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).

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).

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)).

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)).

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).

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)).

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)).

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).

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.)).

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)).

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)).

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).

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).

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)).

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)).

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).

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)).

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.")).

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)).

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).

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).

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)).

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).

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)).

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).

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)).

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).

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)).

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)).

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)).

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)).

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).

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.

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).

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).

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).

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).

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)).

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).

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)).

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).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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).

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).

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)).

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

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.")).

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)).

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).

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).

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)).

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).

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)).

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)).

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)).

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)).

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).

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)).

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; c*ompare* 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)).

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)).

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).

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)).

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)).

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)).

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)).

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)).

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)).

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).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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")).

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)).

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).

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)).

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)).

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)).

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).

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)).

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).

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)).

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)).

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))).

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).

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)).

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)).

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)).

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)).

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).

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).

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).

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)).

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.")).

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)).

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)).

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)).

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)).

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)).

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")).

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)).

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.'")).

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)).

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)).

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)).

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")).

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)).

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.")).

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)).

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)).

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"))).

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

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).

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)).

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")).

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.")).

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.")).

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")).

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")).

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).

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).

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).

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")).

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).

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)).

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")).

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).

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")).

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).

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).

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…")).

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)).

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)).

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))).

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)).

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)).

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))).

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.

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).

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)).

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*)).

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*).

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).

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)).

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).

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)).

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).

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")).

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)).

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).

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)).

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.")).

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)).

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)).

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)).

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)).

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)).

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)).

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.")).

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)).

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*)).

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")).

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).

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)).

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)).

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)).

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)).

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).

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)).

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).

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)).

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)).

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).

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).

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")).

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)).

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")).

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)).

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)).

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)).

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)).

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)).

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).

331. The $10 million upfront payment was not refunded when Endo and Impax terminated the DCA. (Snowden, Tr. 408).

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)).

333. 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)).

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)).

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).

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).

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).

338. Indeed, whether to launch generic Opana ER at risk was under consideration by Impax in 2010. (Koch, Tr. 247).

339. 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).

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)).

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).

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)).

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).

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)).

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).

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).

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)).

348. 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)).

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)).

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).

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).

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).

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).

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).

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).")).

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)).

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)).

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).

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")).

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")).

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).

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).

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)).

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)).

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).

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).

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)).

368. If litigation continued, Impax may have "obtained a favorable judgment" at the district court (CX5007 at 044 (¶ 82) (Hoxie Rebuttal Report)).

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")).

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.")).

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).

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)).

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).

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)).

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*)).

376. The litigation was terminated, and there was no record to go up on appeal to the Federal Circuit. (Figg, Tr. 2043).

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).

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).

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")).

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)).

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)).

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)).

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).

384. **{** **}** (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)).

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).

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")).

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].")).

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).

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)).

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)).

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).

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)).

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).

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)).

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).

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)).

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)).

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)).

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)).

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 . . .")).

401. By late 2009, Endo began preparing for an authorized generic launch in the summer of 2010. (*See* CCF ¶¶ 86-90).

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)).

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)).

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).

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).

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).

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)).

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)).

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?")).

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).

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).

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)).

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)).

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)).

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)).

416. Impax did not forfeit its 180-day exclusivity period. (Snowden, Tr. 484).

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).

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).

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).

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).

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).

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).

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).

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)).

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).

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)).

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)).

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).

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).

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)

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)).

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).

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).

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).

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)).

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%.")).

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).

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")).

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)).

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)).

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)).

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)).

443. Endo did not dispute Impax's calculation of the Endo Credit. (Snowden, Tr. 491).

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).

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)).

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).

447. The $10 million payment was guaranteed and non-refundable. (JX-001 at 010 (¶ 39)).

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)).

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).

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)).

451. Impax never refunded the $10 million that Endo had paid pursuant to Section 3.1 of the DCA. (Snowden, Tr. 408).

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)).

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)).

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)).

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)).

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).

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).

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).

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)).

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.").

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!!!!")).

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")).

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)).

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)).

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)).

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).

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).

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)).

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).

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).

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).

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).

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)).

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).

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)).

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.")).

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.")).

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).

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).

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).

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)).

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)).

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.")).

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")).

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).

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)).

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)).

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).

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).

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)).

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)).

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).

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)).

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.

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).

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)).

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).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

505. Opioid medications exert their effects when the opioid molecules bind to opioid receptors on nerve cells. (CX5002 at 020 (¶ 53) (Savage Report)).

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)).

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).

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)).

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)).

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)).

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)).

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)).

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 . . .")).

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)).

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)).

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)).

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.")).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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.")).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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).

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)).

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)).

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)).

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)).

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)).

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.")).

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.")).

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)).

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)).

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)).

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.")).

571. The existence of a generic drug is, by far, the most important competitive factor affecting drug prices. (Noll, Tr. 1524).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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).

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)).

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).

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)).

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).

586. When there are more generics on the market, Impax expects that the additional generic competition will compete down the price. (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).

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).

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).

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).

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).

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).

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).

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).

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)).

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)).

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)).

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)).

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.")).

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)).

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.)).

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).

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)).

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*)).

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)).

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)).

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)).

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.)).

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.)).

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.")).

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*)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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.)).

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.)).

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.)).

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")).

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.)).

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)).

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)).

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)).

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*)).

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]

[redacted] **}** (CX5000 at 054-55 (¶ 118) (Noll Report); CX5000 at 178, 180 (Exhibits 2A2, 2A4) (Noll Report) (*in camera*)).

632. **{** [redacted] **}** (CX5000 at 054-55 (¶ 118) (Noll Report); CX5000 at 178, 180 (Exhibits 2A2, 2A4) (Noll Report) (*in camera*)).

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)).

634. **{** [redacted] **}** (CX5000 at 055 (¶ 120) (Noll Report); CX5000 at 184 (Exhibits 2B1) (Noll Report) (*in camera*)).

635. **{** [redacted] **}** (CX5000 at 055 (¶ 120) (Noll Report); CX5000 at 185, 187 (Exhibits 2B2, 2B4) (Noll Report) (*in camera*)).

636. **{** [redacted] **}** (CX5000 at 055-56 (¶ 120)

(Noll Report); CX5000 at 186, 188-190 (Exhibits 2B3, 2B5-7) (Noll Report) (*in camera*)).

637. The price data show that generic entry captured market share by offering a substantially lower price. (CX5000 at 056 (¶ 120) (Noll Report)).

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)).

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)).

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)).

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)).

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).

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)).

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)).

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).

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).

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.")).

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)).

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)).

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).

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).

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.")).

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)).

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.")).

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.")).

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)).

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)).

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)).

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)).

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.")).

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)).

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).

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)).

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.")).

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).

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).

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.")).

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)).

669. Ultimately, there is no evidence of significant price competition between brand name opioids with different APIs. (CX4039 (Noll, Dep. at 188-89)).

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)).

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).

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)).

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.")).

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)).

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)).

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)).

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*)).

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)).

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)).

680. {[redacted]} (CX5000 at 075 (¶ 163) (Noll Report); CX5000 at 196-198 (Exhibits 5A1-5A3) (Noll Report) (*in camera*)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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.")).

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)).

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)).

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)).

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)).

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)).

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)).

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 202-204 (Exhibits 5C1-5C3) (Noll Report)).

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)).

698. **{** [redacted] **}** (CX5000 at 078-79 (¶¶ 170, 172) (Noll Report); CX5000 at 205-207 (Exhibits 5D1-5D3) (Noll Report) (*in camera*)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

713. **{** [redacted] **}** (CX5000 at 081 (¶ 179) (Noll Report); CX5000 at 214-216 (Exhibits 5G1-5G3) (Noll Report) (*in camera*)).

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)).

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)).

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)).

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).

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.")).

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)).

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.)).

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)).

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)).

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.")).

724. A promotional strategy that focuses on product differentiation reduces the intensity of price competition, it doesn't increase it. (Noll, Tr. 1402-03).

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).

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).

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 . . .")).

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).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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).

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)).

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)).

744. Dr. Savage has over thirty years of experience with the use of opioids to treat pain. (Savage, Tr. 684-85).

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. 678-79, 709).

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.")).

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).

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.")).

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.")).

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).

751. Indeed, approximately fifty percent of patients don't tolerate the first opioid they try. (Michna, Tr. 2169).

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)).

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.")).

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).

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)).

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).

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)).

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)).

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)).

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)).

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).

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).

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)).

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.")).

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.")).

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)).

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).

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.")).

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 . . .")).

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)).

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).

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).

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 . . .")).

774. Thus, among these patients, opioids that are metabolized by CYP450 are not close therapeutic substitutes for oxymorphone. (CX5000 at 066 (¶ 143) (Noll Report)).

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)).

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)).

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)).

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)).

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.")).

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)).

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.")).

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.")).

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 . . .")).

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)).

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).

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.")).

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 . . .")).

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).

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)).

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)).

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).

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).

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)).

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)).

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.")).

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 . . .")).

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.")).

798. Thus, short acting opioids are not routinely or reliably interchangeable with a long-acting opioid with like Opana ER. (Savage, Tr. 708).

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)).

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)).

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] **}** (CX5000 at 059 (¶ 128) (Noll Report) (*in camera*)).

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).

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 . . . ")).

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).

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 (¶¶ 33-36) (Savage Report)).

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)).

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).

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)).

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)).

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)).

811. The parties have stipulated that "the relevant geographic market for purposes of this litigation is the United States." (JX-001 at 002 (¶ 10)).

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).

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)).

814. A rule of reason analysis includes a determination of market power. (Noll, Tr. 1343; CX5000 at 083 (¶ 184) (Noll Report)).

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)).

816. Economists can ascertain market power in two ways, indirectly and directly. (CX5000 at 083 (¶ 184) (Noll Report); Noll, Tr. 1404-05).

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)).

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)).

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)).

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)).

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)).

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. 1406-07). 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).

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).

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).

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).

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).

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)).

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).

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).

830. In 2010, Endo had 100% of the market for oxymorphone ER. (CX5000 at 085 (¶189) (Noll Report)).

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)).

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.")).

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).

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)).

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)).

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)).

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)).

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).

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).

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).

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 **{** **}** (using total prescriptions), above **{** **}** (using net sales revenue), and usually was around **{** **}** (CX5000 at 085-86 (¶¶ 190-91) (Noll Report) (partially *in camera*)).

842. Under either method, the HHIs are always above **{** **}** 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).

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).

844. The pharmaceutical industry, as a whole, has significant barriers to entry. (Noll, Tr. 1408; CX5000 at 086-87 (¶ 194) (Noll Report)).

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)).

846. The market for brand name drugs is generally protected from entry by patents. (CX5000 at 086-87 (¶ 194) (Noll Report)).

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)).

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)).

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).

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)).

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)).

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 008-09, 087-88 (¶¶ 15, 197) (Noll Report)).

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)).

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)).

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)).

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).

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)).

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).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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*)).

881. **{** [redacted] **}** (CX5000 at 092, 219-26 (¶ 207 & Exs. 7A-7B7) (Noll Report) (partially *in camera*).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

890. **{** [redacted] **}** (Noll, Tr. 1681-82 (*in camera*)).

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)).

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)).

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)).

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)).

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*)).

896. {[redacted]} (CX5000 at 100 (¶ 226) (Noll Report) (partially *in camera*)).

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)).

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)).

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)). .

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)).

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)).

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)).

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, 1381-82). 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, 1381-82).

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).

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.

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)).

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)).

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)).

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)).

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).

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)).

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)).

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*)).

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. 1380-81; CX5000 at 187-90 (Exhibits 2B4 through 2B7) (Noll Report)).

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)).

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)).

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)).

918. Different drugs may be therapeutic substitutes but have different enough characteristics that they are not economic substitutes. (Noll, Tr. 1373).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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).

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)).

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)).

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)).

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)).

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)).

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.

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)).

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")).

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).

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)).

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)).

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.)).

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).

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)).

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*).

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)).

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).

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.

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.)).

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)).

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)).

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.")).

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.

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)).

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 0052-53 (¶ 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)).

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)).

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)).

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)).

956. Endo has always enjoyed a high Lerner Index for Opana ER: always over **{ }** and often between **{ }** (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)).

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)).

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 055-56 (¶ 117) (Noll Rebuttal Report)).

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)).

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.

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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.")).

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. 1425-26). 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).

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)).

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)).

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")).

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)).

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)).

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).

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)).

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)).

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).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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.")).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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).

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 ¶¶ 31-32, 413, above).

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)).

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)).

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.")).

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)).

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)).

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)).

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)).

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).

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)).

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)).

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)).

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).

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).

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).

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)).

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)).

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)).

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)).

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.

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).

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.

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)).

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)).

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.")).

1022. 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.

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)).

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)).

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 at 078, 092-115 (¶ 164, Ex. 4) (Noll Rebuttal Report)).

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).

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).

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.")).

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 when it decided to enter the settlement.

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.

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)).

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).

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 . . . .")).

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 ¶¶ 1035-1039). 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).

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")).

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))).

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 . . . .")).

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")).

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)).

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)).

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).

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).

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)).

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).

1045. Prior to entering the SLA, Impax was preparing to launch generic Opana ER in 2010 or 2011. (*See* CCF ¶¶ 127-202).

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")).

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")).

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).

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).

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)).

1051. When Endo rejected the acceleration trigger, the parties moved instead to what eventually became the Endo Credit. (Snowden, Tr. 385).

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)).

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)).

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")).

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).

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).

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)).

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)).

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")).

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")).

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)).

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")).

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")).

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")).

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)).

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).

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)).

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)).

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)).

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).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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).

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)).

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*)).

1086. At the time of the DCA, Endo's business was not focused on pursuing Parkinson's disease treatments. (*See* CCF ¶¶ 1087-1095).

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)).

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)).

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)).

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)).

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)).

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)).

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).

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)).

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).

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)).

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)).

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)).

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)).

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.")).

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")).

1102. **{** **}** (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)).

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)).

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).

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).

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)).

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)).

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)).

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)).

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)).

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)).

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).

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)).

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)).

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)).

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*)).

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*)).

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).

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)).

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)).

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.")).

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).

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.")).

1124. Endo recognized that the highly abbreviated timeframe for evaluating the DCA was unusual. (*See* CCF ¶¶ 1125-1127).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)). **{** **}** (Geltosky, Tr. 1095 (*in camera*)).

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).

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).

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)).

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)).

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)).

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")).

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).

1140. **{** [redacted] **}** (CX5003 at 009 (¶ 17) (Geltosky Report) (*in camera*)).

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)).

1142. **{** [redacted] **}** (CX1209 at 003 (Endo's Final Opportunity Evaluation Worksheet for IPX-203) (*in camera*)).

1143. **{** [redacted] **}** (Geltosky, Tr. 1097 (*in camera*)). **{** [redacted] **}** (Geltosky, Tr. 1100-101 (*in camera*)).

1144. {[redacted]} (Nestor, Tr. 3042 (*in camera*); Cobuzzi, Tr. 2532) (*in camera*)).

1145. {[redacted]} (CX5003 at 024 (¶ 39) (Geltosky Report) (*in camera*)).

1146. {[redacted]} (Geltosky, Tr. 1096) (*in camera*)).

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*)).

1148. {[redacted]} (CX3167 at 044 (Aug. 2010 Impax Brand R&D presentation) {[redacted]} (*in camera*).

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)).

1150. {[redacted]} (CX5003 at 024 (¶ 38 n.89) (Geltosky Report) (*in camera*)).

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).

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.")).

1153. **{** **}** (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).

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)).

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)).

1156. **{** **}** (Cobuzzi, Tr. 2547-48; Nestor, Tr. 2957 (*in camera*)).

1157. **{** **}** (Geltosky, Tr. 1102) (*in camera*). **{** **}** (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)).

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 . . . .").

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).

1160. **{** [redacted] **}** (Geltosky, Tr. 1092-93 (*in camera*); CX5003 at 051 (¶ 86 n.199) (Geltosky Report) (*in camera*)). **{** [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)).

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).

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.")).

1163. **{** **}** (CX5003 at 027 (¶ 41) (Geltosky Report); Geltosky, Tr. 1101 (*in camera*)).

1164. **{** **}** (Geltosky, Tr. 1101) (*in camera*)). **{** **}** (Geltosky, Tr. 1101) (*in camera*)).

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)).

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)).

1167. **{** **}** (CX3167 at 027 (Aug. 2010 Impax Brand R&D presentation) (*in camera*)).

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.")).

1169. **{** [redacted] **}** (CX5003 at 28 (¶ 43) (Geltosky Report) (*in camera*)).

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)).

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*)).

1172. **{** [redacted] **}** (Geltosky, Tr. 1100 **{** [redacted] **}** (*in camera*); CX5003 at 028 (¶ 43) (Geltosky Report)).

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)).

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)).

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)).

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)).

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)).

1178. Endo did not properly account for the regulatory risks associated with the IPX-203 opportunity. (*See* CCF ¶¶ 1179-1186).

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)).

1180. **{** [redacted] **}** (Geltosky, Tr. 1097-98 (*in camera*)).

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*)).

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)).

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)).

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).

1185. Endo also noted potential **{** **}** (CX1209 at 009 (Endo's Final Opportunity Evaluation Worksheet for IPX-203) (*in camera*)).

1186. **{** **}** (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)).

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).

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)).

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")).

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*)).

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)).

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).

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)).

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?")).

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)).

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)).

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.")).

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)).

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)).

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.")).

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)).

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).

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.")).

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)).

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)).

1206. In addition, many of the assumptions related to IPX-066 were improper when applied to IPX-203. (Geltosky, Tr. 1084-85).

1207. {[redacted]} (Geltosky, Tr. at 1089 (*in camera*)). {[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*)).

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]} CX1209 at 012, 016 (Endo's Final Opportunity Evaluation Worksheet for IPX-203) (*in camera*)).

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]}

[redacted]**}** (CX5003 at 034 (¶5 5) (Geltosky Report) (*in camera*)).

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*)).

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).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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).

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).

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 non-refundable upfront payments. (Geltosky, Tr. 1072).

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).

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.")).

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)).

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).

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).

b) The DCA contains ambiguous terms

1229. The DCA contains a number of ambiguous terms. (*See* CCF ¶¶ 1230-1232).

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)).

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)).

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)).

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).

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).

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)).

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]

[redacted]**}** (RX-365 at 0023 (DCA § 12 ("Noncompete")); CX5003 at 048-49 (¶ 82) (Geltosky Report)); (Geltosky, Tr. 1113-14) (*in camera*).

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*)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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).

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).

1248. {[redacted]} (CX2928 at 011; (Impax Response to Interrogatory No. 17) (*in camera*)). {[redacted]

[redacted] (CX2928 at 011 (Impax Response to Interrogatory No. 17) (*in camera*)). **{** [redacted] **}** (CX2928 at 011 (Impax Response to Interrogatory No. 17) (*in camera*)).

1249. **{** [redacted] **}** (Geltosky, Tr. 1103 (*in camera*)).

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).

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).

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)).

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)).

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)).

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)).

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*)).

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*)).

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)).

1259. **{** [redacted] **}** (Nestor, Tr. 3050 (*in camera*)).

1260. **{** [redacted] **}** (Nestor, Tr. 2961 (*in camera*); CX2928 at 012 (Impax Response to Interrogatory No. 18) (*in camera*)).

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").

1262. **{** [redacted] **}** (Nestor, Tr. 2963 (*in camera*); CX2747 at 001 (Oct. 29, 2015 Macpherson/Ailinger email)).

1263. **{** [redacted] **}** (CX2747 at 001 (Oct. 29, 2015 Macpherson/Ailinger email); Nestor, Tr. 3049) (*in camera*).

1264. In passing on the new microencapsulated formulation of IPX-203, Endo raised a number of issues. **{** **}** (CX3181 at 006, 010 (Oct. 28, 2015 Evaluation of IPX-203 (*in camera*)). **{** **}** (CX3181 at 010 (Oct. 28, 2015 Evaluation of IPX-203) (*in camera*)).

1265. **{** **}** (CX5003 at 53 (¶89) (Geltosky Report) (*in camera*)).

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). **{** **}** (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)).

1267. **{** **}** (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)).

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)).

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)).

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).

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)).

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)).

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).

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).

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).

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).

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)).

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)).

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).

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).

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).

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).

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)).

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)).

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).

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)).

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).

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)).

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)).

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).

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 035-36 (¶ 66) (Hoxie Report)).

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).

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)).

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)).

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)).

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)).

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)).

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)).

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).

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).

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)).

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)).

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).

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).

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)).

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)).

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)).

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).

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).

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.

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)).

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)).

1313. Impax received three benefits to compensate for agreeing that it would not enter until January 2013. (*See* CCF ¶¶ 1314-27, below).

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)).

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).

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*).

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)).

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)).

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)).

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).

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)).

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)).

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)).

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).

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).

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)).

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)).

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).

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).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

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)).

(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)).

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)).

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")).

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)).

(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).

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).

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))).

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.")).

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).

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)).

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).

(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)).

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).

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)).

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)).

(4) Opana ER Settlements with No Payments Had Earlier Entry Dates

1359. **{** [redacted] **}** (CX3383 at 002, 003 **{** [redacted] **}** (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).

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).

1361. Mr. Figg is not offering any opinion as to whether the settlement between Endo and Impax violated the antitrust laws. (Figg, Tr. 2057).

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)).

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).

1364. Mr. Figg is not offering any opinions regarding the contents of the DCA. (Figg, Tr. 1997-98).

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).

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).

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).

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).

1369. Mr. Figg has never worked at Impax and never represented Impax as counsel. (Figg, Tr. 1980).

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)).

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).

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).

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).

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).

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).

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).

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).

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).

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).

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)).

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).

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).

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).

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).

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)).

1386. Mr. Figg would not characterize any of Impax's arguments in the district court as being frivolous. (Figg, Tr. 2014-15).

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 . . . .")).

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)).

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")).

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)).

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).

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).

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)).

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")).

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).

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.")).

1397. The 8,309,122 patent was issued to Endo on November 13, 2012. (JX-001 at 012 (¶ 56)).

1398. The 8,329,216 patent was issued to Endo on December 11, 2012. (JX-001 at 012 (¶ 57)).

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).

1400. The 8,808,737 patent was issued to Endo on August 19, 2014. (JX-001 at 013 (¶ 59)).

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)).

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).

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)).

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)).

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)).

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).

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).

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)).

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")).

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).

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)).

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)).

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")).

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)).

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)).

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))).

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)).

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)).

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)).

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.")).

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)).

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"))).

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)).

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)).

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)).

1426. **{** [redacted] **}** (CX3275 at 001 **{** [redacted] **}** (*in camera*)).

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*))).

1428. { [redacted] } (CX3275 at 012, 014 { [redacted] } (*in camera*)). { [redacted] } (CX3275 at 013 { [redacted] } (*in camera*)). { [redacted] } (CX3275 at 002 { [redacted] } (*in camera*)).

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)).

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)).

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)).

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).

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.

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)).

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.

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).

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)).

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).

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)).

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)).

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).

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).

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")).

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.")).

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).

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).

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).

1448. **{** [redacted] **}** (CX3383 (Actavis settlement) (admitted for fact of the settlement and its terms, not truth of the matter asserted) (*in camera*)).

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")).

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")).

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")).

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")).

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")).

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).

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)).

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))).

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)).

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)).

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).

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.")).

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)).

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)).

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)).

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)).

1465. **{** [redacted] **}** (RX-246 at 0024 (July 2015 Impax Portfolio Executive Committee (PEC) Meeting Presentation) (*in camera*); CX3271 at 011 (Impax 2015 Annual Report)).

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)).

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)).

1468. CNS disorders "include migraine, multiple sclerosis, Parkinson's disease and postherpetic neuralgia." (CX3271 at 013 (Impax 2015 Annual Report)).

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)).

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)).

1471. Impax also has "a couple of product candidates that are in varying stages of development." (CX3271 at 013 (Impax 2015 Annual Report)).

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)).

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).

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)).

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)).

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)).

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)).

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)).

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)).

1480. Impax believes that such "agreements with brand pharmaceutical companies . . . are important to [its] business." (CX3271 at 030 (Impax 2015 Annual Report)).

1481. Impax prefers to include No-AG clauses in its settlements with branded companies. (*See* CCF ¶¶ 1482-1484).

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)).

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)).

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)).

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*)).

1486. {[redacted]} (CX3275 at 011 (2017 Contract Settlement Agreement) (*in camera*)).

1487. {[redacted]} (CX3275 at 013-14 (2017 Contract Settlement Agreement § 1(i)) (*in camera*))).

1488. {[redacted]}

[redacted]
[redacted]**}**
(CX3275 at 013 (2017 Contract Settlement Agreement §§ 1(h), (i)) (*in camera*))).

1489. Endo ceased selling Reformulated Opana ER on September 1, 2017. (JX-001 at 012 (¶ 54)).

1490. **{**[redacted]**}** (CX3275 at 013 (2017 Contract Settlement Agreement § 1(i)) (*in camera*))).

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)).

1492. **{**[redacted]**}** (CX3275 at 004 (§ 10(c)) (2017 Contract Settlement Agreement) (*in camera*)).

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).

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).

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).

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).

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").

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).

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 absence of some other justification, the antitrust laws are likely to forbid the arrangement." *Id.* at 2237.

8. An antitrust market is comprised of a relevant geographic market and a relevant product market.

9. The relevant geographic market for purposes of this litigation is the United States. JX-001 at 002 (¶ 10).

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).

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.

12. Complaint Counsel has met its burden that Endo possessed market power in the extended-release oxymorphone market.

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.

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.

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.

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.

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.C §45(a).

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.

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.

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.

Respectfully submitted,

Dated: December 28, 2017

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Counsel Supporting the Complaint

IN THE MATTER OF IMPAX
DOCKET NO. 9373

COMPLAINT COUNSEL'S WITNESS INDEX

NAME	TITLE	COMPANY	TRANSCRIPT CITE **TOTAL**	TRANSCRIPT CITE ***IN CAMERA***	DATE	VOLUME
Complaint Counsel's Opening Statements	N/A	N/A	Tr. 11:13 - 90:21	N/A	10/24/2017	Volume 1
Respondent Counsel's Opening Statements	N/A	N/A	Tr. 91:01 - 206:06	N/A	10/24/2017	Volume 1
Arthur Koch	Former EVP & CFO	Impax (former)	Tr. 210:11 - 342:01	N/A	10/24/2017 10/25/2017	Volume 1-2
Margaret Snowden	VP of Intellectual Prop.	Impax	Tr. 342:19 - 511:07	N/A	10/25/2017	Volume 2
Chris Mengler	Pres. of Generic Div.	Impax	Tr. 512:09 - 591:09	N/A	10/25/2017	Volume 2
Roberto Cuca	Treasurer & SVP Finance	Endo	Tr. 599:13 - 677:18	N/A	10/26/2017	Volume 3
Seddon Savage, MD MS	Medical Expert (Opioids)	CC's Expert	Tr. 678:07 - 823:04	N/A	10/26/2017	Volume 3
Max Bazerman	Expert in Negotiations & Mgmt Decision Making	CC's Expert Harvard Bus. School	Tr. 831:05 - 935:18	N/A	10/27/2017	Volume 4
Joe Camargo	VP of Supply	Impax (former)	Tr. 946:06 - 1039:10	N/A	10/31/2017	Volume 5
John Geltosky, Ph.D.	Expert in Pharmaceutical Business Development	CC's Expert JEG & Assoc. Biotech	Tr. 1039:21 - 1198:02	Tr. 1088:01 - 1122:20 Tr. 1192:01 - 1197:13	10/31/2017	Volume 5
Bryan Reasons	CFO	Impax	Tr. 1198:16 - 1253:18	N/A	10/31/2017	Volume 5

NAME	TITLE	COMPANY	TRANSCRIPT CITE **TOTAL**	TRANSCRIPT CITE ***IN CAMERA***	DATE	VOLUME
Demir Bingol	Sr. Dir., Oral Pain Solutions Group	Endo (former)	Tr. 1259:14 - 1340:10	N/A	11/2/2017	Volume 6
Roger G. Noll, Ph.D	Expert in Industrial Organization Economics	CC's Expert Stanford University	Tr. 1341:14 - 1696:11	Tr. 1676:01 - 1685:14	11/2/2017 11/3/2017	Volume 6-7
Todd Engle	VP of Sales and Marketing for the Generics Division	Impax	Tr. 1698:08 - 1799:19	N/A	11/3/2017	Volume 7
E. Anthony Figg	Expert in Patent Litigation	RC's Expert Rothwell, Figg, Ernst & Manbeck, P.C.	Tr. 1810:01 - 2097:01	N/A	11/6/2017 11/7/2017	Volume 8-9
Edward Michna	Expert in Pain Management Staff Anesthesiologist	RC's Expert Brigham & Women's Hospital	Tr. 2097:13 - 2194:04	N/A	11/7/2017	Volume 9
Sumanth Addanki, Ph. D.	Expert in Economics of Intellectual Property	RC's Expert	Tr. 2194:22 - 2507:03	Tr. 2257:01 - 2301:23	11/7/2017 11/8/2017	Volume 9 Volume 10
Robert Cobuzzi Jr.	President	Endo Ventures Limited	Tr. 2509:13 - 2635:16	Tr. 2527:01 - 2538:18 Tr. 2609:01 - 2623:19	11/8/2017	Volume 10
Thomas Hoxie	Expert in Patent Litigation	CC's Expert	Tr. 2636:09 - 2916:20	Tr. 2725:01 - 2731:06	11/8/2017 11/9/2017	Volume 10 Volume 11
Michael Nestor	President of the Specialty Pharma/Brand Division	Impax	Tr. 2926:01 - 3057:21	Tr. 2950:01 - 2977:01 Tr. 3039:01 - 3051:14	11/14/2017	Volume 12

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Exhibit No.	Description	Date	BegBates	EndBates	Also Referenced As	Admissibility	Purpose/Notes	*In Camera*	Trial Transcript Citation
CX0001	Intentionally Not Used					N/A			
CX0002	Email from Todd Engle to John Anthony, Chris Mengler, Joe Camargo, et al. re: Oxymorphone w/Attach: 1936_001.pdf; Oxymorphone Forecast Detail 01 11 10 R2.xls	1/11/2010	IMPAX-OPANA-CID00012237	IMPAX-OPANA-CID00012251	GX0002	JX-002			
CX0003	Email from Todd Engle to Chris Mengler, Larry Hsu, Chuck Hildenbrand, et al. re: Quarterly Launch Planning Meeting Background Documentation w/Attach: launch planning 02 02 10 R2.doc	2/2/2010	IMPAX-OPANA-CID00002168	IMPAX-OPANA-CID00002170	GX0003	JX-002			
CX0004	Email from Kevin Sica to Chris Mengler, Todd Engle, Ted Smolenski re: Updated 5 year Plan	2/19/2010	IMPAX-OPANA-CID00007058	IMPAX-OPANA-CID00007060	GX0004	JX-002			Tr. 1721:09; 1721:15; 1722:09; 1722:13; 1726:08; 1728:08; 1730:08; 1767:11
CX0005	Email from Todd Engle to Mike Grigsby, Ted Smolenski, Gary Skalski, et al. re: Tentative Oxy ER approval	5/17/2010	IMPAX-OPANA-CID00006039	IMPAX-OPANA-CID00006039	GX0005	JX-002			
CX0006	Email from Todd Engle to Chuck Hildenbrand, Meg Snowden re: Oxymorphone Question w/Attach: Book2.xls	5/28/2010	IMPAX-OPANA-CID00021740	IMPAX-OPANA-CID00021741	GX0006	JX-002			Tr. 1760:19; 1761:01; 1762:09; 1782:12
CX0007	Email from Todd Engle to Chris Mengler, Larry Hsu, Chuck Hildenbrand, et al. re: Quarterly Launch Planning Meeting May 20, 2010 Agenda Materials w/Attach: QLPM 052010.doc	5/20/2010	IMPAX-OPANA-CID00002150	IMPAX-OPANA-CID00002155	GX0007; GX0107	JX-002			
CX0008	Email from Chris Mengler to Todd Engle, Larry Hsu, Meg Snowden re: Mengler Board Slides	5/14/2010	IMPAX-OPANA-CID00006693	IMPAX-OPANA-CID00006694	GX0008; GX0105; RX-329	JX-002			Tr. 546:03
CX0009	Intentionally Not Used					N/A			
CX0010	Email from Todd Engle to Carole Ben-Maimon, Bryan Reasons, Larry Hsu, et al. re: Maximizing the Oxymorphone ER Opportunity	5/16/2013	IMPAX-OPANA-CID00019374	IMPAX-OPANA-CID00019374	GX0010	JX-002			
CX0011-CX0012	Intentionally Not Used					N/A			
CX0013	Email from Todd Engle to WIlliam Ball, rjh@rjhgroupinc.com, Joe Farkas re: Kaiser 60% off 65% off	2/1/2013	IMPAX-OPANA-CID00004335	IMPAX-OPANA-CID00004336	GX0013	JX-002		Ordered 10/23/2017	
CX0014	Email from Todd Engle to Shawn Fatholahi, Tom Ciampa, Carole Ben-Maimon re: Oxymorphone ER data for your review w/Attach: Graphs 07_17_13.xlsx; Oxymorphone ER weekly data 071213.xlsx	7/22/2013	IMPAX-OPANA-CID00005472	IMPAX-OPANA-CID00005477	GX0014	JX-002			
CX0015-CX0016	Intentionally Not Used					N/A			
CX0017	Email from Rowan D'Annibale to Todd Engle, Joyce de los Reyes re: Opana ER Peak Calculation Steering Committee Meeting w/Attach: IMPAX Prescription Sales and Quarterly Peak Calculations July 2010 - June 2012.xlsx	8/23/2012	IMPAX-OPANA-CID00005543	IMPAX-OPANA-CID00005546	GX0017	JX-002			
CX0018-CX0113	Intentionally Not Used					N/A			
CX0114	Email from Chris Mengler to Michael Nestor re: <no subject>	6/3/2010	IMPAX-OPANA-CID00011817	IMPAX-OPANA-CID00011818		JX-002		Ordered 10/23/2017	
CX0115-CX0116	Intentionally Not Used					N/A			
CX0117	Email from Chris Mengler to Meg Snowden re: ENDP: Endo Pharmaceuticals Agrees to Acquire Penwest Pharmaceuticals and Submits NDA for New Formulation of Long-Acting Oxymorphone Designed to be Crush-Resistant	8/10/2010	IMPAX-OPANA-CID00012004	IMPAX-OPANA-CID00012006	GX0117; RX-360	JX-002			
CX0118-CX0200	Intentionally Not Used					N/A			
CX0201	Email from Ted Smolenski to Joe Camargo, Kevin Sica, Todd Engle, et al. re: Opana ER forecast 1 of 1 w/Attach: Opana ER 1 of 1 forecast--2009-07-22.xls	7/23/2009	IMPAX-OPANA-CID00011906	IMPAX-OPANA-CID00011907	GX0201; RX-567	JX-002			
CX0202	Email from Ted Smolenski to Joe Camargo re: Opana ER forecast 1 of 1	7/30/2009	IMPAX-OPANA-CID00019479	IMPAX-OPANA-CID00019480	GX0202; RX-392	JX-002			
CX0203	Email from Chris Mengler to Ted Smolenski re: opana ER	11/13/2009	IMPAX-OPANA-CID00006922	IMPAX-OPANA-CID00006922	GX0203; GX0101	JX-002			
CX0204	Email from Todd Engle to Chris Mengler, Larry Hsu, Chuck Hildenbrand, et al. re: Meeting Minutes from the Feb 2, 2010 Quarterly Launch Planning Meeting w/Attach: launch planning 02 02 10 R 2Meeting Minutes.doc	2/6/2010	IMPAX-OPANA-CID00002191	IMPAX-OPANA-CID00002193	GX0204; GX0512; GX0102	JX-002			

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CX0205	Email from Ted Smolenski to Joyce De Los Reyes, Kevin Sica, Todd Engle, et al. re: Endo: One Deal Away from Being Interesting w/Attach: ENDP--UBS--2010-02-22.pdf	2/23/2010	IMPAX-OPANA-CID00020815	IMPAX-OPANA-CID00020832	GX0205; RX-396	JX-002			
CX0206	Email from Ted Smolenski to June Hughes re: Oxymne GM %	5/6/2010	IMPAX-OPANA-CID00018218	IMPAX-OPANA-CID00018218	GX0206	JX-002			
CX0207-CX0210	Intentionally Not Used					N/A			
CX0211	Email from Ted Smolenski to Meg Snowden, Chris Mengler, Huong Nguyen, et al. re: Impax - Endo w/Attach: Opana ER CAGR 2010-06-07.xlsx	6/7/2010	IMPAX-OPANA-CID00021881	IMPAX-OPANA-CID00021884	GX0211	JX-002			
CX0212-CX0213	Intentionally Not Used					N/A			
CX0214	Email from Ted Smolenski to Larry Hsu, Chris Mengler re: Research Notes - ENDO First Settlement for Generic Opana ER	2/23/2009	IMPAX-OPANA-CID00020833	IMPAX-OPANA-CID00020833	GX0214; RX-397	JX-002			
CX0215	Intentionally Not Used					N/A			
CX0216	Email from Ted Smolenski to Chris Mengler, David Berman re: opana ER	5/27/2010	IMPAX-OPANA-CID00006048	IMPAX-OPANA-CID00006048	GX0216; GX0110	JX-002			
CX0217	Email from Chris Mengler to Ted Smolenski re: Oxymorphone	6/2/2010	IMPAX-OPANA-CID00019449	IMPAX-OPANA-CID00019450	GX0217; GX0113; RX-389	JX-002			
CX0218	Email from Ted Smolenski to Chris Mengler re: No Subject	6/7/2010	IMPAX-OPANA-CID00019477	IMPAX-OPANA-CID00019477	GX0218; RX-391	JX-002			
CX0219	Email from Ted Smolenski to Larry Hsu, Art Koch re: opana ER	1/8/2011	IMPAX-OPANA-CID00003537	IMPAX-OPANA-CID00003538	GX0219	JX-002			
CX0220-CX0221	Intentionally Not Used					N/A			
CX0222	Email from Ted Smolenski to Kevin Sica, June Hughes, and Larry Kloss re: 5-year forecast 2010-May Update 2010--05- 14v5.xls w/Attach: 5-year forecast 2010-May Update 2010--05- 14v5.xls	5/15/2010	IMPAX-OPANA-CID00007067	IMPAX-OPANA-CID00007068	GX0222	JX-002			
CX0223-CX0300	Intentionally Not Used					N/A			
CX0301	FDA Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations, Application No N21610	9/24/2014	CX0301-001	CX0301-001	GX0301; GX0401	JX-002			Tr. 350:02; 350:05
CX0302	Email from Huong Nguyen to Art Koch, Meg Snowden, echoy@wsgr.com re: Draft Impax/Endo/Penwest Settlement and License Agreement w/Attach: Impax - Endo Settlement Agreement (Opana) [Execution Version].DOC	6/7/2010	IMPAX-OPANA-CID00007031	IMPAX-OPANA-CID00007057	GX0302; RX-338	JX-002			
CX0303	Case 2:09-cv-00831-KSH-PS: Complaint	11/15/2007	CX0303-001	CX0303-071	GX0303	JX-002			
CX0304	Case 2:09-cv-00832-KSH-PS: Complaint	1/25/2008	CX0304-001	CX0304-042	GX0304	JX-002			
CX0305	Case 2:09-cv-00833-KSH-PS: Complaint	7/25/2008	CX0305-001	CX0305-044	GX0305	JX-002			
CX0306	Intentionally Not Used					N/A			
CX0307	Case 2:09-cv-00832-KSH-PS: Answer, Affirmative Defenses and Counterclaims of Defendant Impax Laboratories, Inc.	2/19/2008	CX0307-001	CX0307-008	GX0307	JX-002			
CX0308	Case 2:09-cv-00833-KSH-PS: Answer, Affirmative Defenses and Counterclaims of Defendant Impax Laboratories, Inc.	8/19/2008	CX0308-001	CX0308-012	GX0308	JX-002			
CX0309	Email from Meg Snowden to Huong Nguyen re: Research Notes - ENDO First Settlement for Generic Opana ER w/Attach: ENDO - First Settlement for Generic Opana ER.pdf	2/23/2009	IMPAX-OPANA-CID00022178	IMPAX-OPANA-CID00022185	GX0309; RX-409	JX-002			
CX0310	Letter from Benedict Y. Hur to Jamie Towey and Maren Schmidt re: Opana Investigation and CID to Impax Laboratories, FTC File No. 1410004	9/5/2014	CX0310-001	CX0310-029	GX0310; GX0408	JX-002			
CX0311-CX0313	Intentionally Not Used					N/A			
CX0314	Email from Meg Snowden to Stephanie Hsieh, Huong Thien Nguyen, Don Anthony re: Generic new product launch projection 091808.xls w/Attach: Generic new product launch projection 091808.xls	9/19/2008	IMPAX-OPANA-CID00018229	IMPAX-OPANA-CID00018230	GX0314; GX0001	JX-002			
CX0315	Email from Meg Snowden to Todd Engle re: QLPM 050310 Draftmms w/Attach: QLPM 050310 Draftmms.doc	5/7/2010	IMPAX-OPANA-CID00001879	IMPAX-OPANA-CID00001883	GX0315	JX-002			
CX0316	Intentionally Not Used					N/A			
CX0317	Email from Meg Snowden to Chris Mengler re: t/c with Endo	5/18/2010	IMPAX-OPANA-CID00019431	IMPAX-OPANA-CID00019431	GX0317	JX-002			
CX0318-CX0319	Intentionally Not Used					N/A			

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CX0320	Email from Guy Donatiello to Chris Mengler, Meg Snowden, Alan Levin, et al. re: Highly Confidential - Rule 408 Settlement Communication w/Attach: Endo - Impax - Development Term Sheet (5-26-2010).DOC; Endo - Impax - Settlement Term Sheet(5-26-2010).docx	5/26/2010	IMPAX-OPANA-CID00001716	IMPAX-OPANA-CID00001726	GX0320; GX0403; GX0109; RX-276	JX-002			Tr. 427:04; 427:10; 488:23; 489:06
CX0321	Email from Alan Levin to Chris Mengler, Meg Snowden, Guy Donatiello re: Highly Confidential - Rule 408 Settlement Communication	5/30/2010	IMPAX-OPANA-CID00005952	IMPAX-OPANA-CID00005954	GX0321; GX0111	JX-002			Tr. 538:18; 538:20; 539:01
CX0322	Intentionally Not Used					N/A			
CX0323	Email from Guy Donatiello to Meg Snowden, Chris Mengler, Alan Levin, et al. re: <no subject> w/Attach: Draft Impax - Endo Settlement and License Agreement.DOC	6/4/2010	IMPAX-OPANA-CID00001693	IMPAX-OPANA-CID00001715	GX0323; GX0409; GX1210; RX-275	JX-002			
CX0324	Email from Eliot Choy to Alan Levin, Guy Donatiello, Martin Black, et al. re: Impax - Endo w/Attach: 639178_Result.rtf; Impax - Endo - Rider to Settlement Agreement_(PALIB1_3993057_1).DOC; Impax - Endo - Settlement Agreement_(PALIB1_3992129_3).DOC	6/5/2010	IMPAX-OPANA-CID00001738	IMPAX-OPANA-CID00001783	GX0324; GX0413; GX1812; RX-279	JX-002			Tr. 147:15
CX0325	Intentionally Not Used					N/A			
CX0326	Email from Alison Freeman-Gleason to Justin Watkins, Meg Snowden, Alan Levin, et al. re: Co-Promote Revisions w/Attach: Impax-Endo_Development_and_Co-Promotion_Agreement_final.pdf; et al.	6/7/2010	IMPAX-OPANA-CID00011838	IMPAX-OPANA-CID00011904	GX0326; GX0417; RX-357	JX-002			
CX0327	Email from Robert Cooper to Steve Mollichella, Guy Donatiello, Meg Snowden, et al. re: Upfront payment	6/24/2010	IMPAX-OPANA-CID00003054	IMPAX-OPANA-CID00003055	GX0327	JX-002			
CX0328	Email from Meg Snowden to Guy Donatiello re: Endo/Opana	10/7/2010	IMPAX-OPANA-CID00005749	IMPAX-OPANA-CID00005749	GX0328; RX-314	JX-002			
CX0329	Email from Meg Snowden to Guy Donatiello re: steering committee	12/16/2010	IMPAX-OPANA-CID00002274	IMPAX-OPANA-CID00002275	GX0329; RX-286	JX-002			
CX0330	Email from Guy Donatiello to Chris Mengler, Meg Snowden, Caroline Manogue re: Letter from Endo to Impax Labs w/Attach: img-Z27121156-0001.pdf	12/27/2012	IMPAX-OPANA-CID00012058	IMPAX-OPANA-CID00012060	GX0330; GX1214; GX1822; RX-361	JX-002			
CX0331	Letter from Margaret Snowden to Caroline Manogue re: Settlement and License Agreement of June 8, 2010 Made By and Among Endo Pharmaceuticals Inc., Penwest Pharmaceuticals Co., and Impax Laboratories, Inc.	1/3/2013	IMPAX-OPANA-CID00000322	IMPAX-OPANA-CID00000322	GX0331	JX-002			
CX0332	Email from Huong Nguyen to Guy Donatiello, Meg Snowden re: Settlement and License Agreement by Endo, Penwest, and Impax ("License Agreement") w/Attach: Copy of Endo Credit Calculation (2).xlsx; DOC.PDF	1/22/2013	IMPAX-OPANA-CID00005750	IMPAX-OPANA-CID00005765	GX0332; RX-315	JX-002			Tr. 387:12; 436:16; 490:19
CX0333	Email from Brad Lucas to Dacia Kutnyak, Accounts Receivable, Robin Rieben, et al. re: Endo Deposit - 04/18/2013 - $102,049,199.64	4/18/2013	IMPAX-OPANA-CID00000275	IMPAX-OPANA-CID00000277	GX0333	JX-002			
CX0334-CX0405	Intentionally Not Used					N/A			
CX0406	Email from Chris Mengler to Larry Hsu, Art Koch, Michael Nestor, et al. re: <no subject>	6/2/2010	IMPAX-OPANA-CID00019448	IMPAX-OPANA-CID00019448	GX0406	JX-002			
CX0407	Email from Art Koch to Chris Mengler, Larry Hsu, Chuck Hildenbrand, et al. re: Status	6/3/2010	IMPAX-OPANA-CID00011819	IMPAX-OPANA-CID00011820	GX0407; RX-356	JX-002			Tr. 543:15; 543:22
CX0408-CX0409	Intentionally Not Used					N/A			
CX0410	Email from Alan Levin to Art Koch, Guy Donatiello, Meg Snowden, et al. re: <no subject>	6/4/2010	IMPAX-OPANA-CID00001592	IMPAX-OPANA-CID00001596		JX-002			
CX0411	Email from Guy Donatiello to Meg Snowden, Art Koch, Alan Levin re: Revised Draft #2 w/Attach: #710157v3_BE01_ - Impax- Co-Promotion Agreement.DOC	6/4/2010	IMPAX-OPANA-CID00006365	IMPAX-OPANA-CID00006394	GX0408; RX-280	JX-002			
CX0412-CX0414	Intentionally Not Used					N/A			
CX0415	Email from Alan Levin to Art Koch, Meg Snowden, Larry Hsu, et al. re: Endo/Impax: R&D Collaboration	6/6/2010	IMPAX-OPANA-CID00001727	IMPAX-OPANA-CID00001728	GX0415; RX-277	JX-002			
CX0416	Email from Art Koch to Alan Levin, Meg Snowden, Guy Donatiello, et al. re: Gross Margin	6/6/2010	IMPAX-OPANA-CID00001815	IMPAX-OPANA-CID00001815	GX0416; GX0510; RX-281	JX-002			
CX0417	Intentionally Not Used					N/A			

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CX0418	Email from Thomas Rayski to Huong Nguyen, Guy Donatiello, Jennifer Saionz, et al. re: Draft Impax/Endo/Penwest Settlement and License Agreement w/Attach: Impax - Endo Settlement Agreement (Opana) [Execution Versioin].DOC: Redline.pdf	6/7/2010	IMPAX-OPANA-CID00001910	IMPAX-OPANA-CID00001960	GX0418	JX-002			
CX0419-CX0420	Intentionally Not Used					N/A			
CX0421	Email from Chuck Hildenbrand to Art Koch re: Impax: Inventory Carrying Value - June 30, 2010 - OXM w/Attach: Oxymorphone Expiration Dates	6/21/2010	IMPAX-OPANA-CID00008018	IMPAX-OPANA-CID00008025	GX0421; RX-345	JX-002			
CX0422	Email from Jennifer Hsu to Leslie Benet, Allen Chao, Art Koch, et al. re: BOD Monthly Update -- June 2010 - CONFIDENTIAL w/Attach: BOD Monthly Update June 2010 072310.doc	7/23/2010	IMPAX-OPANA-CID00018515	IMPAX-OPANA-CID00018542	GX0422	JX-002		Ordered 10/23/2017	
CX0423	Email from Mark Donohue to Chris Mengler, Larry Hsu, Art Koch, et al. re: Courtesy of Business Wire: - Endo, Penwest settle patent lawsuits over painkiller	6/8/2010	IMPAX-OPANA-CID00021058	IMPAX-OPANA-CID00021059	GX0423	JX-002			
CX0424	Intentionally Not Used					N/A			
CX0425	Impax Annual Report 2013: Focusing on Quality and Growth (December 31, 2013 SEC Form 10-K)	2/24/2014	CX0425-001	CX0425-157	GX0425	JX-002			Tr. 1206:09, 10, 14, 24; 1207:12
CX0426-CX0501	Intentionally Not Used					N/A			
CX0502	Email from Michael Nestor to Chris Mengler, Larry Hsu, Meg Snowden re: <no subject>	5/26/2010	IMPAX-OPANA-CID00019432	IMPAX-OPANA-CID00019432	GX0502; GX0108; GX0318	JX-002			
CX0503-CX0504	Intentionally Not Used					N/A			
CX0505	Email from Chris Mengler to Larry Hsu re: Mengler Board Slides	5/14/2010	IMPAX-OPANA-CID00007101	IMPAX-OPANA-CID00007102	GX0505; GX0104	JX-002			
CX0506	Email from Chris Mengler to Michael Nestor, Larry Hsu, Meg Snowden, et al. re: Today's Meeting	6/2/2010	IMPAX-OPANA-CID00019444	IMPAX-OPANA-CID00019445	GX0506; GX0112; GX0405	JX-002			Tr. 540:24; 541:24; 3031:09
CX0507	Email from Larry Hsu to Chris Mengler re: Status	6/4/2010	IMPAX-OPANA-CID00018248	IMPAX-OPANA-CID00018250	GX0507; GX0115	JX-002			
CX0508-CX0512	Intentionally Not Used					N/A			
CX0513	Email from Meg Snowden to Larry Hsu, Chris Mengler, Chuck Hildenbrand, et al. re: Oxymorphone ER Tablets Tentatively Approved Today!!	5/13/2010	IMPAX-OPANA-CID00018243	IMPAX-OPANA-CID00018243	GX0513; GX0419; GX0103; GX0313	JX-002			
CX0514	Email from Chris Mengler to Larry Hsu, Art Koch, Michael Nestor, et al. re: 5-year forecast 2010-May Update with Impax.xls w/Attach: 5-year forecast 2010-May Update with Impax.xls	5/16/2010	IMPAX-OPANA-CID00006712	IMPAX-OPANA-CID00006713	GX0514; GX0420; RX-330	JX-002			Tr. 49:24
CX0515	Email from Larry Hsu to Laura Bisbing, Jennifer Hsu re: Mengler Board Slides w/Attach: Mengler Board Presentation Aug10 080510b.ppt	8/8/2010	IMPAX-OPANA-CID00012917	IMPAX-OPANA-CID00012959	GX0515	JX-002		Ordered 10/23/2017	
CX0516	Intentionally Not Used					N/A			
CX0517	Email from Meg Snowden to Larry Hsu, Carole Ben-Maimon, Mark Donohue, et al. re: Letter from Endo to Impax Labs	12/29/2012	IMPAX-OPANA-CID00021673	IMPAX-OPANA-CID00021676	GX0517; RX-404	JX-002			
CX0518	Intentionally Not Used					N/A			
CX0519	Email from Carole Ben-Maimon to Larry Hsu re: Oxymorphone	1/5/2013	IMPAX-OPANA-CID00019290	IMPAX-OPANA-CID00019293	GX0519	JX-002			
CX0520	Intentionally Not Used					N/A			
CX0521	Impax Presentation: IMPAX Pharmaceuticals R&D Update	2/26/2014	IMPAX-OPANA-CID00019495	IMPAX-OPANA-CID00019542	GX0521	JX-002		Ordered 10/23/2017	
CX0522-CX1000	Intentionally Not Used					N/A			
CX1001	Endo Presentation: Corporate Development Update: Endo Board of Directors Meeting	2/24/2010	EPI000821205	EPI000821205	GX1001; RX-041	JX-002			Tr. 2580:17; 2580:19; 2580:22; 2581:15; 2581:21; 2582:05
CX1002	Endo Presentation: Corporate Development & Strategy Departmental Offsite	3/7/2010	EPI001305772	EPI001305772	GX1002	JX-002			Tr. 2582:16; 2582:19; 2582:22; 2583:08
CX1003-CX1004	Intentionally Not Used					N/A			
CX1005	Email from Vik Seoni to Nancy Wysenski, Robert Cobuzzi, Carolyn Kong, et al. re: Latest draft pick w/Attach: FP_Endo Strategic Opportunities_vFinal.PPT	5/30/2008	EPI001114983	EPI001114984	GX1005	JX-002			Tr. 2576:06; 2576:12; 2578:20; 2580:05
CX1006	Email from Robert Cobuzzi to Kevin Pong, Alan Butcher re: IPX66 w/Attach: IPX066_IMPAX_Partner_Confidential_032010_FINAL.PDF; ATT621896.htm: 066 Apr2010AAN poster final poster.ppt; ATT621898.htm	5/20/2010	EPI001433402	EPI001433505	GX1006; RX-068	JX-002			

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CX1007	Email from Robert Cobuzzi to Ernest Kopecky, Paula Clark, Frank Diana, et al. re: IPX066 w/Attach: 066 Apr2010AAN poster final poster.ppt; IPX066_IMPAX_Partner_Confidential_032010_FINAL.PDF	5/25/2010	EPI001445208	EPI001445307	GX1007; GX1703; RX-074	JX-002		Ordered 10/23/2017	Tr. 2547:06; 2590:11; 2590:13
CX1008	Email from Mark Bradley to Robert Cobuzzi re: Project Imperial	5/27/2010	EPI001433631	EPI001433638	GX1008; RX-071	JX-002			Tr. 2585:08; 2585:12; 2585:15; 2585:23; 2588:03; 2588:04; 2589:02; 2591:09; 2591:10
CX1009	Email from Allan Miller to Robert Cobuzzi, Ellen Bernstein, David Godolphin re: Data request w/Attach: Strategic Insights.ppt	5/26/2010	EPI001433613	EPI001433618	GX1009; RX-069	JX-002			
CX1010	Intentionally Not Used					N/A			
CX1011	Email from Alan Levin to Chris Mengler, Guy Donatiello, Robert Cobuzzi re: R&D Collaboration	6/2/2010	EPI000821991	EPI000821991	GX1011; RX-043	JX-002			
CX1012	Email from Robert Cobuzzi to Michael Nestor, Chris Mengler, Alan Levin re: R&D Contract?	6/4/2010	EPI000874111	EPI000874112	GX1012	JX-002			
CX1013	Endo Document: Imperial Opportunity Evaluation Worksheet (OEW) v6	6/7/2010	EPI001306066	EPI001306082	GX1013	JX-002			
CX1014	Endo Document: Imperial Opportunity Evaluation Worksheet (OEW) v10	6/8/2010	EPI001306083	EPI001306099	GX1014	JX-002			
CX1015	Email from Kevin Pong to Mark Bradley, Robert Cobuzzi re: GlaxoSmithKline gains rights to Impax's experimental Parkinson's disease therapy	12/17/2010	EPI001122284	EPI001122284	GX1015; GX1708; RX-058	JX-002			
CX1016	Endo Document: Development and Co-Promotion Agreement by and between Endo Pharmaceuticals Inc. and Impax Laboratories, Inc.	6/7/2010	EPI000821661	EPI000821693	GX1016	JX-002			
CX1017-CX1100	Intentionally Not Used					N/A			
CX1101	Email from Bob Barto to Tara Chapman re: documentation requested w/Attach: 20120103-Endo-NCH-DrugShortage (2).pdf	1/8/2013	EPI000033569	EPI000033578	GX1101	JX-002			Tr. 2601:05; 2601:07
CX1102	Email from Larry Romaine to Kathleen Cronshaw re: All field documents w/Attach: Endo Field Communication Letter_FAQ_ FINAL.pdf, Dear HCP Letter Endo FINAL.pdf, DearPharmacy Letter Endo Products FINAL.pdf, Dear Patient Letter Endo FINAL.pdf...	1/9/2012	EPI001065976	EPI001065991	GX1102	JX-002			
CX1103-CX1105	Intentionally Not Used					N/A			
CX1106	Email from Demir Bingol to Brian Lortie re: OPANA ER Strat. Plan w/Attach: 2010 OPANA Brand Strategic Plan-07-22-09.v7(Presentation).pptx	7/22/2009	EPI001167270	EPI001167271	GX1106; RX-061	JX-002			Tr. 2292:03; 2292:09; 2482:05; 2482:09; 2482:21; 2483:03; 2483:25
CX1107	Document: Declaration of Brian Lortie in Support of Plaintiff's Motion for Preliminary Injunction, Endo v. Actavis, Endo v. Roxane	8/5/2013	EPI001487796	EPI001488267	GX1107	JX-002		Ordered 10/20/2017	
CX1108	Email from Demir Bingol to Robert Prachar and Brian Lortie re: Revopan BoD slides w/Attach: Revopan BoD Slides-11-16-10.pptx	11/16/2010	EPI000189454	EPI000189455	GX1108	JX-002			Tr. 2451:01; 2451:02; 2451:07; 2451:22; 2453:07
CX1109	Intentionally Not Used					N/A			
CX1110	Memo from Brian Lortie to Endo Health Solutions Board of Directors re: Endo Pharmaceuticals Business Unit Performance Update	6/26/2013	EPI000003693	EPI000003696	GX1110	JX-002		Ordered 10/20/2017	
CX1111	Email from Kevin OBrien to Brian Lortie and Kevin OBrien re: Actavis Generic OER w/Attach: OXYMORPHONE ACTAVIS ANALYSOURCE.xlsx	9/24/2013	EPI000427933	EPI000427935	GX1111	JX-002			
CX1112-CX1200	Intentionally Not Used					N/A			
CX1201	FDA Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations: Application No N020612	9/24/2014	CX1201-001	CX1201-001	GX1201; GX1229	JX-002			
CX1202	Intentionally Not Used					N/A			
CX1203	Email from Martin Black to Stephen Hash, Guy Donatiello re: Opana w/Attach: Document.pdf	2/20/2009	EPI000872253	EPI000872274	GX1203; RX-049	JX-002		Ordered 10/20/2017	
CX1204	Intentionally Not Used					N/A			
CX1205	FDA: Oxymorphone Hydrochloride, ANDA no. 079087 Approval History	9/24/2014	CX1205-001	CX1205-003	GX1205; GX1803	JX-002			
CX1206	Email from Robert Cobuzzi to Guy Donatiello, Alan Levin, Roberto Cuca, et al. re: IPX066 w/Attach: DATA LIST.docd; ATT808802.htm	5/22/2010	EPI001588123	EPI001588132	GX1206	JX-002			
CX1207	Intentionally Not Used					N/A			

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CX1208	Email from Robert Cobuzzi to Dave Holveck, Alan Levin, Caroline Manogue, et al. re: Imperial OEW w/Attach: 052810 Imperial OEW v5.docx	6/1/2010	EPI001448405	EPI001448421	GX1208: GX1010; GX1416	JX-002			Tr. 2593:06; 2593:08; 2594:06; 2594:15; 2595:12
CX1209	Email from Robert Cobuzzi to rkimmel@ny.rothinc.com, JohnJDelucca@aol.com, Dave Holveck, et al. re: License with Impax Completed w/Attach: Imperial OEW final.docx	6/8/2010	EPI001448440	EPI001448457	GX1209; RX-077	JX-002		Ordered 10/23/2017	Tr. 1088:12, 13, 19, 23; 1089:06; 1122:05; 1161:06; 2549:10; 2609:12; 2609:19; 2610:01; 2611:20; 2613:13; 2616:14; 2617:21; 2618:10; 2618:22; 2622:07
CX1210-CX1212	Intentionally Not Used					N/A			
CX1213	Case 2:09-cv-00831-KSH-PS: Answer, Affirmative Defenses, Counterclaim and Prayer for Relief of Defendant Impax Laboratories, Inc.	12/20/2007	CX1213-001	CX1213-008	GX1213; GX0306	JX-002			
CX1214	Intentionally Not Used					N/A			
CX1215	Email from Linda Marchione to Guy Donatiello re: Impax Letter dated 1-3-2013 from Margaret Snowden in response to Caroline Manogue's 12-27-2012 Letter w/Attach: Impax Letter dated 1-3-2013 from Margaret Snowden in response to Caroline Manogue's 12-27-2012	1/4/2013	EPI000184308	EPI000184309	GX1215	JX-002			
CX1216	Email from Paula Schiavo to Alan Levin re: Approvals Needing your request w/Attach: To Do: Approval for END-110793-IMPAX LABORATORIES INC Invoice; IMPAX.pdf; To Do: Approval for END-101855-NOVARTIS CONSUMER HEALTH INC. Invoice; ROYALTIES.pdf	4/15/2013	EPI001912283	EPI001912305	GX1216	JX-002			
CX1217	Email from Nancy Olson to Alan Levin, Caroline Manogue, Julie McHugh, et al. re: Executive Pricing Committee Meeting w/Attach: Mycophenolate Mofetil Price A Pricing 6.3.10.pdf: Oxymorphone ER Price Proposal Summary 06-02-10.pdf	5/14/2010	EPI000193074	EPI000193078	GX1217; GX1315	JX-002			
CX1218	Endo Document: Highlights of Opana ER Prescribing Information	5/00/2013	EPI000000451	EPI000000539	GX1218; GX2507; RX-006	JX-002			
CX1219	FDA Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations, Application No N201655	9/24/2014	CX1219-001	CX1219-001	GX1219	JX-002			
CX1220	Email from Tara Chapman to maryann.holovac@fda.hhs.gov, lisa.basham@fda.hhs.gov re: Request to move Opana ER NDA 21-610 to the Orange Book Discontinued List	5/31/2012	EPI000027305	EPI000027305	GX1220; GX2506; RX-008	JX-002			
CX1221-CX1222	Intentionally Not Used					N/A			
CX1223	Email from Bob Barto to Alan Minsk re: Complaint Filed w/Attach: Endo -- Complaint with ECF Header.PDF.PDF; Memorandum in Support of Motion for PI.pdf.pdf	12/3/2012	EPI000754087	EPI000754146	GX1223; GX2508	JX-002			
CX1224	Facsimile from FDA/Office of Regulatory Policy (ORP) to Robert Barto re: Citizen Petition Response (FDA-2012-P-0895)	5/10/2013	EPI000337189	EPI000337198	GX1224	JX-002			
CX1225-CX1300	Intentionally Not Used					N/A			
CX1301	Response of Endo Pharmaceuticals Inc. to Civil Investigative Demands Issued on February 20, 2014 and March 25, 2014	8/11/2014	CX1301-001	CX1301-131	GX1204; GX1301; GX1302; GX1802	JX-002			
CX1302-CX1304	Intentionally Not Used					N/A			
CX1305	Email from Chris Mengler to Alan Levin re: Highly Confidential - Rule 408 Settlement Communication	5/27/2010	EPI000874042	EPI000874043	GX1305; RX-050	JX-002			
CX1306	Email from Roberto Cuca to Alan Levin re: Highly Confidential - Rule 408 Settlement Communication	5/31/2010	EPI001379213	EPI001379216	GX1306	JX-002			
CX1307	Email from Blaine Davis to Dave Holveck, Alan Levin, Jonathan Neely re: Impax Laboratories Receives Tentative FDA Approval for Generic Opana(R) ER 5, 7.5, 10, 15, 20, 30, and 40 mg Tablets	5/14/2010	EPI001688556	EPI001688557	GX1307	JX-002			
CX1308	Email from Alan Levin to Chris Mengler re: <no subject>	6/3/2010	EPI000874166	EPI000874166	GX1308; RX-053	JX-002			
CX1309-CX1310	Intentionally Not Used					N/A			
CX1311	Email from Alan Levin to Dave Holveck re: It's not over till the fat lady sings.....	6/4/2010	EPI002155322	EPI002155322	GX1311; GX1404; RX-124	JX-002			

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Exhibit No.	Description	Date	BegBates	EndBates	Also Referenced As	Admissibility	Purpose/Notes	*In Camera*	Trial Transcript Citation
CX1312-CX1313	Intentionally Not Used					N/A			
CX1314	Email from Roberto Cuca to Alan Levin re: <no subject>	6/1/2010	EPI000873999	EPI000873999	GX1314	JX-002			Tr. 659:11
CX1315	Intentionally Not Used					N/A			
CX1316	Email from Julie McHugh to Alan Levin, Denise Craig, Nancy Olson re: Two Documents for EPC Today at 4:30 w/Attach: FW: Approval Requested - Oxymorphone ER Pricing; FW: Approval Requested - Oxymorphone ERPricing	6/7/2010	EPI001688928	EPI001688930	GX1316	JX-002			
CX1317	Intentionally Not Used					N/A			
CX1318	Email from Cindy Cary to Dave Holveck re: Three Year Forecast for Compensation Discussion at 3 pm w/Attach: Three Year Company Total--OPANA-TRF scenarios (2).xlsx; Three Year Plan 2010 (3).xlsx	2/9/2010	EPI001683075	EPI001683077	GX1318; GX1413	JX-002			
CX1319	Intentionally Not Used					N/A			
CX1320	Email from Nancy Santilli to Alan Levin, Dave Holveck, Robert Cobuzzi, et al. re: Updated Three Year Forecast 2010-2012 w/Attach: Three Year Plan 2010 Final.xlsx	2/11/2010	EPI001685460	EPI001685461	GX1320	JX-002			
CX1321	Email from Alan Levin to Nancy Santilli re: Updated Three Year Forecast 2010-2012	2/11/2010	EPI001685465	EPI001685465	GX1321	JX-002			
CX1322-CX1402	Intentionally Not Used					N/A			
CX1403	Email from Dave Holveck to Alan Levin re: Impax--Status Update	6/1/2010	EPI001688723	EPI001688723	GX1403; RX-097	JX-002			
CX1404	Intentionally Not Used					N/A			
CX1405	Email from Alan Levin to Dave Holveck re: Impax--Status Update (Monday morning)	6/7/2010	EPI000874099	EPI000874099	GX1405	JX-002			
CX1406-CX1413	Intentionally Not Used					N/A			
CX1414	Email from Dave Holveck to Alan Levin re: No Subject	5/17/2010	EPI000873965	EPI000873965	GX1414	JX-002			
CX1415-CX1700	Intentionally Not Used					N/A			
CX1701	Email from Robert Cobuzzi to Brian Lortie, Richard Dudek, Daniel Carbery, et al. re: Corp Dev Update 29Jul2010.ppt w/Attach: Corp Dev Update 29Jul2010.ppt	7/30/2010	EPI000189176	EPI000189177	GX1701	JX-002			Tr. 2568:16; 2568:25; 2569:25; 2570:16
CX1702-CX1703	Intentionally Not Used					N/A			
CX1704	Email from Kevin Pong to Robert Cobuzzi, Alan Butcher re: Imperial OEW w/Attach: 052110 Imperial OEW v1.docx	5/24/2010	EPI001433673	EPI001433681	GX1704	JX-002			
CX1705	Email from Kevin Pong to Mark Bradley, Robert Cobuzzi re: Imperial OEW w/Attach: 052810 Imperial OEW v2.docx	5/28/2010	EPI001433659	EPI001433668	GX1705	JX-002			
CX1706	Endo Document: Imperial Opportunity Evaluation Worksheet (OEW)_v4	5/28/2010	EPI001643881	EPI001643897	GX1706	JX-002			
CX1707	Endo Document: Imperial Opportunity Evaluation Worksheet (OEW) final	6/8/2010	EPI001644520	EPI001644537	GX1707	JX-002		Ordered 10/23/2017	
CX1708	Intentionally Not Used					N/A			
CX1709	Endo Document: Paris OEW 073010 v4	7/30/2010	EPI001941235	EPI001941243	GX1709	JX-002			
CX1710-CX1812	Intentionally Not Used					N/A			
CX1813	Email from Guy Donatiello to Jennifer Saionz, Thomas Rayski, Meg Snowden, et al. re: Impax - Endo w/Attach: Impax - Endo - Settlement Agreement (060710 740pm).DOC	6/7/2010	IMPAX-OPANA-CID00001439	IMPAX-OPANA-CID00001465	GX1813; EPI000593974	JX-002			
CX1814	Intentionally Not Used					N/A			
CX1815	Email from Eliot Choy to Huong Nguyen, Meg Snowden, Jennifer Saionz re: Endo Signature Pages w/Attach: ATT00001.htm; ATT00002.htm; Co-Promote Agmt - Endo Sig Page.pdf; Settlement Agmt - Endo Sig Page.pdf	6/8/2010	IMPAX-OPANA-CID00022190	IMPAX-OPANA-CID00022193	GX1815; EPI000183779	JX-002			
CX1816	Email from Guy Donatiello to Meg Snowden, Christopher Mengler, Robert Cobuzzi re: email address w/Attach: Endo Pharmaceuticals Inc. 10-13-2009.pdf	5/19/2010	EPI000828076	EPI000828079	GX1816; RX-317	JX-002			Tr. 455:15
CX1817	Intentionally Not Used					N/A			

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Exhibit No.	Description	Date	BegBates	EndBates	Also Referenced As	Admissibility	Purpose/Notes	*In Camera*	Trial Transcript Citation
CX1818	Email from Guy Donatiello to Edward Sweeney re: <no subject> w/Attach: Impax Laboratories, Inc.-Development&Co-PromotionAgmtJun10.pdf; Emailing: Impax Laboratories, Inc.-Development&Co-PromotionAgmtJun10.pdf	6/24/2010	EPI000874308	EPI000874343	GX1818	JX-002			
CX1819	Email from Steve Mollichella to Robert Cooper, Guy Donatiello, Meg Snowden, et al. re: Upfront payment	6/24/2010	EPI000874347	EPI000874348	GX1819	JX-002			
CX1820	Intentionally Not Used					N/A			
CX1821	Email from Guy Donatiello to Meg Snowden re: steering committee	12/16/2010	EPI001380387	EPI001380388	GX1821	JX-002			
CX1822-CX2503	Intentionally Not Used					N/A			
CX2504	Email from Bob Barto to Lizhuo Nouaime re: Action letter for NDA 201655 w/Attach: Complete Reponse Letter FINAL.pdf	1/10/2011	EPI000078096	EPI000078101	GX2504; RX-009	JX-002			
CX2505	Email from Tara Chapman to Ivan Gergel, Bob Barto, and Paula Clark re: OPANA ER - APPROVAL LETTER w/Attach: NDA 201655 APPROVAL letter with attachments.pdf	12/9/2011	EPI000080293	EPI000080385	GX2505; RX-010	JX-002			
CX2506-CX2518	Intentionally Not Used					N/A			
CX2519	Presentation: Opana ER Financial Scenario Overview	4/22/2013	EPI000003937	EPI000003943		JX-002			
CX2520	Document: Endo Pharmaceuticals EOC Meeting, Brian Lortie	1/14/2011	EPI000004460	EPI000004631		JX-002			
CX2521-CX2522	Intentionally Not Used					N/A			
CX2523	Email from John Kranyak to Alicia Logan re: RE: Christine Crooks Contact Info w/Attach: OPANA ER Growth Project MR Plan summary deck.pptx, Microsott_Excel_Worksheet1 .xlsx, Microsoft_Excel_Worksheet2.xlsx	7/12/2011	EPI000187180	EPI000187184		JX-002			
CX2524	Email from Brian Lortie to Mark Bradley, Julie McHugh, and Roberto Cuca re: Data request	6/7/2010	EPI000192445	EPI000192457	RX-018	JX-002			
CX2525	Intentionally Not Used					N/A			
CX2526	Email from Chris Mengler to Alan Levin re: Highly Confidential - Rule 408 Settlement Communication	5/27/2010	EPI000874038	EPI000874039		JX-002			
CX2527	Email from Alan Levin to Mark Bradley and Karen Adler re: Impax Update	6/4/2010	EPI000874049	EPI000874049	RX-051	JX-002			
CX2528	Presentation: Revopan Launch Readiness Review	12/16/2010	EPI001538172	EPI001538172		JX-002		Ordered 10/20/2017	
CX2529	Endo Presentation: Opana ER Strategic Platform: Chronic Pain	9/00/2012	EPI000000240	EPI000000303		JX-002			
CX2530	Email from Tara Chapman to Demir Bingol, Bob Barto, Diana Frank, et al. re: EN3288 Review-05-5-10 TC.pptx w/Attach: EN3288 Review-05-5-10 TC.pptx	5/5/2010	EPI000069099	EPI000069100		JX-002			
CX2531	Email from Mark Bradley to Alan Levin, Karen Adler re: Imperial: Counter Offer Considerations	6/5/2010	EPI001688790	EPI001688795		JX-002			
CX2532	Email from Mark Bradley to Alan Levin, Karen Adler, Robert Cobuzzi re: Endo/Impax: R&D Collaboration	6/6/2010	EPI002156059	EPI002156061	RX-125	JX-002			
CX2533	Email from Julie McHugh to Robert Cobuzzi, Alan Levin, Karen Adler, et al. re: Information requested	6/5/2010	EPI002156071	EPI002156074	RX-126	JX-002			
CX2534	Email from Alan Levin to Robert Cobuzzi re: <no subject>	6/6/2010	EPI002156093	EPI002156095		JX-002			Tr. 2605:24; 2606:03; 2606:09
CX2535	Email from Todd Engle to Kevin Sica re: BOD Slides Aug 2012 - Rev 4 Todd.pptx w/Attach: BOD Slides Aug 2012 - Rev 4 Todd.pptx	11/5/2012	IMPAX-OPANA-CID00013814	IMPAX-OPANA-CID00013849		JX-002			
CX2536	Email from Todd Engle to Susan Ostrander re: BOD Slides Feb 2013.pptx w/Attach: BOD Slides Feb 2013.pptx	2/5/2013	IMPAX-OPANA-CID00014814	IMPAX-OPANA-CID00014842		JX-002			
CX2537	Email from Todd Engle to Susan Ostrander re: Todd's Board Slides February 2014 V4.pptx w/Attach: Todd's Board Slides February 2014 V4.pptx	2/7/2014	IMPAX-OPANA-CID00015721	IMPAX-OPANA-CID00015759		JX-002			
CX2538	Email from Susan Ostrander to Todd Engle, Carole Ben-Maimon re: Updated Slides for 7/9/13 Board Presentation w/Attach: July 2013 Board Presenation (2).ppt	7/8/2013	IMPAX-OPANA-CID00016426	IMPAX-OPANA-CID00016454		JX-002			
CX2539	Email from Laura Zhu to Michael Nestor, David Paterson re: Frova, Endo w/Attach: Opana_Sales.xls	1/18/2009	IMPAX-OPANA-CID00022154	IMPAX-OPANA-CID00022156	RX-407	JX-002			

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Exhibit No.	Description	Date	BegBates	EndBates	Also Referenced As	Admissibility	Purpose/Notes	*In Camera*	Trial Transcript Citation
CX2540	Email from Ted Smolenski to Joyce De Los Reyes, David Berman, Meg Snowden, et al. re: ENDP US: Endo Pharmaceuticals Holdings Inc: Tidbits from management meet... w/Attach: mbull.gif; spacer.gif	12/4/2009	IMPAX-OPANA-CID00022170	IMPAX-OPANA-CID00022171	RX-408	JX-002			Tr. 570:16
CX2541	Intentionally Not Used					N/A			
CX2542	Email from Mark Shaw to John Anthony, Chuck Hildenbrand, Joe Camargo re: Impax requested a revised 2010 Oxymorphone Quota	6/10/2010	IMPAX-OPANA-CID00022358	IMPAX-OPANA-CID00022358		JX-002			
CX2543	Case 1:12-cv-01936-RBW: Declaration of Julie H. McHugh in Support of Plaintiff's Motion for Preliminary Injunction and Opposition to Defendants' Motions to Dismiss	12/14/2012	IMPAX-OPANA-CID00022780	IMPAX-OPANA-CID00022784		JX-002			
CX2544	Intentionally Not Used					N/A			
CX2545	Email from Larry Hsu to Richard Ting, Mark Donohue, Carole Ben-Maimon, et al. re: Endo Pharma. (ENDP, BUY): Another Hurdle for Generic Opana - No RLD	6/27/2012	IMPAX-OPANA-CID00023482	IMPAX-OPANA-CID00023485		JX-002			
CX2546-CX2547	Intentionally Not Used					N/A			
CX2548	Impax Spreadsheet: Lot Assignments Final 111711 12/1/2014	12/1/2014	IMPAX-OPANA-CID00024582	IMPAX-OPANA-CID00024582		JX-002			
CX2549	Email from Kent Summers to Mark Rubino, Steve Camper re: Roles, AEs - HFSs w/Attach: OM - HOPE launch plans v11AEs.pptx	10/27/2010	EPI000327296	EPI000327297		JX-002			
CX2550	Email from Debbie Travers to Demir Bingol, Art Vrecenak, Tara Chapman, et al. re: EN3288 Prep for May 10th ELC meeting w/Attach: EN3288 Review-04-28-10 DT comments.pptx	4/29/2010	EPI000130110	EPI000130112		JX-002			
CX2551	Endo Presentation: Opana ER: Host Meeting, 03/14/11	3/14/2011	EPI000289754	EPI000289754		JX-002		Ordered 10/20/2017	
CX2552	Email from Demir Bingol to Cassie Mapp, Chad Simon, Linda Wyse re: Oxymorphone Situation Analysis w/Attach: EN3288-05-17-10.pptx; Microsoft_Office_Excel_97-2003_Worksheet2.xls; Microsoft_Office_Excel_97-2003_Worksheet1.xls	5/19/2010	EPI000314303	EPI000314306		JX-002			
CX2553	Endo Presentation: Oxymorphone Franchise Business Plan 2011 thru 2021	6/8/2010	EPI000292190	EPI000292190		JX-002		Ordered 10/20/2017	
CX2554	Email from Alyssa Dicker to TJ Fuller, Matthew Wieman, Rob Gatley, Rose Wessells, et al. re: RESPONSE REQUESTED - Opana Monograph for MARC w/Attach: Opana_Mono_022112 for MARC.pdf	2/21/2012	EPI000060051	EPI000060137		JX-002			
CX2555	Endo Presentation: Opana ER: Protect and Grow Strategy	12/28/2012	EPI000003964	EPI000003975		JX-002			
CX2556	Email from Darnell Turner to Alicia Logan re: Grunenthal floor prices w/Attach: GRT Floor Price Analysis.xlsx	8/26/2010	EPI000186709	EPI000186713		JX-002			
CX2557	Email from Mark Bradley to James Bradley re: EN3288/OPANA ER scenario follow up w/Attach: Topline EN3288 Forecast-06-28-10 scenarios v2.xlsx	6/30/2010	EPI000315082	EPI000315086	RX-031	JX-002			
CX2558	Endo Presentation: Opana® ER (oxymorphone HCl) Extended-Release tablets, CIIWith INTAC® Technology	10/00/2012	EPI000419710	EPI000419710		JX-002			
CX2559-CX2560	Intentionally Not Used					N/A			
CX2561	Email from Ted Smolenski to Michelle Wong, Richard Ting, Meg Snowden, et al. re: Generic new product launch projection.031808.xls w/Attach: Generic new product launch projection.031808.xls	3/18/2008	IMPAX-OPANA-CID00014243	IMPAX-OPANA-CID00014244		JX-002			
CX2562	Email from Larry Hsu to Michael Nestor, Suneel Gupta, Shawn Fatholahi, et al. re: 2010 Company Key Goals - Confidential Information - Please do not distribute w/Attach: 2010 company key golas.doc	2/28/2010	IMPAX-OPANA-CID00020838	IMPAX-OPANA-CID00020841		JX-002			Tr. 250:08; 251:20
CX2563	Email from Kangwen Lin to Andrew Fox, Art Koch, Chris Mengler, et al. re: Generic meeting update - operation activities for 6/15 meeting w/Attach: OA for Generic meeting June 15.doc	6/15/2010	IMPAX-OPANA-CID00023206	IMPAX-OPANA-CID00023208		JX-002			
CX2564	Email from Mark Bradley to Roberto Cuca, David Macera, and Karen Adler re: 10 Year Outlook - New v4.xls w/Attach: 10 Year Outlook - New v4.xls	3/23/2010	EPI000180093	EPI000180094	RX-012	JX-002			
CX2565	Intentionally Not Used					N/A			

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CX2566	Email from Andy Gesek to Alan Levin, Roberto Cuca, Jack Boyle re: 2013 Apr LBE AG Version.pptx w/Attach: 2013 Apr LBE AG Version.pptx	4/17/2013	EPI000342149	EPI000342150		JX-002			
CX2567	Email from Alan Levin to Roberto Cuca re: Impax - Endo w/Attach: Redline - Impax-Endo Settlement and License Agreement.pdf; Draft Impax - Endo SettlementAgreement (Opana) [Endo Markup] (3).DOC	6/7/2010	EPI001588988	EPI001588937		JX-002			
CX2568-CX2569	Intentionally Not Used					N/A			
CX2570	Document: Impax Strategy for Opana ER	6/27/2012	EPI000003426	EPI000003430		JX-002			
CX2571	Email from Debbie Travers to Kristin Livingston, Beth Aranilla, Tracy Wilson, et al. re: Slides for Opana R&D Project Review w/Attach: Opana Project Review June 08.ppt	6/4/2008	EPI000091510	EPI000091511		JX-002			
CX2572	Email from Linda Kitlinkski to ClinEd re: QBR DRAFT Slides - Opana Brad w/Attach: OPANA Brand QBR-01-30-09.v6.ppt	2/10/2009	EPI000210720	EPI000210721		JX-002		Ordered 10/20/2017	
CX2573	Presentation: EN3288 Commercial Update, Demir Bingol	2/24/2010	EPI000290472	EPI000290472		JX-002			Tr. 1297:13; 1297:14; 1297:24; 1298:01; 1298:08; 1298:15
CX2574	Intentionally Not Used					N/A			
CX2575	Email from Demir Bingol to Tara Chapman, Bob Barto, Diana Frank, and William Fiske re: EN3288 Review-05-5-10 TC.pptx w/Attach: EN3288 Review-05-05-10.v2.pptx	5/6/2010	EPI000631980	EPI000631981		JX-002			
CX2576	Email from Demir Bingol to Kayla Kelnhofer re: No Subject	2/11/2010	EPI000914419	EPI000914421		JX-002			
CX2577	Email from Doug Azzalina to Javier Avalos, Robert Candea, Steven Cooper, and Demir Bingol re: oxymorphone ER AG data request	5/24/2010	EPI000950429	EPI000950430		JX-002		Ordered 10/20/2017	
CX2578	Presentation: OPANA Brand LCM Update	12/11/2007	EPI001296881	EPI001296881		JX-002			
CX2579	Email from David Macera to Chuck Williams and Derek Elphick re: 10 Yr Plan - Revenue Forecast w/Attach: 10 Yr Revenue for Forecast Team v01 121611.xlsx	12/16/2011	EPI001434343	EPI001434344		JX-002			
CX2580	Presentation: EN3288 Launch Scenarios	2/2/2010	EPI001540148	EPI001540148		JX-002			
CX2581	Document: OPANA Lifecycle Management Team Meeting Highlights	2/2/2010	EPI001540841	EPI001540844		JX-002			
CX2582	Email from Demir Bingol to Laurel McDermott re: Slides for EOC w/Attach: EN3288 Strategic Options-06-24-10 v.4.pptx	6/25/2010	EPI001553464	EPI001553465		JX-002			
CX2583	Email from Mark Bradley to Alan Levlin, Julie McHugh, and Karen Adler re: RAP w/Attach: Microsoft_Office_Excel_Worksheet4.xlsx, Microsoft_Office_Excel_97-2003_Worksheet2.xls, Microsoft_Office_Word_Document3.docx, Microsoft_Office_Word_Document6.docx...	10/27/2010	EPI001694497	EPI001694520		JX-002			
CX2584	Email from Alison Freeman-Gleason to Meg Snowden, Michael Nestor, Shawn Fathlahi, et al. re: co-promotion agreement w/Attach: ST-#2537506-v2-Endo_co-promotion_agreement.DOC, ST-#2537507-v1-WS_comparison_Endo_co-promotion_agreement_6_June_10.DOC	6/6/2010	IMPAX-OPANA-CID00001619	IMPAX-OPANA-CID00001682	RX-274	JX-002			
CX2585-CX2593	Intentionally Not Used					N/A			
CX2594	Email from Shawn Fatholahi to Todd Engle and Carole Ben-Maimon re: Actavis' Generic Opana ER Receives FDA Approval	7/15/2013	IMPAX-OPANA-CID00007188	IMPAX-OPANA-CID00007190	RX-339	JX-002			
CX2595-CX2600	Intentionally Not Used					N/A			
CX2601	Email from Shawn Fatholahi to Michael Nestor re: FROVA Rough S&M Analysis w/Attach: Frova Prelim. Opp. Analysis January 2009	1/20/2009	IMPAX-OPANA-CID00020102	IMPAX-OPANA-CID00020107		JX-002		Ordered 10/23/2017	
CX2602-CX2606	Intentionally Not Used					N/A			
CX2607	Declaration of Brian Lortie in Support of Plaintiff's Motion for Preliminary Injunction, Endo Pharmaceuticals Inc v. Actavis Inc. and Actavis South Atlantic LLC, Endo Pharmaceuticals Inc v. Roxane Laboratories, Inc.	8/5/2013	EPI001456200	EPI001456223		JX-002		Ordered 10/20/2017	

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CX2608	Plaintiff-Appellant's Reply In Support of Motion for an Injunction Pending Trial, Endo Pharmaceuticals Inc. v. Actavis, Inc. and Actavis South Atlantic, LLC	9/27/2013	EPI001486613	EPI001487275		JX-002			
CX2609	Decalaration of Henry G. Grabowski, Ph. D. In Support of Plaintiff's Motion for Preliminary Injunction, Endo Pharmaceuticals Inc v. Actavis Inc. and Actavis South Atlantic LLC, Endo Pharmaceuticals Inc v. Roxane Laboratories, Inc.	8/5/2013	EPI001488515	EPI001488566		JX-002		Ordered 10/20/2017	
CX2610	Email from Christine Crooks to Demir Bingol re: Revopan Playbook--PLEASE REVIEW MONDAY w/Attach: 2352_abbnhl_revopan_plybkv_lo5.pptx	12/11/2010	EPI000319915	EPI000319916		JX-002			Tr. 1269:18; 1269:20; 1269:22; 1311:20
CX2611	Email from David Macera to Alan Levin and Karen Adler re: 10 Yr Plan w/Attach: 10 yr Outlook v7 Q3 2012 Case.pdf, 10 Yr Outlook v7 Q3 2013 Case.pdf, 10 yr Outlook v7 Base Case.pdf, 10 yr Outlook with Kansas v7.xlsx	3/21/2011	EPI001901990	EPI001902036		JX-002			
CX2612	Intentionally Not Used					N/A			
CX2613	Email from Todd Engle to Shawn Fatholahi re: Actavis' Generic Opana ER Receives FDA Approval w/Attach: Graphs 07_17_13.xls	8/21/2013	IMPAX-OPANA-CID00007908	IMPAX-OPANA-CID00007914	RX-343	JX-002			
CX2614-CX2615	Intentionally Not Used					N/A			
CX2616	Email from Guy Donatiello to Chris Mengler, Meg Snowden, Alan Levin, et al. re: Highly Confidential - Rule 408 Settlement Communication	5/26/2010	IMPAX-OPANA-CID00005625	IMPAX-OPANA-CID00005626	RX-311	JX-002			
CX2617-CX2624	Intentionally Not Used					N/A			
CX2625	Email from Michael Nestor to David Paterson re: IPX066	5/22/2010	IMPAX-OPANA-CID00006708	IMPAX-OPANA-CID00006711		JX-002			Tr. 3012:06; 3012:07; 3012:09; 3013:16; 3014:25
CX2626	Impax Document: Settlement and License Agreement	7/6/2010	Impax_Opana_PartIII_0000147	Impax_Opana_PartIII_0000172	RX-364	JX-002			Tr. 1926:13
CX2627	Impax Presentation: Board of Directors Meeting February 2010	2/00/2010	Impax_Opana_PartIII_0002024	Impax_Opana_PartIII_0002054	RX-150	JX-002		Ordered 10/23/2017	
CX2628	Impax Presentation: Board of Directors Meeting November 2009	11/11/2009	Impax_Opana_PartIII_0002055	Impax_Opana_PartIII_0002090	RX-151	JX-002		Ordered 10/23/2017	
CX2629	Impax Presentation: Board of Directors Meeting August 2010	8/00/2010	Impax_Opana_PartIII_0002152	Impax_Opana_PartIII_0002193		JX-002			
CX2630	Email from David Paterson to Robert Cobuzzi, Michael Nestor, Chris Mengler, et al. re: IPX066	5/21/2010	IMPAX-OPANA-CID00001683	IMPAX-OPANA-CID00001685		JX-002			
CX2631-CX2634	Intentionally Not Used					N/A			
CX2635	Email from Kevin Sica to Ted Smolenski re: Zorn Model Oxymorphone 03 12 10.xls w/Attach: Zorn Model Oxymorphone 03 12 10.xls	3/12/2010	IMPAX-OPANA-CID00007071	IMPAX-OPANA-CID00007072		JX-002			
CX2636	Email from Todd Engler to Chris Mengler re: Zorn Model Oxymorphone 03 11 10.xls w/Attach Zorn Model Oxymorphone 03 11 10.xls	3/11/2010	IMPAX-OPANA-CID00007123	IMPAX-OPANA-CID00007124		JX-002			
CX2637	Intentionally Not Used					N/A			
CX2638	Email from Kimberly Kam to Steve Mollichella, Laura Bisbing, Meg Snowden re: Co-Promote Revisions w/Attach: Endo Pharmaceuticals Inc._Penwest Pharmaceuticals Settlement and License Agt 6-08-2010.pdf; Endo Pharmaceuticals Inc. Development and Co_Promotion	7/6/2010	IMPAX-OPANA-CID00012071	IMPAX-OPANA-CID00012132	RX-363	JX-002			
CX2639-CX2644	Intentionally Not Used					N/A			
CX2645	Email from Todd Engle to Carole Ben-Maimon re: Teledetailing Campaign for Oxymorphone ER	11/27/2013	IMPAX-OPANA-CID00005411	IMPAX-OPANA-CID00005411	RX-308	JX-002			
CX2646	Email from Shawn Fatholahi to Carole Ben-Maimon, Todd Engle re: Actavis' Generic Opana ER Receives FDA Approval	7/15/2013	IMPAX-OPANA-CID00007217	IMPAX-OPANA-CID00007219	RX-341	JX-002			
CX2647	Intentionally Not Used					N/A			
CX2648	Email from Todd Engle to Bill Riker re: Carole's Board Slides February 2013 V6 2.pptx	4/17/2013	IMPAX-OPANA-CID00012705	IMPAX-OPANA-CID00012746		JX-002			
CX2649-CX2651	Intentionally Not Used					N/A			
CX2652	Email from Kevin Sica to Todd Engle, Carole Ben-Maimon re: Plan Update w/Attach: 2014 5 Year Plan Presentation 10151.pptx; Plan with Sept 13 Forecast Update for Kloss V3.xlsx	10/15/2013	IMPAX-OPANA-CID00015150	IMPAX-OPANA-CID00015162		JX-002		Ordered 10/23/2017	
CX2653	Intentionally Not Used					N/A			
CX2654	Email from Carole Ben-Maimon to Joanne Tempone, Bryan Reasons re: Endo Deal	11/13/2012	IMPAX-OPANA-CID00019027	IMPAX-OPANA-CID00019029	RX-382	JX-002			
CX2655	Intentionally Not Used					N/A			

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Exhibit No.	Description	Date	BegBates	EndBates	Also Referenced As	Admissibility	Purpose/Notes	*In Camera*	Trial Transcript Citation
CX2656	Document: Q1 2013 Impax Laboratories Earnings Conference Call - Final	5/1/2013	CX2656-001	CX2656-014		JX-002			Tr. 1216:03, 05, 10, 15
CX2657	Document: Q2 2013 Impax Laboratories Earnings Conference Call - Final	8/8/2013	CX2657-001	CX2657-010		JX-002			
CX2658	Document: Q3 2012 Impax Laboratories Earnings Conference Call - Final	10/30/2012	CX2658-001	CX2658-014		JX-002			
CX2659	Document: Q3 2013 Impax Laboratories Earnings Conference Call - Final	11/4/2013	CX2659-001	CX2659-012		JX-002			
CX2660	Document: Q4 2012 Impax Laboratories Earnings Conference Call - Final	2/25/2013	CX2660-001	CX2660-017		JX-002			
CX2661	Intentionally Not Used					N/A			
CX2662	Email from Chris Mengler to Laura Bisbing, Larry Hsu, Art Koch, et al. re: Mengler Board Materials w/Attach: Tamsulosin Board May 2010 051310.ppt; BD for May BOD 051610.ppt; Mengler Board Presentation 051610.ppt	5/17/2010	IMPAX-OPANA-CID00018082	IMPAX-OPANA-CID00018105	RX-374	JX-002		Ordered 10/23/2017	Tr. 290:06; 335:02; 335:09; 335:12; 336:10; 336:14; 549:01; 549:03; 549:23; 550:04; 553:04
CX2663	Impax Document: Minutes of the Meeting of the Board of Directors of Impax Laboratories, Inc.	5/25/2010	Impax_Opana_PartIII_0002498	Impax_Opana_PartIII_0002498		JX-002		Ordered 10/23/2017	Tr. 256:14; 257:06; 257:09; 257:11; 280:09; 334:17; 334:19
CX2664	Email from Lisa Walker to Alicia Logan and Missy Combs re: EPC Document w/Attach: Oxymorphone Price Proposal-11-11-10.docx	11/14/2010	EPI000186499	EPI000186508		JX-002			
CX2665	Email from Demir Bingol to Brian Lortie re: Revopan Price Recommendation Document w/Attach: Oxymorphone Price Proposal-09-23-10.docx	9/29/2010	EPI000189249	EPI000189253		JX-002			
CX2666	Intentionally Not Used					N/A			
CX2667	Document: Oxymorphone Franchise Pricing Proposal for Revopan, OPANA ER and OPANA	1/5/2011	EPI000290639	EPI000290647		JX-002			
CX2668	Document: Price Change Proposal Summary Form 9.9% Price Increase for OPANA SKUs	2/2/2009	EPI000293419	EPI000293421		JX-002			
CX2669	Document: Price Change Proposal Summary Form 9.9% Price Increase for OPANA SKUs	9/1/2009	EPI000293431	EPI000293432		JX-002			
CX2670	Document: Executive Pricing Committee Approval Form Price Increase Proposal for OPANA ER	2/1/2010	EPI000293433	EPI000293444		JX-002			
CX2671	Document: Price Change Proposal Summary Form - Opana IR Price Increase	7/1/2009	EPI000293484	EPI000293496		JX-002			
CX2672	Intentionally Not Used					N/A			
CX2673	Email from Demir Bingol to Darnell Turner, Jon Ziss, Theresa Frey, et al. re: Current Strengths Price Increase w/Attach: OPANA Brand (Current Strengths) Price EPC Document-03-01-08-v3.doc	3/1/2008	EPI000299876	EPI000299888		JX-002			
CX2674	Email from Demir Bingol to Theresa Frey re: all cross functional members have approved the 9.9% w/Attach: OPANA (IR) Price EPC Document-09-11-08-v3.doc	9/11/2008	EPI000302043	EPI000302051		JX-002			
CX2675	Email from Lisa Walker to Demir Bingol re: Opana PI - 2/1 w/Attach: EPC Oxy Pain Franchise Pricing 12.1.10.pdf, Frova Lido Opana Voltaren PI.pdf	3/15/2011	EPI000573222	EPI000573240		JX-002			
CX2676	Intentionally Not Used					N/A			
CX2677	Email from Demir Bingol to Deanne Melloy re: EPC Package for New Strengths w/Attach: OPANA ER New Strengths EPC Proposal-01-26-07.doc, Attachment A - Gross-to-Net Analysis 11-08-07.xlsx, Attachment B - Medicaid Impact v3.xls	1/26/2008	EPI000769089	EPI000769096		JX-002			
CX2678	Email from Theresa Fray to Lisa Walker, Demir Bingol, Doug Azzalina, et al. re: EPC approved Price Increases and TX Medicaid Supplemental Rebate w/Attach: EPC - Frova Price Increase Effective 1.1.09.pdf, EPC - Lidoderm Price Increase effective 1.1.09.pdf.	12/11/2008	EPI001035752	EPI001035798		JX-002			
CX2679	Email from Demir Bingol to Pamela Wright and Deanne Melloy re: EPC Package w/Attach: OPANA ER New Strengths EPC Proposal-02-13-08.doc, Attachment A - Gross-to-Net Analysis-11-08-07.xlsx, Attachement B - Medicaid Impact v4-02-08-08.xlsx, Attachment C...	2/13/2008	EPI001541536	EPI001541546		JX-002			
CX2680	Email from Doug Azzalina to Linda Kitlinksi re: Oxymorphone Dear Healthcare w/Attach: Oxymorphone EPC Price and Launch Incentives Proposal_Final 05-07-09.pdf	6/18/2009	EPI001797536	EPI001797545		JX-002			

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CX2681	Email from Dawn Yocorn to Roberto Cuca, Brian Lortie, Kevin O'Brien, et al. re: EPC Approved CVS Caremark Multi Product Part D Proposal w/Attach: EPC Caremark MedD multi-product Pricing Proposal.pdf	1/25/2013	EPI001866066	EPI001866080		JX-002		Ordered 10/20/2017	
CX2682	Impax Presentation: Backup Slides - Impax Generic Business Board of Directors Meeting	5/13/2014	Impax_Opana_PartIII_0002298	Impax_Opana_PartIII_0002318	RX-152	JX-002		Ordered 10/23/2017	
CX2683-CX2684	Intentionally Not Used					N/A			
CX2685	Impax Presentation: Impax New Product Launches - Presentation to Board of Directors	12/10/2013	Impax_Opana_PartIII_0002381	Impax_Opana_PartIII_0002398	RX-154	JX-002		Ordered 10/23/2017	
CX2686	Impax Presentation: Impax Generic Business Board of Directors Meeting	12/4/2012	Impax_Opana_PartIII_0002399	Impax_Opana_PartIII_0002430	RX-155	JX-002		Ordered 10/23/2017	
CX2687-CX2688	Intentionally Not Used					N/A			
CX2689	Impax Document: Minutes of a Special Meeting of the Board of Directors of Impax Laboratories, Inc.	3/28/2014	Impax_Opana_PartIII_0004163	Impax_Opana_PartIII_0004164	RX-166	JX-002			Tr. 463:04
CX2690	Intentionally Not Used					N/A			
CX2691	Impax Document: Minutes of the Meeting of the Board of Directors of Impax Laboratories, Inc.	12/4/2012	Impax_Opana_PartIII_0004179	Impax_Opana_PartIII_0004182		JX-002		Ordered 10/23/2017	
CX2692-CX2694	Intentionally Not Used					N/A			
CX2695	Impax Presentation: Dutasteride (Avodart) Launch Assessment	00/00/0000	Impax_Opana_PartIII_0004256	Impax_Opana_PartIII_0004265	RX-170	JX-002			
CX2696	Letter from Paula Blizzard to Jamie Towey and Maren Schmidt re: CID issued to Impax Laboratories concerning FTC File No. 1410004	7/18/2014	CX2696-001	CX2696-039		JX-002		Ordered 10/23/2017	
CX2697	Email from Art Koch to Larry Hsu re: R&D Collaboration	6/6/2010	IMPAX-OPANA-CID00021793	IMPAX-OPANA-CID00021794	RX-212	JX-002			
CX2698-CX2699	Intentionally Not Used					N/A			
CX2700	Email from Chuck Hildenbrand to Art Koch re: OXM	6/21/2010	IMPAX-OPANA-CID00007944	IMPAX-OPANA-CID00007944		JX-002			
CX2701	Impax Presentation: 2010 Budget Update and 2011 Budget Preview	00/00/0000	Impax_Opana_PartIII_0003771	Impax_Opana_PartIII_0003775	RX-160	JX-002			
CX2702	Intentionally Not Used					N/A			
CX2703	Document: Q3 2011 Impax Laboratories Earnings Conference Call - Final	11/1/2011	CX2703-001	CX2703-014		JX-002			Tr. 261:07; 261:10; 261:13; 261:15
CX2704-CX2709	Intentionally Not Used					N/A			
CX2710	Case 2:16-cv-02526-JLL-JAD: Impax Laboratories, Inc.'s Answer, Affirmative Defenses, and Counterclaims to Plaintiff's Amended Complaint	11/22/2016	Impax_Opana_PartIII_0000545	Impax_Opana_PartIII_0000651		JX-002			
CX2711	Intentionally Not Used					N/A			
CX2712	Email from Ted Smolenski to Meg Snowden, Huong Nguyen, Kevin Sica, et al. re: Prescription Sales and Quarterly Peak Calculations w/Attach: 4Q10 Prescription Sales and Quarterly Peak Calculations 2011-03-17.xlsx	3/19/2011	IMPAX-OPANA-CID00012052	IMPAX-OPANA-CID00012053		JX-002			
CX2713	Email from Todd Engle to Meg Snowden, Houng Nguyen re: Steering Committee w/Attach: IMPAX Prescription Sales and Quarterly Peak Calculations July 2010 Dec 2011.xlsx	3/7/2012	IMPAX-OPANA-CID00012054	IMPAX-OPANA-CID00012057		JX-002			
CX2714	Letter from Impax Laboratories to Endo Pharmaceuticals, Penwest Pharmaceuticals re: Paragraph IV Patent Certification Notice	12/13/2007	IMPAX-OPANA-CID00024463	IMPAX-OPANA-CID00024490		JX-002			
CX2715	Intentionally Not Used					N/A			
CX2716	Endo Presentation: Mission: Deliver the Difference for the Opana Brand in POA II	5/00/2008	ENDO_OP_0069444	ENDO_OP_0069472		JX-002			
CX2717	Endo Presentation: Opana ER Moderate to Severe Chronic Pain Regional Advisory Boards: Executive Summary	00/00/0000	ENDO_OP_0078189	ENDO_OP_0078226		JX-002			
CX2718	Intentionally Not Used					N/A			
CX2719	Email from Jon Ziss to Demir Bingol, Kristin Vitanza re: Opana ER 2008 - 5 Year Plan Forecast 11 05 07 v2.ppt w/Attach: Opana ER 2008 - 5 Year Plan Forecast 11 05 07 v2.ppt	11/5/2007	ENDO_OP_0149584	ENDO_OP_0149601		JX-002			
CX2720	Intentionally Not Used					N/A			
CX2721	Endo Document: Executive Summary Opana ER Pain Management Regional Advisory Board	10/30/2007	ENDO_OP_0283787	ENDO_OP_0283808		JX-002			
CX2722	Letter from Demir Bingol to Healthcare Professional re Opana ER	2/00/2007	ENDO_OP_0299459	ENDO_OP_0299460		JX-002			
CX2723	Intentionally Not Used					N/A			

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Exhibit No.	Description	Date	BegBates	EndBates	Also Referenced As	Admissibility	Purpose/Notes	*In Camera*	Trial Transcript Citation
CX2724	Email from Demir Bingol to Dave Holveck, Brian Lortie, Debbie Travers re: EN3288 Potential Launch Scenarios w/Attach: TRF Project Review-01-27-10.pptx; image001.emf; [Unnamed Presentation]	1/27/2010	EPI000188850	EPI000188851		JX-002			Tr. 1300:18; 1300:19; 1300:21; 1301:05; 1302:15; 1302:16; 1303:03; 1304:17; 1304:18; 1304:23; 1305:10
CX2725	Email from Brian Lortie to Demir Bingol re: EN3288 Potential Launch Scenarios	1/27/2010	EPI000192397	EPI000192398		JX-002			
CX2726	Email from Demir Bingol to Stephen McMorn, Debbie Travers, William Fiske, et al. re: EN3288-104 Topline Results	10/30/2009	EPI000209061	EPI000209062	RX-024	JX-002			
CX2727	Intentionally Not Used					N/A			
CX2728	Email from Demir Bingol to Traci Jackson, Debbie Travers, Art Vrecenak, et al. re: REVISED DATE: EN3288 CCLT Mtg	6/12/2010	EPI000792676	EPI000792677		JX-002			
CX2729	Email from Robert Candea to Steven Cooper, Demir Bingol, Bruce Wallace, et al. re: Approval Requested - Oxymorphone ER Pricing	6/5/2010	EPI000956401	EPI000956404		JX-002			
CX2730	Email from Brian Lortie to Demir Bingol re: Opana ER.pptx w/Attach: Opana ER.pptx	10/26/2010	EPI001297663	EPI001297664		JX-002			
CX2731	Email from Demir Bingol to Pharma.--RDs, Speciality--RDs, Pharmal--DMs, et al. re: 6/6/09 - KV Pharamceutical Company, Purdue Pharma L.P. Settle OxyContin(R)	6/10/2009	EPI001751547	EPI001751547		JX-002			Tr. 1276:10; 1276:11
CX2732	Email from Demir Bingol to Troy Rippley, Steven Cowan re: DEA Justification Document w/Attach: Opana ER Justification-05-15-11.docx	5/16/2011	EPI001773315	EPI001773318		JX-002		Ordered 10/20/2017	
CX2733	Email from Larry Romaine to SalesEndo--RDs, Maria Lane re: Voice Mail to the Field	6/8/2010	EPI001778327	EPI001778327		JX-002			
CX2734	Endo Spreadsheet: Net $1B Opana ER 2015 5 4 11 (Sept Launch higher strengths)	5/4/2011	EPI000290117	EPI000290117		JX-002			
CX2735-CX2737	Intentionally Not Used					N/A			
CX2738	Endo Presentation: ELC 2012 Budget Review, Branded Pharmaceuticals	10/12/2011	EPI000003773	EPI000003841		JX-002			Tr. 2454:06; 2454:16; 2499:08
CX2739	Intentionally Not Used					N/A			
CX2740	Email from Brian Lortie to Mark Bradley re: Data request	6/7/2010	EPI000192537	EPI000192550		JX-002			
CX2741	Endo Document: Settlement and License Agreement between Endo and Penwest Pharmaceuticals	6/18/2010	EPI000828739	EPI000828801		JX-002			
CX2742-CX2743	Intentionally Not Used					N/A			
CX2744	Email from Mark Bradley to Julie McHugh re: Data request	6/7/2010	EPI002161173	EPI002161181		JX-002			
CX2745	Email from Donna Papa to Brian Lortie, Sue Hall, Doug Macpherson, et al. re: Evaluation of IPX-203 w/Attach: Evaluation of IPX-203 (carbidopa_levodopa).pptx	10/28/2015	EPI002190360	EPI002190361		JX-002		Ordered 10/20/2017 & 10/23/2017	
CX2746	Email from Dough Macpherson to Jennifer Dubas re: Evaluation of IPX-203 w/Attach: Evaluation of IPX-203 (carbidopa_levodopa).pptx	10/29/2015	EPI002190362	EPI002190363		JX-002		Ordered 10/20/2017 & 10/23/2017	
CX2747	Email from Doug Macpherson to David Ailinger, Meg Snowden, Nancy Fetrow re: EXTERNAL: ENDO/IMPAX: Amendment to Development and Co-promotional Agreement	10/29/2015	EPI002190364	EPI002190364	RX-136	JX-002			
CX2748	Email from Alan Levin to Mark Bradley re: Final Imperial OEW	6/8/2010	EPI002159909	EPI001379352	RX-131	JX-002			Tr. 2544:21; 2545:04
CX2749	Impax Spreadsheet: Oxymorphone 5 10 20 30 40 06_06_12 full COGS upside	4/16/2013	Impax_Opana_PartIII_0001015	Impax_Opana_PartIII_0001015		JX-002			
CX2750	Email from Mark Bradley to Alan Levin re: Imperial OEW	6/1/2017	EPI002160935	EPI002160936		JX-002			
CX2751-CX2752	Intentionally Not Used					N/A			
CX2753	Email from Meg Snowden to Huong Nguyen re: Mengler Board Slides w/Attach: Zorn Model Oxymorphone 05 14 10.xls	5/14/2010	Impax_Opana_PartIII_0063830	Impax_Opana_PartIII_0063832		JX-002			
CX2754	Email from Meg Snowden to Huong Nguyen re: Zorn Model Oxyrnorphone 03 22 10.xls w/Attach: Zorn Model Oxyrnorphone 03 22 10.xls	3/23/2010	Impax_Opana_PartIII_0063840	Impax_Opana_PartIII_0063841		JX-002			
CX2755	Email from Kevin Sica to Todd Engle re: Endo Opana Disclosures - FW: Charge Message Points w/Attach: Opana ER Peak Calculation for 1Q12.xls	5/2/2012	Impax_Opana_PartIII_0063864	Impax_Opana_PartIII_0063866	RX-213	JX-002			
CX2756-CX2758	Intentionally Not Used					N/A			

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Exhibit No.	Description	Date	BegBates	EndBates	Also Referenced As	Admissibility	Purpose/Notes	*In Camera*	Trial Transcript Citation
CX2759	Case 2:09-cv-00831-KSH-PS US District Court Civil Docket	6/16/2010	CX2759-001	CX2759-022		JX-002			
CX2760-CX2766	Intentionally Not Used					N/A			
CX2767	Email from Jennifer Saionz to Thomas Rayski, Meg Snowden, Chris Mengler, et al. re: Impax - Endo w/Attach: 334990_Result.rtf; Impax - Endo - Settlement Agreement_(PALIB1_3992129_5).DOC	6/7/2010	IMPAX-OPANA-CID00001478	IMPAX-OPANA-CID00001524		JX-002			
CX2768-CX2770	Intentionally Not Used					N/A			
CX2771	Email from Thomas Rayski to Meg Snowden, Chris Mengler, Ted Smolenski, et al. re: Impax - Endo w/Attach: Draft Impax- Endo Settlement Agreement (Opana) [Endo Markup] (3).DOC; Redline - Impax-EndoSettlement and License Agreement.pdf	6/6/2010	IMPAX-OPANA-CID00006732	IMPAX-OPANA-CID00006781	RX-334	JX-002			
CX2772	Email from Alan Levin to Karen Adler, Mark Bradley, Robert Cobuzzi re: Endo/Impax R&D Collaboration	6/6/2010	EPI001586766	EPI001586767	RX-088	JX-002			Tr. 2540:07; 2540:12
CX2773	Intentionally Not Used					N/A			
CX2774	Email from Alan Levin to Mark Bradley re: Imperial OEW	6/1/2010	EPI002160939	EPI002160940		JX-002			
CX2775	Email from Mark Bradley to Julie McHugh re: <no subject> w/Attach: 052110 Imperial OEW v1.docx; IPX_FactSheet_Impax.pdf	5/27/2010	EPI002160941	EPI002160951		JX-002			
CX2776	Email from Mark Bradley to Karen Adler re: R&D Valuation w/Attach: Imperial Valuation v2.xlsx	5/28/2010	EPI002160966	EPI002160967		JX-002		Ordered 10/23/2017	
CX2777	Email from Mark and Cheryl Bradley to Mark Bradley re: Imperial Valuation v6.xlsx w/Attach: Imperial Valuation v6.xlsx	6/6/2010	EPI002161024	EPI002161025		JX-002		Ordered 10/23/2017	
CX2778	Email from Mark and Cheryl Bradley to Mark Bradley re: Imperial Valuation v6.xlsx w/Attach: Imperial Valuation v6.xlsx	6/6/2010	EPI002161067	EPI002161068		JX-002		Ordered 10/23/2017	
CX2779	Email from Mark Bradley to Karen Adler re: Imperial valuation model w/Attach: Imperial Valuation v5.xlsx	6/5/2010	EPI002161113	EPI002161114	RX-135	JX-002		Ordered 10/23/2017	
CX2780	Email from Robert Cobuzzi to Alan Levin, Karen Adler, Mark Bradley, et al. re: Information requested w/Attach: IPX066 Commerical Opportunity 6-4-10.ppt; Copy of IPX066 US Sales Forecast.xls; IPX-203.ppt	6/5/2010	EPI001897548	EPI001897556	RX-105; RX-106; RX-107	JX-002		Ordered 10/23/2017	
CX2781-CX2782	Intentionally Not Used					N/A			
CX2783	Email from Mark Bradley to Mark Schauwecker, Roberto Cuca re: 10 yr Outlook 062410 v2.xls w/Attach: 10 yr Outlook 062410 v2.xls	7/7/2010	EPI000594025	EPI000594026		JX-002			
CX2784	Email from Daniel Carbery to Brian Lortie, Steve Carchedi, Steven Cooper, et al. re: handouts from the ELC meeting today - Some items may be covered at tomorrow's commerical staff meeting with Dave Holveck w/Attach: Lansing OEW v2.doc; et al.	8/31/2009	EPI001923545	EPI001923561		JX-002			Tr. 1065:20, 22; 1066:01, 15, 21, 22; 1067:07; 1078:25; 1079:02
CX2785	Letter from Endo to FTC re CID Response to Specs 1, 8, 33, and 39	6/27/2014	FTC-PROD-0017053	FTC-PROD-0017074		JX-002			
CX2786	Email from David Macera to Paula Schiavo, Roberto Cuca, and Jeffrey Vaupen re: BoD budget deck link w/Attach: BoD Budget Review 2010-10-28c.pptx, Microsoft_Office_Excel_Worksheet1.xlsx, Microsoft_Office_Excel_Worksheet4.xlsx...	10/18/2010	EPI000338517	EPI000338522		JX-002			
CX2787	Email from Roberto Cuca to David Macera re: For our discussion at 4:30 w/Attach: 2011 Product Scenarios.xlsx	10/17/2010	EPI000338544	EPI000338545		JX-002			
CX2788	Intentionally Not Used					N/A			
CX2789	Email from Brian Hogan to Roberto Cuca, David Macera, Darnell Turner, and Lee Lenkner re: Opana ER / Revopan assumptions in Budget w/Attach: Final Factory Units Template - 082510.xlsx, 2011 Net Sales Template.xlsx	9/27/2010	EPI000822934	EPI000822936		JX-002			
CX2790	Intentionally Not Used					N/A			
CX2791	Email from David Macera to Darnell Turner and Mark Schauwecker re: Three Year Plan 2010.xlsx w/Attach: Three Year Plan 2010.xlsx	2/8/2010	EPI001118924	EPI001118925		JX-002			
CX2792	Email from Darnell Turner to David Macera re: Opana ER Forecast	3/8/2010	EPI001119516	EPI001119516		JX-002			
CX2793	Email from Edward DiNapoli to David Macera re: Opana ER Assumptions	9/16/2011	EPI001123902	EPI001123902		JX-002			

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Exhibit No.	Description	Date	BegBates	EndBates	Also Referenced As	Admissibility	Purpose/Notes	*In Camera*	Trial Transcript Citation
CX2794	Email from David Macera to Alan Levin, Karen Adler, and Denise Craig re: BOD 022310 Comp Committee 022310 v2.pptx w/Attach: BOD 022310 Comp Committee 022310 v2.pptx	2/23/2010	EPI001172033	EPI001172034		JX-002			
CX2795-CX2796	Intentionally Not Used					N/A			
CX2797	Email from David Macera to Derek Elphick re: Files w/Attach: 10 yr Outlook with Kansas v14b.xlsx, 10yr Plan summary - DM.xlsx	5/3/2011	EPI001831514	EPI001831516		JX-002			
CX2798	Intentionally Not Used					N/A			
CX2799	Email from Roberto Cuca to David Macera re: Opana ER Scenarios w/Attach: 2013 Opana Scenarios_Summary_12.19.12.xlsx	12/19/2012	EPI000341935	EPI000341937		JX-002			
CX2800-CX2801	Intentionally Not Used					N/A			
CX2802	Email from David Macera to Robert Cooper re: Novartis manufacturing issues: Impact on Endo (RBC Report; Jan 6th)	1/6/2012	EPI001124292	EPI001124292	RX-059	JX-002			
CX2803-CX2804	Intentionally Not Used					N/A			
CX2805	Email from David Macera to Cliff Larsen re: Opana ER upside & downside	11/4/2012	EPI001126150	EPI001126150		JX-002			
CX2806	Email from Derek Elphick to David Macera and Mark Gottlieb re: Leverage Sensitivity Draft with Scenario Analysis Draft w/Attach: Leverage Sensitivity Draft.pptx	12/20/2012	EPI001126447	EPI001126448		JX-002			
CX2807	Intentionally Not Used					N/A			
CX2808	Email from Mark Gottlieb to Alan Levin, Roberto Cuca, David Macera, et al re: New Scenarios - Base Case and Downside	12/22/2012	EPI001737746	EPI001737747		JX-002			
CX2809-CX2810	Intentionally Not Used					N/A			
CX2811	Email from David Macera to Roberto Cuca, Cindy Fryer, and Mark Gottlieb re: Opana ER downside w/Attach: image001.png, image002.png	6/12/2013	EPI000827650	EPI000827654		JX-002			
CX2812	Email from David Macera to Mark Gottlieb re: Model follow up questions	1/17/2013	EPI001127214	EPI001127216		JX-002			
CX2813	Email from David Macera to Joseph Rosenthal re: Opana ER - 10 Year Plan AB scenario w/Attach: 2013 Macera Scenarios.xlsx, ATT00001.htm	5/22/2013	EPI001128674	EPI001128676		JX-002			
CX2814-CX2816	Intentionally Not Used					N/A			
CX2817	Email from Joyce De Los Reyes to Art Koch, Ted Smolenski re: Approval Date Expectations w/Attach: Generic new product launch projection 052808.xls	6/4/2008	IMPAX-OPANA-CID00012325	IMPAX-OPANA-CID00012326		JX-002			
CX2818	Email from Kevin Sica to Denis Paquette, Tony Bright, Joe Camargo, et al. re: January Forecast Submission w/Attach: Forecast Change From Previous Forecast0109.xls	1/9/2009	Impax_Opana_PartIII_0022372	Impax_Opana_PartIII_0022373	RX-180	JX-002			
CX2819	Email from Kevin Sica to Denis Paquette, Tony Bright, Joe Camargo, et al. re: June 09 Forecast Submision w/Attach: Forecast Change From Previous Forecast 0609.xls	6/5/2009	Impax_Opana_PartIII_0006077	Impax_Opana_PartIII_0006078	RX-184	JX-002			
CX2820	Email from Kevin Sica to Denis Paquette, Tony Bright, John Meno, et al. re: Aug 09 Forecast Submission w/Attach: Forecast Change From Previous Forecast 0809.xls	8/7/2009	Impax_Opana_PartIII_0009002	Impax_Opana_PartIII_0009003		JX-002			
CX2821	Email from Kevin Sica to Denis Paquette, Tony Bright, John Meno, et al. re: Sept 09 Forecast Submission w/Attach: Forecast Change From Previous Forecast 0909.xls	9/8/2009	Impax_Opana_PartIII_0004617	Impax_Opana_PartIII_0004618		JX-002			
CX2822	Email from Kevin Sica to Denis Paquette, Tony Bright, John Meno, et al. re: Oct 09 Forecast Submission w/Attach: Forecast Change From Previous Forecast 1009.xls	10/7/2009	Impax_Opana_PartIII_0006069	Impax_Opana_PartIII_0006070		JX-002			
CX2823	Intentionally Not Used					N/A			
CX2824	Email from Kevin Sica to Denis Paquette, Tony Bright, Joe Camargo, et al. re: Jan 10 Forecast Submission w/Attach: Forecast Change from Previous Forecast 0110.xls	1/8/2010	Impax_Opana_PartIII_0008982	Impax_Opana_PartIII_0008983		JX-002			
CX2825	Email from Ted Smolenski to Kevin Sica re: 5-year w/Attach: 5-year forecast 2010-02-10.xls_UPSIDE	2/11/2010	IMPAX-OPANA-CID00007095	IMPAX-OPANA-CID00007096	CX2921	JX-002			

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Exhibit No.	Description	Date	BegBates	EndBates	Also Referenced As	Admissibility	Purpose/Notes	*In Camera*	Trial Transcript Citation
CX2826	Email from Kevin Sica to Chris Mengler, Ted Smolenski, Todd Engle re: 5 Year Forecast w/Attach: 5-year forecast 2010-02-17.xls_UPSIDE	2/17/2010	IMPAX-OPANA-CID00007117	IMPAX-OPANA-CID00007118		JX-002			
CX2827	Intentionally Not Used					N/A			
CX2828	Email from Joyce De Los Reyes to Joe Camargo, Kevin Sica, Chuck Hildenbrand, et al. re: Generic new product launch projection 2010-04-05.xls w/Attach: Generic new product launch projection 2010-04-05.xls	4/5/2010	IMPAX-OPANA-CID00014245	IMPAX-OPANA-CID00014246	RX-369	JX-002			
CX2829	Email from Kevin Sica to Denis Paquette, Tony Bright, Joe Camargo, et al. re: May Forecast Submission w/Attach: Forecast Change From Previous Forecast 0510.xls	5/7/2010	Impax_Opana_PartIII_0022454	Impax_Opana_PartIII_0022455		JX-002			
CX2830	Email from Ted Smolenski to Chris Mengler, Kevin Sica, Todd Engle re: 5-year forecast 2010-May Update 2010--05-14v5.xls w/Attach: 5-year forecast 2010-May Update 2010--05-14v5.xls_UPSIDE	5/15/2010	IMPAX-OPANA-CID00007077	IMPAX-OPANA-CID00007078		JX-002			
CX2831	Email from Ted Smolenski to Art Koch re: 5-year forecast 2010-May Update 2010--05-21--UPSIDE.xls w/Attach: 5-year forecast 2010-May Update 2010--05-21--UPSIDE.xls	5/21/2010	IMPAX-OPANA-CID00006578	IMPAX-OPANA-CID00006579		JX-002			
CX2832-CX2837	Intentionally Not Used					N/A			
CX2838	Email from Kevin Sica to Denis Paquette, Tony Bright, Joe Camargo, et al. re: June Forecast Submission w/Attach: Forecast Change From Previous Forecast 0610.xls	6/7/2010	Impax_Opana_PartIII_0013045	Impax_Opana_PartIII_0013046		JX-002			
CX2839-CX2841	Intentionally Not Used					N/A			
CX2842	Email from Kevin Sica to Denis Paquette, Tony Bright, Joe Camargo, et al. re: July Forecast Submission w/Attach: Forecast Change From Previous Forecast 0710.xls	7/12/2010	Impax_Opana_PartIII_0030783	Impax_Opana_PartIII_0030785		JX-002			
CX2843-CX2844	Intentionally Not Used					N/A			
CX2845	Email from Meg Snowden to Guy Donatiello, Andy Gesek, Roberto Cuca, Carrie Cooper, et al. re: steering committee	12/20/2010	IMPAX-OPANA-CID00006165	IMPAX-OPANA-CID00006166		JX-002			
CX2846-CX2850	Intentionally Not Used					N/A			
CX2851	Impax Document: Consulting Agreement between Impax Laboratories, Inc. and TCS Consulting Group, LLC	4/28/2017	Impax_Opana_PartIII_0081331	Impax_Opana_PartIII_0081336		JX-002			
CX2852	Email from Todd Engle to Chris Mengler, Larry Hsu, Chuck Hildenbrand, et al. re: Meeting Minutes from the Feb 2, 2010 Quarterly Launch Planning Meeting	2/6/2010	Impax_Opana_PartIII_0046715	Impax_Opana_PartIII_0046739		JX-002			
CX2853	Email from Ted Smolenski to Kevin Sica re: 5-year w/Attach: 5-year forecast 2010-02-10.xls_BASE	2/11/2010	IMPAX-OPANA-CID00007095	IMPAX-OPANA-CID00007096		JX-002			
CX2854	Email from Kevin Sica to Chris Mengler, Ted Smolenski, Todd Engle, et al. re: 5 Year Forecast w/Attach: 5-year forecast 2010-02-17.xls	2/17/2010	IMPAX-OPANA-CID00007117	IMPAX-OPANA-CID00007118		JX-002			
CX2855-CX2859	Intentionally Not Used					N/A			
CX2860	Email from Ted Smolenski to Todd Engle, Kevin Sica, Art Koch, et al. re: Oxymorphone	1/7/2011	IMPAX-OPANA-CID00021096	IMPAX-OPANA-CID00021097		JX-002			
CX2861-CX2862	Intentionally Not Used					N/A			
CX2863	Email from John Anthony to Chuck Hildenbrand, Mark Shaw re: Quota	5/28/2010	Impax_Opana_PartIII_0004275	Impax_Opana_PartIII_0004277		JX-002			
CX2864	Email from Todd Engle to Chuck Hildenbrand, John Anthony, Joe Camargo, et al. re: Oxymorphone Quota w/Attach: 3398_001.pdf; API Quota 032310.xls	4/9/2010	Impax_Opana_PartIII_0004872	Impax_Opana_PartIII_0004877		JX-002			
CX2865	Email from John Anthony to Michael J. Morley, Mark Shaw, Joe Camargo re: Withdrawal Impax request for a 2010 revised Oxymorphone Procurement Quota	6/14/2010	Impax_Opana_PartIII_0014615	Impax_Opana_PartIII_0014615		JX-002			
CX2866	Email from Chris Mengler to John Anthony, Todd Engle, Mark Shaw, et al. re: Oxymorphone	1/12/2010	Impax_Opana_PartIII_0014683	Impax_Opana_PartIII_0014687		JX-002			
CX2867	Email from Joe Camargo to John Anthony re: Attached Image	1/7/2010	Impax_Opana_PartIII_0015290	Impax_Opana_PartIII_0015292		JX-002			
CX2868	Email from John Anthony to Chuck Hildenbrand, Mark Shaw re: March 10 Forecast Submission w/Attach: B-2Quota2010.htm	3/9/2010	Impax_Opana_PartIII_0016249	Impax_Opana_PartIII_0016252	RX-175	JX-002			

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CX2869	Email from Joe Camargo to Tamara Alegria re: Oxymorphone	1/11/2010	Impax_Opana_PartIII_0017165	Impax_Opana_PartIII_0017168		JX-002			
CX2870	Email from John Anthony to Larry Glenn, Pat Fiorentino re: Attached Image w/Attach: 0112_001.pdf	3/8/2010	Impax_Opana_PartIII_0017289	Impax_Opana_PartIII_0017291		JX-002			
CX2871-CX2873	Intentionally Not Used					N/A			
CX2874	Email from John Anthony to Mark Shaw, Larry Hsu, Chris Mengler, et al. re: Attached Image w/Attach: 4798_001.pdf	1/6/2010	Impax_Opana_PartIII_0018510	Impax_Opana_PartIII_0018515		JX-002			
CX2875	Intentionally Not Used					N/A			
CX2876	Email from Chris Mengler to John Anthony, Chuck Hildenbrand, Mark Shaw re: Oxymorphone	1/22/2010	Impax_Opana_PartIII_0019737	Impax_Opana_PartIII_0019741		JX-002			
CX2877	Email from John Anthony to Mark Shaw re: Attached Image w/Attach: 0348_001.pdf	4/16/2010	Impax_Opana_PartIII_0022354	Impax_Opana_PartIII_0022355		JX-002			
CX2878	Email from Joe Camargo to Chuck Hildenbrand re: 2010 CII Controlled Substances & Pseudoephedrine Quota request for Impax B-1 & B-2	2/17/2009	Impax_Opana_PartIII_0023017	Impax_Opana_PartIII_0023018		JX-002			
CX2879	Intentionally Not Used					N/A			
CX2880	Email from John Anthony to Michael Morley, Christine Sannerud, Mark Shaw re: Oxymorphone 2010 Quota for Impax	3/2/2010	Impax_Opana_PartIII_0028440	Impax_Opana_PartIII_0028441		JX-002			
CX2881	Email from John Anthony to Mark Shaw, Joe Camargo, Chuck Hildenbrand re: Attached Image w/Attach: 0728_001.pdf	6/17/2010	Impax_Opana_PartIII_0028949	Impax_Opana_PartIII_0028951		JX-002			
CX2882	Email from Todd Engle to Chuck Hildenbrand, John Anthony, Joe Camargo, et al. re: Oxymorphone Quota w/Attach: 3419_001.pdf	4/12/2010	Impax_Opana_PartIII_0029763	Impax_Opana_PartIII_0029765		JX-002			
CX2883-CX2887	Intentionally Not Used					N/A			
CX2888	Email from Chuck Hildenbrand to Art Koch, Jim Devlin, Joe Camargo re: Impax: Inventory Carrying Value - June 30, 2010 - OXM w/Attach: Oxymorphone Expiration Dates	6/24/2010	Impax_Opana_PartIII_0004656	Impax_Opana_PartIII_0004671		JX-002			
CX2889	Email from Chuck Hildenbrand to Larry Hsu, May Chu, Mark Shaw, et al. re: Monthly Highlights w/Attach: Monthly Highlights, Opns, Quality and Compliance - Apr 2010.doc	5/13/2010	Impax_Opana_PartIII_0004815	Impax_Opana_PartIII_0004819		JX-002			
CX2890	Email from Kangwen Lin to Chuck Hildenbrand, Joe Camargo, Andrew Fox, et al. re: Final meeting minutes for oxymorphone tech transfer meeting w/Attach: Oxymorphone 5, 10, 20, 40 mg 30, 15, 7.5mg ER tablets Dec Final.doc	12/14/2009	Impax_Opana_PartIII_0005535	Impax_Opana_PartIII_0005544		JX-002			
CX2891	Email from Kevin Sica to Denis Paquette, Tony Bright, Joe Camargo, et al. re: June 09 Forecast Submission w/Attach: Forecast Change From Previous Forecast 0609.xls	6/5/2009	Impax_Opana_PartIII_0009006	Impax_Opana_PartIII_0009007		JX-002			Tr. 970:16; 971:06, 22
CX2892	Email from Chuck Hildenbrand to Larry Hsu, May Chu, Joe Camargo re: 5 year Plan w/Attach: Production Plan - Capacity, 2010-14.xls; Production Plan - Capacity 2010-14.xls Glatt analysis.xls	12/16/2009	Impax_Opana_PartIII_0011183	Impax_Opana_PartIII_0011185		JX-002			
CX2893	Email from John Anthony to Joe Camargo, Chuck Hildenbrand, Mark Shaw, et al. re: Monthly Quota Chart w/Attach: 2010 Procurement Chart of DEA Pseudoeperdrine Sulfate Quota-05-02-10.xls; et al.	5/6/2010	Impax_Opana_PartIII_0013559	Impax_Opana_PartIII_0013563		JX-002			
CX2894	Email from Chuck Hildenbrand to John Anthony, Joe Camargo, Mark Shaw re: Quota	3/6/2010	Impax_Opana_PartIII_0013591	Impax_Opana_PartIII_0013592		JX-002			
CX2895	Intentionally Not Used					N/A			
CX2896	Email from Joe Camargo to Chuck Hildenbrand, Denis Paquette, Sam Adams, et al. re: Monthly Report w/Attach: Monthly Report, 7-10.doc	8/10/2010	Impax_Opana_PartIII_0017542	Impax_Opana_PartIII_0017544		JX-002			Tr. 996:07, 15; 997:01; 1023:21; 1024:06
CX2897	Intentionally Not Used					N/A			
CX2898	Email from Joe Camargo to Todd Engle and Chuck Hildenbrand re: Launch Planning Input	5/12/2010	Impax_Opana_PartIII_0021986	Impax_Opana_PartIII_0021987	RX-179	JX-002			Tr. 977:05, 24; 1016:11
CX2899	Email from Chuck Hildenbrand to Joe Camargo, Jeff Blumenfeld, Kangwen Lin, et al. re: MBO Accomplishments w/Attach: C. Hildenbrand 2010 MBOs 030910.doc, W0 targets w accomplishments.doc	2/6/2011	Impax_Opana_PartIII_0024286	Impax_Opana_PartIII_0024288		JX-002			
CX2900	Intentionally Not Used					N/A			
CX2901	Email from Chuck Hildenbrand to Joe Camargo re: <no subject>	5/26/2010	Impax_Opana_PartIII_0025384	Impax_Opana_PartIII_0025384	RX-182	JX-002			

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CX2902	Email from Willi Huang to Joe Camargo, Chuck Hildenbrand, Kangwen Lin, et al. re: Oxymorphone	5/5/2011	Impax_Opana_PartIII_0026107	Impax_Opana_PartIII_0026108		JX-002			
CX2903	Intentionally Not Used					N/A			
CX2904	Email from Joe Camargo to Chuck Hildenbrand, Tony Bright, Jim Larrowe, et al. re: June Plan	5/25/2010	Impax_Opana_PartIII_0030026	Impax_Opana_PartIII_0030026	RX-187	JX-002			Tr. 1017:08
CX2905	Email from Joe Camargo to Chuck Hildenbrand re: Monthly Report w/Attach: Monthly Report, 5-10.doc	6/11/2010	Impax_Opana_PartIII_0030763	Impax_Opana_PartIII_0030765		JX-002			Tr. 989:14; 990:05, 10; 1022:25; 1023:07
CX2906	Email from Todd Engle to Chris Mengler, Larry Hsu, Richard Ting, et al. re: Agenda and hand out for the Quarterly Launch Planning Meeting today	11/24/2009	Impax_Opana_PartIII_0044720	Impax_Opana_PartIII_0044723		JX-002			
CX2907	Intentionally Not Used					N/A			
CX2908	Email from Kangwen Lin to Andrew Fox, Art Koch, Chris Mengler, et al. re: Generic meeting update - operation activities for 6/15 meeting w/Attach: OA for Generic meeting June 15.doc	6/15/2010	Impax_Opana_PartIII_0046747	Impax_Opana_PartIII_0046749		JX-002			
CX2909	Intentionally Not Used					N/A			
CX2910	Email from Joe Camargo to Chris Mengler re: Alternate Sourcing Projects	4/9/2009	Impax_Opana_PartIII_0049209	Impax_Opana_PartIII_0049210		JX-002			
CX2911-CX2913	Intentionally Not Used					N/A			
CX2914	Email from Joe Camargo to Andrew Fox, Art Koch, Bob Friedel, et al. re: Updated Checklist w/Attach: Product Launch Checklist.xls	6/8/2010	Impax_Opana_PartIII_0077849	Impax_Opana_PartIII_0077850	RX-226	JX-002			
CX2915	Email from Joe Camargo to Andrew Fox, Art Koch, Chuck Hildenbrand, et al. re: Updated Checklist w/Attach: Product Launch Checklist.xls	10/27/2009	Impax_Opana_PartIII_0079132	Impax_Opana_PartIII_0079133		JX-002			
CX2915A	Email from Joe Camargo to Andrew Fox, Art Koch, Chuck Hildenbrand, et al. re: Updated Checklist w/Attach: Product Launch Checklist.xls	10/27/2009	Impax_Opana_PartIII_0079132	Impax_Opana_PartIII_0079133		JX-002			
CX2916	Email from John Anthony to Todd Engle, Chris Mengler, Mark Shaw re: Oxymorphone w/Attach: 1936_001.pdf; Oxymorphone Forecast Detail 01 11 10 R2.xls	1/12/2010	Impax_Opana_PartIII_0019522	Impax_Opana_PartIII_0019537		JX-002			
CX2917	Letter from John Anthony to Christine Sannerud, DEA re: Oxymorphone Procurement Quota Year 2010	1/18/2010	Impax_Opana_PartIII_0081690	Impax_Opana_PartIII_0081692		JX-002			
CX2918	Letter from John Anthony to Christine Sannerud, DEA re: Oxymorphone Procurement Quota Year 2010	4/15/2010	Impax_Opana_PartIII_0081693	Impax_Opana_PartIII_0081695		JX-002			
CX2919	Impax Document: Minutes of the Meeting of the Board of Directors of Impax Laboratories, Inc.	8/17/2010	Impax_Opana_PartIII_0004185	Impax_Opana_PartIII_0004188		JX-002		Ordered 10/23/2017	
CX2920	Email from Chris Mengler to Larry Hsu, Todd Engle, Meg Snowden re: Mengler Board Slides	5/14/2010	Impax_Opana_PartIII_0063833	Impax_Opana_PartIII_0063834		JX-002			
CX2921	Intentionally Not Used					N/A			
CX2922	Email from Willi Huang to Ray Smith, Shan Gao, Joe Camargo, et al. re: At Risk Inventory report for March 2011 w/Attach: At Risk Inventory March 11 R0.xls	4/1/2011	Impax_Opana_PartIII_0005732	Impax_Opana_PartIII_0005733		JX-002			Tr. 1024:17; 1025:23; 1031:05
CX2923	Document: Complaint Counsel's Notice of Deposition of Impax Laboratories, Inc.	5/12/2017	CX2923-001	CX2923-007		JX-002			
CX2924	Email from Anna Fabish to the FTC re: Docket 9373 - Objections to Notice of Deposition of Impax Laboratories w/Attach: June 14 2017 Ltr to N Leefer re 33c1 deposition objections and designations.pdf	6/27/2017	CX2924-001	CX2924-007		JX-002			
CX2925-CX2926	Intentionally Not Used					N/A			
CX2927	Document: Respondent Impax Laboratories, Inc.'s Objections and Responses to Complaint Counsel's Second Set of Interrogatories	6/2/2017	CX2927-001	CX2927-029		JX-002			Tr. 279:25
CX2928	Document: Respondent Impax Laboratories, Inc.'s Objections and Responses to Complaint Counsel's Third Set of Interrogatories	6/29/2017	CX2928-001	CX2928-018		JX-002		Ordered 10/23/2017	
CX2929	Email from Larry Hsu to Chuck Hildenbrand, Chris Mengler, Art Koch, et al. re: Oxymorphone ER Tablets Tentatively Approved Today!!	5/14/2010	Impax_Opana_PartIII_0044621	Impax_Opana_PartIII_0044622	RX-195	JX-002			Tr. 308:20; 355:25; 356:15; 356:19; 584:05
CX2930	Email from Meg Snowden to Art Koch, Larry Hsu, Michael Nestor, et al. re: Highly Confidential - Rule 408 Settlement Communication w/Attach: Endo - Impax - Development Term Sheet (5-26-2010).DOC; Endo - Impax - Settlement Term Sheet (5-26-2010).docx	5/26/2010	IMPAX-OPANA-CID00006719	IMPAX-OPANA-CID00006729	RX-331	JX-002			Tr. 3016:05; 3016:07
CX2931-CX2932	Intentionally Not Used					N/A			

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Exhibit No.	Description	Date	BegBates	EndBates	Also Referenced As	Admissibility	Purpose/Notes	*In Camera*	Trial Transcript Citation
CX2933	Meeting Scheduler re: Co-Promote Teleconference with Attendees: Brian Lortie, Alan Levin, Robert Cobuzzi, Meg Snowden, et al.	6/7/2010	IMPAX-OPANA-CID00006143	IMPAX-OPANA-CID00006143	RX-326	JX-002			
CX2934	Intentionally Not Used					N/A			
CX2935	Email from Justin Watkins to Alison Freeman Gleason, Meg Snowden, Alan Levin, et al. re: Co-Promote Revisions w/Attach: #710157v9_BE01_ - Impax - Co-Promotion Agreement.DOC; et al.	6/7/2010	IMPAX-OPANA-CID00006853	IMPAX-OPANA-CID00006918		JX-002			
CX2936	Email from Meg Snowden to Joyce De Los Reyes re: Generic new product launch projection 2010-06-08 MS.xls	6/14/2010	IMPAX-OPANA-CID00020529	IMPAX-OPANA-CID00020530		JX-002			
CX2937	Intentionally Not Used					N/A			
CX2938	Email from Meg Snowden to Tim Scott and Mark Schlossberg re: EXTERNAL:RE: Impax License Agreement	4/21/2016	IMPAX-ENDO-DNJ0001564	IMPAX-ENDO-DNJ0001568		JX-002			
CX2939	Email from Meg Snowden to Fred Wilkinson, Douglas Boothe, and Mark Schlossberg re: Endo v. Impax	11/3/2016	IMPAX-ENDO-DNJ0005272	IMPAX-ENDO-DNJ0005275		JX-002			
CX2940-CX2941	Intentionally Not Used					N/A			
CX2942	Email from Guy Donatiello to Meg Snowden re: Impax License Agreement	10/1/2015	EPI002195693	EPI002195695		JX-002			
CX2943	Email from Guy Donatiello to Meg Snowden, George Gordon, Jennifer Dubas, et al. re: EXTERNAL: Impax License Agreement	4/19/2016	EPI002195706	EPI002195709		JX-002			
CX2944	Email from Guy Donatiello to Bob Rhoad, Martin Black, Matthew Maletta, et al. re: Letter to Mr. Chris Mengler and Ms. Margaret Snowden, Impax Laboratories, Inc.	10/31/2016	EPI002195723	EPI002195725		JX-002			Tr. 2905:01; 2905:05
CX2945-CX2946	Intentionally Not Used					N/A			
CX2947	Impax Presentation: Company Goal and Strategy November 17, 2009	11/17/2009	Impax_Opana_PartIII_0003904	Impax_Opana_PartIII_0003916		JX-002			
CX2948	Email from Suneel Gupta to Michael Nestor re: Endo contact person	6/3/2010	IMPAX-OPANA-CID00001599	IMPAX-OPANA-CID00001599	RX-269	JX-002			
CX2949	Email from Robert Cobuzzi to Michael Nestor, Chris Mengler, Alan Levin re: R&D Contact?	6/4/2010	IMPAX-OPANA-CID00001611	IMPAX-OPANA-CID00001612	RX-273	JX-002			
CX2950-CX2951	Intentionally Not Used					N/A			
CX2952	Email from Laura Zhu to Michael Nestor re: IPX066	5/21/2010	IMPAX-OPANA-CID00006714	IMPAX-OPANA-CID00006716		JX-002			
CX2953	Email from Bryan Reasons to Michael Nestor, Suneel Gupta re: Impax/Endo Development and Co-Promotion Agreement Milestones w/Attach: image001.png; image002.png	4/16/2013	IMPAX-OPANA-CID00007983	IMPAX-OPANA-CID00007987	RX-344	JX-002			
CX2954	Email from Suneel Gupta to Steve Mollichella, Meg Snowden, Michael Nestor re: Co-Promote Revisions	7/1/2010	IMPAX-OPANA-CID00011919	IMPAX-OPANA-CID00011923	RX-358	JX-002			
CX2955	Email from Michael Nestor to Suneel Gupta re: BoD slides w/Attach: BOD draft ver3.ppt	8/1/2010	IMPAX-OPANA-CID00012655	IMPAX-OPANA-CID00012699	RX-368	JX-002		Ordered 10/23/2017	
CX2956	Email from Michael Nestor to Brandon Smith re: Slide format w/Attach: BOD 07092013.ppt	7/5/2013	IMPAX-OPANA-CID00016072	IMPAX-OPANA-CID00016091	RX-370	JX-002		Ordered 10/23/2017	
CX2957	Email from Mark Donohue to Michael Nestor re: Call w/Attach: Impax Key Topic Messaging Points - Sept 28 2012.docx	9/27/2012	IMPAX-OPANA-CID00018692	IMPAX-OPANA-CID00018703		JX-002			
CX2958	Email from Larry Hsu to Bryan Reasons, Carole Ben-Maimon, Michael Nestor, et al. re: What has been disclosed	7/5/2012	IMPAX-OPANA-CID00019206	IMPAX-OPANA-CID00019208		JX-002			
CX2959	Intentionally Not Used					N/A			
CX2960	Email from Chris Mengler to Meg Snowden, Art Koch, Larry Hsu, et al. re: <no subject>	6/3/2010	IMPAX-OPANA-CID00019454	IMPAX-OPANA-CID00019454		JX-002			
CX2961	Email from Larry Hsu to Art Koch, Meg Snowden, Michael Nestor, et al. re: Status	6/5/2010	IMPAX-OPANA-CID00019476	IMPAX-OPANA-CID00019476		JX-002			
CX2962	Email from Meg Snowden to Michael Nestor, Shawn Fatholahi, Suneel Gupta, et al. re: R&D Collaboration	6/6/2010	IMPAX-OPANA-CID00021838	IMPAX-OPANA-CID00021839	RX-569	JX-002			
CX2963	Email from Michael Nestor to Meg Snowden, Art Koch, Larry Hsu, et al. re: Info requested by Endo on successor to IPX-066	6/4/2010	IMPAX-OPANA-CID00022261	IMPAX-OPANA-CID00022261		JX-002			
CX2964	Email from Jennifer Saionz to Alan Levin, Guy Donatiello, Martin Black, et al. re: Impax - Endo w/Attach: Impax inserts_(PAU 81_3993075_1) .DOC	6/6/2010	IMPAX-OPANA-CID00001416	IMPAX-OPANA-CID00001438	RX-267	JX-002			

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Exhibit No.	Description	Date	BegBates	EndBates	Also Referenced As	Admissibility	Purpose/Notes	*In Camera*	Trial Transcript Citation
CX2965	Email from Justin Watkins to Alison Freeman Gleason, Meg Snowden, Michael Nestor, et al. re: Co-Promotion Agreement - Revised Draft w/Attach: #710157v7_BE01_ - Impax - Co-Promotion Agreement DOC; et al.	6/7/2010	IMPAX-OPANA-CID00001525	IMPAX-OPANA-CID00001591		JX-002			
CX2966	Email from David Paterson to Robert Cobuzzi, Michael Nestor, Chris Mengler, and Meg Snowden re: IPX066 w/Attach: 066 Apr2010AAN poster final poster.ppt, IPX066_IMPAX_Partner_Confidential_032010_FINAL.pdf	5/19/2010	IMPAX-OPANA-CID00001974	IMPAX-OPANA-CID00002103	RX-284	JX-002			
CX2967	Email from Sibel Ucpinar to Todd Engle re: Opana ER volume 1 of 5 w/Attach: 2007-06-25 79-087 Original ANDA vol 1 of 7.pdf	10/17/2012	IMPAX-OPANA-CID00009918	IMPAX-OPANA-CID00010400	RX-349	JX-002			
CX2968	Intentionally Not Used					N/A			
CX2969	Email from Martin Black to Stephen Hash, Guy Donatiello re: Opana w/Attach: Document.pdf	2/20/2009	Actavis_FTC_Opana_000156	Actavis_FTC_Opana_000177		JX-002		Ordered 10/20/2017	
CX2970	Intentionally Not Used					N/A			
CX2971	Actavis Spreadsheet: FM8-1-Oxymorphone ER V2	2/13/2008	Actavis_FTC_Opana_000334	Actavis_FTC_Opana_000334		JX-002		Ordered 10/20/2017	
CX2972	Actavis Spreadsheet: FM-Oxymorphone ER #2	8/27/2010	Actavis_FTC_Opana_000347	Actavis_FTC_Opana_000347		JX-002		Ordered 10/20/2017	
CX2973	Actavis Document: Product Introduction Notification, Oxymorphone HCL ER Tab	9/17/2013	Actavis_FTC_Opana_000376	Actavis_FTC_Opana_000376		JX-002			
CX2974	Actavis Document: Temporarily Unavailable Notification, Oxymorphone HCL ER	5/2/2016	Actavis_FTC_Opana_000378	Actavis_FTC_Opana_000378		JX-002			
CX2975	Actavis Spreadsheet: Oxymorphone ER August 2013	12/17/2013	Actavis_FTC_Opana_000379	Actavis_FTC_Opana_000379	RX-001	JX-002		Ordered 10/20/2017	
CX2976	Case 2:16-cv-02526-JLL-JAD: Document 1: Complaint	5/4/2016	CX2976-001	CX2976-156		JX-002	Admitted solely for nonhearsay purposes, i.e., not for the truth of any matter asserted		
CX2977-CX2983	Intentionally Not Used					N/A			
CX2984	Impax Document: Minutes of the Regular Meeting of the Board of Directors of Impax Laboratories, Inc.	12/9/2015	Impax_Opana_PartIII_0004195	Impax_Opana_PartIII_0004208		JX-002		Ordered 10/23/2017	
CX2985	Intentionally Not Used					N/A			
CX2986	Email from Suneel Gupta to Adrienne Ford, Bryan Reasons, Michael Nestor, et al. re: Impax/Endo Development and Co-Promotion Agreement Milestones	10/29/2013	IMPAX-OPANA-CID00005538	IMPAX-OPANA-CID00005539	RX-309	JX-002			
CX2987-CX2989	Intentionally Not Used					N/A			
CX2990	SAT: Actavis 30(b)(6)	5/24/2017	CX2990-001	CX2990-006		JX-002			
CX2991-CX2994	Intentionally Not Used					N/A			
CX2995	Email from Carolyn Kong to Bob Barto re: QuRE: Summary of June 26 LCM Followup Meeting	6/30/2008	EPI000091528	EPI000091530		JX-002			
CX2996	Email from Erika George to Bob Barto re: Voice Mail Message ('4262') (35 seconds)	6/30/2008	EPI000091531	EPI000091531		JX-002			
CX2997	Email from Munira Rampersaud to Tara Chapman re: Generic Oxymorphone ER	1/23/2010	EPI000098031	EPI000098033		JX-002			
CX2998	Email from Ira Lentz to Tara Chapman re: Generic Oxymorphone ER w/Attach: P-25963-A P-25964-A; Endo P25963A P25964A 10-13-09.pdf; P22848A, P22845A, P22847A; et al.	10/19/2009	EPI000120230	EPI000120238		JX-002			
CX2999	Email from Ira Lentz to Tara Chapman re: Generic Oxymorphone ER w/Attach: Endo P-26099-A P-26100-A P-26101-A 11-20-09.pdf	11/20/2009	EPI000122808	EPI000122813		JX-002			
CX3000	Email from Ira Lentz to Tara Chapman re: Destruction of Generic Oxymorphone ER Tabs	6/11/2010	EPI000132119	EPI000132119		JX-002			
CX3001	Email from Missy Combs to Jeanne Brackins, Alicia Logan re: Oxymorphone ER potential 8-2010 launch scenario.xlsx w/Attach: Oxymorphone ER potential 8-2010 launch scenario.xlsx	10/3/2009	EPI000186383	EPI000186384		JX-002			
CX3002	Email from Alicia Logan to Brian Lihou re: (NEEDED FOR LAUNCH) Oxymorphone ER BOM correction and Change control w/Attach: Scan001.PDF	5/25/2010	EPI000383935	EPI000383941		JX-002			
CX3003	Email from Alicia Logan to Doug Azzalina re: Oxymorphone ER Launch Volumes	5/26/2010	EPI000383942	EPI000383942		JX-002			
CX3004	Email from Alicia Logan to Lisa Walker, Jason Bender re: Generic Launches	4/27/2010	EPI000938484	EPI000938486		JX-002			

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Exhibit No.	Description	Date	BegBates	EndBates	Also Referenced As	Admissibility	Purpose/Notes	*In Camera*	Trial Transcript Citation
CX3005	Email from Rene Curtis to Alicia Logan re: Oxymorphone ER labels	5/4/2010	EPI000948491	EPI000948491		JX-002			
CX3006	Email from Cassie Mapp to Demir Bingol re: CI Question w/Attach: Opana ER Generic Market Defense Final Presentation 12-16-2008.ppt	4/14/2010	EPI001552909	EPI001552910		JX-002			
CX3007	Email from Nancy Olson to Alan Levin, Caroline Manogue, Julie McHugh, et al. re: Executive Pricing Committee Meeting w/Attach: Oxymorphone ER Price Proposal Summary 06-02-10.pdf; Mycophenolate Mofetil Price A Pricing 6.3.10.pdf	6/4/2010	EPI001688857	EPI001688861		JX-002			
CX3008	Endo Document: Generics Summary September 9 2009	9/9/2009	EPI002011791	EPI002011793		JX-002			
CX3009	Email from Brian Hogan to Roberto Cuca re: Opana ER Combined P&L scenarios - Jul-10 generics.xlsx w/Attach: Opana ER Combined P&L scenarios - Jul-10 generics.xlsx	6/1/2010	EPI001588866	EPI001588867		JX-002			
CX3010	Email from Guy Donatiello to Alan Levin, Robert Cobuzzi, Roberto Cuca re: Imperial Alternatives	5/30/2010	EPI002201683	EPI002201685		JX-002			
CX3011	Email from Clark Baker to Brian Hogan, Demir Bingol, Lee Lenkner, et al. re: Opana ER / IR P&L Scenario Model w/Attach: OPANA Generic Scenarios.xlsx	5/25/2010	EPI000314222	EPI000314224		JX-002			
CX3012	Intentionally Not Used					N/A			
CX3013	Email from Roberto Cuca to Jack Boyle re: Impax contract w/Attach: Endo Credit.xlsx	3/13/2012	EPI000594257	EPI000594258		JX-002			
CX3014-CX3016	Intentionally Not Used					N/A			
CX3017	Email from Brian Hogan to Roberto Cuca, Lee Lenkner re: Opana ER / IR P&L Scenario Model w/Attach: OPANA Brand P&L Model Scenarios - Generic launch v3.xlsx	5/28/2010	EPI001588856	EPI001588859		JX-002			Tr. 645:17, 20; 652:07; 653:20; 656:06, 12, 17; 658:05
CX3018	Intentionally Not Used					N/A			
CX3019	Email from Roberto Cuca to Jack Boyle, Daniel Rudio re: BoD slides w/Attach: NCH Impact Slide.ppt	4/6/2012	EPI001595189	EPI001595190		JX-002			
CX3020-CX3024	Intentionally Not Used					N/A			
CX3025	Email from Alan Levin to Roberto Cuca re: Impax - Endo	6/7/2010	EPI001688925	EPI001688926	RX-098	JX-002			
CX3026-CX3033	Intentionally Not Used					N/A			
CX3034	Email from Carrie Cooper to Roberto Cuca, Andy Gesek, Suzanne Bair re: steering committee	1/20/2011	EPI002159928	EPI002159930		JX-002			
CX3035-CX3037	Intentionally Not Used					N/A			
CX3038	Email from Brian Hogan to Roberto Cuca re: EN3288 Core Commercial Launch Team (CCTL) Update	4/2/2010	EPI002196175	EPI002196188		JX-002			Tr. 2448:08; 2454:01; 2498:05
CX3039	Email from Roberto Cuca to Alan Levin, Darnell Turner, David Macera re: Per share price impact of generic Opana ER launch	3/15/2010	EPI002196198	EPI002196219		JX-002			
CX3040-CX3041	Intentionally Not Used					N/A			
CX3042	Email from Roberto Cuca to Erin Rybaltowski re: Finance materials for posting w/Attach: ELC mtg Mar 19-21 -- Finance Overview -- 2013-03-15.pptx; Microsoft_Excel_Worksheet1 .xlsx; Microsoft_Excel_Worksheet2.xlsx; et al.	3/18/2013	EPI002197252	EPI002197256		JX-002			
CX3043	Email from Roberto Cuca to Julie McHugh re: Penwest	6/9/2010	EPI002198102	EPI002198102		JX-002			
CX3044	Intentionally Not Used					N/A			
CX3045	Email from Roberto Cuca to Alan Levin, Edward Sweeney, Guy Donatiello re: Opana ER	6/4/2010	EPI002199918	EPI002199919		JX-002			
CX3046	Email from Jack Boyle to Alan Levin, Roberto Cuca re: OPANA ER PRESS RELEASE DRAFTS	4/16/2013	EPI002200864	EPI002200866		JX-002			
CX3047	Email from Cindy Fryer to Jim Wolfe, Moti Rubin, Kevin Gibbs, et al. re: Introduction - Last RAP Attached w/Attach: ENdo_RAP_vFinal_06.05.13.pptx	7/16/2013	EPI002217646	EPI002217647		JX-002			
CX3048	Email from Roberto Cuca to Todd Engle, Carrie Cooper re: Steering Committee w/Attach: IMPAX Prescription Sales and Quarterly Peak Calculations July 2010 - Dec 2011.xlsx	3/7/2012	IMPAX-OPANA-CID00005714	IMPAX-OPANA-CID00005717	RX-313	JX-002			

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Exhibit No.	Description	Date	BegBates	EndBates	Also Referenced As	Admissibility	Purpose/Notes	*In Camera*	Trial Transcript Citation
CX3049	Endo Press Release: Endo Health Solutions Responds to FDA 's Denial of OPANA® ER Citizen Petition and the Potential Approval of Additional Non-Abuse Deterrent Formulations of Generic Oxymorphone	5/10/2013	CX3049-001	CX3049-003		JX-002			
CX3050	Intentionally Not Used					N/A			
CX3051	Endo Presentation: Ratings Agency Presentation	7/19/2013	EPI002160028	EPI002160028		JX-002			
CX3052	Intentionally Not Used					N/A			
CX3053	Email from Ray Smith to Joe Camargo, Chuck Hildenbrand, and Meg Snowden re: OXM	6/4/2010	Impax_Opana_PartIII_0002588	Impax_Opana_PartIII_0002589		JX-002			Tr. 993:15, 25; 994:04; 995:05
CX3054	Intentionally Not Used					N/A			
CX3055	Email from Kevin Sica to Denis Paquette re: January Forecast Submission w/Attach: Forecast Change From Previous Forecast0109.xls	1/9/2009	Impax_Opana_PartIII_0006087	Impax_Opana_PartIII_0006088		JX-002			
CX3056-CX3057	Intentionally Not Used					N/A			
CX3058	Email from Joe Camargo to Sammy Bhardway, Alexander Garza, Tamara Alegria, et al. re: Attached Image w/Attach: 0728_001.pdf	6/17/2010	Impax_Opana_PartIII_0013410	Impax_Opana_PartIII_0013412		JX-002			
CX3059	Intentionally Not Used					N/A			
CX3060	Email from Joe Camargo to John Anthony, Todd Engle, Chris Mengler, et al. re: Oxymorphone	1/11/2010	Impax_Opana_PartIII_0030639	Impax_Opana_PartIII_0030641		JX-002			
CX3061	Email from Joe Camargo to Leatha Revels, Kangwen Lin, Denis Paquette, et al. re: Oxymorphone PV Start	1/8/2010	Impax_Opana_PartIII_0015365	Impax_Opana_PartIII_0015365		JX-002			
CX3062	Email from Huyen Vo to Joe Camargo, Denis Paquette, Gerard D. Cravello re: <no subject>	5/26/2010	Impax_Opana_PartIII_0018294	Impax_Opana_PartIII_0018294		JX-002			
CX3063	Email from Joe Camargo to Chuck Hildenbrand, Chris Mengler, and Todd Engle re: March 10 Forecast Submission	3/9/2010	Impax_Opana_PartIII_0018507	Impax_Opana_PartIII_0018509	RX-177	JX-002			
CX3064	Intentionally Not Used					N/A			
CX3065	Email from Joe Camargo to Denis Paquette, Chuck Hildenbrand, Kevin Sica, et al. re: Final March Plan w/Attach: March Plan in Lots and Hours.xls	2/18/2010	Impax_Opana_PartIII_0026043	Impax_Opana_PartIII_0026044		JX-002			
CX3066-CX3068	Intentionally Not Used					N/A			
CX3069	Email from Joe Camargo to Chuck Hildenbrand re: Updated Version w/Attach: 2010 Performance to Objectives.doc	1/17/2011	Impax_Opana_PartIII_0033451	Impax_Opana_PartIII_0033453		JX-002			Tr. 999:09, 15, 23; 1000:13; 1001:19; 1033:09; 1034:22
CX3070-CX3072	Intentionally Not Used					N/A			
CX3073	Email from Ted Smolenski to Joe Camargo, Kevin Sica, Chuck Hildenbrand, et al. re: Generic new product launch projection 2009-02-02.xls w/Attach: Generic new product launch projection 2009-02-02.xls	2/2/2009	Impax_Opana_PartIII_0069451	Impax_Opana_PartIII_0069452		JX-002			
CX3074-CX3075	Intentionally Not Used					N/A			
CX3076	Email from Joe Camargo to Andrew Fox, Art Koch, Chuck Hildenbrand et al. re: Checklist w/Attach: Product Launch Checklist.xls	5/26/2010	Impax_Opana_PartIII_0077872	Impax_Opana_PartIII_0077873		JX-002			
CX3077	Intentionally Not Used					N/A			
CX3078	Email from Joe Camargo to Andrew Fox re: Updated Checklist w/Attach: Product Launch Checklist.xls	5/11/2010	Impax_Opana_PartIII_0079088	Impax_Opana_PartIII_0079089		JX-002			Tr. 980:25, 981:12, 17; 1013:24; 1014:15
CX3079	Intentionally Not Used					N/A			
CX3080	Impax Document: Consulting Agreement	6/1/2017	Impax_Opana_PartIII_0081324	Impax_Opana_PartIII_0081329		JX-002			
CX3081	Email from Joe Camargo to John Anthony, Mark Shaw, and Chuck Hildenbrand re: Impax requested a revised 2010 Oxymorphone Quota	6/9/2010	IMPAX-OPANA-CID00021069	IMPAX-OPANA-CID00021069		JX-002			Tr. 992:13
CX3082	Email from Todd Engle to Kevin Sica, Meg Snowden re: QLPM Sales Forecasts w/Attach: QLPM 051410 Draft.doc	5/18/2010	IMPAX-OPANA-CID00002107	IMPAX-OPANA-CID00002112		JX-002			
CX3083	Email from Todd Engle to Kevin Sica re: Oxymorphone ER peak sales	1/22/2013	IMPAX-OPANA-CID00004062	IMPAX-OPANA-CID00004062		JX-002			
CX3084	Intentionally Not Used					N/A			
CX3085	Email from Chris Mengler to Larry Hsu, Art Koch re: 5-year forecast 2010-May Update 2010--05-14v4.xls w/Attach: 5-year forecast 2010-May Update 2010--05-14v4.xls	5/14/2010	IMPAX-OPANA-CID00006958	IMPAX-OPANA-CID00006959		JX-002			
CX3086-CX3088	Intentionally Not Used					N/A			

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Exhibit No.	Description	Date	BegBates	EndBates	Also Referenced As	Admissibility	Purpose/Notes	*In Camera*	Trial Transcript Citation
CX3089	Email from Joyce De Los Reyes to Joe Camargo, Charles Hildenbrand, Pete Valko, et al. re: Generic new product launch projection 081208.xls	8/12/2008	IMPAX-OPANA-CID00012345	IMPAX-OPANA-CID00012346		JX-002			
CX3090-CX3091	Intentionally Not Used					N/A			
CX3092	Email from Steve Mollichella to Kevin Sica, Todd Engle re: ENDO Payment Calculation w/Attach: Opana ER Peak Calculation for 4Q12 R1 with IMS data.xls	1/29/2013	Impax_Opana_PartIII_0063870	Impax_Opana_PartIII_0063871	RX-215	JX-002			
CX3093-CX3095	Intentionally Not Used					N/A			
CX3096	Impax Presentation: Board Presentation (Non-GAAP)	00/00/2014	Impax_Opana_PartIII_0002842	Impax_Opana_PartIII_0002868		JX-002		Ordered 10/23/2017	Tr. 1223:18; 1224:02
CX3097-CX3101	Intentionally Not Used					N/A			
CX3102	Email from Sean Palmer to Mark Donohue re: Furyk Rating Agency Presentation w/Attach: Impax RAP_v10.20.14.pptx	10/19/2014	Impax_Opana_PartIII_0041757	Impax_Opana_PartIII_0041807		JX-002		Ordered 10/23/2017	
CX3103-CX3104	Intentionally Not Used					N/A			
CX3105	Email from Larry Kloss to Bryan Reasons and George Hill re: 7 Year Plan Summary - 9-9-14 - Update (ALTERNATE w/o IPX 203) w/Attach: 7 Year Plan Summary - 9-9-14 - Update.xlsx	9/8/2014	Impax_Opana_PartIII_0058604	Impax_Opana_PartIII_0058605	RX-203	JX-002		Ordered 10/23/2017	
CX3106	Email from Larry Kloss to Michael Nestor re: IPX203 Financial (Base) Forecast w/Attach: IPX203 Project Timeline_costing (Base_Optimistic)_14Aug2015.potx, IPX203 Operational (Optimistic) Forecast 2015-08-14.xlsx, IPX203 Operational (Optimistic) Forecast...	8/15/2015	Impax_Opana_PartIII_0063716	Impax_Opana_PartIII_0063725	RX-210	JX-002		Ordered 10/23/2017	
CX3107	Email from Larry Kloss to Bryan Reasons, Michael Nestor, Fred Wilkinson, et al. re: 2015 Plan - Executive Review 11-20-14 R1 (Update) w/Attach: Dec 14 BOD 2015 Plan 11-20-14 R1.pdf	11/19/2014	Impax_Opana_PartIII_0063751	Impax_Opana_PartIII_0063765		JX-002		Ordered 10/23/2017	
CX3108-CX3110	Intentionally Not Used					N/A			
CX3111	Email from Joyce de los Reyes to Richard Ting and April Isaacson re: PEC meeting (9AM PT/ 12PM ET) w/Attach: PEC 2015-07-02.pptx	7/2/2015	Impax_Opana_PartIII_0081075	Impax_Opana_PartIII_0081123	RX-239	JX-002		Ordered 10/23/2017	
CX3112	Impax Memorandum from Meg Snowden to Endo Pharmaceuticals Inc. and Penwest Pharmaceuticals Co. re: Settlement and License Agreement by and among Endo Pharmaceuticals Inc., Penwest Pharmaceuticals Co., and Impax Laboratories, Inc. dated June 8, 2010	1/18/2013	IMPAX-OPANA-CID00000323	IMPAX-OPANA-CID00000347		JX-002			
CX3113-CX3114	Intentionally Not Used					N/A			
CX3115	Email from Todd Engle to Larry Hsu, Carole Ben-Maimon, Bryan Reasons, and George Hill re: Updated Materials for Today's Generic Sales and Marketing Meeting w/Attach: Generic Sales and Marketing Meeting Sept 16 2013.pptx	10/2/2013	IMPAX-OPANA-CID00005436	IMPAX-OPANA-CID00005450		JX-002			
CX3116	Intentionally Not Used					N/A			
CX3117	Email from Jeff Miller to Timothy Niedrist re: Update Requested => Impax-Endo Agreement w/Attach: Update Requested => Impax-Endo Agreement	7/2/2012	IMPAX-OPANA-CID00011740	IMPAX-OPANA-CID00011754	RX-355	JX-002			
CX3118	Intentionally Not Used					N/A			
CX3119	Email from Leann Nassar to Bryan Reasons re: Carole's BOD Presentation w/Attach: BOD Slides 12412 Final Generic.pptx	11/21/2012	IMPAX-OPANA-CID00013639	IMPAX-OPANA-CID00013671		JX-002			
CX3120	Intentionally Not Used					N/A			
CX3121	Email from Steve Mollichella to Suneel Gupta, Bryan Reasons, Wenchi Liu, et al. re: Impax-Form 10K-Question w/Attach: 10K Alliance Agreements-R2.xlsx	2/13/2012	IMPAX-OPANA-CID00018543	IMPAX-OPANA-CID00018544		JX-002			
CX3122	Email from Steve Mollichella to Suneel Gupta re: Impax-Form 10K-Question	2/14/2012	IMPAX-OPANA-CID00018550	IMPAX-OPANA-CID00018550		JX-002			
CX3123-CX3124	Intentionally Not Used					N/A			
CX3125	Email from Joanne Tempone to Carole Ben-Maimon and Bryan Reasons re: Endo Deal	11/13/2012	IMPAX-OPANA-CID00019021	IMPAX-OPANA-CID00019022		JX-002			
CX3126	Email from Larry Hsu to Carole Ben-Maimon, Bryan Reasons, Todd Engle, et al. re: Documents I think You'll Find of Interest	2/7/2013	IMPAX-OPANA-CID00019320	IMPAX-OPANA-CID00019323		JX-002			

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Exhibit No.	Description	Date	BegBates	EndBates	Also Referenced As	Admissibility	Purpose/Notes	*In Camera*	Trial Transcript Citation
CX3127-CX3128	Intentionally Not Used					N/A			
CX3129	Endo Spreadsheet: Endo Contribution Margin Report - Period	6/11/2014	EPI000731506	EPI000731506		JX-002			
CX3130	Email from Roberto Cuca to Alan Levin, Darnell Turner, and David Macera re: Per share price impact of generic Opana ER launch	3/15/2010	EPI002159607	EPI001588193	RX-130	JX-002			
CX3131	Email from Alan Levin to Roberto Cuca, Karen Adler, Mark Bradley, and Denise Craig re: Impax and Sandoz Litigations Settled w/Attach: Sandoz June 2010 FINAL Joint-1.doc	6/8/2010	EPI002200039	EPI002200047		JX-002			
CX3132	Email from Alan Levin to Robert Cobuzzi re: IPX066	5/22/2010	EPI002201680	EPI002201682		JX-002			
CX3133	Email from Alan Levin to Blaine Davis re: Penwest Royalties	6/7/2010	EPI002201727	EPI002201728		JX-002			
CX3134	Endo Document: Key Messages	6/4/2010	EPI002209609	EPI002209611		JX-002			
CX3135	Endo Document: Minutes of a Special Meeting of the Board of Directors of Endo Pharmaceuticals Holdings Inc.	5/27/2010	EPI002219841	EPI002219842		JX-002			
CX3136	Email from Caroline Manogue to Jonathan Neely, Alan Levin, Sean Lannon, et al. re: Jefferies Investor Slides v3.pptx w/Attach: Jefferies Investor Slidesv3.pptx, ENDP Jefferies Global Life Sciences Script v3.docx	6/9/2010	EPI002221135	EPI002221149		JX-002			
CX3137-CX3139	Intentionally Not Used					N/A			
CX3140	Impax Presentation: Impax Generic Business Board of Directors Meeting December 11, 2014	12/11/2014	Impax_Opana_PartIII_0003069	Impax_Opana_PartIII_0003109		JX-002		Ordered 10/23/2017	
CX3141	Intentionally Not Used					N/A			
CX3142	Email from Sammy Bhardwaj to Tamara Alegria, Joe Camargo and John Anthony re: Attached Image	3/8/2010	Impax_Opana_PartIII_0015359	Impax_Opana_PartIII_0015360		JX-002			
CX3143-CX3145	Intentionally Not Used					N/A			
CX3146	Email from Todd Engle to Joe Camargo re: Nov Manufacturing Plan w/Attach: Nov 09 Plan in Lots 091012.xls	10/22/2009	Impax_Opana_PartIII_0034840	Impax_Opana_PartIII_0034841		JX-002			
CX3147	Intentionally Not Used					N/A			
CX3148	Email from Todd Engle to Kevin Sica and Thomas Sammier re: Copy of Oxymorphone ER price increase model Aug 2015 TMS 8-8-15.xls w/Attach: Copy of Oxymorphone ER price increase model Aug 2015 TMS 8-8-15.xls	8/19/2015	Impax_Opana_PartIII_0052672	Impax_Opana_PartIII_0052673		JX-002		Ordered 10/23/2017	
CX3149	Email from Mike Grisby to Todd Engle re: M&D Price Adjustment Request: Oxymorphone HCl ER CII Inventory w/Attach: Gen Prod Rev Oxymorph ER 030716 - 1.pdf, Gen Prod Rev Oxymorph ER 030716 - 2.pdf	3/16/2016	Impax_Opana_PartIII_0052702	Impax_Opana_PartIII_0052706		JX-002		Ordered 10/23/2017	
CX3150	Email from William Ball to Tracy Plouffe, Jim MacDonald and Todd Engle re: Oxymorphone price increases w/Attach: OptiSource Price Increase - Oct. 2015.doc	1/21/2016	Impax_Opana_PartIII_0052804	Impax_Opana_PartIII_0052807		JX-002		Ordered 10/23/2017	
CX3151-CX3153	Intentionally Not Used					N/A			
CX3154	Email from Larry Hsu to Todd Engle, Chris Mengler, and Meg Snowden re: Mengler Board Slides	5/14/2010	Impax_Opana_PartIII_0063822	Impax_Opana_PartIII_0063823		JX-002			
CX3155	Email from Todd Engle to Chris Menger and Meg Snowden re: Zorn Model Oxymorphone 03 22 10.xls	3/23/2010	Impax_Opana_PartIII_0063847	Impax_Opana_PartIII_0063848		JX-002			
CX3156	Email from Ted Smolenski to Joyce De Los Reyes, Kevin Sica, Todd Engle, Chris Mengler, et al. re: Endo: One Deal Away from Being Interesting w/Attach: ENDP--UBS--2010-02-22.pdf	2/23/2010	Impax_Opana_PartIII_0080324	Impax_Opana_PartIII_0080341		JX-002			
CX3157	Email from Jason Laeser to Anna Fabish, Ted Hassi, Stephen McIntyre, et al. re: In the Matter of Impax Laboratories, Inc., Docket 9373 w/Attach: Letter to Impax 081117.pdf; Impax DEA quota request documents - oxymorphone quota.pdf	8/11/2017	Impax_Opana_PartIII_0081769	Impax_Opana_PartIII_0081823		JX-002			
CX3158	Email from Kent Summers to Heather Thomson, Ann Harty, Todd Berner, et al. re: EN3288 Value Strategy: Slides for Monday w/Attach: EN3288 HOST 030110v7.pptx	2/28/2010	EPI000325812	EPI000325818		JX-002			Tr. 721:07, 08. 24;
CX3159	Email from Nicholas Albert to Joshua Drew, Kevin O'Connell, William Best, et al. re: sales training referenced in Opana ER RiskMap Update Report w/Attach: Exalgo Backgrounder.pdf; EXALGO Annotated PI.pdf	9/17/2010	EPI000281799	EPI000281852		JX-002			

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CX3160	Document: Endo Pharmaceuticals Holdings Inc. SEC Form 10-K 2009	2/26/2010	CX3160-001	CX3160-228		JX-002			
CX3161	Intentionally Not Used					N/A			
CX3162	Document: Impax White Paper to FTC	2/16/2015	CX3162-001	CX3162-045		JX-002			
CX3163	Document: Answer of Respondent Impax Laboratories Inc. to the Federal Trade Commission's Administrative Complaint	2/7/2017	CX3163-001	CX3163-024		JX-002			
CX3164	Document: Respondent Impax Laboratories, Inc.'s Objections and Responses to Complaint Counsel's Requests for Admission	8/3/2017	CX3164-001	CX3164-022		JX-002			
CX3165	Email from David Paterson to Suneel Gupta re: IPX203	11/17/2014	Impax_Opana_PartIII_0059855	Impax_Opana_PartIII_0059855		JX-002			
CX3166	Impax Presentation: Impax Pharmaceutical R&D	1/24/2013	IMPAX-OPANA-CID00019616	IMPAX-OPANA-CID00019694		JX-002		Ordered 10/23/2017	
CX3167	Impax Presentation: Brand R&D Presentation	8/11/2010	IMPAX-OPANA-CID00019989	IMPAX-OPANA-CID00020051		JX-002		Ordered 10/23/2017	
CX3168	Email from Richard Reeve to Kevin Pong, Mark Bradley, Debbie Travers, et al. re: Project Biloxi: Revisions to the OEW w/Attach: 041211 Biloxi OEW v13 RR.docx, Microsoft_Powerpoint_Slide1.sldx	4/13/2011	EPI000161793	EPI000161829		JX-002			
CX3169	Email from Demir Bingol to Brian Lortie and Steven Cowan re: EOC action item re: Opane ER / 3288 supply chain	2/8/2011	EPI000189554	EPI000189556		JX-002			
CX3170	Email from Sam Rasty to Demir Bingol re: Opana A&P cost question w/Attach: OEW for Project Nevada - Nekfar-118 license 16May08 + market opp.doc, Unnamed Presentation, Unnamed Document	5/28/2008	EPI000300513	EPI000300526		JX-002			
CX3171	Email from Jocelyn Gilmour to Mahen Gundecha, Demir Bingol, Carolyn Kong, et al. re: Old Project Newcastle Information w/Attach: OROS Hydromorphone.doc, Neuromed OEW v3.doc, Unnamed Presentation, Newcastle TPP.doc, Key Questions on Newcastle (dp comments)	6/22/2009	EPI000771172	EPI000771191		JX-002		Ordered 10/20/2017	
CX3172	Email from Meg Snowden to Robert Cobuzzi, Chris Mengler, Michael Nestor, et al. re: IPX066	5/19/2010	EPI000873937	EPI000873937		JX-002			
CX3173	Email from Pranay Patel to Andy Gesek re: Revised Cuba OEW Commercial 4-27-12 w/Attach: Revised Cuba OEW Commercial 4-27-12.docx	4/27/2012	EPI001124711	EPI001124727		JX-002			
CX3174	Email from David Paterson to Robert Cobuzzi, Michael Nestor, Chris Mengler, and Meg Snowden re: IPX066 w/Attach: IPX066_IMPAX_Partner_Confidential_032010_FINAL.pdf, 066 Apr2010AAN poster final poster.ppt	5/20/2010	EPI001433193	EPI001433293		JX-002			
CX3175	Email from Robert Cobuzzi to Donna Petak re: Licensing Update for BoD Book w/Attach: Corp Dev Update for Oct BOD (7).pptx, Freeport OEW v6 091509.docx, Lansing OEW 092509 v3.doc, Unnamed Presentation, Unnamed Presentation, Astoria OEW 100809 v12.docx..	10/16/2009	EPI001828150	EPI001828209		JX-002			
CX3176	Endo Document: IPX-203 Opportunity Evaluation Worksheet (OEW)	6/00/2009	EPI001849033	EPI001849050		JX-002		Ordered 10/23/2017	
CX3177	Endo Cover Email Withheld as Privileged, Attachments: April 2010 Government Affairs Activity Report, Agenda for the Board of Directors Meeting (April 28, 2010), Financial Forecast Board of Directors Meeting Presentation, Commercial Operating Model...	4/00/2010	EPI001896379	EPI001896435		JX-002			
CX3178	Email from Michael Nestor to Robert Cobuzzi and Suneel Gupta re: Information requested	6/4/2010	EPI002156025	EPI002156026		JX-002			
CX3179	Email from Kevin Pong to Guy Donatiello, Charles Gombar and Robert Cobuzzi re: Project Imperial: JDC	9/17/2010	EPI002156098	EPI002156098		JX-002			
CX3180	Email from Robert Cobuzzi to Kevin Pong re: Bob, Kevin Pong need to speak w/ you for 1 minute before the Qatar call. Did not mention subject. Thanks, Donna	9/14/2010	EPI002156228	EPI002156229		JX-002			
CX3181	Email from Donna Papa to Andy Gesek, Nancy Fefrow, Craig Paterson, et al. re: Evaluation of IPX-203 (carbidopa_levodopa).pptx w/Attach: Duopa PI.pdf, Evaluation of IPX-203 (Carbidopa_levodopa).pptx, Rytary PI.pdf	10/28/2015	EPI002190281	EPI002190359		JX-002		Ordered 10/20/2017 & 10/23/2017	Tr. 1108:06, 08, 19; 1109:04; 1110:24; 1112:05; 1113:11; 1114:09; 1119:17; 1120:14; 1121:16; 1192:07, 11; 1194:15

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Exhibit No.	Description	Date	BegBates	EndBates	Also Referenced As	Admissibility	Purpose/Notes	*In Camera*	Trial Transcript Citation
CX3182	Email from Guy Donatiello to Ginola Johnson re: Agreements w/Attach: Sandoz - Endo Settlement Agreement EXECUTION VERSION.pdf; Impax - Endo Settlement Agreement_Opana_[Execution Version].pdf; Impax-Endo Co-Promotion Agreement.pdf	6/21/2010	EPI000828479	EPI000828555		JX-002			
CX3183	Email from Art Koch to Alan Levin, Meg Snowden, Guy Donatiello, et al. re: Gross Margin	6/7/2010	EPI000874092	EPI000874092		JX-002			
CX3184	Email from Brian Lortie to Julie McHugh re: Update	6/7/2010	EPI001170646	EPI001170647		JX-002			
CX3185	Email from Todd Engle to Joe Camargo, Meg Snowden re: Launch Planning Input w/Attach: QLPM 051810 Draft.doc	5/18/2010	Impax_Opana_PartIII_0077527	Impax_Opana_PartIII_0077571		JX-002			
CX3186	Email from Meg Snowden to Guy Donatiello re: Signature pages	6/8/2010	IMPAX-OPANA-CID00002220	IMPAX-OPANA-CID00002220		JX-002			
CX3187	Email from Larry Hsu to Ted Smolenski, Art Koch re: opana ER	1/8/2011	IMPAX-OPANA-CID00003557	IMPAX-OPANA-CID00003558	RX-293	JX-002			
CX3188	Endo Press Release: Endo Pharmaceuticals Reports Strong Third Quarter 2010 Financial Results; Reaffirms 2010 Financial Guidance and Provides Financial Guidance for 2011	11/1/2010	CX3188-001	CX3188-018		JX-002			
CX3189	Endo Press Release: Endo Pharmaceuticals Agrees to Acquire Penwest Pharmaceuticals and Submits NDA for New Formulation of Long-Acting Oxymorphone Designed to be Crush-Resistant	8/9/2010	CX3189-001	CX3189-007		JX-002			
CX3190	Document: Respondent Impax Laboratories, Inc.'s Objections and Responses to Complaint Counsel's Second Set of Interrogatories (Revised)	8/10/2017	CX3190-001	CX3190-029		JX-002		Ordered 10/23/2017	
CX3191	Actavis Spreadsheet: Oxymorphone Sales Accruals	3/29/2017	Actavis_FTC_Opana_000375	Actavis_FTC_Opana_000375		JX-002		Ordered 10/20/2017	
CX3192	Actavis Document: 2009 Opana Settlement Agreement	2/20/2009	ACTLID00000001	ACTLID00000022		JX-002		Ordered 10/20/2017	
CX3193	Endo Presentation: EN3288 Strategic Recommendation	2/16/2010	EPI000004174	EPI000004190		JX-002			
CX3194	Endo Document: US FDA Advisory Committee Briefing Document EN3288	12/2/2010	EPI000006894	EPI000007031		JX-002			
CX3195	Email from Tara Chapman to Frank Yuen, Jill Connell, Linda Kitlinski, et al. re: Opana ER RiskMAP Update Report - Due April 30 w/Attach: Opana ER RiskMap Update Report (01Oct2008-31Dec2008).doc	4/3/2009	EPI000116711	EPI000116735		JX-002			
CX3196	Endo Document: BOA Merrill Lynch Analysis: Raising PO to $35	9/14/2010	EPI000183325	EPI000183347		JX-002			
CX3197	Email from Marv Kelly to Edward DiNapoli, Brian Lortie, Larry Romaine, et al. re: Branded Pharma Day 1_edited backup final.pptx w/Attach: Branded Pharma Day 1_edited backup final.pptx	3/18/2013	EPI000191570	EPI000191580		JX-002			
CX3198	Email from Andy Gesek to Brian Lortie re: Branded Pharmaceuticals deep dive 82913.pptx w/Attach: Branded Pharmaceuticals deep dive 82913.pptx	8/29/2013	EPI000191948	EPI000191949		JX-002			
CX3199	Endo Presentation: 2009-2013 Opana Brand Single Strategy Plan	7/21/2008	EPI000206065	EPI000206067		JX-002		Ordered 10/20/2017	
CX3200	Email from Anthony Analla to Ronald Jackson re: Message from John Kranyak, Sr. Director Market Research and Insights	1/5/2011	EPI000901059	EPI000901060		JX-002			
CX3201	Email from Kristin Vitanza to Kelley Ferris, Anita Brandon re: Delatestlry w/Attach: 2-14-11 Discontinuation Opana ER.PDF	8/1/2011	EPI000980097	EPI000980099		JX-002			
CX3202	Email from Cliff Larsen to Andy Gesek re: Opana ER Scenario Request by KV	5/16/2013	EPI001128605	EPI001128605		JX-002			
CX3203	Email from Brian Risk to Brian Munroe re: Letter to FDA and Opana Citizens Petitions w/Attach: Date-Stamped Opana ER CP 31 Aug 2012.pdf; Endo CP Submission (8-13-12) date-stamped.pdf; Coalition letter to FDA re ADF conditions 101812.pdf	10/18/2012	EPI001180038	EPI001180099	GX1221; RX-065	JX-002			Tr. 477:03
CX3204	Endo Document: Plaintiff's Opposition to Defendants' and Intervenor's Motions to Dismiss and Plaintiff's Reply in Support of Motion for Preliminary Injunction	12/14/2012	EPI001624475	EPI001624514		JX-002			
CX3205	Endo Document: Project Greenland: Grunenthal ADF formulation of Oxymorphone	12/13/2007	EPI002155994	EPI002155999		JX-002			
CX3206	Endo Document: Pricing Proposal Submission Form: GPO Hospital Contract Strategy for Opana ER	4/19/2012	EPI002173430	EPI002173434		JX-002		Ordered 10/20/2017	

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CX3207	Endo Document: Pricing Proposal Submission Form: OPANA ER (CRF) Unit Dose (UD) Line Extension WAC Pricing & Discount Strategies	11/7/2012	EPI002173492	EPI002173494		JX-002			
CX3208	Email from Ted Smolenski to Joe Camargo, Chuck Hildenbrand re: Oxymorphone HCl Tablets 5 mg & 10 mg (Acceptance for Filing Letter Received) and Oxymorphone ER (Final Approval Received) - It's a Double Celebration! w/Attach: Oxymorphone IR Acceptance for F	6/16/2010	Impax_Opana_PartIII_0045547	Impax_Opana_PartIII_0045557		JX-002			
CX3209	Email from Jeff McCown to George Hill, Connie Chiang, David Howard re: Dara w/Attach: Project Dara Financials_(8 11 14).xlsx	8/11/2014	Impax_Opana_PartIII_0060481	Impax_Opana_PartIII_0060482		JX-002		Ordered 10/23/2017	
CX3210	Email from Michelle Mikolai to Todd Engle re: COA and BE Summary Data w/Attach: FDA Approval Letter_Oxymorphone HCl ER Tablets.pdf; MSDS_Oxymorphone Hydrochloride.pdf; Package Insert_Oxymorphone HCl ER Tablets.pdf	1/16/2013	IMPAX-OPANA-CID00002349	IMPAX-OPANA-CID00002363		JX-002			
CX3211	Email from Chris Mengler to Larry Hsu re: Mengler Board Slides w/Attach: Mengler Board Presentation 051310.ppt	5/14/2010	IMPAX-OPANA-CID00018106	IMPAX-OPANA-CID00018127		JX-002			
CX3212	Letter from Joshua Davis to Maren Schmidt re: Endo CID Response to Specs 1, 8, 33, 39	6/27/2014	CX3212-001	CX3212-021		JX-002			
CX3213	Document: Endo Pharmaceuticals Holdings Inc. SEC Form 10-K 2007	2/26/2008	CX3213-001	CX3213-279		JX-002			
CX3214	Document: Endo Pharmaceuticals Holdings Inc. SEC Form 10-K 2010	2/28/2011	CX3214-001	CX3214-594		JX-002			
CX3215	Document: Endo Pharmaceuticals Holdings Inc. SEC Form 10-K 2012	3/1/2013	CX3215-001	CX3215-355	RX-496	JX-002			
CX3216	Document: Endo Pharmaceuticals Holdings Inc. SEC Form 10-Q March 31, 2010	5/3/2010	CX3216-001	CX3216-103		JX-002			
CX3217	Impax Press Release: Impax Comments on Status of ANDA for Generic Opana(R) ER	10/4/2007	CX3217-001	CX3217-002		JX-002			
CX3218	Impax Press Release: Impax Comments on Lawsuit Related to Generic Version of Opana(R) ER	11/19/2007	CX3218-001	CX3218-002		JX-002			
CX3219	Document: Q2 2011 Endo Pharmaceuticals Holdings Earnings Call Transcript	8/9/2011	CX3219-001	CX3219-029		JX-002			
CX3220	Document: Q2 2012 Endo Pharmaceuticals Holdings Earnings Call Transcript	8/7/2012	CX3220-001	CX3220-027		JX-002			
CX3221	Document: Q4 2011 Endo Pharmaceuticals Holdings Earnings Call Transcript	2/24/2012	CX3221-001	CX3221-028		JX-002			
CX3222	Impax Presentation: Board of Directors Meeting May 2010	5/00/2010	Impax_Opana_PartIII_0003917	Impax_Opana_PartIII_0003939	RX-163	JX-002			
CX3223	Impax Document: Minutes of a Special Meeting of the Board of Directors of Impax Laboratories, Inc.	7/5/2013	Impax_Opana_PartIII_0004183	Impax_Opana_PartIII_0004184	RX-168	JX-002			Tr. 467:19
CX3224	Intentionally Not Used					N/A			
CX3225	Email from Kevin Sica to Denis Paquette, Tony Bright, Joe Camargo, et al. re: Dec 09 Forecast Submission w/Attach: Forecast Change From Previous Forecast 1209.xls	12/7/2009	Impax_Opana_PartIII_0006052	Impax_Opana_PartIII_0006053		JX-002			
CX3226	Email from Kevin Sica to Denis Paquette, Tony Bright, Joe Camargo, et al. re: Feb 10 Forecast Submission w/Attach: Forecast Change From Previous Forecast 0210.xls	2/5/2010	Impax_Opana_PartIII_0006056	Impax_Opana_PartIII_0006057		JX-002			
CX3227	Email from Kevin Sica to Denis Paquette, Tony Bright, Joe Camargo, et al. re: April Forecast Submission w/Attach: Forecast Change From Previous Forecast 0410.xls	4/7/2010	Impax_Opana_PartIII_0006060	Impax_Opana_PartIII_0006062		JX-002			
CX3228	Email from Kevin Sica to Denis Paquette, Tony Bright, Joe Camargo, et al. re: July 09 Forecast Submission w/Attach: Forecast Change From Previous Forecast 0709.xls	7/8/2009	Impax_Opana_PartIII_0006075	Impax_Opana_PartIII_0006076		JX-002			
CX3229	Email from Kevin Sica to Denis Paquette, Tony Bright, John Meno, et al. re: Nov 09 Forecast Submission w/Attach: Forecast Change From Previous Forecast 1109.xls	11/6/2009	Impax_Opana_PartIII_0008996	Impax_Opana_PartIII_0008997		JX-002			
CX3230	Email from Kevin Sica to Denis Paquette, Tony Bright, Joe Camargo, et al. re: March 10 Forecast Submission w/Attach: Forecast Change From Previous Forecast 0310.xls	3/5/2010	Impax_Opana_PartIII_0022449	Impax_Opana_PartIII_0022450		JX-002			
CX3231	Spreadsheet: Commercial Forecast - 5-Yr 2010 May Update.xlsx	00/00/0000	Impax_Opana_PartIII_0081650	Impax_Opana_PartIII_0081650		JX-002			

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Exhibit No.	Description	Date	BegBates	EndBates	Also Referenced As	Admissibility	Purpose/Notes	*In Camera*	Trial Transcript Citation
CX3232	Email from Larry Kloss to Art Koch re: 5-year forecast 2010-May Update 201--05-14v5.xls w/Attach: 5-year forecast 2010-May Update 201--05-14v5.xls	5/15/2010	IMPAX-OPANA-CID00007080	IMPAX-OPANA-CID00007081		JX-002			
CX3233	Intentionally Not Used					N/A			
CX3234	Compl., Endo Pharm. Inc. v. Par Pharm. Co., No. 1:12-cv-09261-UA (S.D.N.Y. Dec. 19, 2012)	12/19/2012	CX3234-001	CX3234-003		JX-002	Admitted solely for nonhearsay purposes, i.e., not for the truth of any matter asserted		
CX3235	Dkt. No. 209, Endo Pharm. Inc. v. Actavis LLC, No. 14-cv-01381-RGA (D. Del. Apr. 7, 2017)	4/7/2017	CX3235-001	CX3235-001		JX-002	Admitted solely for nonhearsay purposes, i.e., not for the truth of any matter asserted		
CX3236	Intentionally Not Used					N/A			
CX3237	Endo Pharm. Inc. v. Teva Pharm. USA, Inc., No. 15-2021 (Fed. Cir. appeal docketed Sept. 15, 2015)	9/15/2015	CX3237-001	CX3237-001		JX-002	Admitted solely for nonhearsay purposes, i.e., not for the truth of any matter asserted		
CX3238-CX3239	Intentionally Not Used					N/A			
CX3240	Endo Press Release: Endo Announces Commercial Availability of Opana® ER (oxymorphone HCl) Extended-Release and Opana® (oxymorphone HCl) Immediate-Release Tablets CII	7/24/2006	CX3240-001	CX3240-005		JX-002			
CX3241	Endo Press Release: Endo Completes Transition of OPANA® ER Franchise to New Formulation Designed to be Crush Resistant	6/14/2012	CX3241-001	CX3241-002		JX-002			
CX3242	Letter from Caroline Manogue and Benjamin Palleiko to Gary Buehler, FDA re: NDA No. 21-610 -- Opana ER (oxymorphone HCl) extended release tablets ANDA No. 79-087 (Impax Laboratories)	10/25/2007	EPI001604413	EPI001604430		JX-002			
CX3243	Document: FDA Approval Letter, Opana ER, NDA No. 201655	12/9/2011	CX3243-001	CX3243-009		JX-002			
CX3244	Impax Press Release: IMPAX Announces FDA Acceptance of ANDA for Generic Version of Opana® ER	12/17/2007	CX3244-001	CX3244-002		JX-002			
CX3245	Impax Press Release: Impax Laboratories Receives Tentative FDA Approval for Generic Opana(R) ER 5, 7.5, 10, 20, 30 and 40 mg Tablets	5/14/2010	CX3245-001	CX3245-002		JX-002			
CX3246	Document: Opana ER (NDA No. 021610) Label	8/2/2006	CX3246-001	CX3246-002		JX-002			
CX3247	U.S. Food & Drug Administration, Drugs@FDA, "Numorphan," NDA No. 011738	8/1/2017	CX3247-001	CX3247-003		JX-002			
CX3248	U.S. Food & Drug Administration, Drugs@FDA, "Opana ER," NDA No. 021610	8/1/2017	CX3248-001	CX3248-006		JX-002			
CX3249	U.S. Patent No. 5,662,933	11/3/1995	CX3249-001	CX3249-001		JX-002			
CX3250	U.S. Patent No. 7,276,250	7/3/2002	CX3250-001	CX3250-001		JX-002			
CX3251	U.S. Patent No. 8,309,060	1/9/2012	CX3251-001	CX3251-001		JX-002			
CX3252	U.S. Patent No. 8,309,122	2/28/2007	CX3252-001	CX3252-001		JX-002			
CX3253	U.S. Patent No. 8,329,216	6/29/2006	CX3253-001	CX3253-001		JX-002			
CX3254	U.S. Patent No. 8,808,737	3/3/2010	CX3254-001	CX3254-001		JX-002			
CX3255	U.S. Patent No. 8,871,779	3/3/2007	CX3255-001	CX3255-001		JX-002			
CX3256	Document: Avinza Prescribing Information	4/00/2014	CX3256-001	CX3256-027		JX-002			
CX3257	Document: Butrans Prescribing Information	6/00/2014	CX3257-001	CX3257-041		JX-002			
CX3258	Document: Dolophine Prescribing Information	4/00/2015	CX3258-001	CX3258-024		JX-002			
CX3259	Document: Duragesic Prescribing Information	3/00/2017	CX3259-001	CX3259-056		JX-002			
CX3260	Document: Embeda Prescribing Information	12/00/2016	CX3260-001	CX3260-030		JX-002			
CX3261	Document: Exalgo Prescribing Information	3/00/2010	CX3261-001	CX3261-030		JX-002			
CX3262	Document: Hysingla Prescribing Information	12/00/2016	CX3262-001	CX3262-020		JX-002			
CX3263	Document: Kadian Prescribing Information	12/00/2016	CX3263-001	CX3263-035		JX-002			
CX3264	Document: MS Contin Prescribing Information	4/00/2014	CX3264-001	CX3264-022		JX-002			
CX3265	Document: Nucynta Prescribing Information	12/00/2016	CX3265-001	CX3265-033		JX-002			
CX3266	Document: Opana ER Prescribing Information	12/00/2016	CX3266-001	CX3266-026		JX-002			
CX3267	Document: Opana Prescribing Information	7/00/2012	CX3267-001	CX3267-015		JX-002			
CX3268	Document: OxyContin Prescribing Information	12/00/2016	CX3268-001	CX3268-029		JX-002			
CX3269	Document: Ultram ER Prescribing Information	7/00/2014	CX3269-001	CX3269-023		JX-002			
CX3270	Document: Zohydro Prescribing Information	12/00/2016	CX3270-001	CX3270-028		JX-002			
CX3271	Impax Annual Report 2015: We Care to Make a Difference (December 31, 2015 SEC Form 10-K)	2/22/2016	CX3271-001	CX3271-160		JX-002			
CX3272	Document: Declaration of Margaret Snowden Verifying all Impax Interrogatory Responses	8/10/2017	CX3272-001	CX3272-002		JX-002			

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Exhibit No.	Description	Date	BegBates	EndBates	Also Referenced As	Admissibility	Purpose/Notes	*In Camera*	Trial Transcript Citation
CX3273	Document: Declaration of Demir Bingol, Civil Action Nos. 09-cv-831 (KSH) (PS), 09-cv-832 (KSH) (PS), 09-cv-833 (KSH) (PS)	5/21/2010	CX3273-001	CX3273-010	RX-486	JX-002			Tr. 1280:22; 1280:24; 1281:01; 1281:02; 1281:14; 1281:21; 1282:02; 1282:05; 1282:15; 1283:08; 1286:18; 1287:23; 1287:25; 1288:13; 1292:23; 1315:23
CX3274	Email from Chris Mengler to Chuck Hildenbrand, Art Koch, Meg Snowden, et al. re: Oxymorphone ER Tablets Tentatively Approved Today!!	5/13/2010	Impax_Opana_PartIII_0068875	Impax_Opana_PartIII_0068876		JX-002			
CX3275	Document: Contract Settlement Agreement [Execution Version]	8/5/2017	Impax_Opana_PartIII_0081712	Impax_Opana_PartIII_0081742		JX-002		Ordered 10/23/2017	Tr. 2724:08; 2729:10
CX3276	Document: First Amendment to 2010 Settlement and License Agreement [Execution Version]	8/5/2017	Impax_Opana_PartIII_0081743	Impax_Opana_PartIII_0081763		JX-002			
CX3277	Case 2:16-cv-02526-JLL-JAD Amended Complaint and Exhibits A, B, C, D	8/1/2016	CX3277-001	CX3277-163		JX-002	Admitted solely for nonhearsay purposes, i.e., not for the truth of any matter asserted		
CX3278	Impax Annual Report 2010 (December 31, 2010 SEC Form 10-K)	2/25/2011	CX3278-001	CX3278-144		JX-002			Tr. 267:15
CX3279	Impax Annual Report 2011 (December 31, 2011 SEC Form 10-K)	2/28/2012	CX3279-001	CX3279-092		JX-002			
CX3280	Impax Annual Report 2012 (December 31, 2012 SEC Form 10-K)	2/26/2013	CX3280-001	CX3280-140		JX-002			
CX3281	Actavis Spreadsheet: NPA Opioids 2014-10-07	10/9/2014	ACTLID00216620	ACTLID00220254	RX-005	JX-002			
CX3282	Actavis Spreadsheet: NPA Topical Treatments 2014-10-07	10/9/2014	ACTLID00220255	ACTLID00220255		JX-002			
CX3283	Actavis Spreadsheet: NSP Opioids 2014-10-07	10/7/2014	ACTLID00235955	ACTLID00242664		JX-002			
CX3284	Actavis Spreadsheet: NSP Topical Treatments 2014-10-07	10/9/2014	ACTLID00242665	ACTLID00248717		JX-002			
CX3285	Endo Presentation: Chronic and Breakthrough Pain Treatment Flow	3/00/2009	EPI000001067	EPI000001227		JX-002			
CX3286	Endo Spreadsheet: WAC Price	5/22/2014	EPI000066412	EPI000066412		JX-002			
CX3287	Endo Spreadsheet: Lidoderm-Opana ER 2009-2014	5/22/2014	EPI000066414	EPI000066414		JX-002			
CX3288	Endo Spreadsheet: Specification 60 - COGS 2008-Q12014	6/11/2014	EPI000731501	EPI000731501		JX-002			
CX3289	Endo Spreadsheet: Specification 60 - 2008-2013 ER 522-70	6/11/2014	EPI000731502	EPI000731502		JX-002		Ordered 10/20/2017	
CX3290	Endo Spreadsheet: Specification 60 - 2014 Lido and TRF	6/15/2014	EPI000731513	EPI000731513		JX-002		Ordered 10/20/2017	
CX3291	Endo Spreadsheet: Specification 58	7/22/2014	EPI001492559	EPI001492559		JX-002		Ordered 10/20/2017	
CX3292	Endo Spreadsheet: Final 2016 Opana ER	6/26/2017	EPI002200322	EPI002200322		JX-002		Ordered 10/20/2017	
CX3293	Impax Spreadsheet: COPA Q1 2015	3/15/2017	Impax_Opana_PartIII_0000001	Impax_Opana_PartIII_0000001		JX-002			
CX3294	Impax Spreadsheet: Oxymorphone ER Shipment Data Jan 15 to Feb 17	3/16/2017	Impax_Opana_PartIII_0000003	Impax_Opana_PartIII_0000003		JX-002		Ordered 10/23/2017	
CX3295	Impax Spreadsheet: IMS data All	3/16/2017	Impax_Opana_PartIII_0000004	Impax_Opana_PartIII_0000004		JX-002			
CX3296	Impax Spreadsheet: Monthly Module Views- Rx (NPA)_1_Apr-30-2017	5/8/2017	Impax_Opana_PartIII_0002021	Impax_Opana_PartIII_0002021	RX-149	JX-002		Ordered 10/23/2017	
CX3297	Impax Spreadsheet: copa data q1 2015	5/1/2017	Impax_Opana_PartIII_0002022	Impax_Opana_PartIII_0002022		JX-002		Ordered 10/23/2017	
CX3298	Impax Spreadsheet: Monthly Module Views- Sales (NSP)_1_May-17-2017	5/17/2017	Impax_Opana_PartIII_0002023	Impax_Opana_PartIII_0002023		JX-002		Ordered 10/23/2017	
CX3299	Impax Spreadsheet: Oxymorphone AMP WAC AWP	3/11/2014	IMPAX-OPANA-CID00000270	IMPAX-OPANA-CID00000274		JX-002			
CX3300	Impax Spreadsheet: COPA data	3/19/2014	IMPAX-OPANA-CID00000350	IMPAX-OPANA-CID00000483		JX-002			
CX3301	Impax Spreadsheet: CARS Indirect Historical Pricing for Oxymorphone HCl (3-21-14)	3/21/2014	IMPAX-OPANA-CID00001064	IMPAX-OPANA-CID00001079		JX-002		Ordered 10/23/2017	
CX3302	Impax Spreadsheet: NSP 0715	7/15/2014	IMPAX-OPANA-CID00020806	IMPAX-OPANA-CID00020806		JX-002			
CX3303	Impax Spreadsheet: NPA 0715 data pull	7/15/2014	IMPAX-OPANA-CID00020807	IMPAX-OPANA-CID00020807		JX-002			
CX3304	Impax Spreadsheet: 2014 oxymorphone Sales	1/9/2015	IMPAX-OPANA-CID00023835	IMPAX-OPANA-CID00023835		JX-002		Ordered 10/23/2017	
CX3305	IMS_NPA_2003-2008 - HIGHLY CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER	00/00/0000	IMS_NPA_2003-2008 - HIGHLY CONFIDEN	IMS_NPA_2003-2008 - HIGHLY CONFIDEN		JX-002		Ordered 10/23/2017	
CX3306	IMS_NSP_2003-2008 - HIGHLY CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER	00/00/0000	IMS_NSP_2003-2008 - HIGHLY CONFIDEN	IMS_NSP_2003-2008 - HIGHLY CONFIDEN		JX-002		Ordered 10/23/2017	
CX3307	OXYMORPHONE_IR_2009-2010 - HIGHLY CONFIDENTIAL	00/00/0000	OXYMORPHONE_IR_2009-2010 - HIGHLY C	OXYMORPHONE_IR_2009-2010 - HIGHLY C		JX-002		Ordered 10/23/2017	
CX3308	Email from Larry Hsu to Chris Mengler, Todd Engle, Meg Snowden, et al. re: Mengler Board Slides	5/14/2010	Impax_Opana_PartIII_0063824	Impax_Opana_PartIII_0063825		JX-002			
CX3309	Case 2:09-cv-00831-KSH-PS: Transcript of May 14, 2010 Teleconference	5/17/2010	CX3309-001	CX3309-020		JX-002			

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Exhibit No.	Description	Date	BegBates	EndBates	Also Referenced As	Admissibility	Purpose/Notes	*In Camera*	Trial Transcript Citation
CX3310	Email from Anna Fabish to Nick Leefer, Ted Hassi, Michael Antalics, et al. re: Docket 9373 - Forecast and Board of Director Documents in Impax"s Productions w/Attach: 7202017_Letter_to_Complaint_Counsel_ re_Board_Documents_and_Forecasts_.pdf	7/21/2017	CX3310-001	CX3310-010		JX-002			
CX3311	Email from William Hicks to Jamie Towey, Paula Blizzard re: Civil Investigative Demand to Impax Laboratories, Inc. (FTC File No. 141004) w/Attach: March 27, 2014 Ltr. to J. Towey.PDF	3/27/2014	CX3311-001	CX3311-006		JX-002			
CX3312	Letter from Anna Fabish to Nick Leefer re: In re Impax Laboratories, Inc., Dkt. No. 9373	5/11/2017	CX3312-001	CX3312-010		JX-002		Ordered 10/23/2017	
CX3313	Document: Q4 2009 Impax Laboratories Earnings Conference Call - Final	2/25/2010	CX3313-001	CX3313-015		JX-002			
CX3314	Letter from Joshua Davis to J. Maren Schmidt re: FTC File No. 1410004 / Endo Pharmaceuticals Inc.	6/16/2014	CX3314-001	CX3314-008		JX-002			
CX3315	Intentionally Not Used					N/A			
CX3316	Email from J. Maren Schmidt to Barbara Wootton, Jamie Towey, Eric Sprague, et al. re: Endo Pharmaceuticals Inc.	4/20/2015	CX3316-001	CX3316-005		JX-002			
CX3317	Actavis Document: ActionSTAT Additional Pack Size Availability for Oxymorphone Hydrochloride Extended-Release	1/2/2014	Actavis_FTC_Opana_000377	Actavis_FTC_Opana_000377		JX-002			
CX3318	Endo Spreadsheet: 2008-2013 ER 553-70	6/11/2014	EPI000731503	EPI000731503		JX-002		Ordered 10/20/2017	
CX3319	Endo Spreadsheet: 2008-2013 ER 571-70	6/11/2014	EPI000731504	EPI000731504		JX-002		Ordered 10/20/2017	
CX3320	Endo Spreadsheet: 2008-2013 ER 617-70	6/11/2014	EPI000731505	EPI000731505		JX-002		Ordered 10/20/2017	
CX3321	Endo Spreadsheet: 2008-2013 ER 674-70	6/11/2014	EPI000731507	EPI000731507		JX-002		Ordered 10/20/2017	
CX3322	Endo Spreadsheet: 2008-2013 ER 693-70	6/11/2014	EPI000731508	EPI000731508		JX-002		Ordered 10/20/2017	
CX3323	Endo Spreadsheet: 2008-2013 ER 907-70	6/11/2014	EPI000731509	EPI000731509		JX-002		Ordered 10/20/2017	
CX3324	Endo Spreadsheet: 2008-2013 ER 907-75	6/11/2014	EPI000731510	EPI000731510		JX-002			
CX3325	Endo Spreadsheet: 2012-2013 TRF ALL	6/11/2014	EPI000731512	EPI000731512		JX-002		Ordered 10/20/2017	
CX3326	Endo Spreadsheet: Final 2014 OPANA ER	7/5/2017	EPI002200323	EPI002200323		JX-002		Ordered 10/20/2017	
CX3327	Endo Spreadsheet: Final 2015 Opana ER	7/5/2017	EPI002200324	EPI002200324		JX-002		Ordered 10/20/2017	
CX3328	Impax Spreadsheet: Copy of Oxymorphone ER - GTN&COGS Apr'15 to Feb'17	3/16/2017	Impax_Opana_PartIII_0000002	Impax_Opana_PartIII_0000002		JX-002		Ordered 10/23/2017	
CX3329	Email from Danielle Morelli to Andrew Fox, Tim Jones re: Oxymorphone	6/1/2011	IMPAX-OPANA-CID00020787	IMPAX-OPANA-CID00020792	RX-395	JX-002			
CX3330	Email from Barbara Wootton to Maren Schmidt, Jamie Towey, Eric Sprague, et al. re: FTC File No. 1410004--HIGHLY CONFIDENTIAL w/Attach: Endo Responses to V. Chen Additional Data Questions.pdf; EPI - HIGHLY CONFIDENTIAL Indirect customers.xlsx; et al.	6/9/2015	FTC-PROD-0016597	FTC-PROD-0016607		JX-002			
CX3331	Email from Steven Reade to Maren Schmidt, Jamie Towey, Eric Sprague, et al. re: Endo Pharmaceuticals Inc. w/Attach: 2.13.15 Letter to FTC.PDF; 2.13.15 Responses to FTC Data Questions.pdf	2/13/2015	FTC-PROD-0017763	FTC-PROD-0017772		JX-002			
CX3332	Email from Justin Watkins to Eliot Choy, Doug Macpherson, Guy Donatiello re: Endo Signature Pages w/Attach: Co-Promote Agmt - Endo Sig Page.pdf; Settlement Agmt - End Sig Page.pdf	6/8/2010	EPI000183779	EPI000183781		JX-002			
CX3333	Email from Art Koch to Alan Levin, Guy Donatiello, Meg Snowden, et al. re: <no subject>	6/4/2010	EPI000874044	EPI000874048		JX-002			
CX3334	Email from Alan Levin to Julie McHugh re: Good news....	6/3/2010	EPI001379279	EPI001379279		JX-002			
CX3335	Email from David Paterson to Robert Cobuzzi, Michael Nestor, Meg Snowden, et al. re: IPX066 w/Attach: DATA LIST.doc	5/22/2010	EPI001433181	EPI001433188		JX-002			
CX3336	Email from Alan Levin to Roberto Cuca re: Highly Confidential - Rule 408 Settlement Communication	5/31/2010	EPI001688706	EPI001688709		JX-002			
CX3337	Intentionally Not Used					N/A			

Exhibit No.	Description	Date	BegBates	EndBates	Also Referenced As	Admissibility	Purpose/Notes	*In Camera*	Trial Transcript Citation
CX3338	Email from Kevin Pong to Stephen Bai, Paula Clark, Frank Diana, et al. re: Project Imperial DD Reports w/Attach: Project Imperial_Regulatory DD Report_Clark.docx; Project Imperial_ CDMA DDReport_Kopecky.docx; Project Imperial_Clin Pharm DD Report_Bai.doc	6/3/2010	EPI002156237	EPI002156256		JX-002			
CX3339	Email from Ivan Gergel to Stephen Bai, Frank Diana, Sandeep Gupta re: Information Requested	6/5/2010	EPI002159879	EPI002159881		JX-002			Tr. 2603:18; 2603:20; 2603:23
CX3340	Email from Karen Adler to Edward Sweeney re: You are not alone	6/5/2010	EPI002161112	EPI002161112		JX-002			
CX3341	Email from Mark Bradley to Julie McHugh, Lori Tierney re: Data request	6/7/2010	EPI002161155	EPI002161163		JX-002			
CX3342	Impax Document: Co-Promotion Agreement dated as of June xx, 2010 by and between Endo Pharmaceuticals Inc. and [Impax Laboratories, Inc.] DBR DRAFT	6/4/2010	Impax_Opana_PartIII_0002558	Impax_Opana_PartIII_0002585		JX-002			
CX3343	Email from Michael Nestor to Suneel Gupta re: IPX203	3/17/2015	Impax_Opana_PartIII_0056586	Impax_Opana_PartIII_0056586		JX-002			
CX3344	Intentionally Not Used					N/A			
CX3345	Email from David Ailinger to David Paterson, Suneel Gupta, Michael Nestor re: Endo IPX-203 w/Attach: Endo08072015.ppt	8/7/2015	Impax_Opana_PartIII_0063726	Impax_Opana_PartIII_0063735	RX-211	JX-002		Ordered 10/23/2017	
CX3346	Intentionally Not Used					N/A			
CX3347	Email from Todd Engle to Chris Mengler, Larry Hsu, Chuck Hildenbrand, et al. re: Quarterly Launch Planning Meeting Background Documentation w/AttachL launch planning 02 02 10 R2.doc	2/2/2010	Impax_Opana_PartIII_0044547	Impax_Opana_PartIII_0044571	RX-194	JX-002			Tr. 1751: 09; 1751:11; 1752:10; 1753:10; 1753:15; 1771:24; 1772:08; 1788:19; 1789:07
CX3348	Email from Todd Engle to Chris Mengler, Larry Hsu, Chuck Hildenbrand, et al. re: Quarterly Launch Planning Meeting May 20, 2010 Agenda Materials w/Attach: QLPM 052010.doc	5/20/2010	Impax_Opana_PartIII_0069160	Impax_Opana_PartIII_0069201	RX-216	JX-002			Tr. 556:08; 556:13; 557:06; 557:20; 558:03; 1755:08; 1756:03; 1756:10; 1756:14; 1757:05; 1775:10; 1789:15; 1789:17; 1790:11
CX3349	Email from Art Koch to Alan Levin, Meg Snowden, Michael Nestor, et al. re: <no subject>	6/6/2010	IMPAX-OPANA-CID00001411	IMPAX-OPANA-CID00001412	RX-042	JX-002			
CX3350	Intentionally Not Used					N/A			
CX3351	Email from Jonathan Neely to Dave Holveck, Alan Levin, Julie McHugh, et al. re: Documents for Tomorrow's Earnings Call Prep Session w/Attach: ENDP Q2 2010 financial results conference call script v8.docx; et al.	7/22/2010	EPI001175573	EPI001175620		JX-002			
CX3352	Letter from Christine Levin to Bradley Albert re: In the Matter of Impax Laboratories, Inc., Dkt. No. 9373	7/26/2017	CX3352-001	CX3352-002		JX-002			
CX3353	Letter from Christine Levin to Bradley Albert re: In the Matter of Impax Laboratories, Inc., Dkt. No. 9373	8/2/2017	CX3353-001	CX3353-011		JX-002			
CX3354	Letter from Christine Levin to Eric Sprague re: clarification to Brad Albert'sJune 22, 2017 letter concerning Endo's transaction data	8/9/2017	CX3354-001	CX3354-001		JX-002			
CX3355	FDA Document: Introduction for the FDA Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioid Analgesics	5/00/2017	CX3355-001	CX3355-021		JX-002			Tr. 747:05, 06; 749:07; 750:01, 14; 754:01; 2172:14; 2172:17; 2173:11
CX3356	Case 2:16-cv-02526-JLL-JAD: Motion to Dismiss	7/11/2016	CX3356-001	CX3356-050		JX-002	Admitted solely for nonhearsay purposes, i.e., not for the truth of any matter asserted		
CX3357	Case 2:16-cv-02526-JLL-JAD: Amended Motion to Dismiss	8/29/2016	CX3357-001	CX3357-049		JX-002	Admitted solely for nonhearsay purposes, i.e., not for the truth of any matter asserted		
CX3358	Case 2:16-cv-02526-JLL-JAD: Declaration in Support of Motion to Dismiss	8/29/2016	CX3358-001	CX3358-010		JX-002	Admitted solely for nonhearsay purposes, i.e., not for the truth of any matter asserted		
CX3359	Case 2:16-cv-02526-JLL-JAD: Brief in Opposition of Motion to Dismiss	10/3/2016	CX3359-001	CX3359-047		JX-002	Admitted solely for nonhearsay purposes, i.e., not for the truth of any matter asserted		
CX3360	Case 2:16-cv-02526-JLL-JAD: Reply Brief in Support of Motion to Dismiss	10/11/2016	CX3360-001	CX3360-020		JX-002	Admitted solely for nonhearsay purposes, i.e., not for the truth of any matter asserted		

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CX3361	Case 2:16-cv-02526-JLL-JAD: Opinion	10/25/2016	CX3361-001	CX3361-014		JX-002	Admitted solely for nonhearsay purposes, i.e., not for the truth of any matter asserted		
CX3362	Case 2:16-cv-02526-JLL-JAD: Order	10/25/2016	CX3362-001	CX3362-001		JX-002	Admitted solely for nonhearsay purposes, i.e., not for the truth of any matter asserted		
CX3363	Case 2:16-cv-02526-JLL-JAD: Joint Discovery Plan	1/30/2017	CX3363-001	CX3363-011		JX-002	Admitted solely for nonhearsay purposes, i.e., not for the truth of any matter asserted		
CX3364	Case 2:16-cv-02526-JLL-JAD: Pretrial Scheduling Order	2/6/2017	CX3364-001	CX3364-004		JX-002	Admitted solely for nonhearsay purposes, i.e., not for the truth of any matter asserted		
CX3365	Case 2:16-cv-02526-JLL-JAD: Letter from Brian Goldberg to Judge Dickson re: Joint Proposed Revised Scheduling Order	5/4/2017	CX3365-001	CX3365-039		JX-002	Admitted solely for nonhearsay purposes, i.e., not for the truth of any matter asserted		
CX3366	Case 2:16-cv-02526-JLL-JAD: Discovery Confidentiality Order	5/5/2017	CX3366-001	CX3366-029		JX-002	Admitted solely for nonhearsay purposes, i.e., not for the truth of any matter asserted		
CX3367	Case 2:16-cv-02526-JLL-JAD: Revised Scheduling Order	5/5/2017	CX3367-001	CX3367-001		JX-002	Admitted solely for nonhearsay purposes, i.e., not for the truth of any matter asserted		
CX3368	Case 2:16-cv-02526-JLL-JAD: Joint Letter to Judge Dickson re: Discovery Disputes	5/10/2017	CX3368-001	CX3368-009		JX-002	Admitted solely for nonhearsay purposes, i.e., not for the truth of any matter asserted		
CX3369	Case 2:16-cv-02526-JLL-JAD: Notice of Withdrawal of Pro Hac Vice Counsel	6/16/2017	CX3369-001	CX3369-003		JX-002	Admitted solely for nonhearsay purposes, i.e., not for the truth of any matter asserted		
CX3370	Case 2:16-cv-02526-JLL-JAD: Notice of Unopposed Motion to Seal	7/13/2017	CX3370-001	CX3370-027		JX-002	Admitted solely for nonhearsay purposes, i.e., not for the truth of any matter asserted		
CX3371	Case 2:16-cv-02526-JLL-JAD: Order to Seal	7/20/2017	CX3371-001	CX3371-007		JX-002	Admitted solely for nonhearsay purposes, i.e., not for the truth of any matter asserted		
CX3372	Case 2:16-cv-02526-JLL-JAD: Letter from Brian Goldberg to Judge Linares re: Stipulation and Order	8/8/2017	CX3372-001	CX3372-004		JX-002	Admitted solely for nonhearsay purposes, i.e., not for the truth of any matter asserted		
CX3373	Case 2:16-cv-02526-JLL-JAD: Order of Dismissal	8/21/2017	CX3373-001	CX3373-004		JX-002	Admitted solely for nonhearsay purposes, i.e., not for the truth of any matter asserted		
CX3374	Email from Kevin Sica to Kevin Sica re: May 09 Forecast Submission w/Attach: Forecast Change From Previous Forecast 0509.xls	5/7/2009	Impax_Opana_PartIII_0006079	Impax_Opana_PartIII_0006080		JX-002			
CX3375	Email from Kevin Sica to Denis Paquette re: April 09 Forecast Submission UPDATED w/Attach: Forecast Change From Previous Forecast 0409 UPDATED.xls	4/7/2009	Impax_Opana_PartIII_0006081	Impax_Opana_PartIII_0006082		JX-002			
CX3376	Email from Kevin Sica to Denis Paquette re: March Forecast Submission w/Attach: Forecast Change From Previous Forecast 0309.xls	3/6/2009	Impax_Opana_PartIII_0006083	Impax_Opana_PartIII_0006084		JX-002			
CX3377	Email from Kevin Sica to Denis Paquette re: February Forecast Submission w/Attach: Forecast Change From Previous Forecast0209.xls	2/6/2009	Impax_Opana_PartIII_0006085	Impax_Opana_PartIII_0006086		JX-002			
CX3378	Email from Pamela Politis to Lamar Caison, Yelena Bond re: PAragraph iv agreements w/Attach: Impax Laboratories, Inc.-Settlement&LicenseAgmt(PenwestPhamn)Jun10.pdf: et al.	11/12/2010	EPI001985443	EPI001985456		JX-002			
CX3379-CX3382	Intentionally Not Used					N/A			

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Exhibit No.	Description	Date	BegBates	EndBates	Also Referenced As	Admissibility	Purpose/Notes	*In Camera*	Trial Transcript Citation
CX3383	Actavis Document: Settlement and License Agreement	2/20/2009	ACTLID00049661	ACTLID00049661		JX-002	Admitted solely for nonhearsay purposes, i.e., not for the truth of any matter asserted	Ordered 10/20/2017	
CX3384-CX3433	Intentionally Not Used					N/A			
CX3434	Case 2:16-cv-02526-JLL-JAD: Docket	9/11/2017	CX3434-001	CX3434-005		JX-002	Admitted solely for nonhearsay purposes, i.e., not for the truth of any matter asserted		
CX3435	Case 2:16-cv-02526-JLL-JAD: Complaint	5/4/2016	CX3435-001	CX3435-156		JX-002	Admitted solely for nonhearsay purposes, i.e., not for the truth of any matter asserted		
CX3436	Case 2:16-cv-02526-JLL-JAD: Impax Laboratories, Inc.'s Answer, Affirmative Defenses, and Counterclaims to Plaintiff's Amended Complaint	11/22/2016	CX3436-001	CX3436-107		JX-002	Admitted solely for nonhearsay purposes, i.e., not for the truth of any matter asserted		
CX3437	Case 2:16-cv-02526-JLL-JAD: Amended Complaint	8/1/2016	CX3437-001	CX3437-163		JX-002	Admitted solely for nonhearsay purposes, i.e., not for the truth of any matter asserted		Tr. 2083:08; 2088:13; 2089:09; 2892:10
CX3438	Email from Susan Ostrander to Carole Ben-Maimon re: Board Presentation from 8/22 meeting w/Attach: 4a-Generic Aug2012 FINAL.pptx	11/5/2012	Impax_Opana_PartIII_0080393	Impax_Opana_PartIII_0080427		JX-002		Ordered 10/23/2017	Tr. 1741:25; 1742:02; 1742:13; 1742:24; 1746:20; 1746:21; 1748:1; 1765:21; 1790:22; 1790:23; 1791:12
CX3439	Document: Respondent Impax's Responses and Objections to CC's First Set of Interrogatories	5/5/2017	CX3439-001	CX3439-010		JX-002			
CX3440	Document: Respondent Impax's Supplemental Responses and Objections to First Set of Interrogatories	5/22/2017	CX3440-001	CX3440-004		JX-002			
CX3441	Document: Respondent Impax's Responses and Objections to CC's Interrogatory No. 19 (Revised)	8/11/2017	CX3441-001	CX3441-017		JX-002		Ordered 10/23/2017	
CX3442	Document: Respondent Impax's Responses and Objections to CC's Third Set of Interrogatories (Revised)	8/11/2017	CX3442-001	CX3442-019		JX-002		Ordered 10/23/2017	
CX3443	Email from Brian Hogan to Roberto Cuca re: Opana ER / IR P & L Scenario Model w/Attach: Opana ER Net ASP analysis - generic v4.xlsx	5/26/2010	EPI000180183	EPI000180188		JX-002			
CX3444	Email from James Bradley to Brian Lortie, Andy Gesek re: Three year forecast- revised w/Attach: Three Year Company Total--OPANA-TRF scenarios.xlsx; Three Year Plan 2010.xlsx	2/5/2010	EPI000710067	EPI000710069		JX-002			
CX3445	Email from Demir Bingol to Brian Lortie re: Opana ER Combined P&L scenarios - Jul-10 generics.xlsx w/Attach: Opana ER Combined P&L scenarios - Jul-10 generics.xlsx	6/1/2010	EPI001553350	EPI001553351		JX-002			
CX3446	Email from Karen Adler to Robert Cobuzzi, Alan Butcher, Robert Barrett, et al. re: Three Year Forecast for Compensation Discussion at 3 pm w/Attach: Three Year Plan 2010 (3) .xlsx; Three Year Company Total--OPANA-TRF scenarios (2).xlsx	2/11/2010	EPI001828479	EPI001828481		JX-002			
CX3447	Email from Alan Levin to Erik Groot, Nancy Santilli, Karen Adler, et al. re: Endo: Ratings Agency Presentation w/Attach: 090724-ENDP-Ratings Agency Presentation-V58.ppt; et al.	8/9/2009	EPI001892413	EPI001892427		JX-002			
CX3448	Endo Spreadsheet: Lidoderm, Opana TRF, Opana ER Orig. FY08 Jan- FY14 Dec	12/00/2014	EPI-000003392	EPI-000003392		JX-002			
CX3449	Impax Document: Paragraph IV Patent Certification: 5,662,933	00/00/0000	IMPAX-OPANA-CID00000017	IMPAX-OPANA-CID00000018	RX-466	JX-002			
CX3450	Impax Document: Paragraph IV Patent Certification: 5,958,456	00/00/0000	IMPAX-OPANA-CID00000019	IMPAX-OPANA-CID00000020	RX-265	JX-002			
CX3451	Impax Document: Paragraph IV Patent Certification: 7,276,250	00/00/0000	IMPAX-OPANA-CID00000021	IMPAX-OPANA-CID00000022		JX-002			
CX3452	Endo Document: Delcaration of Guy Donatiello in Support of Plaintiff's Motion for Preliminary Injunction	9/10/2013	EPI001489431	EPI001489708		JX-002			
CX3453	Email from Brian Lortie to Julie McHugh re: Opana ER impact	6/1/2010	EPI002442186	EPI002442187		JX-002			
CX3454	Email from Marjorie O'Brien to Guy Donatiello, Pamela Politis, Ginola Johnson re: LEGAL EXPENSES - FORECAST w/Attach: Litigation Details for May LBE Forecast.xlsx	5/10/2010	EPI002395438	EPI002395439		JX-002			
CX3455	Case 1:12-cv-08985-TPG-GWG: Transcript	9/19/2013	CX3455-001	CX3455-057		JX-002			

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CX3456	Case 09-cv-831, 832, 833: Declaration of John S. Russell, M.S.	5/21/2010	EPI002496955	EPI002496985		JX-002			
CX3457-CX3999	Intentionally Not Used					N/A			
CX4000	Excerpt of IH Transcript: Paul Bisaro (Actavis)	11/20/2014	CX4000-001	CX4000-051		JX-002			
CX4001	IH Transcript: Arthur A. Koch, Jr (Impax)	10/27/2014	CX4001-001	CX4001-072		JX-002			
CX4002	IH Transcript: Theodore Smolenski (Impax)	9/30/2014	CX4002-001	CX4002-088		JX-002			Tr. 1658:09
CX4003	IH Transcript: Margaret Snowden (Impax)	10/15/2014	CX4003-001	CX4003-080		JX-002			
CX4004	IH Transcript: Todd Engle (Impax)	8/20/2014	CX4004-001	CX4004-113		JX-002			Tr. 1745:15; 1745:16; 1745:22
CX4005	IH Transcript: Alan Levin (Endo) Day 1	11/13/2014	EPI002160614	EPI002160688	RX-516	JX-002			
CX4006	IH Transcript: Alan Levin (Endo) Day 2	11/14/2014	ENDO-OPANA-000001782	ENDO-OPANA-000001839	RX-517	JX-002			
CX4007	IH Transcript: Brian Lortie (Endo)	9/18/2014	EPI002160510	EPI002160613	RX-505	JX-002			
CX4008	IH Transcript: Caroline Manogue (Endo) Day 1	9/25/2014	ENDO-OPANA-000002562	ENDO-OPANA-000002649	RX-506	JX-002			
CX4009	IH Transcript: Caroline Manogue (Endo) Day 2	12/2/2014	ENDO-OPANA-000002650	ENDO-OPANA-000002719	RX-520	JX-002			
CX4010	IH Transcript: Christopher Mengler (Impax)	9/10/2014	CX4010-001	CX4010-087		JX-002			
CX4011	IH Transcript: David Holveck (Endo)	11/18/2014	EPI002160689	EPI002160778	RX-518	JX-002			
CX4012	Excerpt of IH Transcript: Guy Donatiello (Endo)	12/9/2014	ENDO-OPANA-000001104	ENDO-OPANA-000001210		JX-002			
CX4013	IH Transcript: Kevin Pong, Ph.D. (Endo)	12/4/2014	ENDO-OPANA-000003125	ENDO-OPANA-000003203	RX-521	JX-002			
CX4014	IH Transcript: Larry Hsu (Impax)	10/30/2014	CX4014-001	CX4014-075		JX-002			
CX4015	IH Transcript: Robert Barto (Endo)	11/25/2014	ENDO-OPANA-000000001	ENDO-OPANA-000000077	RX-519	JX-002			
CX4016	Excerpt of IH Transcript: Robert Cobuzzi (Endo)	9/11/2014	ENDO-OPANA-000000438	ENDO-OPANA-000000560		JX-002			
CX4017	Deposition Transcript: Alan Levin (Endo)	8/10/2017	CX4017-001	CX4017-074	RX-543	JX-002			
CX4018	Deposition Transcript: Arthur A. Koch, Jr. (Impax)	6/6/2017	CX4018-001	CX4018-061		JX-002			
CX4019	Deposition Transcript: Brian Lortie (Endo)	6/27/2017	CX4019-001	CX4019-070		JX-002			
CX4020	Deposition Transcript: Bryan Reasons (Impax)	8/11/2017	CX4020-001	CX4020-060		JX-002		Ordered 10/23/2017	
CX4021	Deposition Transcript: Carole Ben-Maimon (Impax)	5/31/2017	CX4021-001	CX4021-078		JX-002			
CX4022	Deposition Transcript: Christopher Mengler (Impax)	5/25/2017	CX4022-001	CX4022-093		JX-002			
CX4023	Deposition Transcript: Chuck Hildenbrand (Impax)	7/25/2017	CX4023-001	CX4023-086		JX-002			
CX4024	Deposition Transcript: David Macera (Endo)	7/12/2017	CX4024-001	CX4024-067	RX-537	JX-002			
CX4025	Deposition Transcript: Demir Bingol (Endo)	6/15/2017	CX4025-001	CX4025-079		JX-002			
CX4026	Deposition Transcript: Huong Nguyen (Impax)	6/29/2017	CX4026-001	CX4026-079	RX-535	JX-002			
CX4027	Deposition Transcript: John Anthony (Impax)	7/25/2017	CX4027-001	CX4027-074		JX-002			
CX4028	Deposition Transcript: Joseph Carmargo (Impax)	8/9/2017	CX4028-001	CX4028-092		JX-002			
CX4029	Deposition Transcript: Kevin Sica (Impax)	8/8/2017	CX4029-001	CX4029-044	RX-542	JX-002			
CX4030	Deposition Transcript: Larry Hsu (Impax)	7/28/2017	CX4030-001	CX4030-054		JX-002			
CX4031	Deposition Transcript: Mark Bradley (Endo)	7/6/2017	CX4031-001	CX4031-076	RX-536	JX-002			
CX4032	Deposition Transcript: Margaret Snowden (Impax)	8/2/2017	CX4032-001	CX4032-093		JX-002			
CX4033	Deposition Transcript: Michael Nestor (Impax)	8/4/2017	CX4033-001	CX4033-075		JX-002		Ordered 10/23/2017	Tr. 3019:24
CX4034	Deposition Transcript: Richard Rogerson (Actavis)	8/4/2017	CX4034-001	CX4034-043	RX-541	JX-002			
CX4035	Deposition Transcript: Roberto Cuca (Endo)	8/4/2017	CX4035-001	CX4035-067		JX-002			
CX4036	Deposition Transcript: Shawn Fatholahi (Impax)	5/23/2017	CX4036-001	CX4036-066	RX-533	JX-002			
CX4037	Deposition Transcript: Theodore Smolenski (Impax)	7/18/2017	CX4037-001	CX4037-105		JX-002			
CX4038	Deposition Transcript: Todd Engle (Impax)	8/17/2017	CX4038-001	CX4038-076		JX-002			
CX4039	Deposition Transcript: Roger G. Noll	10/2/2017	CX4039-001	CX4039-108		JX-002			
CX4040	Deposition Transcript: Max H. Bazerman	9/28/2017	CX4040-001	CX4040-088		JX-002			
CX4041	Deposition Transcript: Seddon R. Savage	9/29/2017	CX4041-001	CX4041-058		JX-002			
CX4042	Deposition Transcript: John Geltosky	9/27/2017	CX4042-001	CX4042-086		JX-002			
CX4043	Deposition Transcript: Thomas Hoxie	10/6/2017	CX4043-001	CX4043-118		JX-002			
CX4044	Deposition Transcript: Sumanth Addanki	10/5/2017	CX4044-001	CX4044-106		JX-002			
CX4045	Deposition Transcript: E. Anthony Figg	9/29/2017	CX4045-001	CX4045-121		JX-002			
CX4046	Deposition Transcript: Edward Michna	10/3/2017	CX4046-001	CX4046-079		JX-002			
CX4047-CX4999	Intentionally Not Used					N/A			
CX5000	Expert Report: Roger G. Noll	8/25/2017	CX5000-001	CX5000-292		JX-002	Admitted on condition that expert testifies at the hearing of this matter	Ordered 11/28/2017	Tr. 1650:13; 1677:15; 1677:16; 1680:07; 1680:08
CX5001	Expert Report: Max H. Bazerman	8/18/2017	CX5001-001	CX5001-069		JX-002	Admitted on condition that expert testifies at the hearing of this matter		
CX5002	Expert Report: Seddon R. Savage	8/25/2017	CX5002-001	CX5002-106		JX-002	Admitted on condition that expert testifies at the hearing of this matter		Tr. 706:03, 04; 727:20; 735:20; 738:06; 740:19; 2189:02; 2189:04; 2193:02
CX5003	Expert Report: John Geltosky	8/25/2017	CX5003-001	CX5003-070		JX-002	Admitted on condition that expert testifies at the hearing of this matter		Tr. 706:03, 04; 727:20; 735:20; 738:06; 740:19; 1130:23

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CX5004	Rebuttal Expert Report: Roger G. Noll	9/20/2017	CX5004-001	CX5004-117		JX-002	Admitted on condition that expert testifies at the hearing of this matter		Tr. 1606:25
CX5005	Rebuttal Expert Report: Max H. Bazerman	9/20/2017	CX5005-001	CX5005-015		JX-002	Admitted on condition that expert testifies at the hearing of this matter		
CX5006	Rebuttal Expert Report: Seddon R. Savage	9/20/2017	CX5006-001	CX5006-021		JX-002	Admitted on condition that expert testifies at the hearing of this matter		
CX5007	Rebuttal Expert Report: Thomas Hoxie	9/20/2017	CX5007-001	CX5007-053		JX-002	Admitted on condition that expert testifies at the hearing of this matter		
CX5008-CX6019	Intentionally Not Used					N/A			
CX6020	Congressional Budget Office, Prices for Brand-Name Drugs under Selected Federal Programs, June 2005	07/00/2005	CX6020-001	CX6020-024		JX-002			
CX6021	Centers for Disease Control and Prevention, Opioid Morphine Equivalent Factors (March 2015)	03/00/2015	CX6021-001	CX6021-001		JX-002			
CX6022 - CX6032	Intentionally Not Used					N/A			
CX6033	Endo Press Release: Endo Recieves FDA Approval for Opana(R) ER (oxymorphone HCl) Extended-Release and Opana(R) (oxymorphone HCl) Immediate Release Tablets CII	6/23/2006	CX6033-001	CX6033-001		JX-002			
CX6034	Endo Press Release: Endo Pharmaceuticals to Launch Three New Dosage Strengths of OPANA® ER	3/3/2008	CX6034-001	CX6034-003		JX-002			
CX6035	Endo Press Release: Endo Provides Update On OPANA® ER	7/6/2017	CX6035-001	CX6035-010		JX-002			
CX6036 - CX6037	Intentionally Not Used					N/A			
CX6038	FDA Letter from Bob Rappaport to Susan Rinnea, Alza Corporation re: NDA 19-813/S-039	2/4/2005	CX6038-001	CX6038-004		JX-002			
CX6039	FDA Letter from Keith Webber to Monique Weitz, Actavis South Atlantic LLC re: ANDA 079046	12/13/2010	CX6039-001	CX6039-007		JX-002			
CX6040	FDA Document: Chemical Review Application: BuTransTM (Buprenorphine) Transdermal System	12/19/2000	CX6040-001	CX6040-037		JX-002			
CX6041	FDA Document: FENTANYL TRANSDERMAL SYSTEM - fentanyl patch, extended release	2/9/2011	CX6041-001	CX6041-028		JX-002			
CX6042	FDA Document: Generic Drugs: Questions & Answers	8/15/2017	CX6042-001	CX6042-008		JX-002			
CX6043	FDA Document: Guidance for Industry: Bioavailability and Bioequivalence Studies Submitted in NDAs or INDs — General Considerations	3/00/2014	CX6043-001	CX6043-029		JX-002			
CX6044	FDA Document: FDA Listing of Authorized Generics as of June 30, 2017	6/30/2017	CX6044-001	CX6044-092		JX-002			
CX6045	FDA Document: Drugs@FDA: FDA Approved Drug Products - Oxymorphone Hydrochloride	8/15/2017	CX6045-001	CX6045-002		JX-002			
CX6046	FDA Document: Drugs@FDA: FDA Approved Drug Products - Oxymorphone Hydrochloride Therapeutic Equivalents	8/15/2017	CX6046-001	CX6046-002		JX-002			
CX6047	FDA Document: FDA recommends against the continued use of propoxyphene	11/19/2010	CX6047-001	CX6047-005		JX-002			
CX6048	FDA Press Release: FDA requests removal of Opana ER for risks related to abuse	6/8/2017	CX6048-001	CX6048-003		JX-002			
CX6049	Document: Fentanyl 019813_ORIGINAL APPROVAL_PACKAGE	8/7/1990	CX6049-001	CX6049-344		JX-002			
CX6050	FDA Presentation: Regulatory History of Opana ER	3/13/2017	CX6050-001	CX6050-165		JX-002			
CX6051	Intentionally Not Used					N/A			
CX6052	Federal Trade Commission, Authorized Generic Drugs: Short-Term Effects and Long-Term Impacts, (August 2011)	8/00/2011	CX6052-001	CX6052-270		JX-002			
CX6053	Federal Trade Commission, Generic Drug Entry Prior to Patent Expiration: An FTC Study (July 2002)	7/00/2002	CX6053-001	CX6053-129		JX-002			
CX6054	U.S. Department of Justice and the Federal Trade Commission, Horizontal Merger Guidelines (2010)	8/19/2010	CX6054-001	CX6054-037		JX-002			

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CX6055	Federal Trade Commission, Pay-For-Delay: How Drug Company Pay-Offs Cost Consumers Billions (2010)	1/00/2010	CX6055-001	CX6055-016		JX-002			
CX6056 - CX6059	Intentionally Not Used					N/A			
CX6060	Impax Press Release: Impax Laboratories Receives Final FDA Approval for Generic OPANA® ER Tablets	7/22/2010	CX6060-001	CX6060-002		JX-002			
CX6061 - CX6085	Intentionally Not Used					N/A			
CX6086	Federal Trade Commission, "The Past and Future of Direct Effects Evidence", Remarks of J. Thomas Rosch, March 30, 2011	3/30/2011	CX6086-001	CX6086-017		JX-002			
CX6087 - CX6098	Intentionally Not Used					N/A			
CX6099	Centers for Disease Control and Prevention Guideline for Prescribing Opioids for Chronic Pain – United States, 2016	3/18/2016	CX6099-001	CX6099-052		JX-002			
CX6100	Centers for Disease Control and Prevention Morbidity and Mortality Weekly Report (MMWR) (November 4, 2011)	11/4/2011	CX6100-001	CX6100-036		JX-002			
CX6101 - CX6106	Intentionally Not Used					N/A			
CX6107	FDA Document: Joint Meeting of the Drug Safety and Risk Management and Anesthetic and Analgesic Drug Products Advisory Committees (March 13, 2017)	3/13/2017	CX6107-001	CX6107-354		JX-002			
CX6108 - CX6131	Intentionally Not Used					N/A			
CX6132	Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Summary of Agreements Filed in FY 2007, Federal Trade Commission Bureau of Competition. May 2008	05/00/2008	CX6132-001	CX6132-008		JX-002			
CX6133	Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Summary of Agreements Filed in FY 2006, Federal Trade Commission Bureau of Competition. January 2007	1/00/2007	CX6133-001	CX6133-010		JX-002			
CX6134	Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Summary of Agreements Filed in FY 2009, Federal Trade Commission Bureau of Competition. April 2011.	4/00/2011	CX6134-001	CX6134-009		JX-002			
CX6135 - CX6136	Intentionally Not Used					N/A			
CX6137	Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Summary of Agreements Filed in FY 2004, Federal Trade Commission Bureau of Competition. December 2004.	12/00/2004	CX6137-001	CX6137-008		JX-002			
CX6138	Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Summary of Agreements Filed in FY 2008, Federal Trade Commission Bureau of Competition. January 2010.	1/00/2010	CX6138-001	CX6138-008		JX-002			
CX6139	Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Summary of Agreements Filed in FY 2013, Federal Trade Commission Bureau of Competition. December 2014.	12/00/2014	CX6139-001	CX6139-004		JX-002			
CX6140	Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Summary of Agreements Filed in FY 2014, Federal Trade Commission Bureau of Competition. January 2016.	1/00/2016	CX6140-001	CX6140-004		JX-002			

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CX6141	Letter from the FDA to Endo Pharmaceuticals re NDA 201655 Approval	12/9/2011	CX6141-001	CX6141-006		JX-002			
CX6142 - CX6143	Intentionally Not Used					N/A			
CX6144	Authorized Generic Drugs: Short-Term Effects and Long-Term Impact (Federal Trade Commission, August 2011)	8/00/2011	CX6144-001	CX6144-270		JX-002			
CX6145 - CX6146	Intentionally Not Used					N/A			
CX6147	Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug,Improvement, and Modernization Act of 2003, Summary of Agreements Filed in FY 2005, Federal Trade Commission Bureau of Competition. April 2006.	4/00/2006	CX6147-001	CX6147-007		JX-002			
CX6148	Generic Drug Entry Prior to Patent Expiration: An FTC Study (Federal Trade Commission, July 2002)	7/00/2002	CX6148-001	CX6148-129		JX-002			

CERTIFICATE OF SERVICE

I hereby certify that on December 28, 2017, I filed the foregoing document electronically using the FTC's E-Filing System, which will send notification of such filing to:

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I also certify that I delivered via electronic mail a copy of the foregoing document to:

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December 28, 2017 By: /s/ *Charles A. Loughlin*
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CERTIFICATE FOR ELECTRONIC FILING

I 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.

December 28, 2017 By: /s/ *Charles A. Loughlin*
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