UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: **Maureen K. Ohlhausen, Acting Chairman**
Terrell McSweeny

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

OPINION AND ORDER OF THE COMMISSION

By Acting Chairman Maureen K. Ohlhausen, for the Commission:

On January 19, 2017, the Commission issued an administrative complaint alleging that a litigation settlement agreement between Impax Laboratories, Inc. ("Impax") and Endo Pharmaceuticals, Inc. ("Endo") was an anticompetitive agreement in violation of Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45. The Complaint alleges that Impax agreed to abandon a legal challenge of Endo patents and to delay launching its generic version of an Endo drug (Opana ER) in exchange for a large, unjustified "reverse payment" from Endo.

In its Answer to the Complaint,[1] Impax asserts an affirmative defense that the challenged conduct had substantial procompetitive justifications, benefited consumers, and avoided infringement of valid patents. Answer at 21. Impax further asserts that the procompetitive justifications outweigh any alleged anticompetitive effects.[2]

[1] This opinion uses the following abbreviations for citations to the record:
Comp.: Complaint
Answer: Answer of Respondent Impax Laboratories Inc. to the Federal Trade Commission's Administrative Complaint
CCB: Memorandum of Law in Support of Complaint Counsel's Motion for Partial Summary Decision
CCSUF: Complaint Counsel's Statement of Undisputed Facts
CCRRSMF: Complaint Counsel's Reply to Impax Laboratories Inc.'s "Statement of Material Facts That Remain in Dispute"
ROB: Respondent Impax Laboratories, Inc.'s Memorandum of Law in Opposition to Complaint Counsel's Motion for Partial Summary Decision
RSMF: Respondent Impax Laboratories, Inc.'s Statement of Material Facts that Remain in Dispute

[2] Impax's Eighth Affirmative Defense reads:

Before us at this time is Complaint Counsel's Motion for Partial Summary Decision, which contends that certain justifications that Impax might assert in defense of its challenged agreement fail as a matter of law and cannot serve as defenses. CCB at 1-2.

Under Rule 3.24 of the Commission's Rules of Practice, a party may move for summary decision "upon all or any part of the issues being adjudicated." 16 C.F.R. §3.24(a)(1). We review motions for partial summary decision using the same legal standard as applies under Federal Rule of Civil Procedure 56 in federal courts. *See N. Carolina Bd. of Dental Exam'rs*, 151 F.T.C. 607, 610-11 (2011), *aff'd N. Carolina Bd. of Dental Exam'r v. FTC*, 717 F.3d 359 (4th Cir. 2013), *aff'd* 135 S. Ct. 1101 (2015). A party moving for summary decision must show that "there is no genuine dispute as to any material fact," and that it is "entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); *see also* 16 C.F.R. § 3.24(a)(2) ("If the Commission . . . determines that there is no genuine issue as to any material fact regarding liability or relief, it shall issue a final decision and order.").

I. BACKGROUND FACTS

The background facts, as alleged in the Complaint and described in the parties' briefs, are largely undisputed. Consistent with the requirements of Commission Rule 3.24, Complaint Counsel submitted "a separate and concise statement of the material facts as to which the moving party contends there is no genuine issue for trial." 16 C.F.R. § 3.24(a)(1). Here, "Impax does not dispute most of the facts advanced in Complaint Counsel's Motion, [although] Impax does dispute material facts" that are relevant for other parts of the case. ROB at 4 n.3; *see also* RSMF at 1 n.1.

The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq*., as amended by the Drug Price Competition and Patent Term Restoration Act of 1984 (or the "Hatch-Waxman Act") and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, codified at 21 U.S.C. §§ 355(b) (2), 355(j) and 35 U.S.C. § 271(e), establishes procedures designed to facilitate competition from generic drugs while maintaining incentives for pharmaceutical companies to develop new drugs. Under the Hatch-Waxman scheme, the U.S. Food and Drug Administration ("FDA") requires a company seeking to market a new pharmaceutical product to identify any patents that it believes reasonably could be asserted against a generic company that makes, uses, or sells a generic version of the branded product. *See* 21 U.S.C. §§ 355(b)(1) and (c)(2); 21 C.F.R. §§ 314.53(b) and (c)(2). These patents are listed in an FDA publication,

---

> The alleged conduct had substantial pro-competitive justifications, benefited consumers and the public interest, and avoided potential infringement of valid patents. These pro-competitive justifications outweigh any alleged anticompetitive effects of the alleged conduct. There were no less restrictive alternatives that could have achieved these same pro-competitive outcomes.

Answer at 21.

"Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly known as the "Orange Book").

A company seeking to market a generic version of a branded drug may file an Abbreviated New Drug Application ("ANDA") with the FDA. The generic applicant must demonstrate 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. When the brand-name drug is covered by one or more patents listed in the Orange Book, a company seeking to market a generic version before the patents expire must make a "paragraph IV certification" in its ANDA certifying that the listed patents are invalid, unenforceable, and/or will not be infringed by the generic drug. If a company makes a paragraph IV certification, it must notify the patent holder of the filing of its ANDA. If the patent holder initiates a patent infringement suit against the company within 45 days, 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) expiration of a 30-month regulatory stay.

Opana ER is an extended-release opioid used to relieve pain. CCSUF ¶¶ 1, 3. Endo received FDA approval to market Opana ER in June 2006 and launched the product in July 2006. *Id*. ¶¶ 4, 5. In June 2007, Impax filed an ANDA seeking FDA approval to market a generic version of Opana ER. *Id*. ¶ 9.

[redacted] *Id*. ¶ 7. [redacted] *Id*. Impax then submitted a new ANDA with paragraph IV certifications that, according to the Complaint, asserted that Impax's generic version of Opana ER did not infringe the '933 or '456 patents. *Id*. ¶ 10; Compl. ¶ 38.

Endo sued Impax for infringement of the '933 and '456 patents, which triggered a 30-month stay on FDA approval of Impax's ANDA. CCSUF ¶ 15. Following that stay, Impax received the FDA's final approval in June 2010. *Id*. ¶ 19.

Trial in the infringement case began on June 3, 2010. *Id*. ¶ 17. On June 8, 2010, before the trial's outcome was known, Impax and Endo settled the patent infringement case and executed a Settlement and License Agreement (the "Settlement Agreement"). *Id*. ¶ 20.

[redacted] *Id*. ¶ 21. [redacted]

[redacted] *Id*. ¶ 22.[3] [redacted]

[4] *Id*. ¶ 23.

[redacted] *Id*. ¶ 24. Endo and Impax also entered a development and co-promotion agreement for a potential treatment for Parkinson's disease that Impax was developing. *Id*. ¶¶ 20, 25. According to the Complaint, the purpose and effect of the authorized generic arrangements and cash payments were "to induce Impax to abandon its patent challenge and agree not to compete with a generic version" of Endo's Opana ER "until January 2013." Comp. ¶¶ 74-75.

In July 2010, Endo filed a supplemental New Drug Application for a reformulated version of Opana ER, which the FDA approved in December 2011. CCSUF ¶ 29. In 2012, Endo ceased selling original Opana ER and began selling the reformulated Opana ER. *Id*. ¶ 30.

At the time Impax and Endo entered the Settlement Agreement, Endo had pending applications for additional patents relating to Opana ER. In November and December 2012, the U.S. Patent and Trademark Office ("USPTO") issued three patents to Endo, Nos. 8,309,060, 8,309,122, and 8,329,216. *Id*. ¶¶ 32-33. In December 2012, Endo began asserting these patents against drug manufacturers seeking to market generic versions of Opana ER. *Id*. ¶ 34. Endo did not assert these patents against Impax's generic version of original Opana ER. *Id*. In August 2015, the U.S. District Court for the Southern District of New York held that the '122 and '216 patents were not invalid and were infringed by generic versions of original Opana ER produced by defendants other than Impax and by generic versions of reformulated Opana ER, including Impax's. *See Endo Pharm. Inc. v. Amneal Pharm., LLC*, 2015 WL 9459823, at *2 (S.D.N.Y. Aug. 18, 2015), *amended in part*, 2016 WL 1732751 (S.D.N.Y. Apr. 29, 2016), *appeal reactivated*, Nos. 2015-2021 *et al*. (Fed. Cir. Aug. 4, 2016). The court issued an injunction prohibiting all defendants from selling their infringing products; consequently, all defendants except Impax are enjoined from selling generic versions of original Opana ER until the patents expire, and all defendants, including Impax, are enjoined from selling the reformulated version. *Id*. at *66. Complaint Counsel assert that the injunction expires in 2029. CCSUF ¶ 36. Impax suggests that the '122 and '216 patents expire in 2023. RSMF at 10. The U.S. Patent and Trademark Office issued two additional patents covering Opana ER in 2014; one patent was

[3] Impax and Endo have been litigating a dispute regarding the Settlement Agreement's provisions relating to future patents. Complaint Counsel assert that that dispute has "no significance for the legal issue presented by this motion" and therefore "assume that Impax's position in that dispute is correct" for purposes of the motion at hand. CCB at 4 n.1. For purposes of this Opinion and Order, we too will make that assumption. Complaint Counsel now state that Impax and Endo have settled their lawsuit but provide no details. CCRRSMF at 2 n.2.

[4] [redacted]

issued to Endo and the other to Mallinkcrodt, which has provided an exclusive field-of-use license to Endo. CCSUF ¶ 35.

II. PROCEDURAL HISTORY

To determine the nature of Impax's claim of procompetitive justifications, Complaint Counsel served an interrogatory asking Impax to "[i]dentify all procompetitive justifications and benefits to consumers and the public interest referenced in the Eighth Defense in Your Answer to the Complaint in this case, and explain the factual basis for Your answer to this Interrogatory, including all facts and documents You rely on . . . ." Compl. Counsel's Mot. to Compel Resp. to Interrog. Nos. 2 & 3 at 2 (June 1, 2017). In its response to the interrogatory, Impax stated that the interrogatory "involves an opinion or contention that relates to fact or the application of law to fact. Therefore, under Federal Trade Commission Rule of Practice § 3.35(b)(2), no answer is required until the close of discovery. Impax will supplement its response . . . in due course." *Id*. Ex. B (Resp't Impax Laboratories, Inc.'s Obj. and Resps. to Compl. Counsel's First Set of Interrogs. at 7).[5]

Complaint Counsel filed a motion to compel a response to the interrogatory with Chief Administrative Law Judge ("ALJ") D. Michael Chappell. *See* Compl. Counsel's Mot. to Compel Resp. to Interrog. Nos. 2 & 3 (June 1, 2017). Judge Chappell denied the motion. He explained that deferring an answer to contention interrogatories until the close of discovery is the usual position established by Commission Rule 3.35(b)(2) and found that Complaint Counsel had not demonstrated appropriate circumstances to require the contention interrogatories be answered before the end of discovery. *See* Order Den. Compl. Counsel's Mot. to Compel Resp. to Interrog. Nos. 2 and 3 at 3-4 (June 12, 2017).

Consequently, Impax had not yet fully articulated or described its procompetitive justifications for the conduct alleged in the Complaint when Complaint Counsel filed the Motion for Partial Summary Decision.

III. COMPLAINT COUNSEL'S MOTION AND IMPAX'S RESPONSE

Complaint Counsel argue that certain justifications that Impax may identify should be rejected because they are inconsistent with the logic of the Supreme Court's decision in *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013). Complaint Counsel contend that these justifications are not legally viable.

First, according to Complaint Counsel, *Actavis* precludes an argument that entry before patent expiration is procompetitive. CCB at 10. Complaint Counsel argue that *Actavis*

[5] Rule 3.35(b)(2) states that an interrogatory that seeks "an opinion or contention that relates to fact or the application of law to fact . . . need not be answered until after designated discovery has been completed, but in no case later than 3 days before the final prehearing conference." 16 C.F.R. § 3.35(b)(2).

recognized that the challenged patent may not be valid or infringed, so the proper benchmark is not a comparison to the full preclusive effect of the patent. *Id*. Complaint Counsel explain, "A reverse-payment settlement that allows the generic to enter the market before patent expiration [also] eliminates the risk of competition prior to the agreed-upon entry date." *Id*. Therefore, Complaint Counsel argue, "the Supreme Court necessarily rejected the proposition that a reverse-payment settlement could be rendered lawful because it allowed for entry prior to patent expiration." *Id*. at 11.

Second, Complaint Counsel contend that *Actavis* precludes Impax from claiming the elimination of patent and business uncertainty as a justification for a reverse-payment settlement. CCB at12. According to Complaint Counsel, while the Supreme Court recognized the business certainty benefits of patent settlements, it nonetheless concluded that those benefits "did not justify the significant risk of substantial anticompetitive effects that reverse payments pose." *Id*.

Finally, Complaint Counsel claim that patent rulings that occur after the Settlement Agreement cannot justify the reverse payment because, under *Actavis*, the assessment of competitive effects focuses on circumstances at the time the agreement was entered, when the outcome of litigation was uncertain. CCB at 15. Here, Complaint Counsel contend that "the relevant harm to competition under *Actavis* is not that, absent the reverse payment, generic entry would necessarily have been earlier, but rather that the payment served to eliminate the *risk* (even if 'small') that competition would have been earlier." *Id*. at 17-18 (citing *Actavis*, 133 S. Ct. at 2236).

Impax responds that Complaint Counsel's motion seeks to upend traditional rule-of-reason analysis and, while ostensibly directed at procompetitive benefits, would effectively truncate Complaint Counsel's *prima facie* showing. It explains that, under the rule of reason, the plaintiff bears the initial burden of showing a substantially adverse effect on competition, and only if that burden is met must the defendant come forward with procompetitive justifications. ROB at 11. Impax argues that *Actavis* rejected Complaint Counsel's premise that any reverse payment necessarily creates antitrust concern and therefore requires justification by defendants. *Id*. (citing *Actavis*, 133 S. Ct. at 2237 (rejecting argument that reverse payment settlements are presumptively unlawful)). According to Impax, "'[t]he existence and degree of any anticompetitive consequence may . . . vary' based on a payment's characteristics and 'any other convincing justification.'" *Id*. at 11-12 (alteration in original) (quoting *Actavis*, 133 S. Ct. at 2237).

Courts look to "a challenged restraint's actual effects," Impax insists, "without limitations on the temporal scope of the evidence." *Id*. at 13 (citations omitted). "[H]ypothetical competitive effects" should not be elevated over "known competitive impact," *id*. at 19 (emphasis omitted); actual market effects are always relevant, *id*. at 2-3, 13-16; and "closing the courtroom door to actual competitive-effects evidence is" inappropriate, *id*. at 1. Impax also

argues that the specific procompetitive effects challenged by Complaint Counsel – including entry before patent expiration and patent-related defenses – have been recognized in cases, including *Actavis*. *Id*. at 24-27.

IV. ANALYSIS

Complaint Counsel's Motion for Partial Summary Decision asks the Commission to declare that three results of the settlement agreement – (i) authorizing Impax to enter prior to expiration of various existing and future Endo patents; (ii) providing Impax with certainty that it could launch its generic products free from the risk of infringing Endo's existing and future patents; and (iii) enabling Impax to continue selling its generic product despite a court ruling that two Endo patents obtained after the settlement were valid and infringed – are not cognizable as defenses to the conduct challenged in the Complaint. CCB at 1, 18. Complaint Counsel seek an order foreclosing Impax from making arguments to justify or otherwise defend the Settlement Agreement on those bases. *Id*. For two reasons, however, Complaint Counsel's motion is premature.

The first reason relates to the posture of this proceeding. As of the time that Complaint Counsel framed their motion (August 3, 2017) and the time that Impax filed its opposition (August 31, 2017), Impax had not specified its contentions regarding procompetitive benefits. Impax's Affirmative Defense 8 merely asserts that "[t]he alleged conduct had substantial pro-competitive justifications, benefited consumers and the public interest, and avoided potential infringement of valid patents." Although Complaint Counsel sought more details, the ALJ determined that Complaint Counsel had not shown need to accelerate the timing specified by Commission Rule 3.35(b)(2), which permits Impax to defer responding until after the close of discovery (but in no case later than three days before the final prehearing conference). *See* Order Den. Compl. Counsel's Mot. to Compel Resp. to Interrog. Nos. 2 and 3 at 3-4 (June 12, 2017).[6]

Consequently, the Motion for Summary Decision rests on characterizations of Impax's likely positions drawn by Complaint Counsel from statements made by Impax during the pre-complaint investigation or at the Initial Pretrial Conference. CCB at 6.[7] In opposing that Motion, Impax describes Complaint Counsel's characterizations as "strawmen" and reaffirms that it has not yet fully articulated its procompetitive justifications. ROB at 3. Consequently, Complaint Counsel's Motion asks us to prevent further argument on positions that Impax has not clearly adopted, without knowing whether those positions have been accurately portrayed or whether they are meant to be applied individually or in combination; intended to be treated as

[6] Most fact discovery was to close on August 11, 2017, depositions of experts were to conclude by October 2, 2017, and the final prehearing conference was scheduled for October 19, 2017. Second Revised Scheduling Order (June 19, 2017).

[7] In contrast, when the Commission recently awarded partial summary decision in *1-800 Contacts*, Complaint Counsel directed their motion to the entirety of two specific affirmative defenses, the text of which defined their content. *See In re 1-800 Contacts, Inc.*, FTC Dkt. No. 9372, 2017 WL 511541, at *1-2 (Feb. 1, 2017).

relevant or as dispositive; or asserted as presenting countervailing efficiencies or as reducing the magnitude of any anticompetitive effects. In light of this procedural posture, we are currently unwilling to render summary decision.

Our second reason for finding Complaint Counsel's Motion premature relates to the nature of its subject matter and the state of the relevant law. Complaint Counsel ask us to reject specific aspects of possible procompetitive benefits before the structure of the relevant rule-of-reason inquiry has been determined. Indeed, although the Motion ostensibly focuses on Impax's justifications, it rests substantially on Complaint Counsel's view of the "rule of reason principles" applicable to this proceeding. CCB at 9. We have reservations about attempting to specify a complete rule-of-reason framework at this stage of the proceeding. Some background is necessary here.

In *Actavis*, the Supreme Court, *inter alia*, made three important, but limited rulings relating to the nature of the antitrust liability inquiry. First, the Court held that reverse payment settlements are not to be judged under the so-called "scope of the patent" test, under which reverse payment arrangements automatically pass muster so long as their anticompetitive effects fall within the scope of the exclusionary potential of the patent. 133 S. Ct. at 2227, 2230-32. Consequently, a reverse payment settlement can sometimes violate antitrust law even if generic entry is allowed prior to the patent's expiration date, *id*. at 2227, or if the patent permits the branded firm to charge drug prices sufficient to recoup the reverse payments. *Id*. at 2230. The Court explained that the scope of the patent test erroneously assumes that the patent is valid and infringed and fails to give weight to procompetitive antitrust policies. *Id*. at 2230-32.

Second, the Court held that anticompetitive effects should not be presumed from the mere presence of a reverse payment. *Id*. at 2237. A quick-look review, the Court stated, is appropriate only when an observer with even a "rudimentary" knowledge of economics could conclude that the practice in question would have an anticompetitive effect, a criterion not satisfied by reverse payment settlements. *Id*.

Finally, the Court held that the analysis should proceed under the rule of reason. *Id*. The Court explained that it will "normally not [be] necessary to litigate patent validity," *id*. at 2236; *see also id*. at 2237; and it observed that justifications for reverse payments may include litigation costs saved through settlement, compensation attributable to other services rendered by the generic firm, or, potentially, other considerations. *Id*. at 2236. Overall, "the likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification." *Id*. at 2237. After noting that it was not requiring that plaintiffs demonstrate the virtues or vices of the patent system or account for every possible supporting fact or theory that might have minimal bearing on the possibility of anticompetitive consequences, the Supreme Court left it "to the lower

courts" to determine how to structure the rule-of-reason antitrust litigation in the *Actavis* case. *Id*. at 2237-38.

Speaking at the most general level, two federal appellate courts have held that the "traditional" rule of reason is applicable in reverse payment cases. *King Drug Co. of Florence v. Smithkline Beecham Corp.*, 791 F.3d 388, 399 (3rd Cir. 2015); *see also In re Loestrin 24 Fe Antitrust Litig.*, 814 F.3d 538, 551 n.12 (1st Cir. 2016). Beyond this, the Third Circuit has provided a generalized recitation of the elements of a rule of reason inquiry[8] and has repeated various rulings in *Actavis*.[9] Apart from generalities, however, the federal appellate courts have offered only scattered guidance. *See, e.g.*, *In re Lipitor Antitrust Litig.*, 868 F.3d 231, 256 (3rd Cir. 2017) ("[D]efendants have the burden of justifying [a] . . . large reverse payment"); *id*. at 263 ("[I]ntent is not an element of an antitrust claim"); *Loestrin*, 814 F.3d at 551 n.12 (noting that the size of the reverse payment is a strong indicator of market power and is central to the antitrust query).[10]

The most comprehensive appellate discussion has been provided by the California Supreme Court in a case involving the California antitrust statute, the Cartwright Act. *See In re Cipro Cases I & II*, 348 P.3d 845 (Cal. 2015).[11] The court reasoned that patents should be viewed probabilistically: thus, for a patent with a 50 percent chance of being upheld, the patent could be viewed as likely to continue to govern competition for half of its remaining life, on average. *Id*. at 864. A reverse payment settlement that delays generic entry only to that midpoint would replicate the expected level of competition, thereby reflecting the patent's

[8] The Third Circuit explains that, under standard formulations, the plaintiff bears the initial burden of showing that the challenged agreements produced adverse anticompetitive effects within the relevant markets. *See King Drug*, 791 F.3d at 412. In a reverse payment case, the court elaborates, "the plaintiff must prove payment for delay, or, in other words, payment to prevent the risk of competition." *Id.* (citation omitted). If plaintiff makes the requisite showing, defendant then has the burden to show procompetitive justifications. *Id*. The plaintiff may rebut the defendant's justifications by demonstrating that "the restraint is not reasonably necessary to achieve the stated objective." *Id*. (quoting *United States v. Brown Univ.*, 5 F.3d 658, 669 (3rd Cir. 1993)).

[9] *See, e.g., King Drug*, 791 F.3d at 412.

[10] Some appellate discussions have provided guidance regarding the requirements applicable to a private plaintiff's showing that a reverse payment settlement caused injury. *See, e.g.*, *In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132, 164-70 (3rd Cir. 2017): *In re Nexium (Esomeprazole) Antitrust Litig.*, 842 F.3d 34, 61-65 (1st Cir. 2016). The courts, however, have distinguished the private injury showing from the demonstration of liability under the rule-of-reason inquiry. *See Wellbutrin*, 868 F.3d at 170 n.64 (refraining from discussing the rule of reason other than observing that it is fact intensive and not easily applied at the summary judgment stage); *Nexium*, 842 F.3d at 59-60.

[11] The California court viewed interpretations of federal law such as *Actavis* as "at most instructive, [but] not conclusive" with regard to application of the Cartwright Act. *Cipro*, 348 P.3d at 858 (internal quotation marks and citations omitted). Some federal district courts, however, have found the California court's *Cipro* analysis persuasive in the Sherman Act context. *See, e.g.*, *In re K-Dur Litig.*, 2016 WL 755623, at *13 (D. N.J. Feb. 25, 2016) (expressly adopting *Cipro*'s statement of the *prima facie* case and the respective burdens of plaintiff and defendant); *see also In re Aggrenox Antitrust Litig.*, 2015 WL 4459607, at *9 (D. Conn. July 21, 2015) (describing *Cipro* as "one of the most thorough and thoughtful discussions of *Actavis* yet issued by any court").

strength; delay beyond that point would constitute anticompetitive harm.[12] "An agreement to exchange compensation for elimination of any portion of the period of competition that would have been expected had a patent been litigated[," therefore,] is a violation of the Cartwright Act." *Id*. at 865. The California court operationalized this analysis by postulating that a large reverse payment that cannot otherwise be explained is cause to believe that there has been payment for exclusion beyond the point that would have resulted, on average, from litigating the case to conclusion. *Id*. at 867.[13]

Finally, "[v]arious district courts have struggled to fill the gaps [regarding the structure of the rule-of-reason inquiry] that *Actavis* left open, and not always with consistent results." *In re Aggrenox Antitrust Litig.*, 199 F. Supp. 3d 662, 669 (D. Conn. 2016).[14] These courts have not yet fully worked out their analyses. Suggestions by some courts, at the motion to dismiss stage, have yet to be applied. *See, e.g., In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d 224, 245 (D. Conn. 2015). Others have offered insights expressly premised on specific fact patterns. *See, e.g., In re Wellbutrin XL Antitrust Litig.*, 133 F. Supp. 3d 734 (E.D. Pa. 2015) (describing a framework for analyzing a reverse payment settlement that allowed the underlying patent litigation to continue), *aff'd,* 868 F.3d 132 (3rd Cir. 2017). Another court sent the case to a jury

---

[12] *Cipro*, 348 P.3d at 863-64; *see also id*. at 859; *King Drug*, 791 F.3d at 409 ("[W]e read *Actavis* to hold that antitrust law may prohibit settlements that are anticompetitive because, without justification, they delay competition for longer than the patent's strength would otherwise permit.").

[13] *Cipro* summarized:

> To make out a prima facie case that a challenged agreement is an unlawful restraint of trade, a plaintiff must show the agreement contains both a limit on the generic challenger's entry into the market and compensation from the patentee to the challenger. The defendants bear the burden of coming forward with evidence of litigation costs or valuable collateral products or services that might explain the compensation; if the defendants do so, the plaintiff has the burden of demonstrating the compensation exceeds the reasonable value of these. If a prima facie case has been made out, the defendants may come forward with additional justifications to demonstrate the settlement agreement nevertheless is procompetitive. A plaintiff who can dispel these justifications has carried the burden of demonstrating the settlement agreement is an unreasonable restraint of trade under the Cartwright Act.

348 P.3d at 871.

[14] Previously, the *Aggrenox* court had sought interlocutory appellate guidance regarding the proof required to establish an antitrust violation and causation of antitrust injury. *See In re Aggrenox Antitrust Litig.*, 2015 WL 4459607, at *10 (D. Conn. July 21, 2015) (listing factors that, if proved by plaintiff, would establish "an antitrust violation *and* causation of antitrust injury" without separating the factors applicable to each issue). The court of appeals declined the invitation. *See In re Aggrenox Antitrust Litig.*, 2016 WL 4204478, at *1 n.1 (D. Conn. Aug. 9, 2016). The district court then, for a second time, certified an issue for interlocutory appeal, this time a ruling regarding the relevance of evidence pertaining to the substitutability of other drugs for the product at issue. *Aggrenox*, 199 F. Supp. 3d at 669. The court of appeals again declined to provide interlocutory review. *In re Aggrenox Antitrust Litig.*, Case 3.14-md-02516-SRU (2nd Cir. Jan. 9, 2017).

with questions that suggest only the outline of a framework. *See Nexium*, 842 F.3d at 49-50 (quoting the trial court's jury verdict form).[15]

Plainly, the Commission could articulate its own rule-of-reason framework for application in this case. That would require briefs that have not been filed[16] and, perhaps, argument that has not been heard, but that could be done. There are fundamental reasons, however, that dissuade us from pursuing that course. Without the facts before us, and an understanding of how the parties intend to marshal those facts, a formulation that unnecessarily establishes the law of the case risks straight-jacketing the proceeding in ways that impede effective inquiry and appropriate resolution.

Nonetheless, proceeding with caution, we can still address the essential issues raised by Complaint Counsel's Motion. We see that Motion as essentially raising two issues: (i) what is the role of evidence suggesting that the Settlement Agreement allowed entry of Impax's generic product prior to patent expirations?[17] and (ii) what is the role of evidence of post-Settlement-Agreement judicial rulings that patents issued after the settlement were valid and infringed by other generic products? Compl. Counsel's Mot. for Partial Summ. Decision at 1. Complaint Counsel ask us to declare that these considerations are not cognizable procompetitive benefits and seek an order prohibiting Impax from "justify[ing] or otherwise defend[ing] the alleged reverse-payment" on those bases. Compl. Counsel's Proposed Or. at 1.

As to entry prior to patent expiration, we agree with Complaint Counsel insofar as Impax might assert that the mere fact of entry prior to patent expiration is dispositive. In *Actavis*, the generic firm received the right to enter 65 months before patent expiration, but the Court, rejected the scope of the patent test and found that entry prior to expiration did not preclude the FTC's cause of action. *See* 133 S.Ct. at 2229.

We are not however, able to state at this time that entry prior to patent expiration is not a factor to be considered in assessing the competitive consequences of the challenged reverse payment agreement. Although *Actavis* holds that the risk that a large and unjustified reverse payment will delay entry is a sufficient basis for a valid cause of action, it does not rule upon the

[15] Previously, the trial court had sketched its view of the rule of reason in decisions concerned with motions to dismiss and motions for summary judgment. *See In re Nexium (Esomeprazole) Antitrust Litig.*, 42 F. Supp. 3d 231, 262-63, 294 (D. Mass. 2014) (summary judgment), *aff'd*, 842 F.3d 34; *In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d 367, 387-93 (D. Mass. 2013) (motions to dismiss). In rejecting plaintiffs' appeal from an adverse jury verdict, the First Circuit based its analysis on the absence of antitrust injury and did not set out a rule-of-reason framework. *See Nexium*, 842 F.3d 34.

[16] Complaint Counsel's Motion for Partial Summary Decision focuses directly on selected procompetitive defenses. Although portions of the briefs present positions regarding the nature of the relevant competitive harm, the framework for the rule of reason has not been comprehensively briefed.

[17] Complaint Counsel suggest that Impax has asserted distinct claims of procompetitive benefit deriving from (i) the right to sell its generic product prior to patent expiration and (ii) the certainty that the generic products could be sold free from the risk of patent infringement liability. These benefits largely overlap, and we consequently treat them together.

relevance of evidence or the cognizability of arguments that might relate to the likelihood or magnitude of such delay. If, for example, an analysis like that in *Cipro* were applied, entry prior to patent expiration might be found to enable generic competition on or prior to the entry date that would have resulted, on average, from litigating the patent suit to conclusion; under *Cipro*, such entry could have bearing on whether there was an anticompetitive effect. At a minimum, the *extent* to which a settlement allows entry prior to patent expiration affects the magnitude of any anticompetitive effect and may be relevant if balancing anticompetitive harms and procompetitive benefits becomes necessary. Consequently, we are not in a position at this time to bar all argument to justify or defend the alleged reverse payment in the Settlement Agreement on grounds that it permits generic entry before the expiration of Endo's patents, as Complaint Counsel request.

With regard to the contention that the Settlement Agreement enabled Impax to continue selling its generic product despite a court ruling that two subsequently issued patents were not invalid and were infringed by various generic products, we again agree with Complaint Counsel that these rulings are not dispositive.[18] Again, however, we are unable at this time to state that the rulings are irrelevant. For example, under *Cipro*, the centerpiece of analysis is "whether a settlement postpones market entry beyond the average point that would have been expected *at the time* in the absence of agreement," 348 P.3d at 870 (emphasis added) (citation omitted), understood as a reflection of the underlying patent strength. *Id*. at 864. Although Complaint Counsel emphasize *Cipro*'s further explanation that "[a]greements must be assessed as of the time they are made," *id*. (citation omitted),[19] subsequent rulings of validity and infringement arguably might shed light on the expectations likely to have been held by the parties at the time of their settlement agreement. We are not willing to shut off all such argument at this time.

Moreover, this case involves factual circumstances not presented in *Actavis*. In particular, this case involves patents beyond those in litigation at the time of the Settlement Agreement, and a provision of that agreement allowed generic entry notwithstanding the potential that such patents might issue. Some courts have held that the context of the broader settlement agreement in which a reverse payment occurs is relevant in assessing its

[18] *See Cipro*, 348 P.3d at 870 (stating that "later evidence of validity will not automatically demonstrate an agreement was procompetitive"). We note, in this regard, that the referenced rulings do not even fully resolve issues of validity or infringement. The referenced infringement rulings do not expressly reach Impax's generic version of original Opana ER. *See* CCSUF at 34, 36. In any case, the validity/infringement rulings are still the subject of appeal. *See id*. at 36.

[19] *See also Apotex Inc. v. Cephalon, Inc.*, 2017 WL 2473148, at *5 (E.D. Pa. June 8, 2017) (explaining that "the *Actavis* rule of reason analysis is focused on whether the settlements were reasonable at the time they were entered"); *Wellbutrin XL*, 133 F. Supp. 3d at 753 (evaluating the settlement's reasonableness "at the time it was entered into").

anticompetitive effects.[20] At this point, issues posed by the additional patents and by the post-Settlement-Agreement validity and infringement rulings remain open.

What is needed at this time is development of a record, ordering of that record under a proposed rule-of-reason framework, and, ultimately, briefing of disputed issues concerning the appropriateness of that framework and of its application to the facts presented. Lest anything we have said be misapprehended, we have not adopted the *Cipro* framework, or any other structure for the rule of reason. At this point, that structure remains an open issue, and complete resolution of the issues raised by Complaint Counsel's Motion must await development of that structure and a more definitive presentation of the context in which those issues arise. Other than as expressly stated above, we have not prescribed how this case must be presented. We expect that this proceeding ultimately will provide considerable guidance regarding the rule-of-reason analysis of reverse payment settlement agreements, but we will allow the proceeding to unfold without rigidly constraining its course.

Accordingly,

IT IS ORDERED THAT:

1. Complaint Counsel's Motion for Partial Summary Decision is **DENIED**; and

2. The hearing in this proceeding shall continue under a schedule specified by the Chief Administrative Law Judge, pursuant to the Commission's Rules of Practice for Adjudicative Proceedings.

By the Commission.

Donald S. Clark
Secretary

SEAL:
ISSUED: October 27, 2017

[20] *See, e.g.*, *Wellbutrin XL*, 133 F. Supp. 3d at 753-54 (stating that "failing to evaluate the agreement as a whole would overlook context essential to determining any possible anticompetitive effects"); *Aggrenox*, 94 F. Supp. 3d at 243 (explaining that a settlement agreement should be viewed "holistically").