

Complaint

IN THE MATTER OF

IMPAX LABORATORIES, INC.COMPLAINT AND INITIAL DECISION IN REGARD TO ALLEGED
VIOLATIONS OF SECTION 5 OF THE FEDERAL TRADE COMMISSION
ACT*Docket No. 9373; File No. 141 0004**Complaint, January 19, 2017 – Initial Decision, May 11, 2018*

This case addresses Impax Laboratories, Inc.'s reverse-payment agreement with Endo Pharmaceuticals Inc. to obstruct lower-cost generic competition to Opana ER, one of Endo's core branded prescription drug products. The complaint alleges that Impax Laboratories, Inc. violated section 5 of the Federal Trade Commission Act through its agreement in restraint of trade with Endo Pharmaceuticals, Inc. to eliminate the risk of generic competition to Opana ER for at least 2½ years. In his Initial Decision, the Administrative Law Judge found that the evidence failed to demonstrate that the Challenged Agreement constituted an unreasonable restraint of trade in violation of Section 5 of the Federal Trade Commission Act and dismissed the Complaint. Complaint Counsel appealed the Initial Decision and Respondent filed a cross-appeal.

Participants

For the *Commission*: Daniel Bradley, Dan Butrymowicz, Synda Mark, Maren Schmidt, Eric Sprague, Jamie Towey, and Rebecca Weinstein.

For the *Respondent*: Anna Fabish and Ted Hassi, O'Melveny & Myers LLP.

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act, and by virtue of the authority vested in it by said Act, the Federal Trade Commission ("Commission"), having reason to believe that Impax Laboratories, Inc. ("Impax"), a corporation, hereinafter sometimes referred to as "Respondent," has violated the provisions of said Act, and it appearing to the Commission that a proceeding in respect thereof would be in the public interest, hereby issues its complaint stating its charges in that respect as follows:

Complaint

Nature of the Case

1. This action challenges an anticompetitive reverse-payment agreement between Impax and Endo Pharmaceuticals Inc. (“Endo”) to obstruct lower-cost generic competition to Opana ER, one of Endo’s core branded prescription drug products. In 2009, Opana ER was responsible for \$172 million of Endo’s net sales, comprising approximately 12% of Endo’s total annual revenues. The threat of generic entry to Opana ER posed significant financial risks for Endo. Endo knew that generic competition would decimate its Opana ER sales and that any delay in generic competition would be highly profitable for Endo, but very costly for consumers.

2. By 2010, generic entry appeared imminent. Several years earlier, Impax had submitted an application with the U.S. Food and Drug Administration to market a generic version of Opana ER. In that application, Impax asserted that Endo’s Opana ER patents were either invalid or would not be infringed by Impax’s generic version of Opana ER. Endo sued Impax for alleged patent infringement. Throughout the first half of 2010, with the patent infringement trial approaching, Impax prepared to launch its generic Opana ER product as soon as it received regulatory approval. Faced with Impax’s threat to its lucrative Opana ER franchise, Endo bought off its potential competitor.

3. In June 2010, Endo agreed to pay Impax to abandon its patent challenge and forgo entering the market with its lower-cost generic version of Opana ER for 2½ years, until January 2013. This payment included two separate components. First, Endo guaranteed that Impax would receive supracompetitive profits by being the only seller of generic Opana ER during its first 180 days on the market. Even though Endo had the legal right and financial incentive to compete with an authorized generic version of Opana ER as soon as Impax entered with its generic product, Endo agreed that it would refrain from offering an authorized generic Opana ER product during Impax’s initial 180 days of marketing (a “no-AG commitment”). If market conditions were to change to devalue this no-AG commitment, Endo further agreed to pay Impax a cash amount based on Impax’s expected profits for that six-month period of generic exclusivity. Second, Endo agreed to

Complaint

pay Impax up to \$40 million purportedly for an independent development and co-promotion deal. The financial terms of this deal, however, made no business or economic sense for Endo independent of Impax's agreement to stay off the market for over 2½ years. To date, Endo has paid Impax over \$112 million from these two components.

4. The purpose and effect of this anticompetitive agreement was to ensure that Endo would not face generic competition for Opana ER until at least January 2013. As a result, patients were denied the opportunity to purchase lower-cost generic versions of Opana ER, forcing them and other purchasers to pay hundreds of millions of dollars a year more for this medication.

Respondent

5. Respondent Impax Laboratories, Inc. is a for-profit Delaware corporation, with its principal place of business at 30831 Huntwood Avenue, Hayward, California 94544. Impax engages in the business of, among other things, developing, manufacturing, and marketing generic drugs. Impax entered into the anticompetitive agreement challenged in this complaint.

Jurisdiction

6. Respondent is, and at all times relevant herein has been, a corporation, as "corporation" is defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

7. Respondent's general business practices and the unfair methods of competition alleged herein are "in or affecting commerce" within the meaning of Section 5 of the FTC Act, 15 U.S.C. § 45.

Background**A. Federal law facilitates approval of generic drugs**

8. 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

Complaint

Act”) and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, 21 U.S.C. §§ 355(b)(2) and 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.

9. 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. These NDA-based products generally are referred to as “brand-name drugs” or “branded drugs.”

10. The FDA requires NDA holders to identify any patents that the NDA holder believes reasonably could be asserted against a generic company that makes, uses, or sells a generic version of the branded drug. The NDA holder 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. 21 C.F.R. § 314.53.

11. 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. 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. 21 U.S.C. § 355(j)(2)(A)(iv).

12. The FDA assigns a generic drug an “AB” rating if it is therapeutically equivalent to a brand-name drug. 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. A generic drug also must

Complaint

contain identical amounts of the same active ingredient(s) as the brand-name drug, although its inactive ingredients may vary.

13. When a brand-name drug is covered by one or more patents listed in the Orange Book, a company seeking to market a generic version of that drug before the patents expire must make a “paragraph IV certification” in its ANDA certifying that the patents are invalid, unenforceable, and/or will not be infringed by the generic drug.

14. If a company makes a paragraph IV certification, it must notify the patent holder of its certification. 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.

15. When a generic drug otherwise meets the FDA’s criteria for approval but final approval is blocked by statute or regulation, such as the Hatch-Waxman 30-month stay, the FDA may tentatively approve the relevant ANDA. Tentative approval does not permit an ANDA filer to market its generic version of the drug. The FDA can issue final approval of a tentatively-approved drug once the relevant 30-month stay expires.

16. The Hatch-Waxman Act provides the first generic company or companies filing an ANDA containing a paragraph IV certification (“first filer”) with a period of protection from competition with other ANDA filers. This is referred to as the “180-day exclusivity” or “first-filer exclusivity” period. The Supreme Court observed that the 180-day exclusivity period “can prove valuable, possibly worth several hundred million dollars” to the first filer.

17. A brand drug company can market a generic version of its own brand product at any time, including during the first filer’s exclusivity period. In that case, no ANDA is necessary because the brand company already has approval to sell the drug under its NDA. Such generics commonly are known as “authorized

Complaint

generics.” An authorized generic 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.

18. In the absence of generic competition, a brand drug company typically will not undercut the profits on its branded drug by introducing a lower-priced authorized generic version of that drug. When an ANDA filer enters, however, an authorized generic may become attractive to the NDA holder as a means of maintaining some of the revenue it otherwise would lose to the generic competitor.

19. If an NDA holder discontinues the relevant drug, then the FDA moves the drug covered by the NDA to the Orange Book’s Discontinued Drug Product List. Generic drugs referencing the discontinued NDA still may be sold, but they will not be listed in the Orange Book as AB-rated to any branded product.

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

20. 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. When a pharmacist fills a prescription written for a branded drug, these laws allow or require the pharmacist to dispense an AB-rated generic version of the drug instead of the more expensive branded drug, unless a physician directs or the patient requests otherwise. Conversely, these laws generally do not permit a pharmacist to substitute a non-AB-rated generic for a branded drug unless the physician specifically prescribes it by writing the chemical name of the drug, rather than the brand name, on the prescription.

21. State substitution laws were enacted in part because the pharmaceutical market does not function well. 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. The doctor who selects the drug, however, does not pay for it and generally has little incentive to consider price when deciding

Complaint

which drug to prescribe. Instead, the patient, or in most cases a third-party payer such as a public or private health insurer, pays for the drug. But these purchasers have little input over what drug is actually prescribed.

22. 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.

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, healthcare plans, and federal and state governments. The first generic competitor's product is typically offered at a 20% to 30% discount to the branded product. Subsequent generic entry creates greater price competition with discounts reaching 85% or more off the brand price. According to a 2010 Congressional Budget Office report, the retail price of a generic is 75% lower, on average, than the retail price of a brand-name drug. In 2015 alone, the Generic Pharmaceutical Association reported that use of generic versions of brand-name drugs saved the U.S. healthcare system \$227 billion.

24. 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. As a result of these policies and lower prices, many consumers routinely switch from a branded drug to an AB-rated generic drug upon its introduction. Consequently, AB-rated generic drugs typically capture over 80% of a branded drug's unit and dollar sales within six months of market entry.

25. Consumers also benefit from competition between an authorized generic drug and an ANDA-based generic drug. Empirical evidence shows that competition from an authorized generic drug during the first-filer's 180-day exclusivity results, on average, in retail prices that are 4% to 8% lower and wholesale

Complaint

prices that are 7% to 14% lower than prices without authorized generic competition.

26. Competition from an authorized generic also typically has a significant financial impact on the first ANDA entrant. An authorized generic typically takes a significant share of the first ANDA entrant's generic sales, thereby reducing revenues during its 180-day exclusivity period by an average of 40% to 52%. Thus, if a brand company agrees to refrain from launching an authorized generic, it can double the first filer's revenues during the 180-day exclusivity period. This financial impact is well-known in the pharmaceutical industry.

Anticompetitive Conduct

A. Opana ER was a successful and rapidly growing branded drug

27. Oxymorphone is a semi-synthetic opioid, originally developed over one hundred years ago. Opioids are one of the world's oldest known classes of drugs, and they have long been used to relieve pain. The FDA first approved oxymorphone in 1960.

28. Opana ER is an extended-release formulation of oxymorphone. 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." 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. 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.

29. Endo launched Opana ER in 2006 as the only extended-release version of oxymorphone on the market. The drug, available in seven dosage strengths (5, 7.5, 10, 15, 20, 30, and 40 mg), is used to treat pain for a wide variety of conditions, ranging from chronic back problems to cancer.

Complaint

30. Opana ER quickly became Endo's second best-selling drug. After a modest start of \$5 million in sales in 2006, sales grew to \$172 million in 2009. First quarter 2010 sales of \$66 million indicated continued growth.

31. Endo sells Opana ER at prices far above Endo's cost of manufacturing the product, making Opana ER highly profitable. Even accounting for other direct expenses Endo allocates to selling and marketing Opana ER, Endo's profit margin on Opana ER, ranging between 67% and 79%, is substantial.

**B. Potential generic competition from Impax threatened
Endo's growing Opana ER business**

32. Opana ER's increasing sales drew the attention of numerous generic companies. Opana ER was an attractive target for generic drug makers because oxymorphone had been available for decades and was not subject to any meaningful patent protection. 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. The '143 patent was not a meaningful, long-term barrier to generic competition because it was set to expire in September 2008. Endo's New Dosage Form exclusivity was set to expire in June 2009. With growing sales and no meaningful patent protection identified in the Orange Book, numerous generic entrants began preparing ANDAs for generic versions of Opana ER.

33. Following notice that a generic company had filed an ANDA to market a generic version of Opana ER, Endo listed three additional patents in the Orange Book in October 2007, well over a year after launching Opana ER.

34. 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. This patent expires in 2023.

35. On October 19, 2007, Endo listed two additional patents pertaining to a controlled release mechanism—No. 5,662,933 (the "'933 patent") and No. 5,958,456 (the "'456 patent"). These

Complaint

patents had been issued by the U.S. Patent and Trademark Office up to a decade earlier—in 1997 and 1999, respectively. 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. The '933 and '456 patents expired in August 2013.

36. Eventually, at least nine companies submitted ANDAs seeking approval to market a generic version of Opana ER, including Impax, Actavis, and Watson. 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. In response to each paragraph IV certification, Endo filed a patent infringement case, asserting that the generic product infringed either the '456 patent, the '933 patent, or both. Endo never asserted that any of the generic products infringed the '250 patent.

37. Impax submitted its ANDA, No. 79-087, on June 29, 2007 seeking approval to market a generic version of Opana ER. Although the FDA initially accepted the ANDA for substantive review, it later rescinded that acceptance due to certain deficiencies. Impax re-submitted ANDA No. 79-087, and the FDA accepted the application as of November 23, 2007.

38. On December 13, 2007, Impax notified Endo that it had submitted ANDA No. 79-087 with a paragraph IV certification stating that Impax's proposed generic product did not infringe Endo's '933 or '456 patents.

39. On January 25, 2008, Endo sued Impax for allegedly infringing the '456 and '933 patents. Because Endo sued Impax within 45 days of its paragraph IV notification, an automatic 30-month stay resulted. This stay prevented the FDA from granting final approval to Impax's ANDA until June 14, 2010, absent an earlier court finding that Impax's product did not infringe Endo's patents or that the patents were invalid or unenforceable.

40. Impax was the first generic company to file an ANDA with a paragraph IV certification for the 5, 10, 20, 30, and 40 mg strengths of Opana ER. Impax received first-filer exclusivity for

Complaint

those dosage strengths, precluding the FDA from approving any other generic versions of Opana ER until 180 days after Impax's generic launch. These dosage strengths account for over 95% of all Opana ER sales. Given Impax's first-filer status, if Endo could delay Impax's entry, Endo would delay all generics from entering the market for those dosages of Opana ER.

C. Endo paid Impax to drop its patent challenge and refrain from competing until January 2013

41. Throughout the first half of 2010, Impax prepared to launch its generic version of Opana ER at the expiration of the Hatch-Waxman 30-month stay on June 14, 2010, even if the patent challenge remained unresolved. Such generic entry is commonly referred to as an "at-risk launch."

42. On May 13, 2010, the FDA tentatively approved Impax's application for a generic version of Opana ER; final approval had to wait one month for the expiration of the Hatch-Waxman stay. Following the FDA's grant of tentative approval, the prospect of an Impax at-risk launch gained momentum. On May 13, 2010, Impax CEO Larry Hsu instructed his top executives to "alert" the Board of Directors of a "potential oxymorphone [*sic*] launch" and that "we will have a special Board conference call when we do decide to launch at risk on a later date." In materials presented to the Board of Directors that same month, Impax changed the "Current Assumption[]" for Opana ER from "no launch" to "At Risk Launch."

43. As of May 20, 2010, Impax had completed process validation, demonstrating that its manufacturing process was capable of consistently producing commercial quantities of generic Opana ER. Process validation is one of the final steps required by the FDA before launch. In addition, Impax had produced nine of the 17 lots required for launch quantities (equivalent to three months of generic market supply) and had sufficient inventory of active pharmaceutical ingredient to complete the remaining lots. Impax had also requested authorization from the Drug Enforcement Agency to purchase the additional active pharmaceutical ingredient needed to produce larger quantities of generic oxymorphone ER.

Complaint

44. Impax's impending launch presented a substantial risk to Endo's Opana ER monopoly. Endo knew that entry of AB-rated generic versions of Opana ER would cause Endo's Opana ER sales to drop rapidly and dramatically—possibly by as much as 85% within a year.

45. To protect and extend its Opana ER franchise in the face of potential generic entry, Endo had been working on a reformulated “crush resistant” version of Opana ER (“Reformulated Opana ER”) that would not be subject to automatic substitution from generic versions of its original formulation of Opana ER (“Original Opana ER”). Endo did not publicly disclose its reformulation plans.

46. Endo knew that the success of Reformulated Opana ER would hinge on whether Endo could introduce the product before it faced AB-rated generic competition for Original Opana ER. It is well known in the pharmaceutical industry that if generic versions of the original product (here, Original Opana ER) enter the market before the brand's follow-on product (here, Reformulated Opana ER), the follow-on product is likely to be much less successful. Indeed, Endo predicted that if a generic version of Original Opana ER were already on the market when it introduced Reformulated Opana ER, the reformulated version would capture only 30% to 32% of the Original Opana ER volumes.

47. In contrast, if Endo were to launch Reformulated Opana ER before generic entry, then Endo could expect to convert virtually the entire franchise to its reformulated product. Given these market realities, industry analysts have observed that “it is essential that the brand holder switch their patents to the new formulation before generic launch.”

48. Endo knew, however, that it would be unable to obtain FDA approval for its Reformulated Opana ER and convert the market before Impax could enter with its generic version of Original Opana ER. Endo, therefore, decided to purchase the time it needed by paying Impax not to compete until January 2013.

49. On or about June 8, 2010—just a week before Impax was expected to receive final FDA approval for its generic Opana ER

Complaint

and two days into the patent infringement trial—Endo and Impax reached a settlement embodied in two documents: (1) a Settlement and License Agreement; and (2) a Development and Joint Promotion Agreement (hereinafter, together the “Opana ER Agreement”).

50. Under the Opana ER Agreement, Endo agreed to pay Impax to abandon its patent challenge and to refrain from launching its generic version of Opana ER until January 1, 2013, approximately eight months before the expiration of the patents asserted in the infringement suit. This payment included two separate components. First, Endo guaranteed that Impax would receive a cash value commensurate with the supracompetitive profits that come with being the only seller of generic Opana ER for 180 days (“Guaranteed No-AG Payment”). Second, Endo agreed to pay Impax up to \$40 million purportedly for an independent development and co-promotion deal (“Side Deal Payment”).

51. Impax could not have obtained the Guaranteed No-AG Payment and the Side Deal Payment even if it had won the patent infringement litigation with Endo.

52. The FDA granted final approval to Impax’s ANDA for generic Opana ER for the 5, 10, 20, and 40 mg dosages on June 14, 2010, and for the 30 mg dosage on July 22, 2010. Absent the Opana ER Agreement, Impax would have been legally permitted to launch its generic product at risk.

1. Guaranteed No-AG Payment

53. Endo had the legal right and financial incentive to compete with an authorized generic version of Opana ER as soon as Impax entered with its generic product. Under the Opana ER Agreement, however, Endo agreed not to offer a competing authorized generic Opana ER product during Impax’s 180-day exclusivity period for the 5, 10, 20, 30, and 40 mg strengths.

54. The no-AG commitment was extremely valuable to Impax. With a no-AG commitment, the first filer’s revenue will approximately double on average compared to what the first filer

Complaint

would make if it faced authorized generic competition. A first filer makes significantly more without generic competition because: (1) the authorized generic takes a significant share of generic sales from the first filer; and (2) competition between the first-filer generic and the authorized generic drives down generic drug prices. The financial effects of an authorized generic on the first-filer generic are well known in the pharmaceutical industry.

55. The no-AG commitment was costly to Endo. Brand companies often introduce AGs to stem the large losses that result from the rapid shift from sales of branded drugs to cheaper generic products. Before settlement, Endo had been planning to launch an authorized generic if Impax launched at risk, estimating \$25 million in authorized generic revenues during the first six months following generic entry. Endo forecasted that launching an authorized generic would recoup as much as 35% of the branded Opana ER revenues it expected to lose during that time.

56. Impax suspected, however, that Endo was planning to shift the market to a reformulated version of Opana ER before the negotiated entry date and recognized that such a move would both undermine the value of the no-AG commitment as well as decimate the potential sales for Impax's first-to-file generic product. Endo denied any plans to introduce a reformulated version of Opana ER, despite its active efforts to do so.

57. Notwithstanding Endo's assurances, Impax sought to "protect [itself] from making no money." Impax proposed ways to address its concern through provisions that would expedite generic entry if Endo successfully introduced a reformulated product. Endo, however, rejected these proposals in favor of a so-called "Endo Credit."

58. Under the Endo Credit arrangement, Endo agreed to a "make good payment" to ensure that Impax would receive the supracompetitive profits that come with being the only seller of generic Opana ER even if Endo devalued the no-AG commitment by shifting the market to Reformulated Opana ER. Specifically, if, by the fourth quarter of 2012, Original Opana ER sales fell by more than 50% from the peak quarterly sales between the third quarter of 2010 and the third quarter of 2012, Endo would provide

Complaint

Impax with a cash payment. The dollar value of the Endo Credit was based on a formula designed to approximate Impax's expected profits as the only seller of a generic version of Opana ER assuming Endo had not launched Reformulated Opana ER. As Endo itself has explained, the Endo Credit was to ensure that Impax received "the expected bargained for benefit" of the no-AG commitment.

59. Ultimately, Endo introduced Reformulated Opana ER and discontinued Original Opana ER before Impax's generic Opana ER entry date under the settlement. Consequently, the value of the no-AG commitment fell and triggered Endo's obligation to pay Impax the Endo Credit, resulting in a payment from Endo to Impax of more than \$102 million.

2. Side Deal Payment

60. On or about the same day that Endo and Impax entered into the Settlement and License Agreement, Endo and Impax also entered into a development and co-promotion deal concerning a potential treatment for Parkinson's disease, code-named IPX-203. At the time of the deal, IPX-203 was still in the very early stages of pre-clinical development: Impax had not yet developed a formulation for the product, submitted an Investigational New Drug application to the FDA, or initiated any sort of clinical trials. Fewer than 1% of drugs in pre-clinical development ultimately receive FDA approval.

61. The development and co-promotion deal provided Impax with immediate cash, plus the potential for more in the future. Under the deal, Endo agreed to pay Impax \$10 million in cash up front and up to \$30 million in additional milestone payments. If Impax succeeded in developing the drug and obtaining FDA approval, Endo would have the right to co-promote the product in the United States to non-neurologists and to receive 65% to 100% of the profits generated by prescriptions from those doctors.

D. Endo's payment to Impax is large

62. At the time of the settlement, Impax expected to, and did, derive significant value from the Opana ER Agreement in the

Complaint

form of: (1) a Side Deal Payment of at least \$10 million and up to \$40 million; and (2) a Guaranteed No-AG Payment of at least \$37 million and potentially more than \$100 million. To date, Endo has paid Impax more than \$112 million under the Opana ER Agreement.

63. Endo's payment to Impax, both expected and actual, is large. First, the \$10 million payment under the development and co-promotion deal was guaranteed and non-refundable.

64. Second, the structure of the Guaranteed No-AG Payment ensured that Impax would derive significant financial value from either the no-AG commitment or the Endo Credit or both. Indeed, as Impax's chief negotiator explained, the possibility that Impax would receive little value from either the no-AG commitment or the Endo Credit was "so unlikely it wasn't worth worrying about."

65. Before the settlement, Impax expected that Endo would launch an authorized generic to compete with Impax's generic Opana ER product. According to Impax's internal forecasts, competition from an authorized generic would take 40% to 50% of Impax's expected unit sales and decrease the price of the remaining sales by more than 36%. With the no-AG commitment, Impax would not face this competition, retaining all generic Opana ER sales for six months at a supracompetitive price. At the time of the Opana ER Agreement, the value of the no-AG commitment to Impax ranged from \$37 to \$77 million.

66. If, however, consistent with its strategic plan, Endo destroyed the market opportunity for Impax's generic version of Original Opana ER, including the value of the no-AG commitment, then Impax would receive a cash payment under the Endo Credit. The Endo Credit payment was based on various factors affecting Impax's expected profits during the no-AG commitment period, including the generic substitution rate, expected generic pricing as a percentage of brand pricing, and Impax's net profit margin. If triggered, Endo's likely payment under the Endo Credit would be at least \$46 million and could exceed \$100 million (as actually occurred).

Complaint

67. Thus, as of the time the parties entered into the Opana ER Agreement, the total value of Endo's expected payment, including the Guaranteed No-AG Payment (at least \$37 million) and the Side Deal Payment (at least \$10 million), was at least \$47 million and potentially greater than \$100 million.

68. Endo's actual and likely payment to Impax far exceeds any reasonable measure of avoided litigation costs in the parties' underlying patent litigation. The settlement occurred late in the litigation, after trial had begun. By that time, Endo already had expended more than \$7 million in litigation fees and costs. Any remaining litigation costs would have been a small fraction of Endo's payment, whether measured against the actual amount paid (\$112 million) or any amount anticipated at the time of the Opana ER Agreement.

69. Endo's payment was designed to, and did, induce Impax to abandon its Opana ER patent challenge and agree to refrain from marketing its generic Opana ER product until January 2013. Impax's decision to settle was driven not by the strength of Endo's patent protection for Opana ER, but by the large payment Endo made to Impax. As Impax's president of generics stated to the CEO: "That money is really important as we all know."

70. Endo's payment to Impax exceeded the amount Impax projected to earn by launching its generic version of Opana ER. In May 2010—just a month before entering into the settlement—Impax projected its generic Opana ER product would generate about \$48 million in profits in its first 2½ years on the market—less than half the amount Endo already has paid Impax under the Opana ER Agreement. In fact, Endo's payment exceeded the sales generated by Impax's five new generic launches in 2013, including its generic version of Original Opana ER. As Impax explained in an SEC filing, its net income growth in 2013 was "primarily attributable" to Endo's \$102 million cash payment under the Opana ER Agreement.

71. Endo was willing to make this large payment to Impax because the January 2013 entry date would enable Endo to maintain monopoly prices for Opana ER throughout that period and beyond.

Complaint

E. Endo's large payment to Impax is not justified

72. Endo's large payment to Impax cannot be justified solely as compensation for the services to be performed by Impax.

73. The Guaranteed No-AG Payment is not compensation for goods or services provided by Impax to Endo. Indeed, Impax was not required to provide any goods or perform any service in exchange for the more than \$102 million Guaranteed No-AG Payment.

74. The purpose and effect of Endo's Guaranteed No-AG Payment were to induce Impax to abandon its patent challenge and agree not to compete with a generic version of Original Opana ER until January 2013. The payment is explicitly part of the Settlement and License Agreement and makes no economic sense absent Impax's agreement not to market a generic version of Opana ER until January 2013. Endo would not have agreed to the Guaranteed No-AG Payment without also securing Impax's agreement not to market a generic version of Opana ER until January 2013. Likewise, Impax would not have agreed to a January 2013 entry without also securing Endo's commitment to the Guaranteed No-AG Payment.

75. In addition, Endo's Side Deal Payment cannot be justified solely as compensation for the services to be performed by Impax under the deal. Instead, the purpose and effect of Endo's payment were to induce Impax to abandon its patent challenge and agree not to compete with a generic version of Original Opana ER until January 2013. Endo would not have agreed to make the large Side Deal Payment without also securing Impax's agreement not to market a generic version of Opana ER until January 2013. Likewise, Impax would not have agreed to a January 2013 entry without also securing the large Side Deal Payment.

76. Substantial evidence shows the direct link between Endo's Side Deal Payment and Impax's agreement to the January 2013 entry date, including:

- a. Endo and Impax never discussed a development agreement outside the context of settlement

Complaint

negotiations. Instead, the development deal and the Endo-Impax settlement agreement were negotiated and drafted at the same time, by the same people, and were held in escrow until both agreements were finalized.

- b. Impax had tried unsuccessfully for years to find a partner willing to invest in the development of a neurological drug in return for the right to co-promote the drug only to non-neurologists. As Impax's CEO explained: "So, we've been, for several years, we'll be looking for partner willing to take just the primary care physicians piece, and that's not easy. Most of the people don't want it. They say, why, if you want me to take that part, I want the whole market."
- c. Endo's substantial investment in the very early stages of drug development was contrary to the company's stated objective to invest in "marketed/market ready assets."
- d. Despite the incompatibility with Endo's corporate development strategy, and the absence of any other interested investor, Endo was nonetheless willing to accept limited co-promotion rights for the early-stage development project.
- e. The due diligence schedule for this purportedly independent business transaction was explicitly tied to the timing of the Opana ER patent trial and settlement negotiations. Due to the artificially compressed due diligence schedule and insufficient information on the proposed product, Endo based its financial valuation of the deal on a different Impax development project involving a wholly different drug.
- f. The \$10 million up-front payment was the largest Endo ever paid for a pre-clinical development product.
- g. Endo received nothing in return for its payment. Impax's development of the subject project, IPX-203, has been significantly delayed. In December 2015,

Complaint

without a single clinical trial completed, the parties terminated the side deal “by mutual agreement.”

77. In short, the financial terms of the development and co-promotion deal made no business or economic sense for Endo independent of Impax’s agreement to defer generic Opana ER entry until January 2013. The development and co-promotion deal provided the vehicle for Endo to pay Impax cash immediately as part of an overall compensation package to abandon its patent litigation and agree to stay out of the market for over 2½ years.

78. There are no other procompetitive benefits, countervailing efficiencies, or increases in consumer welfare from the Opana ER Agreement that outweigh the significant competitive harm caused by eliminating the risk of Impax’s generic entry until January 2013.

79. Moreover, Endo’s large payment to Impax was not reasonably necessary to achieve any potential procompetitive objective of the Opana ER Agreement.

F. Endo settled with the other Opana ER first filer with no reverse payment, and a significantly earlier entry date

80. On or about June 8, 2007, Actavis submitted ANDA No. 79-046 to the FDA for its generic version of Opana ER for the 5, 10, 20, and 40 mg dosages. After Endo listed the three patents purportedly relating to Opana ER in the Orange Book, Actavis submitted a paragraph IV certification stating that its proposed generic product did not infringe Endo’s patents and/or that Endo’s patents were invalid or unenforceable. On February 12, 2008, Actavis notified Endo that it had submitted ANDA No. 79-046 with a paragraph IV certification. On March 28, 2008, Endo sued Actavis for alleged infringement of only the ’456 patent. Because Endo sued Actavis within 45 days of its paragraph IV notification, an automatic 30-month stay resulted.

81. On or about May 29, 2008, Actavis notified Endo that it had amended its ANDA for a generic version of Opana ER to include 7.5 and 15 mg dosages and submitted a paragraph IV

Complaint

certification stating that its proposed generic product did not infringe Endo's patents. On July 11, 2008, Endo sued Actavis for alleged infringement of only the '456 patent. Because Endo sued Actavis within 45 days of its paragraph IV notification, an automatic 30-month stay resulted, preventing the FDA from granting final approval to Actavis's ANDA until November 2010, absent an earlier court finding that Actavis's product did not infringe Endo's patents or that the patents were invalid or unenforceable.

82. Actavis was the first generic company to file an ANDA with a paragraph IV certification for the 7.5 and 15 mg dosage strengths of Opana ER. As the first filer, Actavis was eligible for 180 days of exclusivity for those two dosage strengths as against any other ANDA product.

83. In February 2009, less than one year into the patent litigation, Endo settled its suit against Actavis. Under the terms of the settlement, Endo granted Actavis a covenant not to sue and a license for the sole asserted patent, the '456 patent, to begin marketing its generic version of Opana ER on July 15, 2011. In addition, Endo granted Actavis a covenant not to sue for the '250 and '933 patents—the two other patents listed in the Orange Book that Endo had not asserted in the litigation. That settlement involved no payment from Endo to Actavis.

84. Although Actavis had a license to enter in 2011, it was blocked from launching any of the five dosage strengths for which Impax was eligible for 180-day exclusivity (5, 10, 20, 30, and 40 mg), until such exclusivity expired or was otherwise lost.

Market Power

85. Until at least January 2013, Endo exercised market power in a relevant market that is no broader than extended-release oxymorphone ("oxymorphone ER") tablets approved by the FDA for sale in the United States. Endo shared its extended monopoly profits with Impax in exchange for its agreement to impede generic competition.

Complaint

86. There is substantial evidence of Endo's market power. Both Endo and Impax had forecast a dramatic decline in the average price of oxymorphone ER following entry of an AB-rated generic version of Opana ER. For example, Impax estimated that within one year of generic entry, AB-rated generic versions of Opana ER would be priced at approximately 5% of the brand product's WAC and would capture up to 90% of unit sales.

87. Even without an AB rating, Endo expected generic entry to have a dramatic impact on Reformulated Opana ER's revenues and unit sales: "[I]f additional generic companies enter the market with generic non-crush resistant oxymorphone extended release tablets [original formulation], Endo will experience immediate, dramatic, and irreparable price erosion and loss of sales." Indeed, as Endo predicted, Impax's and Actavis's non-AB-rated generic oxymorphone ER products captured significant share from Reformulated Opana ER through competitive pricing, with discounts of up to 40% off the brand price. In 2013, Impax's and Actavis's generic versions of Opana ER accounted for approximately 28% of all oxymorphone ER unit sales for all dosage strengths in 2013, increasing to approximately 37% for the first half of 2014. These results are consistent with Endo's own prediction that even non-AB-rated generics eventually would capture 40% or more of branded Opana ER sales.

88. If Endo were already facing robust competition to Opana ER, then the entry of generic oxymorphone ER would not have eroded the sales volume of branded Opana ER or the price of oxymorphone ER products so rapidly and dramatically.

89. In addition, other long-acting opioid products used to relieve moderate to severe pain have not meaningfully constrained Endo's pricing or sales of Opana ER. From 2007 to 2012, despite the availability of several other long-acting opioid products, Endo regularly raised the wholesale acquisition cost of Opana ER, from about \$9 per pill (40 mg) to over \$12 per pill (40 mg) without impacting sales. During that same period, the entry of new branded long-acting opioid products, such as Embeda and Exalgo, had no discernable impact on Opana ER prices or unit sales.

Complaint

90. Moreover, oxymorphone ER is not reasonably interchangeable with other pain relief medications used to treat the same or similar conditions. As Endo itself represented to the FDA and the medical community, “there is no therapeutically equivalent or pharmaceutically alternative substitutable product” to Opana ER. The abrupt discontinuation of an opioid product can result in severe withdrawal symptoms. Switching a patient from one opioid to another presents serious underdosing and overdosing risks to the patient and requires careful medical monitoring. Therefore, patients that have begun a successful course of treatment with an opioid such as Opana ER are unlikely to switch to another pain medication for economic reasons.

91. From its launch in 2006 through 2012, Opana ER accounted for 90% to 100% of the unit sales of oxymorphone ER products. By the end of 2013, even with competition from Impax’s and Actavis’s generic oxymorphone ER products, Endo’s branded Opana ER retained a 70% share of all oxymorphone ER unit sales because Endo converted the market to Reformulated Opana ER prior to generic entry.

92. Substantial barriers to entry exist in the oxymorphone ER market. Potential new branded drug competitors need to conduct expensive clinical trials and obtain FDA approval. Potential sellers of generic oxymorphone ER also face substantial barriers to entry, including the need to obtain FDA approval, costly specialized equipment and facilities, and Endo’s ability to trigger an automatic 30-month stay of FDA approval by filing a patent infringement lawsuit.

Harm to Consumers and Competition

93. By impeding generic competition, Respondent’s agreement with Endo denied consumers and other purchasers of Opana ER access to AB-rated generic versions of Opana ER that would offer the same therapeutic benefit as branded Opana ER but at a fraction of the price.

94. The agreement between Impax and Endo precluding Impax from launching a generic version of Opana ER until January 2013 harmed competition and consumer welfare by

Complaint

eliminating the risk that Impax would have marketed its generic version of Opana ER before that date. Through its agreement with Endo, Impax eliminated the potential that: (1) Impax would have launched its generic version of Opana ER before January 2013; or (2) Endo would have agreed to settle the patent litigation on terms that did not compensate Impax, but provided for generic entry earlier than January 2013.

95. Before the Opana ER Agreement, Impax had been preparing to enter with a generic version of Opana ER as early as FDA approval, which it received in June 2010. That entry would have quickly and significantly reduced Endo's market share, promoted economic efficiency, and led to significant price reductions for extended-release oxymorphone products. Impax abandoned its generic entry plans because it received a share of Endo's monopoly profits in the form of the Guaranteed No-AG Payment and the Side Deal Payment. Without the large payment, Impax would have launched its generic version of Opana ER prior to January 2013.

96. Entry of Impax's generic product would have given consumers the choice between branded Opana ER and lower-priced AB-rated substitutes for Opana ER. Many consumers would have purchased lower-priced AB-rated generic drugs rather than higher-priced branded Opana ER. Endo's contemporaneous forecasts assumed that approximately 85% of Opana ER unit sales would switch to an AB-rated generic version of Opana ER. Consumers likely would save hundreds of millions of dollars by purchasing generic versions of Opana ER. By entering into the anticompetitive agreement, Impax shared in Endo's additional monopoly profits at the expense of consumers.

97. Impax's agreement with Endo also prevented competition from other potential generic oxymorphone ER products for the most prescribed strengths of generic Opana ER, comprising 95% of total Opana ER sales. Under the Hatch-Waxman Act, Impax had 180-day exclusivity for those strengths, which prohibited the FDA from approving any other generic versions of Opana ER for those strengths until Impax's 180-day exclusivity period either expired or was forfeited. Because of Impax's anticompetitive agreement with Endo, the 180-day exclusivity period did not

Complaint

begin to run until January 2013, the entry date Endo paid Impax to accept. The Opana ER Agreement, therefore, precluded all generic Opana ER competition for the most prescribed strengths until January 2013. As a result of this conduct, Endo maintained its market power over oxymorphone ER products for 2½ years, allowing it to charge supracompetitive prices for Opana ER.

98. Absent injunctive relief, there is a cognizable danger that Impax will engage in similar violations causing future harm to competition and consumers. Respondent knowingly entered into and carried out a collusive anticompetitive scheme to preserve and share in Endo's monopoly profits. Impax did so conscious of the fact that this agreement would greatly enrich Impax and Endo at the expense of consumers.

99. Impax has incentives and the demonstrated interest to continue to enter such agreements in the future. Impax has entered into other similar reverse-payment agreements. For example, Impax has been sued for entering into a reverse-payment settlement involving the drug Solodyn.

100. Impax continues to develop and manufacture pharmaceutical products. Impax is regularly involved in multiple patent litigations relating to different drugs. Each of these patent litigations provides the incentive and opportunity to enter into another reverse-payment agreement.

Violation Alleged

101. As set forth above, Impax agreed to restrain competition in violation of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a).

102. The acts and practices of Respondent, as alleged herein, constitute an unfair methods of competition in or affecting commerce in violation of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45. Such acts and practices, or the effects thereof, will continue or recur in the absence of appropriate relief.

Complaint

NOTICE

Notice is hereby given to Respondent that the nineteenth day of September, 2017, at 10:00 a.m., is hereby fixed as the time and Federal Trade Commission offices, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580, as the place when and where a hearing will be had before an Administrative Law Judge of the Federal Trade Commission, on the charges set forth in this complaint, at which time and place you will have the right under the Federal Trade Commission Act to appear and show cause why an order should not be entered requiring you to cease and desist from the violations of law charged in the complaint and prohibiting you from future violations of the law similar to those charged in the complaint.

You are notified that the opportunity is afforded you to file with the Commission an answer to this complaint on or before the fourteenth (14th) day after service of it upon you. An answer in which the allegations of the complaint are contested shall contain a concise statement of the facts constituting each ground or defense; and specific admission, denial, or explanation of each fact alleged in the complaint or, if you are without knowledge thereof, a statement to that effect. Allegations of the complaint not thus answered shall be deemed to have been admitted.

If you elect not to contest the allegations of fact set forth in the complaint, the answer shall consist of a statement that you admit all of the material allegations to be true. Such an answer shall constitute a waiver of hearing as to the facts alleged in the complaint and, together with the complaint, will provide a record basis on which the Commission shall issue a final order disposing of the proceeding. In such answer, you may, however, reserve the right to submit proposed findings of fact and conclusions of law under § 3.46 of said Rules.

Failure to file an answer within the time above provided shall be deemed to constitute a waiver of your right to appear and to contest the allegations of the complaint, and shall authorize the Commission, without further notice to you, to find the facts to be as alleged in the complaint and to enter a final decision containing

Complaint

appropriate findings and conclusions and a final order disposing of the proceeding.

The Administrative Law Judge shall hold a prehearing scheduling conference not later than ten (10) days after an answer is filed by Respondent. Unless otherwise directed by the Administrative Law Judge, the scheduling conference and further proceedings will take place at the Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580. Rule 3.21(a) requires a meeting of the parties' counsel as early as practicable before the prehearing scheduling conference, and Rule 3.31(b) obligates counsel for each party, within five (5) days of receiving the answer of Respondent, to make certain initial disclosures without awaiting a formal discovery request.

NOTICE OF CONTEMPLATED RELIEF

Should the Commission conclude from the record developed in any adjudicative proceedings in this matter that Respondent has violated or is violating Section 5 of the FTC Act, as amended, as alleged in the complaint, the Commission may order such relief against Respondent as is supported by the record and is necessary and appropriate, including, but not limited to:

1. Ordering Respondent to cease and desist from the conduct alleged in the complaint to violate Section 5 of the FTC Act, and to take all such measures as are appropriate to correct or remedy, or to prevent the recurrence of, the anticompetitive practices engaged in by Respondent, or similar practices.
2. Prohibiting Respondent from entering into or attempting to enter into an agreement settling a patent infringement dispute in which: (i) the brand drug company provides to the generic drug company anything of the value *other than* the right to market its generic drug product prior to the expiration of the patent that is the basis of the patent litigation; and (ii) the generic drug company agrees not to research, develop, manufacture, market, or sell the generic drug product that is the subject of the patent litigation for any period of time.

Complaint

3. Prohibiting Respondent from entering into an agreement with another drug company that, in form or substance, prevents, restricts, or disincentives the brand drug company from competing with an authorized generic version of its drug product for some period of time.
4. Ordering Respondent to submit at least one report to the Commission sixty days after issuance of the Order, and other reports as required, describing how it has complied, is complying, and will comply in the future.
5. Requiring, for a period of time, that Respondent document all communications with parties in which it is engaged in Hatch-Waxman patent litigation to document all settlement discussions, including the persons involved, the nature of the communication, and its duration, and that Respondent submit such documentation to the Commission.
6. Ordering Respondent to file annual compliance reports to the Commission describing its compliance with the requirements of the order. The order would terminate twenty years from the date it becomes final.
7. Requiring that Respondent's compliance with the order may be monitored at Respondent's expense by an independent monitor, for a term to be determined by the Commission.
8. Any other relief appropriate to prevent, correct, or remedy the anticompetitive effects in their incipience of any or all of the conduct alleged in the complaint.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this nineteenth day of January, 2017, issues its complaint against Respondent.

By the Commission.

Initial Decision

INITIAL DECISION**I. INTRODUCTION****A. Summary of Complaint and Answer**

The Administrative Complaint in this case (“Complaint”), issued by the Federal Trade Commission (“FTC” or “Commission”) on January 19, 2017, alleges that a reverse payment settlement agreement between Respondent Impax Laboratories, Inc. (“Impax” or “Respondent”) 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 (“FTC Act”). Complaint ¶¶ 1, 3. The Complaint alleges that, through a settlement agreement entered into in June 2010 (the “Challenged Agreement” or the “Endo-Impax Settlement”), Impax, a generic drug manufacturer, agreed to abandon its legal challenge to patents held by Endo for a branded drug manufactured by Endo (Opana ER) and to forego launching its generic version of Opana ER until January 2013, in exchange for a large, unjustified “reverse payment” from Endo. Complaint ¶¶ 1, 3. According to the Complaint, the purpose and effect of the Endo-Impax Settlement was to ensure that Endo would not face generic competition for Opana ER until January 2013. Complaint ¶ 4.

Respondent filed its Answer and Defenses (“Answer”) to the Complaint on February 7, 2017. Respondent denied most material allegations in the Complaint and further asserted ten affirmative defenses, including its Eighth Defense, which averred that the challenged conduct had substantial procompetitive justifications, benefited consumers, and avoided infringement of valid patents, and that these procompetitive justifications have outweighed any alleged anticompetitive effects. Answer at 21.

B. Procedural History

Although the Complaint challenges an agreement between Impax and Endo, Endo is not a party to this enforcement action. As a result of a federal court action against Endo and others arising from a patent settlement in connection with Lidoderm,

Initial Decision

another product manufactured by Endo, Endo settled with the FTC and agreed to a stipulated order and permanent injunction that apparently resolved any FTC concerns regarding the conduct of Endo in this case. *See Federal Trade Commission v. Endo Pharms*, No. 17-cv-00312 (N.D. Cal. Feb. 2, 2017). Accordingly, this litigation proceeded only against Impax.

On August 10, 2017, Complaint Counsel filed a motion for partial summary decision with the Commission, requesting that the Commission declare that certain procompetitive justifications are not legally cognizable defenses to the conduct challenged in the Complaint, pursuant to the Supreme Court's decision in *FTC v. Actavis*, 133 S. Ct. 2223 (2013). *In re Impax Labs, Inc.*, 2017 FTC LEXIS 130, at *11. Specifically, Complaint Counsel sought to preclude three arguments as to procompetitive benefits: (1) that the Endo-Impax Settlement enabled Impax to enter prior to expiration of various existing and future Endo patents; (2) that the Endo-Impax Settlement provided Impax with certainty that it could launch its generic products free from the risk of infringing Endo's existing and future patents; and (3) that the Endo-Impax Settlement enabled Impax to continue selling its generic product, while other potential generic sellers of Opana ER were enjoined due to a court ruling that two Endo patents obtained after the Endo-Impax Settlement were valid and infringed by such sellers. *Id.* at *15 (Oct. 27, 2017). Complaint Counsel sought an order foreclosing Impax from making arguments to justify or otherwise defend the Endo-Impax Settlement on those bases. *Id.*

Under the Commission's Rules of Practice, the motion was not decided by the Administrative Law Judge ("ALJ"), but by the Commission.¹ By Order issued October 27, 2017, the

¹ The Commission amended Rule 3.22 of its Rules of Practice in 2009 to allow "the Commission to decide legal questions and articulate applicable law when the parties raise purely legal issues." Proposed rule amendments; request for public comment, 73 Fed. Reg. 58,832, 58,836 (Oct. 7, 2008). "[C]ommenters (including the [Section of Antitrust Law of the American Bar Association ('Section')], criticized the [Commission's] proposed Rule change as unfairly invading the province of the independent ALJ and compromising the Commission's dual roles as prosecutor and adjudicator." Interim final rules with request for comment, 74 Fed. Reg. 1804, 1809 (Jan. 13, 2009). "For example, the Section argued that the proposed changes . . . could raise concerns about the impartiality and fairness of the Part 3 proceeding by permitting the

Initial Decision

Commission denied Complaint Counsel's motion. *Id.* at *33. The Commission reasoned that the motion was premature because: (1) Respondent had not yet fully articulated the bases for its assertion of procompetitive justifications, *Id.* at *15-18; and (2) the structure of the rule of reason for a reverse-payment settlement should be determined based on briefing and a factual record at trial. *Id.* at *18, *26-27. The Commission stated: "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." *Id.* at *26-27. The Commission concluded: "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." *Id.* at *32-33.

The evidentiary hearing began on October 24, 2017 and was completed on November 14, 2017. The hearing record was closed by Order dated November 17, 2017.² Complaint Counsel and Respondent ("the parties") filed concurrent post-trial briefs and proposed findings of fact on December 20, 2017.

Commission to adjudicate dispositive issues, including motions to dismiss challenging the facial sufficiency of a complaint, shortly after the Commission has voted out the complaint finding that it has 'reason to believe' there was a law violation, without the benefit of an opinion by an independent ALJ." *Id.* A joint comment from former FTC Chairman Robert Pitofsky and Michael N. Sohn "similarly argued that the proposed rules, including Rule 3.22, would arguably infringe on the fairness of the Part 3 proceeding if the Commission more frequently 'invades what has heretofore been the province of an independent ALJ.'" *Id.* Dismissing these objections, the Commission amended its Rules of Practice to give to itself the authority to decide "[m]otions to dismiss filed before the evidentiary hearing, motions to strike, and motions for summary decision[.]" 16 C.F.R. § 3.22(a).

² Over 1,250 exhibits were admitted into evidence, 37 witnesses testified, either live or by deposition, and there are 3,066 pages of trial transcript. The parties' post-trial briefs, proposed findings of fact and conclusions of law, reply briefs and replies to proposed findings of fact and conclusions of law total 2,869 pages.

Initial Decision

By Order issued January 5, 2018, Endo was permitted to intervene in this action for the limited purpose of responding to Complaint Counsel's Post-Trial Brief and Proposed Order and opposing (1) any findings related to the alleged competitive effects of a 2017 settlement agreement between Endo and Impax and (2) any remedy that would order the nullification of that 2017 settlement, or otherwise affect Endo's rights under that agreement. Endo's brief on these issues, filed on January 16, 2018, has been considered.

Rule 3.51(a) of the Commission's Rules of Practice states that "[t]he Administrative Law Judge shall file an initial decision within 70 days after the filing of the last filed initial or reply proposed findings of fact, conclusions of law and order" 16 C.F.R. § 3.51(a). The parties filed replies to each other's proposed findings of fact, conclusions of law, and post-trial briefs and to Endo's January 16, 2018 brief on February 7, 2018.³ Closing arguments were held on February 15, 2018.

Seventy days from the last filed reply proposed findings and conclusions and briefs was April 18, 2018, and, absent an order pursuant to Rule 3.51, the Initial Decision was to be filed on or before April 18, 2018. Based on the voluminous and complex record in this matter, an Order was issued on April 6, 2018, finding good cause for extending the time period for filing the Initial Decision by 30 days. Accordingly, issuance of this Initial Decision by May 18, 2018 is in compliance with Commission Rule 3.51(a).

C. Evidence

This Initial Decision is based on a consideration of the whole record relevant to the issues, including the exhibits properly admitted into evidence, deposition transcripts, and the transcripts of testimony at trial, and addresses the material issues of fact and law. The briefs and proposed findings of fact and conclusions of law, and the replies thereto, submitted by the parties, and all

³ The Commission's January 19, 2018 order extended the deadline for the parties to file their concurrent reply briefs and replies to proposed findings to February 7, 2018.

Initial Decision

contentions and arguments therein were thoroughly reviewed and considered.

Proposed findings of fact submitted by the parties but not accepted in this Initial Decision were rejected, either because they were not supported by the evidence or because they were not dispositive or material to the determination of the merits of the case. Similarly, legal contentions and arguments of the parties that are not addressed in this Initial Decision were rejected, because they lacked support in fact or law, were not material, or were otherwise lacking in merit.⁴ In addition, all expert opinion evidence submitted in this case has been fully reviewed and considered. Except as expressly relied on or adopted in this Initial Decision, such opinions have been rejected, as either unreliable, unsupported by the facts, or unnecessary to the findings and conclusions herein.

Under Commission Rule 3.51(c)(1), “[a]n initial decision shall be based on a consideration of the whole record relevant to the issues decided, and shall be supported by reliable and probative evidence.” 16 C.F.R. § 3.51(c)(1); see *In re Chicago Bridge & Iron Co.*, 138 F.T.C. 1024, 1027 n.4, 2005 FTC LEXIS 215, at *3 n.4 (Jan. 6, 2005). Under the Administrative Procedure Act (“APA”), an ALJ may not issue an order “except on consideration of the whole record or those parts thereof cited by a Party and

⁴ Ruling upon a decision of the Interstate Commerce Commission, and interpreting language in the Administrative Procedure Act that is almost identical to language in Commission Rule 3.51(c)(1), the United States Supreme Court held that “[b]y the express terms of [that Act], the Commission is not required to make subordinate findings on every collateral contention advanced, but only upon those issues of fact, law, or discretion which are ‘material.’” *Minneapolis & St. Louis Ry. Co. v. United States*, 361 U.S. 173, 193-94 (1959). *Accord Stauffer Labs., Inc. v. FTC*, 343 F.2d 75, 82 (9th Cir. 1965). See also *Borek Motor Sales, Inc. v. NLRB*, 425 F.2d 677, 681 (7th Cir. 1970) (holding that it is adequate for the Board to indicate that it had considered each of the company’s exceptions, even if only some of the exceptions were discussed, and stating that “[m]ore than that is not demanded by the [APA] and would place a severe burden upon the agency”). Furthermore, the Commission has held that ALJs are not required to discuss the testimony of each witness or all exhibits that are presented during the administrative adjudication. *In re Amrep Corp.*, 102 F.T.C. 1362, 1670, 1983 FTC LEXIS 17, at *566-67 (Nov. 2, 1983).

Initial Decision

supported by and in accordance with the reliable, probative, and substantial evidence.” 5 U.S.C. § 556(d). All findings of fact in this Initial Decision are supported by reliable, probative, and substantial evidence. Citations to specific numbered findings of fact in this Initial Decision are designated by “F.”⁵

The parties’ burdens of proof are governed by Commission Rule 3.43(a), Section 556(d) of the APA and case law. Pursuant to Commission Rule 3.43(a), “[c]ounsel representing the Commission . . . shall have the burden of proof, but the proponent of any factual proposition shall be required to sustain the burden of proof with respect thereto.” 16 C.F.R. § 3.43(a). Under the APA, “[e]xcept as otherwise provided by statute, the proponent of a rule or order has the burden of proof.” 5 U.S.C. § 556(d). The APA, “which is applicable to administrative adjudicatory proceedings unless otherwise provided by statute, establishes ‘ . . . the traditional preponderance-of-the evidence standard.’” *In re Rambus, Inc.*, 2006 FTC LEXIS 101, at *45 (Aug. 20, 2006) (quoting *Steadman v. SEC*, 450 U.S. 91, 95-102 (1981)), *rev’d on other grounds*, 522 F.3d 456 (D.C. Cir. 2008)).

Pursuant to Commission Rule 3.45(b), several orders were issued in this case granting *in camera* treatment to material, after finding, in accordance with the Rule, that its public disclosure would likely result in a clearly defined, serious injury to the entity requesting *in camera* treatment or that the material constituted “sensitive personal information,” as that term is defined in

⁵ References to the record are abbreviated as follows:

CX – Complaint Counsel’s Exhibit

RX – Respondent’s Exhibit

JX – Joint Exhibit

Tr. – Transcript of testimony before the Administrative Law Judge

Dep. – Transcript of Deposition

IHT – Transcript of Investigational Hearing

CCB – Complaint Counsel’s Post-Trial Brief

CCRB – Complaint Counsel’s Post-Trial Reply Brief

CCFF – Complaint Counsel’s Proposed Findings of Fact

CCRRFF – Complaint Counsel’s Reply to Respondent’s Proposed Findings of Fact

RB – Respondent’s Post-Trial Brief

RFF – Respondent’s Proposed Findings of Fact

Initial Decision

Commission Rule 3.45(b). In addition, when the parties sought to elicit testimony at trial that revealed information that had been granted *in camera* treatment, the hearing went into an *in camera* session.

Commission Rule 3.45(a) allows the ALJ “to grant *in camera* treatment for information at the time it is offered into evidence subject to a later determination by the [administrative] law judge or the Commission that public disclosure is required in the interests of facilitating public understanding of their subsequent decisions.” *In re Bristol-Myers Co.*, Nos. 8917-19, 90 F.T.C. 455, 457, 1977 FTC LEXIS 25, at *6 (Nov. 11, 1977). As the Commission later reaffirmed in another leading case on *in camera* treatment, since “in some instances the ALJ or Commission cannot know that a certain piece of information may be critical to the public understanding of agency action until the Initial Decision or the Opinion of the Commission is issued, the Commission and the ALJs retain the power to reassess prior *in camera* rulings at the time of publication of decisions.” *In re General Foods Corp.*, No. 9085, 95 F.T.C. 352, 356 n.7; 1980 FTC LEXIS 99, at *12 n.7 (March 10, 1980). Thus, in instances where a document or trial testimony had been given *in camera* treatment, but the portion of the material cited to in this Initial Decision does not in fact require *in camera* treatment, such material is disclosed in the public version of this Initial Decision, pursuant to Commission Rule 3.45(a) (the ALJ “may disclose such *in camera* material to the extent necessary for the proper disposition of the proceeding”). Where *in camera* information is used in this Initial Decision, it is indicated in bold font and braces (“{ }”) in the *in camera* version and is redacted from the public version of the Initial Decision, in accordance with Commission Rule 3.45(e).

D. Summary of Initial Decision

This decision arises from the first Part III administrative trial involving a reverse payment patent settlement agreement since the Supreme Court’s decision in *FTC v. Actavis*, 133 S. Ct. 2223 (2013). The evidence shows that, under the Challenged Agreement, Endo provided Impax with a reverse payment, the purpose and effect of which was to induce Impax to give up its

Initial Decision

patent challenge and agree not to launch a generic Opana ER until January 2013. Payment by a patent holder to a generic challenger to induce the generic challenger to drop its challenge and agree to stay out of the market, rather than face the risk of patent invalidation and resulting generic competition, is an anticompetitive harm under *Actavis*.

Under the facts of this case, however, the magnitude and extent of any anticompetitive harm is largely theoretical, based on an inference that, absent the Challenged Agreement, Impax's entry date, and therefore generic competition, would have been earlier than January 2013. The evidence shows that such earlier entry was unlikely. Moreover, even if, absent the Challenged Agreement, Impax would have entered the market substantially earlier than January 2013, the evidence demonstrates that the Challenged Agreement provided real and substantial procompetitive benefits to consumers that outweigh any anticompetitive effect. Among other things, the Challenged Agreement granted Impax a broad patent license covering Endo's existing and subsequently-acquired Opana ER-related patents, which has enabled Impax to sell generic Opana ER without interruption since launching its product in January 2013, while all other potential generic drug manufacturers have been enjoined by patent litigation. Indeed, Impax's product is not only the sole generic oxymorphone ER product available to consumers, but the only available oxymorphone ER product.

Weighing the anticompetitive harm and the procompetitive benefits, the evidence fails to prove that the Challenged Agreement was anticompetitive on balance. Rather, the evidence proves that the procompetitive benefits of the Challenged Agreement outweigh the anticompetitive harm. Thus, the evidence fails to demonstrate that the Challenged Agreement constituted an unreasonable restraint of trade. Accordingly, the evidence fails to prove a violation of Section 5 of the FTC Act. The Complaint must, therefore, be **DISMISSED**.

II. FINDINGS OF FACT

A. Background

1. Jurisdiction

1. Impax Laboratories, Inc. (“Impax”) is a for-profit corporation with its principal place of business at 30831 Huntwood Avenue, Hayward, California. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-001 ¶ 1).
2. In addition to its Hayward, California headquarters, Impax operates out of its facilities in Middlesex, New Jersey, among other locations. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-001 ¶ 2).
3. Impax engages in the business of, among other things, developing, manufacturing, and marketing generic pharmaceutical drugs (“generics” or “generic drugs”). (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-001 ¶ 3).
4. Impax is a corporation, as “corporation” is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-001 ¶ 4).
5. Impax has engaged in, 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. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-001-02 ¶ 5).

2. Hatch-Waxman framework

6. 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 (the “Hatch-

Initial Decision

Waxman Act”) and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, 21 U.S.C. §§ 355(b)(2) and 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. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-002-03 ¶ 12).

7. 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. 21 U.S.C. § 355. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-003 ¶ 13).
8. NDA-based products generally are referred to as “brand-name drugs,” “branded drugs,” or “brand drugs.” (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-003 ¶ 14).
9. The FDA requires NDA holders to identify patents that the NDA holder believes could reasonably be asserted against a generic company that makes, uses, or sells a generic version of the branded drug. 21 C.F.R. § 314.53. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-003 ¶ 15).
10. The NDA holder 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 or within 30 days after approval of the NDA. 21 C.F.R. § 314.53. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-003 ¶ 16).
11. A company seeking to market a generic version of a branded drug may file an Abbreviated New Drug Application (“ANDA”) with the FDA. 21 U.S.C. § 355(j). (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-003 ¶ 17).

Initial Decision

12. 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. 21 U.S.C. § 355(j)(2)(A)(iv). (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-003 ¶ 18).
13. Upon showing that the generic drug is therapeutically equivalent to the approved branded drug, the generic company may rely on the studies submitted in connection with the approved branded drug's NDA to establish that the generic drug is safe and effective. 21 U.S.C. § 355(j)(2)(A). (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-003-04 ¶ 19).
14. The FDA assigns a generic drug an "AB" rating if it is therapeutically equivalent to a brand-name drug. 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. A generic drug must also contain identical amounts of the same active ingredient(s) as the brand-name drug, although its inactive ingredients may vary. FDA, *Approved Drug Products with Therapeutic Equivalence Evaluations*, Preface § 1.7. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-004 ¶ 20).
15. When a brand-name drug is covered by one or more patents listed in the Orange Book, a company seeking to market a generic version of that drug before the patents expire must make a "Paragraph IV certification" in its ANDA certifying that the patents are invalid, unenforceable, and/or will not be infringed by the generic drug. 21 U.S.C. § 355(j)(2)(A)(vii)(IV). (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-004 ¶ 21).
16. If an ANDA filer makes a Paragraph IV certification, it must notify the patent holder of its certification and the factual and legal bases for its assertion(s) that the relevant

Initial Decision

patent is invalid, unenforceable, and/or not infringed. 21 U.S.C. § 355(j)(2)(B). (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-004 ¶ 22).

17. If the patent holder initiates a patent infringement suit against an ANDA filer within 45 days of receiving such notice (F. 16), the FDA may not grant final approval of the ANDA until the earliest of: (1) patent expiration date; (2) district court resolution of the patent litigation in favor of the generic company; or (3) the expiration of an automatic 30-month stay. 21 U.S.C. § 355(j)(5)(B)(iii). (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-004 ¶ 23).
18. When a generic drug otherwise meets the FDA's criteria for approval but final approval is blocked by statute or regulation, such as the Hatch-Waxman 30-month stay, the FDA may tentatively approve the relevant ANDA. 21 U.S.C. § 355(j)(5)(B)(iv). (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-005 ¶ 24).
19. Tentative approval of an ANDA by the FDA does not permit an ANDA filer to market its generic version of the drug. 21 U.S.C. § 355(j)(5)(B)(iv)(II)(dd)(BB). (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-005 ¶ 25).
20. The FDA can issue final approval of a tentatively-approved drug once the 30-month stay expires. 21 U.S.C. § 355(j)(5)(B)(iii). (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-005 ¶ 26).
21. The Hatch-Waxman Act provides the first generic company or companies filing an ANDA containing a Paragraph IV certification ("first filer") to a particular branded drug with a period referred to as the "180-day exclusivity" or "first-filer exclusivity" period. During this 180-day exclusivity period, no other generic manufacturer can sell its version of that particular branded drug. 21 U.S.C. § 355(j)(5)(B)(iv). (Joint Stipulations of

Initial Decision

Jurisdiction, Law, Fact, and Authenticity, JX001-005 ¶ 27; Second Set of Joint Stipulations, JX003 ¶ 7).

22. A brand drug company can market a generic version of its own brand product at any time, including during the first filer's exclusivity period. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-005 ¶ 28).
23. For a brand drug 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. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-005 ¶ 29).
24. Brand drug companies' generic versions of their own brand products commonly are known as "authorized generics" ("AGs"). (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-005 ¶ 30).
25. An authorized generic 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. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-005 ¶ 31).

3. Competition between brand and generic manufacturers

26. A patient can obtain a prescription drug only if a doctor (or someone who is authorized to write prescriptions) writes a prescription for that drug. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-007 ¶ 11).
27. Doctors who select the medications they prescribe for their patients do not pay for the medications. Generally, when selecting appropriate medications for patients, doctors' primary concerns are efficacy and safety, rather than the cost of medications. (CX5002 (Savage Expert Report at

Initial Decision

063-64 ¶ 177, 180); Savage, Tr. 770-71; Michna, Tr. 2187-88; CX4046 (Michna, Dep. at 148-49)).

28. The patient, or in most cases a third-party payor such as a public or private health insurer, pays for the drug. These purchasers often have little input over what drug is actually prescribed, because physicians ultimately select and prescribe appropriate drug therapies. (CX5000 (Noll Expert Report at 031 ¶ 67); CX5002 (Savage Expert Report at 063 ¶ 177)).
29. 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. When a pharmacist fills a prescription written for a branded drug, these laws allow or require the pharmacist to dispense an AB-rated generic version of the drug instead of the more expensive branded drug, unless a physician directs or the patient requests otherwise. Conversely, these laws generally do not permit a pharmacist to substitute a non-AB-rated generic for a branded drug unless the physician specifically prescribes it by writing the chemical name of the drug, rather than the brand name, on the prescription. (Second Set of Joint Stipulations, JX003 ¶ 72).
30. Because of the price advantages of generic drugs over branded drugs, many third-party payors 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 (Noll Expert Report at 030-32 ¶¶ 65, 67-69); CX6052 at 084-85).
31. Generic manufacturers typically charge lower prices than branded drug sellers. The first one or two generic products are typically offered at a 10% to 25% discount off the price of the branded product. Subsequent generic entry creates greater price competition which typically leads to discounts between 50% to 80% off the brand

Initial Decision

price. (CX5000 (Noll Expert Report at 048 ¶ 104); CX2607 (Lortie Decl. at 012 ¶ 29); CX6055 at 010).

32. Automatic substitution of the generic drug for the branded drug is the primary way that generic companies make their sales. (Mengler, Tr. 522; Engle, Tr. 1703).

4. Opioids

33. Opioid medications (“opioids”) are prescription drugs indicated for the treatment of moderate to severe pain. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-006 ¶ 2; Savage, Tr. 700-01).
34. Opioids are derived from opium. (Michna, Tr. 2104).
35. There are three types of opioids: ultra-fast-acting, immediate-release, and extended-release. (Michna, Tr. 2105; *see* Savage, Tr. 693).
36. Ultra-fast-acting opioids are medications that are absorbed through the mouth and have an initial onset of pain relief in about fifteen minutes. They are used to treat pain that comes on very suddenly and that may dissipate within an hour. (Michna, Tr. 2105).
37. Immediate-release (“IR”) opioids are short-acting pain medications that take effect within 30 to 45 minutes of ingestion and tend to last 3 to 6 hours. They are used to treat acute, short-lived pain as well as chronic pain. (Michna, Tr. 2106, 2118; Savage, Tr. 693, 702, 705).
38. Extended-release (“ER”) opioids provide continuous levels of medication in a patient’s blood over several hours, with effects lasting from 8 to 24 hours, and in the case of transdermal applications – patches that deliver medication through the skin – up to 7 days. (Michna, Tr. 2106; *see* Savage, Tr. 702).
39. Extended-release opioids have been pharmacologically formulated to provide gradual release of the opioid

Initial Decision

medication. In particular, the physical chemical structure of the tablet, capsule, or bead provides for slower release of the medication and, in turn, more gradual absorption by the body. (Savage, Tr. 693, 704-05).

40. Extended-release opioids generally are used for patients with sustained pain lasting longer than 12 to 24 hours, as well as chronic pain that requires relief 24 hours a day. (Savage, Tr. 705).

B. Context for the Endo-Impax Litigation and Settlement**1. Opana ER**

41. Oxymorphone belongs to the class of drugs known as opioids. It is a semi-synthetic opioid used to relieve pain. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-006 ¶¶ 1-2).
42. The FDA first approved oxymorphone to relieve pain in 1960. (Second Set of Joint Stipulations, JX003 ¶ 1).
43. Opana ER is an extended-release formulation of oxymorphone. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-006 ¶ 3).
44. Opana ER is used to treat pain for a wide variety of conditions, ranging from chronic back problems to pain caused by cancer. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-006 ¶ 5).
45. Endo Pharmaceuticals Inc. (“Endo”) and Penwest Pharmaceuticals (“Penwest”) collaborated on the development and commercialization of Opana ER. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-011 ¶ 47).
46. The FDA approved Endo’s NDA for 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.” (Joint

Initial Decision

Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-006 ¶ 4).

47. In July 2006, Endo announced the commercial availability of Opana ER. At the time of launch in 2006, Opana ER was the only extended-release version of oxymorphone on the market.⁶ (Second Set of Joint Stipulations, JX003 ¶ 3).
48. Endo ultimately offered Opana ER in seven dosage strengths (5, 7.5, 10, 15, 20, 30 and 40 milligram (“mg”)). (Second Set of Joint Stipulations, JX003 ¶ 3).

2. Endo’s initial patents for Opana ER

49. When Endo launched Opana ER in 2006, it listed a single patent in the Orange Book as covering Opana ER: U.S. Patent No. 5,128,143 (“the ’143 patent”). (CX3242 at 003).
50. The ’143 patent was set to expire in September 2008. (Second Set of Joint Stipulations, JX003 ¶ 4; CX3242 at 003).
51. In October 2007, 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”) (“the initial patents”). (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-006 ¶ 9).
52. Endo listed the ’250 patent in the Orange Book on October 2, 2007. The ’250 patent will expire in February 2023. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-006 ¶¶ 9-10; Snowden, Tr. 351).
53. Endo listed the ’933 and ’456 patents on October 19, 2007. The ’933 and ’456 patents expired in September

⁶ As set forth in F. 110, Endo introduced a reformulated version of Opana ER in 2012. Unless otherwise specified, the term “Opana ER” as used herein refers to original Opana ER.

Initial Decision

2013. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-006 ¶¶ 9-10; Snowden, Tr. 351).

54. The '250, '933, and '456 patents all pertain to the controlled-release mechanism of the oxymorphone formulation. (Second Set of Joint Stipulations, JX003 ¶ 6).

3. Overview of Endo-Impax litigation and settlement

a. Impax's Abbreviated New Drug Applications

55. In June 2007, Impax filed an Abbreviated New Drug Application (No. 79-087) for a generic version of Opana ER, also referred to as generic oxymorphone ER.⁷ (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-007 ¶ 11; Second Set of Joint Stipulations, JX003 ¶ 4).
56. As of June 2007, the '143 patent was the only patent listed in the Orange Book as covering Opana ER. (Second Set of Joint Stipulations, JX003 ¶ 4; CX2967 at 014, 017).
57. Impax's June 2007 ANDA utilized a Paragraph III certification for 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. (Second Set of Joint Stipulations, JX003 ¶ 4; CX2967 at 017).
58. Following Endo's listing of additional patents in the Orange Book in October 2007 (F. 51-53), Impax amended its ANDA to include Paragraph IV certifications for the '250, '933, and '456 patents. With respect to the '250, '933 and '456 patents, Impax certified that, "in its opinion and to the best of its knowledge," those patents were "invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of the oxymorphone

⁷ Endo and Impax both refer to a generic version of Endo's Opana ER as either "generic Opana ER" or "generic oxymorphone ER" interchangeably.

Initial Decision

hydrochloride extended-release tablets for which” Impax’s ANDA had been submitted. Impax was the first company to file an ANDA with Paragraph IV certifications for the 5, 10, 20, 30, and 40 mg dosages strengths of Opana ER. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-007 ¶¶ 12, 13; Second Set of Joint Stipulations, JX003 ¶ 7; Snowden, Tr. 355).

59. 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. (Second Set of Joint Stipulations, JX003 ¶ 7).
60. On December 13, 2007, Impax sent Endo notice of its Paragraph IV certifications for the ’250, ’933, and ’456 patents. In its notice, Impax asserted that its product did not infringe these patents. (Second Set of Joint Stipulations, JX003 ¶ 8; Snowden, Tr. 355, 413; CX2714).

**b. The filing of the Endo-Impax patent litigation
and FDA approval of Impax’s ANDA**

61. On January 25, 2008, Endo and Penwest filed a patent infringement lawsuit against Impax in the federal district court in Delaware, alleging that Impax’s ANDA for generic oxymorphone ER infringed Endo’s ’456 and ’933 patents (“Endo-Impax patent litigation”). (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-007 ¶ 15; Snowden, Tr. 413-14).
62. The filing of the Endo-Impax patent litigation triggered a statutory 30-month stay, meaning that the FDA could not approve Impax’s ANDA until the earlier of the expiration of 30 months or resolution of the patent dispute in Impax’s favor. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-007 ¶ 15).
63. The 30-month stay was set to expire on June 14, 2010. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-007 ¶ 16).

Initial Decision

64. The FDA granted tentative approval to Impax's ANDA on May 13, 2010. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-007 ¶ 17).
65. Tentative FDA approval is effectively the last step in an ANDA filer's approval efforts. (Koch, Tr. 340-41; see Snowden, Tr. 417-18 (tentative approval from FDA "suggest[s] that Impax was almost certain to get final approval at the conclusion of the 30-month stay")).
66. Impax received final approval for Impax's generic oxymorphone ER product on the 5, 10, 20, and 40 mg dosage strengths on June 14, 2010, upon expiration of the statutory 30-month stay. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-008 ¶ 21).
67. The FDA granted final approval to Impax's ANDA for the 30 mg dosage strength of generic oxymorphone ER on July 22, 2010. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-008 ¶ 22).

c. Summary of proceedings

68. In the Endo-Impax patent litigation, Endo alleged that Impax's generic oxymorphone ER infringed Endo's '456 and '933 patents. Endo did not allege that Impax's generic oxymorphone ER infringed Endo's '250 patent. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-007 ¶ 15; Snowden, Tr. 415-16; CX0304 at 002 ¶ 5).
69. Impax sought to transfer the Endo-Impax patent litigation from the federal district court in Delaware to the federal district court in New Jersey because the Delaware court was overloaded and Impax hoped the case would move faster in New Jersey. The court granted Impax's request and transferred the case to the federal district court in New Jersey. (Snowden, Tr. 357-58).

Initial Decision

70. The district court presiding over the Endo-Impax patent litigation held claim construction hearings on December 21, 2009 and March 19, 2010. (Second Set of Joint Stipulations, JX003 ¶ 18).
71. On April 5, 2010, the court in the Endo-Impax patent litigation issued an amended order on claim construction. The court adopted the constructions for “hydrophobic material” and “sustained release” proposed by Endo, and the parties stipulated to the construction of “homopolysaccharide.” (Second Set of Joint Stipulations, JX003 ¶ 19).
72. On May 19, 2010, the court scheduled the Endo-Impax patent infringement trial to begin on June 3, 2010 and continue through June 17, 2010. (Second Set of Joint Stipulations, JX003 ¶ 22).
73. The trial in the Endo-Impax patent litigation began on June 3, 2010. (Second Set of Joint Stipulations, JX003 ¶ 24; Figg, Tr. 1906; Hoxie, Tr. 2767).
74. On June 8, 2010, the Endo-Impax patent litigation was settled and the parties entered into the Settlement and License Agreement (“SLA”) and the Development and Co-Promotion Agreement (“DCA”). (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-007-08 ¶¶ 18-19; Second Set of Joint Stipulations, JX003 ¶ 26).
75. The SLA incorporates the DCA. (Second Set of Joint Stipulations, JX003 ¶ 69). The SLA and the DCA are referred to collectively in this Initial Decision as the “Challenged Agreement” or the “Endo-Impax Settlement.”
76. At the time that Endo and Impax settled their patent litigation, the outcome of Endo’s patent infringement suit was uncertain. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-008 ¶ 20; Second Set of Joint Stipulations, JX003 ¶ 26).

Initial Decision

4. Costs of litigation

77. Although litigation costs vary substantially among cases, a survey by the American Intellectual Property Lawyers Association estimated that the median litigation cost for all patent cases with more than \$25 million at stake averages about \$5.5 million for each party. When such a case is handled by firms with more than 76 attorneys, the median litigation cost averages approximately \$7 million for each party. (CX5000 (Noll Expert Report at 108 ¶ 247 & n.278)).
78. At the time of the Endo-Impax Settlement, which occurred during trial, Endo had spent between \$6 and \$7 million and Impax had spent about \$4.7 million on litigation in the infringement case. (CX2696 at 013-14; CX3212 at 009-10; CX5000 (Noll Expert Report at 108 ¶ 247)).
79. The top end of the range that Impax uses in its budgeting process to estimate costs for a generic patent litigation is about \$3 to \$4 million per litigation. This \$3 to \$4 million estimate represents total expenses from the start of litigation to completion and is based primarily on expenses for outside counsel, such as hourly attorneys' fees. Impax might also allocate some expenses for its internal legal department's work on patent litigation, but those are minor amounts. (Reasons, Tr. 1221-22).
80. During a public earnings conference call in November 2011, Impax's then-chief financial officer ("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" and that Impax was going to save \$3 million in litigation expenses because of settlements, including the Endo settlement. (Koch, Tr. 262-63; CX2703 at 004).
81. 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. (F. 77-80; Noll, Tr. 1463).

Initial Decision

5. Other Endo litigation on initial Opana ER patents

82. Eight companies submitted ANDAs seeking approval to market a generic version of Opana ER. 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. (Second Set of Joint Stipulations, JX003 ¶ 5; CX2607 at 008-09 (Lortie Decl. ¶ 24)).
83. In addition to suing Impax (F. 61), Endo sued all other Opana ER ANDA filers, alleging infringement of one or more of Endo's initial patents. Those suits settled, with the generic companies receiving patent licenses covering only the patents-in-suit. (Snowden, Tr. 440; RX441; RX442; RX443; CX3192).
84. Actavis South Atlantic LLC ("Actavis") filed its ANDA on February 14, 2008 covering all dosage strengths of Opana ER. Actavis was the first to file an ANDA for the 7.5 and 15 mg dosages of Opana ER. (Second Set of Joint Stipulations, JX003 ¶ 12; Snowden, Tr. 370; CX6039 at 003).
85. In March 2008, Endo sued Actavis, alleging that Actavis' ANDA covering the 5, 10, 20, and 40 mg dosages of generic oxymorphone ER infringed the '456 and '933 patents. (Second Set of Joint Stipulations, JX003 ¶ 13).
86. In July 2008, after Actavis amended its ANDA to include the 7.5, 15, and 30 mg dosages of generic oxymorphone ER, Endo filed a second suit against Actavis, alleging that Actavis' ANDA for those dosages infringed the '456 and '933 patents. (Second Set of Joint Stipulations, JX003 ¶ 14).
87. Effective February 20, 2009, Actavis settled the patent litigation with Endo relating to generic Opana ER and received a license to the litigated patents starting no later than July 15, 2011. (Second Set of Joint Stipulations,

Initial Decision

JX003 ¶ 15; CX3383 (Actavis settlement); Snowden, Tr. 370-71).

88. Actavis launched its 7.5 and 15 mg generic Opana ER products, for which it possessed first-filer exclusivity, in July 2011. (CX4034 (Rogerson, Dep. at 13)).
89. Actavis launched its 5, 10, 20, 30, and 40 mg generic Opana ER products on September 17, 2013, several months after the expiration of Impax's first-filer exclusivity. (CX2973; see CX4034 (Rogerson, Dep. at 13)).

6. Endo's market power

90. At the time Endo entered into the Endo-Impax Settlement in June 2010, Endo had 100% of the market share for oxymorphone ER. (CX5000 (Noll Expert Report at 083 ¶ 189)).
91. In the pharmaceutical industry, brand-name drug patent holders have the ability to exclude firms from the market in the sense that they are entitled by law to delay competitive entry by generic manufacturers. (CX5000 (Noll Expert Report at 086 ¶ 199)).
92. Barriers to entry in the pharmaceutical industry include intellectual property rights, such as patents, and regulatory impediments, such as provisions of the Hatch-Waxman Act (F. 93). (Noll, Tr. 1408; CX5000 (Noll Expert Report at 084-85 ¶ 194)).
93. The regulatory procedures imposed by the Hatch-Waxman Act allow a brand-name drug to be protected against entry in two ways. First, 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. Second, 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. (Joint Stipulations of Jurisdiction,

Initial Decision

Law, Fact, and Authenticity, JX001-004 ¶ 23; CX5000 (Noll Expert Report at 084-85 ¶ 194)).

94. The 30-month stay imposed by the Hatch-Waxman Act (F. 93) benefited Endo in the form of a regulatory entry barrier to the market for oxymorphone ER. (CX5000 (Noll Expert Report at 086-87 ¶ 194)).
95. Because the Paragraph IV procedures of Hatch-Waxman prevent entry by the first-filer generic for up to 30 months after a generic firm files an ANDA and by other generics for another 180 days, the patents at issue in the Impax infringement case gave Endo the power to exclude competitors even if its patents eventually were found not to be valid or infringed. (CX5000 (Noll Expert Report at 086-87 ¶ 199)).

7. Endo's plan to reformulate Opana ER

96. Since 2007, Endo had been working on a reformulated "crush-resistant" version of Opana ER ("reformulated Opana ER") to replace the original version. Reformulated Opana ER was also referred to internally by Endo as EN3288 and Revopan. (CX3214 at 015; CX3199 at 046; RX007 at 0001).
97. Introducing a reformulated Opana ER was a potential way for Endo to preserve the value of its Opana ER franchise even after generics became available for original Opana ER. (CX3205 at 001 ("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 [tamper-resistant 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.")).
98. Reformulating Opana ER would extend the life of the brand through additional patent protection and other possible roadblocks for potential generic competitors.

Initial Decision

(CX2724 at 005 (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; CX3251).

99. In order to maximize the value of reformulated Opana ER, Endo’s goal was to launch the reformulated product before the entry of a generic for original Opana ER, with sufficient time to transition patients from original Opana ER to reformulated Opana ER. Endo forecasted peak-year sales of more than \$199 million in 2016 if reformulated Opana ER beat generics and was the first to enter the market. If, however, reformulated Opana ER was launched after generic entry, estimated peak annual sales in 2016 were \$10 million. (CX2578 at 008-09 (Dec. 11, 2007 Opana Brand LCM Update, stating that Endo’s “Priority #1” was to “Beat Generics by 1 Year”)).
100. Endo forecasted that launching reformulated Opana ER ahead of a launch of a generic for original Opana ER would result in an increased demand for the reformulated product because patients will have been transitioned to the reformulated product. (CX2724 at 006; CX2578 at 008-09; CX4025 (Bingol, Dep. at 95-96)).
101. Endo forecasted significant erosion of its Opana ER franchise if Endo was unable to get reformulated Opana ER approved in a timely manner. If Endo launched reformulated Opana ER at the same time that a generic for original Opana ER came onto the market, reformulated Opana ER would capture at most 30% to 32% of Endo’s sales of original Opana ER. (CX1106 at 004; CX2724 at 006 (generic entry would result in steep drop in Opana ER sales unless EN3288 were approved with tamper resistance claims ahead of generic entry); CX1320 at 003 (projecting only \$11.9 million in Oxy TRF revenues for 2011); 007 (forecasting rapid generic erosion upon generic entry in July 2011); 024 (“Oxymorphone TRF conversion from OPANA ER base volume: 30% to 32% conversion of base volume; Conversion curve begins at launch (July 2011); Peak conversion (30%) reached in 40 months”)).

Initial Decision

102. Endo planned to remove original Opana ER from the market after introducing reformulated Opana ER. (CX1108 at 008 (noting that “it is likely that removal of Opana ER will be a condition of Revopan approval by FDA” and assuming launch of Revopan in February 2011 and ending shipment of Opana ER by October 2011)).
103. Launching reformulated Opana ER as far ahead as possible of generic entry on original Opana ER 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 63-64); CX2578 at 009).
104. 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”)).
105. In 2010, Endo forecasted filing its application for approval of reformulated Opana ER with the FDA during the third quarter of 2010 and that the approval process would take between four and ten months. Depending on various assumptions, Endo forecasted launching reformulated Opana ER sometime in 2011. (CX2575 at 004; CX1108 at 008 (assuming launch in February 2011); CX3038 at 001 (projecting range for launch between December 2010 and June 2011); *see also* CX2573 at 004 (projecting May 2011 launch); CX2724 at 005 (projecting range for launch between January and September 2011)).
106. Endo understood that patients cannot be switched immediately from one long-acting opioid to another because physicians are “very careful as they adjust dosages” for patients. Endo sought “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.” Such a transition would take about six to nine months. (CX4019 (Lortie, Dep. at 39-42, 156-57); Mengler, Tr. 530-31).

Initial Decision

107. Endo's plan to reformulate Opana ER and transition the market to the new product, prior to entry of a generic original Opana ER, would be adversely affected if Impax launched its generic at risk⁸ in June 2010. (CX2724 at 001).
108. If Impax launched a generic Opana ER at risk, Endo planned to launch an authorized generic for original Opana ER. (CX2576 at 003 ("We will launch on word/action of first generic competitor."); CX2581 at 001 ("Endo is prepared to launch an authorized generic if another generic is approved first."); CX2573 at 004 (Endo planned a "[l]aunch of authorized generic" in the event that Impax launched at risk); CX3007 at 003 ("If Impax launches, Endo will launch its authorized generic . . .")).
109. Endo did not intend to launch both a reformulated Opana ER and an authorized generic of original Opana ER at the same time. This is because it would have been "very difficult [for Endo] to justify" having a crushable authorized generic on the market at the same time as a crush-proof reformulation. Endo "intended to replace one product with the other, and that would be the only [Opana ER] product that [Endo] had on the market." (CX4019 (Lortie, Dep. at 117-18); Bingol, Tr. 1338-39; *see also* CX1108 at 008 (Endo forecast noting that "it is likely that removal of Opana ER will be a condition of Revopan approval by FDA"))).
110. In March 2012, Endo stopped distributing original Opana ER and launched reformulated Opana ER. (Second Set of Joint Stipulations, JX003 ¶ 33; CX4017 (Levin, Dep. 139)).
111. On June 8, 2017, the FDA publicly requested that Endo voluntarily withdraw its reformulated Opana ER product from the marketplace. On September 1, 2017, Endo ceased sales of reformulated Opana ER. (Second Set of Joint Stipulations, JX003 ¶¶ 55, 57).

⁸ An "at-risk launch" is further explained in F. 451-464.

C. The Challenged Agreement**1. Preliminary negotiations**

112. Impax and Endo first attempted to settle their patent dispute in the fall of 2009, before the claim construction hearing in the Endo-Impax patent litigation. (RX359; RX285; Second Set of Joint Stipulations, JX003 ¶¶ 16-17).
113. At the time of the settlement negotiations (fall 2009 until settlement on June 8, 2010), Larry Hsu was Impax's chief executive officer ("CEO"), Chris Mengler was president of Impax's generics division, Margaret Snowden was Impax's vice president of intellectual property litigation and licensing, and Arthur Koch was Impax's CFO. Mr. Mengler was Impax's lead settlement negotiator until he was replaced as the lead negotiator by Mr. Koch and Ms. Snowden on June 4, 2010. (Koch, Tr. 217-18, 227-30, 310-11, 322-23; Snowden, Tr. 362).
114. At the time of the settlement negotiations (fall 2009 until settlement on June 8, 2010), Guy Donatiello was Endo's senior vice president of intellectual property and Alan Levin was Endo's CFO. Mr. Donatiello and Mr. Levin were the principal negotiators for Endo. (Snowden, Tr. 362, 373-74).
115. Impax was aware during settlement discussions with Endo in the fall of 2009 that Endo already had agreed to a July 15, 2011 entry date for Actavis' generic oxymorphone ER dosages. (CX4003 (Snowden, IHT at 56-57); CX0309 at 001-02).
116. Settlement discussions between Endo and Impax in the fall of 2009 included potential generic entry dates. Specifically, Ms. Snowden proposed to Mr. Donatiello that Impax should be able to enter around July 2011 or possibly December 2011 or January 2012, to approximate the midpoint between the expiration of the 30-month stay in June 2010 (F. 63) and the expiration of the asserted

Initial Decision

patents in September 2013 (F. 53). Mr. Donatiello rejected Ms. Snowden's proposal, arguing that Impax's entry date should be around the midpoint between the conclusion of litigation through appeal and patent expiration. (CX4003 (Snowden, IHT at 56-57); Snowden, Tr. 418-20; Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-006 ¶ 10).

117. Settlement discussions between Endo and Impax in the fall of 2009 included discussions of a potential product collaboration. (See II.C.3).
118. Settlement discussions between Endo and Impax that had commenced in the fall of 2009 ended after a conference call on December 7, 2009. (CX1301 at 112).
119. Impax and Endo resumed settlement discussions in mid-May 2010, approximately one month before the June 14, 2010 expiration of the 30-month stay of Impax's ANDA imposed by the Hatch-Waxman Act and approximately three weeks before the scheduled June 3, 2010 trial in the Endo-Impax patent litigation. (Snowden, Tr. 418; CX0310 at 004; CX1301 at 112; F. 63, 73).
120. On or about May 14, 2010, Endo became aware that Impax had received tentative FDA approval for generic Opana ER, based on a press release issued by Impax. Endo had a discussion with its outside counsel the same day regarding the status of settlement discussions with Impax. (CX1307 at 001; CX1301 at 112).
121. In an internal Impax email between Dr. Hsu and Mr. Mengler on May 14, 2010, Dr. Hsu hypothesized a settlement with Endo with a January 2011 launch and a no-AG provision,⁹ to which Mr. Mengler replied that he would "love" a settlement. (CX0505 at 001).

⁹ A no-AG provision, also referred to as a no-AG agreement, is a provision through which a brand-name drug company agrees not to launch an authorized generic in competition with the generic drug company's product during the 180-day exclusivity period. (Koch, Tr. 235; Snowden, Tr. 392).

Initial Decision

122. On May 17, 2010, Mr. Donatiello of Endo contacted Ms. Snowden of Impax by voicemail and email to resume settlement discussions. That afternoon, Ms. Snowden and Mr. Donatiello discussed a potential settlement for the first time since December 2009. (CX0310 at 004; RX316 at 0001; CX4003 (Snowden, IHT at 83-84)).
123. The SLA and the DCA were negotiated together, with contract terms for both agreements discussed in the same documents exchanged between Endo and Impax. (Koch, Tr. 244; *see, e.g.*, CX0320; RX565; CX0406 at 001; CX0407 at 001-02; CX3183 at 001).

2. The Settlement and License Agreement**a. Overview of relevant provisions**

124. Under the SLA, Impax agreed not to launch its generic oxymorphone ER product until January 1, 2013. (RX364 at 0001-02, 0009 (executed SLA §§ 1.1, 4.1(a)) (granting license and defining the “Commencement Date”)).
125. Under the SLA, Endo granted Impax a license both to the initial Opana ER patents (defined in the SLA as the ’933, ’456, and ’250 patents and any reissuances thereof), and to “any patents and patent applications owned by Endo or Penwest . . . that cover or could potentially cover the manufacture, use, sale, offer for sale, importation, marketing or distribution of products . . . that are the subject of the Impax ANDA . . .” (RX364 at 0009 (SLA § 4.1(a)); Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-009-10 ¶ 35).
126. Under the SLA, Endo provided Impax with a “covenant not to sue,” which prohibited Endo and its affiliates from suing Impax for patent infringement on any of the patents licensed pursuant to section 4.1(a) (F. 125). (RX364 at 010 (SLA § 4.1(b)); *see also* Figg, Tr. 1963-64; Hoxie, Tr. 2885).

Initial Decision

127. Under the SLA, the license granted by Endo to Impax to sell generic Opana ER was exclusive during Impax's 180-day first-filer exclusivity period for the five dosage strengths for which Impax had filed an ANDA. This exclusive license grant meant that Endo could not sell an authorized generic product of these five dosages until Impax's 180-day exclusivity period ended. (RX364 at 0010-11 (SLA § 4.1(c)); CX3164 at 009-10).
128. Under the SLA, Impax would be obligated to pay Endo a 28.5% royalty on Impax's generic Opana ER sales during Impax's 180-day exclusivity period in the event that sales of Opana ER grew by a specific percentage prior to Impax's entry. Specifically, the royalty was owed if Opana ER sales in the quarter before Impax's licensed entry "exceed[ed] \$46,973,081 compounded quarterly at an annual rate of ten percent" Otherwise, Impax had no obligation to pay a royalty. (RX364 at 0012 (SLA § 4.3)).
129. Under the SLA, pursuant to a provision titled "Endo Credit," Endo would be obligated to make a cash payment to Impax in the event Endo's Opana ER dollar sales (as calculated by units multiplied by the wholesale acquisition cost ("WAC")) 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). (RX364 at 0003-06, 0012 (SLA §§ 1.1, 4.4, definitions of "Endo Credit," "Market Share Profit Factor," "Market Share Profit Value," "Pre-Impax Amount," "Prescription Sales," "Quarterly Peak," and "Trigger Threshold"))).
130. In January 2013, Impax launched generic oxymorphone ER in the 5, 10, 20, 30, and 40 mg dosage strengths per the terms of the SLA. (Second Set of Joint Stipulations, JX003 ¶ 40).

Initial Decision

b. Negotiations of the SLA**i. Initial term sheet**

131. On May 26, 2010, Mr. Donatiello of Endo sent to Mr. Mengler and Ms. Snowden of Impax two term sheets.¹⁰ Endo's initial term sheet for the SLA included a proposed license agreement with a no-AG provision. Specifically, the proposed license agreement provided that Impax would have 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 agreements executed as of the effective date of the License Agreement with Impax." (CX0320 at 009-10).
132. Endo's May 26, 2010 initial term sheet for the SLA included a proposed license agreement that granted Impax a license to sell generic Opana ER with a commencement date of March 10, 2013 and provided that Impax would not enter the market prior to that commencement date. (CX0320 at 009).
133. Delaying Impax's entry was valuable to Endo. Endo calculated that "[e]ach month that generics are delayed beyond June 2010 is worth ~\$20 million in net sales per month." Endo forecasted that if Impax launched its generic in July 2010, Endo would lose approximately \$100 million in branded Opana ER sales during the first six months Impax was on the market. Endo forecasted that it would lose 85% of its branded Opana ER sales within three months of generic entry. (CX1106 at 005; CX3445 at 001, 002; CX1320 at 007).
134. The proposed license agreement included with Endo's May 26, 2010 initial term sheet for the SLA was limited to the then-issued Opana ER patents (defined as the '933,

¹⁰ The May 26, 2010 term sheet relating to the DCA is discussed in F. 294.

Initial Decision

‘456 and ‘250 patents), and any issued continuations thereof. (CX0320 at 006-07, 009-10).

135. The proposed license agreement included with Endo’s May 26, 2010 initial term sheet for the SLA contained a provision requiring Impax to pay royalties to Endo at a rate of 35% on Impax’s gross sales of generic Opana ER during Impax’s 180-day exclusivity period, if Endo’s gross sales of Opana ER during the three full calendar months before Impax’s entry date exceeded a certain specified dollar amount. (CX0320 at 010).

ii. Impax’s counteroffer

136. Impax responded to Endo’s May 26, 2010 initial term sheets (F. 131) on May 27, 2010, with a counteroffer. (RX318).
137. Impax’s May 27, 2010 counteroffer to Endo, transmitted by Mr. Mengler to Mr. Levin of Endo, provided for a generic launch date of January 1, 2013, “with no authorized generic and certain acceleration triggers, including market degradation to any alternate product.” (RX318 at 0001; Koch, Tr. 237-38; Snowden, Tr. 432; Mengler, Tr. 532).
138. An acceleration provision or trigger 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)).
139. Impax wanted a market acceleration provision as “protection in case Endo had any intentions of moving the market to a next-generation product.” Impax had included similar provisions in other patent settlements with brand companies. (CX4032 (Snowden, Dep. at 104); CX4003 (Snowden, IHT at 121-22)).

Initial Decision

140. Although Impax did not have specific information about Endo's plans to reformulate Opana ER, Impax was concerned that Endo had "a secret plan to damage the market" with the introduction of a reformulated Opana ER product. (CX0217 at 001; see Snowden, Tr. 433-34; Mengler, Tr. 569-70; CX4017 (Levin, Dep. at 118)).
141. Impax had seen analyst reports suggesting that Endo was working on crush-resistant drugs generally. (CX2540 at 001; Mengler, Tr. 579-80).
142. In light of concern about opioid abuse, the FDA encouraged opioid manufacturers to "figure out a way to make them tamper-resistant [and] the primary manner in which companies were doing that was to make the tablet in such a manner that [it] couldn't be crushed." (Mengler, Tr. 569).
143. Impax was aware that Purdue Pharma, L.P., the manufacturer of OxyContin, had introduced a reformulated, crush-resistant version of its product and was withdrawing its original formulation. (Mengler, Tr. 569; CX4017 (Levin, Dep. at 118-19)).
144. Impax's May 27, 2010 counteroffer to Endo revised Endo's formula for calculating royalties to Endo in connection with the license to sell generic Opana ER by raising the amount of gross sales that would trigger a royalty payment, and revising the royalty calculation. (RX318 at 0001).
145. After receiving Impax's May 27, 2010 counteroffer, Mr. Levin of Endo responded by email that the parties were "[c]learly . . . too far apart" and suggested a conference call among Mr. Mengler and Ms. Snowden for Impax, and Mr. Levin and Mr. Donatiello for Endo. (CX1305 at 001).
146. Negotiators for Endo and Impax conferred by telephone on May 27, 2010, and over the weekend of May 28 and 29, 2010. (CX1301 at 113; CX310 at 005).

Initial Decision

iii. Rejection of acceleration trigger and development of the Endo Credit

147. Endo opposed the concept of accelerated entry and rejected Impax's request for a market acceleration trigger. Endo insisted to Impax "that they had no interest in" moving the market to a crush-resistant version of Opana ER and "they weren't planning to." (CX4032 (Snowden, Dep. at 104, 106-07); Snowden, Tr. 385; CX4014 (Hsu, IHT at 85-87)).
148. Endo's rejection of an acceleration trigger increased Impax's concern that Endo was going to switch the market to a crush-resistant version of Opana ER. (Mengler, Tr. 568).
149. Because the proposed settlement provided for "a period of time between the date of [FDA] approval and the . . . launch [in] January [2013]. [Impax was] worried about the control the brand had over their product during that time, and [Impax was] looking for a way to gain – take back some of that control away from the brand." (Koch, Tr. 240-41).
150. Mr. Mengler responded to Endo's insistence that Endo was not planning to move the market to a crush-resistant version of Opana ER that, "if you're telling me the truth and the product is really going to grow, well, you know, there will be something in it for you as well [and] if you're not telling me the truth, you're going to pay me what I would have made anyway." (CX4010 (Mengler, IHT at 35-36); *see also* CX4026 (Nguyen, Dep. at 164-66) (the "gist" of the Endo Credit was "Mr. Mengler basically telling Endo to put its money where its mouth was"))).
151. At an in-person meeting among negotiators for Endo and Impax held on June 1, 2010, Endo proposed to Impax 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%." (RX387 at 0001

Initial Decision

(June 1, 2010 Mengler internal email recapping the “current proposal”); *see also* CX0310 at 005).

152. On June 1, 2010, Mr. Mengler of Impax, in an internal email to Dr. Hsu, Ms. Snowden and others, described the current proposal as including a generic launch date of February 1, 2013, with acceleration triggers. In addition, “[i]f the product grows beyond certain levels, we pay them [a percentage of profits] during the six month exclusivity . . . [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%.” Mr. Mengler stated his opinion that he “still like[s] January” for the agreed generic launch date and that “[t]he make-good trigger is too low. A similar arrangement with, say a 75% number might be quite attractive.” (RX387).
153. Once Endo refused to agree to an acceleration trigger, and agreed instead to the concept of a make-whole payment, Impax stopped pursuing an acceleration trigger. (CX4018 (Koch Dep. at 71); Snowden, Tr. 385).
154. On the afternoon of June 3, 2010, negotiators for Endo and Impax reached an agreement in principle for settling the litigation. That same day, in an internal email from Mr. Mengler of Impax to Dr. Hsu, Ms. Snowden, Mr. Koch, and others, Mr. Mengler described the key provisions for the SLA. Generic launch would be January 1, 2013. The royalty provisions were further adjusted and “[i]f the units decline by more than 50% from peak at launch, make whole provisions kick in that protect the downside.” (CX0407 at 001-02; CX3334 at 001 (Mr. Levin reporting that Endo had “reached a handshake agreement with Impax); CX4012 (Donatiello, IHT at 139) (“Endo and Impax reached an agreement in princip[le] 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”).
155. On June 4, 2010, Mr. Mengler was replaced as Impax’s lead negotiator by Mr. Koch and Ms. Snowden. After an

Initial Decision

internal Impax management discussion that day, at the instruction of Impax management, Mr. Koch and Ms. Snowden had a conference call with Endo in which they proposed dropping the existing terms for the SLA and DCA, and entering into a “simple settlement” with the same July 15, 2011 entry date that Endo provided to Actavis in their settlement. (CX4032 (Snowden, Dep. at 97-99); Snowden, Tr. 372-74; CX507 at 001).

156. In response to Impax’s June 4, 2010 proposal for a simple settlement with a July 15, 2011 entry date (F. 155), Mr. Levin of Endo expressed anger that the terms of the deal he had negotiated with Mr. Mengler were not being honored, refused Impax’s request, and insisted on reverting back to the deal he had negotiated with Mr. Mengler. (CX4032 (Snowden, Dep. at 99-102); Snowden, Tr. 374-75).

iv. Finalizing the SLA**(a) No-AG provision and Endo Credit**

157. Between June 4 and June 7, 2010, Endo and Impax exchanged numerous drafts, and redlined revisions thereto, of the SLA. (See, e.g., CX0323 (June 4, 2010 Endo first draft); CX0324 (June 5, 2010 Impax revisions); CX2771 (June 6, 2010 Endo revisions); CX1813 (June 7, 2010 Endo revisions); CX2767 (June 7, 2010 Impax revisions); RX336 (June 7 Impax revisions); RX322 (June 7 Endo revisions); RX364 (SLA)).
158. Each draft of the SLA exchanged by Endo and Impax, as well as the final executed SLA, provided for an entry date of January 1, 2013. (See, e.g., CX0323 § 1.1 (definition of “Commencement Date”), § 4.1(a); CX0324 (same); CX2771 (same); CX1813 (same); CX2767 (same); RX336 (same); RX364 (SLA)).
159. Endo’s initial term sheet to Impax, provided on May 26, 2010, as well as each settlement draft exchanged by Endo and Impax, contained a no-AG provision. (See, e.g., F.

Initial Decision

131; CX0323 § 4.1(c); CX0324; CX2771; CX1813; CX2767; RX336; RX364 (SLA)).

160. Endo drafted the first iteration of the make-whole provision, which was included in the first draft of the SLA Endo sent to Impax on Friday June 4, 2010 as section 4.4 of the SLA. Under Endo's 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. The amount Endo would ultimately be obligated to pay depended on Impax's sales during its 180-day exclusivity period. Generally, the lower Impax's net profits during the exclusivity period, the lower the amount Endo was obligated to pay. (CX0323 at 001, 005-07, 012 (June 4, 2010 draft SLA § 1.1 (definitions of "Impax's Net Profit," "Impax Product," "Exclusivity Period," "Pre-Impax Amount," "Three Month Shipment Amount," and "Trigger Threshold"), § 4.4).
161. Roberto Cuca, Endo's vice president of financial planning and analysis, was tasked with developing a provision that became known as "the Endo Credit" (F. 95-96). Mr. Cuca's "goal was to make the provision be as beneficial to Endo as possible." Mr. Cuca looked for ways to "improve the economic effect of this provision to Endo." (CX4035 (Cuca, Dep. at 68-69, 96-97); Cuca, Tr. 612, 614-15).
162. On Saturday, June 5, 2010, counsel for Impax sent a revised draft of the SLA to Endo. Impax renamed Endo's section 4.4 the "Endo Credit" and proposed two changes to Endo's proposal. 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 than API. 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 exclusivity period, but rather on the revenues Impax would have expected to make

Initial Decision

during the exclusivity period had Endo not switched the market. 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 001, 045 (June 5, 2010 draft SLA § 4.4, definitions of “Endo Credit,” “Market Share Factor,” “Market Share Value,” “Pre-Impax Amount,” “Trigger Threshold,” and “Quarterly Peak.”)).

163. On Sunday, June 6, 2010, Endo responded to Impax’s proposal for the Endo Credit with two additional changes. 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 cost (WAC), instead of unit sales. Second, Endo wanted the amount to reflect Impax’s expected profits during the exclusivity period, rather than Impax’s expected revenues, which would effectively reduce any amount to be paid to Impax under the Endo Credit. (CX2771 at 001, 005-07, 014 (June 6, 2010 draft SLA § 1.1 (definitions of “Endo Credit,” “Market Share Profit Factor,” “Market Share Profit Value,” “Pre-Impax Amount,” “Prescription Sales,” and “Quarterly Peak”), § 4.4; Cuca, Tr. 639). *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.”)).
164. Endo believed that incorporating Impax’s net profit margin into the Endo Credit was consistent with the objective of “trying to make [Impax] 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).
165. Impax agreed to the two changes to the Endo Credit proposed by Endo in Endo’s June 6, 2010 revised draft to Impax. (CX2767 at 004, 006-07, 013 (June 7, 2010 Impax draft SLA § 4.4, definitions of “Endo Credit,” “Market

Initial Decision

Share Profit Factor,” “Market Share Profit Value,” “Pre-Impax Amount,” “Prescription Sales,” and “Quarterly Peak”); RX364 at 0003-06, 0012 (SLA § 1.1 (definitions of “Endo Credit,” “Market Share Profit Factor,” “Market Share Profit Value,” “Pre-Impax Amount,” “Prescription Sales,” and “Quarterly Peak”), § 4.4).

(b) Scope of patent license

166. Both Endo’s May 26, 2010 initial term sheet for the SLA and Endo’s June 4, 2010 first draft of the SLA limited Impax’s license to the three patents then listed in the Orange Book for Opana ER (the ’933, ’456, and ’250 patents). (CX0320 at 006-07, 009-10 (May 26, 2010 Endo term sheets); CX0323 at 006, 010 (June 4, 2010 draft SLA §§ 1.1, 4.1(a))).
167. At the time the negotiations were being conducted, Impax was aware that Endo had additional pending patent applications relating to Opana ER and recognized that Endo could acquire still other patents. (RX398 at 001; RX568; Mengler, Tr. 571-72; Snowden, Tr. 440, 442-43; *see also* Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-010 ¶ 36).
168. Given the possible effects of Endo’s additional patent applications relating to Opana ER, a reasonable litigant would have been concerned with Endo’s future patents. (Figg, Tr. 1938).
169. On June 5, 2010, Impax proposed broadening the patent license in the SLA to “any patents and patent applications owned by or licensed to Endo . . . that cover or could potentially cover” Impax’s generic oxymorphone ER product. (CX0324 at 030 (June 5, 2010 Impax revised draft of 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)).

Initial Decision

170. Endo accepted Impax's language, referenced in F. 169. (CX2771 (June 6 Endo revisions); CX1813 (June 7 Endo revisions); CX2767 (June 7 Impax revisions); RX336 (June 7 Impax revisions); RX322 (June 7 Endo revisions)).

c. Value transferred to Impax under the SLA

i. No-AG provision

171. First-filer exclusivity (F. 21) is very valuable to a generic drug manufacturer. First-filer exclusivity gives the first filer 180 days, or "six months of runway," before any potential entry by another generic and helps the generic company make more money. (Koch, Tr. 232-33).
172. A first-filer generic manufacturer makes a substantial portion of its profits during the 180-day exclusivity period. 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).
173. Impax was the first company to file an ANDA with Paragraph IV certifications for the 5, 10, 20, 30, and 40 mg dosages of oxymorphone ER, which comprised all of the dosages of Opana ER except the 7.5 and 15 mg dosages. The five doses as to which Impax was the first to file constitute the five most popular dosages of Opana ER, comprising 95% of Endo's Opana ER sales. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-007 ¶ 13; Mengler, Tr. 525; Koch, Tr. 231-32; Snowden, Tr. 354, 414).
174. As the first filer on the 5, 10, 20, 30 and 40 mg dosages of oxymorphone ER, Impax was entitled to 180 days of generic exclusivity. During that 180 days, no other ANDA filer could market a 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. (Joint Stipulations of Jurisdiction,

Initial Decision

Law, Fact, and Authenticity, JX001-007 ¶ 14; Second Set of Joint Stipulations, JX003 ¶ 7; Snowden, Tr. 414; *see also* Mengler, Tr. 522-23).

175. 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. An authorized generic is generally launched by the brand company or another company licensed by the brand company. Launching an authorized generic helps a company partially recoup sales of the branded product that are lost to generic competition. (Mengler, Tr. 523; Koch, Tr. 233; Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-005 ¶¶ 28-31; Reasons, Tr. 1211-12).
176. The 180-day exclusivity period does not prevent the brand company from launching an authorized generic. The brand company, 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* Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-005 ¶ 28; Second Set of Joint Stipulations, JX003 ¶ 7).
177. Having an authorized generic competitor during the 180-day exclusivity period generally results in a decrease in the first filer’s prices of approximately 30 to 35%. The first filer’s share of the generic market will also be reduced as the first generic manufacturer will have to split the sales with the authorized generic manufacturer. (Reasons, Tr. 1213-14; Mengler Tr. 524).
178. Endo, as the holder of the approved NDA for Opana ER, could market its own authorized generic version of Opana ER during Impax’s exclusivity period. (Second Set of Joint Stipulations, JX003 ¶ 7).
179. Impax was aware that an authorized generic would adversely impact Impax’s market share and profits. (CX0514 at 004 (5/16/2010 email from Chris Mengler

Initial Decision

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 (2/11/2010 email from Ted Smolenski attaching 5-year forecast 2010 showing same)).

180. If there were no authorized generic, then Impax would be the only generic product on the market during its 180-day exclusivity period and could charge a higher price for generic Opana ER compared to a marketplace that had two companies selling generic products. (Reasons, Tr. 1215; Snowden, Tr. 392).
181. Impax executives estimated that if Endo launched an authorized generic when Impax entered the market, Endo's authorized generic would capture as much as half of sales of generic Opana ER 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 (Smolenski, IHT at 80-81); CX0202 at 001).
182. Impax would generally seek a no-AG provision as an element of negotiating a settlement agreement with a brand manufacturer. 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).
183. Mr. Mengler, Impax's primary negotiator with Endo, believed that getting a no-AG provision would be beneficial to Impax. Along with obtaining the earliest possible entry date, a no-AG agreement is among the more important things that Impax would seek in a negotiation in order to get the best possible deal for Impax. (Mengler, Tr. 526).
184. A six-month no-AG provision was one of the terms included as part of the Endo-Impax settlement throughout the settlement negotiations. (F. 159).

Initial Decision

185. The no-AG provision in the SLA prohibited Endo from selling an authorized generic product for any of the five specified dosages as to which Impax was first to file until after Impax's 180-day exclusivity period ended. (F. 127; RX364 at 0010-11 (SLA § 4.1(c)).
186. At time of the execution of the SLA, Impax did not know whether, absent the settlement, Endo would launch an authorized generic. (CX3164 at 019-20).
187. The no-AG provision in the SLA guaranteed to Impax that Impax, as the first to file on generic Opana ER, would be the only seller of generic Opana ER during 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)).
188. The no-AG provision in the SLA 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 the 180-day exclusivity period and would earn greater profits by not having to share generic sales with an Endo authorized generic. (CX5000 (Noll Expert Report at 153-55 ¶¶ 346-48); Noll, Tr. 1452-54).
189. In 2010, Impax forecasted the effect of an authorized generic by Endo on Impax's expected generic sales. In what Impax referred to as the "upside" scenario, Impax assumed that Endo's authorized generic Opana ER would enter about two months after Impax's launch of generic Opana ER. Under the upside scenario, Impax's share of generic sales was estimated to fall to 60% and Impax's average price was estimated to fall by 36% (from 55% of brand WAC to 35%). Under what Impax referred to as its "base" scenario, Impax assumed that Endo's authorized generic Opana ER would enter simultaneously with Impax, would capture half of the market, and would cause prices to fall by the same 36%. (CX4037 (Smolenski, Dep. at 147-50, 166); CX0004 at 005-19; CX0222 at 004-

Initial Decision

11; CX2825 at 008-17; CX2830 at 004-09; CX2831 at 003-08; CX2853 at 007-15).

190. Complaint Counsel's economic expert, Professor Roger Noll, applying Impax's forecasts in 2010 (F. 189), calculated that under Impax's upside scenario, entry by an authorized generic during Impax's 180-day exclusivity period would cause Impax's revenues to fall by 61.6%, or approximately \$23 million. Under Impax's "base" assumptions (F. 189), entry by an authorized generic during Impax's 180-day exclusivity period would cause Impax's revenues to fall by 68%, or approximately \$33 million. (CX5000 (Noll Expert Report at 155 ¶ 350)).
191. In May 2010, Todd Engle, of Impax's sales and marketing team, prepared an analysis for Dr. Hsu and Mr. Mengler of the effect of an authorized generic on Impax's profits during Impax's 180-day exclusivity period, which projected lost profits in the amount of \$24.5 million if an AG entered within two to four weeks after Impax's launch of generic oxymorphone ER. (CX2753 at 004 (six month lost profits model for oxymorphone ER, predicting profits of \$53 million with no AG, and \$28.5 million with AG)).
192. On June 1, 2010, Endo approximated the revenues it would gain from launching an authorized generic of Opana ER, if Impax launched at risk and Endo launched its authorized generic on July 1, 2010, to be \$25 million. (CX1314).
193. The no-AG provision in the SLA was worth between \$23 and \$33 million in projected sales revenue to Impax at the time Impax entered into the SLA. F. 189-191.
194. The no-AG provision 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, pursuant to the SLA. If Endo's sales of original Opana ER reached a sufficiently high level prior to Impax's generic entry, Impax would be obligated to pay a royalty to Endo in the amount of 28.5% of Impax's net sales of generic Opana

Initial Decision

ER. 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. 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. (RX364 at 0012 (SLA § 4.3); CX5001 (Bazerman Expert Report at 026 ¶ 51); CX5000 (Noll Expert Report at 155-56 ¶¶ 350-51); Mengler, Tr. 533).

ii. Endo Credit

195. Under section 4.4 of the SLA, titled "Endo Credit," Endo agreed to pay Impax an amount, determined by a mathematical formula, in the event that prescription sales of Opana ER declined by more than 50% from the quarterly peak sales during the time period from July 2010 to September 2012. (RX364 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).
196. The formula for calculating the Endo Credit incorporates a number of factors that relate to Impax's sales of generic Opana ER multiplied by the market opportunity for the 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. (RX364 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"

Initial Decision

definition), 0006 (“Trigger Threshold” definition), 0012 (“Endo Credit” provision)).

(a) Purpose of the Endo Credit

197. The Endo Credit was designed to “back-up” the value of the no-AG provision and provide value to Impax regardless of whether Endo launched a reformulated version of Opana ER. (F. 198-215).
198. When brand companies introduce a reformulated drug, they often cease marketing and selling the original product. They can also withdraw the original product’s reference-listed drug designation, preventing generic products from having AB-rated status. (CX4003 (Snowden, IHT at 30-31); CX4014 (Hsu, IHT at 152)).
199. By introducing a reformulated drug, the brand company can greatly reduce the opportunity for generic versions of the original drug since those generic products are no longer bioequivalent to – and not subject to automatic substitution in place of – the reformulated product. (Snowden, Tr. 434; CX4030 (Hsu, Dep. at 108); Koch, Tr. 238 (reformulation can “switch patients away from the brand product” as to which Impax has the generic “in favor of a line extension” not covered by the ANDA)).
200. Impax’s generic Opana ER would not be AB-rated to a reformulated Opana ER product. (Mengler, Tr. 528).
201. Protecting the market for Impax’s entry date was a priority for Impax. (Snowden, Tr. 490).
202. Because “the generic would rely on the . . . automatic substitution in the pharmacy,” not having a reference brand product means that pharmacists “can’t substitute” the generic for the branded drug. (CX4014 (Hsu, IHT at 152)).
203. For a generic drug to be sold where there is no branded drug for which it is automatically substituted, doctors must

Initial Decision

actually write out a prescription for the generic product. (CX4014 (Hsu, IHT at 152); CX4004 (Engle, IHT at 221)).

204. If Endo were to move to a reformulated Opana ER, then Impax's market opportunity for its generic product would be significantly reduced or even zero, because Opana ER in its original form disappears or becomes insignificant. (Snowden, Tr. 434; Mengler, Tr. 527).
205. Mr. Mengler was concerned that reformulation was an effort by Endo to "subvert the value of the deal" he was trying to put together to get Impax's product on the market. (Mengler, Tr. 526-27).
206. If Endo did destroy the market for Impax's generic Opana ER, Mr. Mengler wanted Impax "to be made whole for the profits that [Impax] would have otherwise achieved." (Mengler, Tr. 533).
207. 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.")).
208. 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. According to Mr. Mengler, "something that didn't protect us from the downside was . . . a deal-breaker." (Mengler, Tr. 535-36; CX4010 (Mengler, IHT at 44)).
209. 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, because the total market potential for generic Opana ER would be decreasing. The Endo Credit payment was designed to

Initial Decision

“correct for the loss in the value of the market that had occurred before the generic entry date.” (Reasons, Tr. 1218; CX4035 (Cuca, Dep. at 69-70)).

210. 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, the Endo Credit provision was designed to provide Impax with a payment. (Reasons, Tr. 1218-19; CX4020 (Reasons, Dep. at 55-56)).
211. The Endo Credit was designed as insurance against the risk of Endo reformulating Opana ER. If the market for Opana ER did not decline, the value of the no-AG provision would be higher, but if Endo effected a “switchout” to reformulated Opana ER, then the Endo Credit provision was designed to provide Impax with a payment. (Koch, Tr. 265-66; Reasons, Tr. 1218-19; CX4020 (Reasons, Dep. at 55-56)).
212. If Endo’s obligation to pay the Endo Credit were triggered, based on declining sales of Opana ER prior to Impax’s generic entry, the calculations of the Endo Credit were designed to approximate the net profits Impax would have expected to make during its six-month exclusivity period, with no AG. 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). (RX364 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%. (RX364 at 0004 (SLA § 4.4, definitions of “Market Share Profit Value”); Cuca, Tr. 640-41).
213. The Endo Credit provision “was intended to insulate” Impax from the risk of substantial decrease in Opana ER sales prior to the agreed generic entry date. The goal was,

Initial Decision

“if the market changed substantially before the date that the parties agreed that Impax could launch, there would be a way of making Impax whole” by providing Impax with the profits that Impax otherwise would have achieved during its 180-day exclusivity period, had a change in the marketplace not occurred. (Cuca, Tr. 617; CX4035 (Cuca, Dep. at 81-82); Mengler, Tr. 533).

214. The Endo Credit provision was designed to provide an approximation of the profits that Impax would have earned from sales of generic Opana ER during Impax’s six-month exclusivity period, based on pricing, share and other assumptions. (CX4010 (Mengler, IHT at 36-37); 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.”)).
215. During a November 2011 earnings call, Impax’s CFO, Mr. Koch, who also helped negotiate the SLA, discounted the impact of Endo switching Opana ER to a new formulation because of the terms of the Endo-Impax Settlement, stating: “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).

**(b) Dollar value of the Endo Credit at the
time of settlement**

216. The dollar value of the Endo Credit was uncertain at the time of settlement. The dollar value was contingent on unknown future events that were outside of Impax’s control, such as the figure for quarterly peak sales for Opana ER prior to generic entry, which was the biggest “input” in the Endo Credit formula. (Cuca, Tr. 629; Snowden, Tr. 437-38).
217. The formula that determined any Endo Credit payment required (1) determining Endo’s quarterly peak sales

Initial Decision

between July 2010 and September 2012; (2) determining the “Pre-Impax amount” of Opana ER sales, meaning the sales of Opana ER in the fourth quarter of 2012, immediately prior to Impax’s January 2013 generic entry; (3) comparing the quarterly peak number to the pre-Impax amount, and determining if the pre-Impax amount is less than 50%, which triggered a payment obligation; and (4) multiplying the difference between the quarterly peak number and the pre-Impax number by a specified amount to calculate the final sum due. Each of these formula inputs was unknown at the time of settlement. (Snowden, Tr. 437-38; *see* RX364 at 006; Engle, Tr. 1749-50).

218. Impax did not forecast a payment under the Endo Credit in Impax’s business forecasts. (Mengler, Tr. 582; CX4038 (Engle, Dep. at 187-88)).
219. Financial projections by Endo and Impax at the time of the settlement anticipated continued growth in Opana ER sales. (CX0222 at 003-11 (Impax forecasts for Opana ER); CX2530 at 007-08 (Endo forecasts for Opana ER)).
220. Prior to the settlement, Mr. Cuca ran some calculations for the Endo Credit formula to “make sure that it was producing outputs that [he] thought it was supposed to be producing.” Using the Excel program, Mr. Cuca spent approximately five minutes entering potential “peak sales” figures into the Endo Credit formula to make sure it produced a sensible result. These calculations produced a range of payouts, including a possible zero payment. For the “peak sales” input, Mr. Cuca relied on Endo sales forecasts. (Cuca, Tr. 628-31; CX4035 (Cuca, Dep. 79-84)).
221. Prior to the settlement, Impax’s director of market planning, Ted Smolenski, told Mr. Mengler that there were certain circumstances under which the Endo Credit would not result in a payment to Impax, including a situation in which Endo would withdraw its NDA for original Opana ER and time the elimination of sales in such a way that the Endo Credit would result in zero

Initial Decision

payment. Mr. Mengler decided not to pursue the issue further because he did not deem the potential to be likely enough to be “worth the energy” to try to “correct for it in the agreement.” (Mengler, Tr. 589-90; CX4037 (Smolenski, Dep. at 253); *see also* CX0219 at 001 (Smolenski email to Hsu describing “downside scenario as probably unlikely” and stating that Mengler viewed the “potential downside scenario” as “so unlikely it wasn’t worth worrying about”)).

- 222. The amount of any payment under the Endo Credit could not be estimated before learning the quarterly peak sales of Opana ER between July 2010 and September 2012. (Cuca, Tr. 668-69).
- 223. Endo first reported a liability under the Endo Credit in May 2012. (RX494 at 0007 (Endo SEC Form 8-K from May 1, 2012); CX4017 (Levin, Dep. at 140-41)).
- 224. In or about May 2012, Endo took a pre-tax charge in the amount of \$110 million “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.” (RX117 at 0021 (Endo SEC Form 10-Q for 1Q12 showing \$110 million “[a]ccrual for payment to Impax related to sales of Opana ER”)).

(c) 2013 payment under the Endo Credit

- 225. Endo filed a supplemental New Drug Application (No. 201655) for a reformulated version of Opana ER (“reformulated Opana ER”) in July 2010. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-011 ¶ 48; CX3189).
- 226. The FDA approved Endo’s supplemental NDA for a reformulated version of Opana ER in December 2011. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-011 ¶ 48).

Initial Decision

227. At the end of 2011, after discovering manufacturing deficiencies, the FDA shut down the plant where Novartis Consumer Health, Inc. (“Novartis”), another pharmaceutical company, manufactured original Opana ER for Endo. The shutdown of the Novartis plant caused a supply disruption for original Opana ER and required Endo to scale up its manufacturing of reformulated Opana ER. (CX4017 (Levin, Dep. at 136-39)).
228. The Novartis plant shutdown at the end of 2011 created a “supply chain crisis” for original Opana ER. (CX4017 (Levin, Dep. at 136-39); *see* RX094 at 0003-04; RX563 at 0001; RX139 at 0001).
229. In or about February 2012, the FDA ordered Endo to cease selling original Opana ER in order to avoid consumer confusion. Specifically, the FDA informed Endo that “once any tablets of CRF [crush-resistant formulation] were sold, [Endo] could no longer sell any tablets of the old formulation.” (CX4017 (Levin, Dep. at 138-39, 155); RX100 at 0001; RX094 at 0004).
230. In March 2012, Endo stopped distributing original Opana ER and launched reformulated Opana ER. (Second Set of Joint Stipulations, JX003 ¶ 33; CX4017 (Levin, Dep. 139)).
231. It was not until after the Novartis supply disruption in late 2011, the FDA’s order to stop selling original Opana ER in February 2012, and the launching of reformulated Opana ER in March 2012, that Endo first concluded that it would have to make a payment under the Endo Credit provision. The first time Endo knew that its sales of Opana ER would be zero was in the last quarter of 2012, after the supply interruption caused by the Novartis plant shutdown. (Cuca, Tr. 665, 671, 677; Reasons, Tr. 1203, 1229; RX039; RX094 at 0003-06).
232. On May 31, 2012, Endo requested that the FDA move original Opana ER to the Orange Book Discontinued List. (Second Set of Joint Stipulations, JX003 ¶ 34).

Initial Decision

233. In August 2012, Endo filed multiple citizen petitions with the FDA, in which Endo argued that the FDA should (1) determine that original Opana ER was discontinued for safety reasons and could no longer serve as a reference-listed drug for any ANDA; (2) refuse to approve any ANDA pending for original Opana ER; and (3) withdraw any already-granted approvals for original Opana ER ANDAs. (Snowden, Tr. 476-77, 479-80; CX3203 (Endo's citizen petitions); Second Set of Joint Stipulations, JX003 ¶ 34).
234. Impax formally responded to the petition and offered scientific evidence that the discontinuation of Endo's original Opana ER was unrelated to safety or effectiveness. (Snowden, Tr. 480).
235. The FDA concluded that Endo did not withdraw original Opana ER for safety or efficacy reasons. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-012 ¶ 51).
236. On January 18, 2013, Ms. Snowden, Impax's vice president for intellectual property litigation and licensing, provided Endo with written documentation supporting payment under the Endo Credit provision in the amount of \$102,049,199.64. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-011 ¶ 45; Snowden, Tr. 386-89; CX0332 at 007-08).
237. 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. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-011 ¶ 46; Reasons, Tr. 1204; CX0333; CX1301 at 007).

iii. Complaint Counsel's expert's valuations

238. Complaint Counsel's economic expert, Professor Noll devised four examples of what the potential value of the no-AG and Endo Credit could be to Impax based on assumptions as to future events. Professor Noll did not

Initial Decision

attach any probabilities to the assumed events occurring. (Noll, Tr. 1613, 1650-51; CX5000 (Noll Expert Report at 240 Appendix F)).

- 239. Professor Noll's purported calculations of the value of the Endo Credit (F. 238) were based on discounting the amount of the actual payment under the Endo Credit in 2013. (CX5000 (Noll Expert Report at 169)).
- 240. Professor Noll did not calculate the expected value of the Endo Credit at the time of settlement. (Noll, Tr. 1591, 1613, 1651-52; Addanki, Tr. 2384).
- 241. Professor Noll acknowledged that he had not seen any documents predating June 2010 in which either Impax or Endo estimated the value for the Endo Credit. (Noll, Tr. 1611).
- 242. Professor Noll acknowledged that whether the Endo Credit would be paid, or the amount that would be paid, depended on contingent events and that there was a possibility that Impax would not receive any payment under the Endo Credit. (Noll, Tr. 1611-12).
- 243. Although Professor Noll acknowledged that it is important to take agreements as a whole, Professor Noll did not consider the value of the patent license rights Impax received under the SLA. (Noll, Tr. 1648).

3. The Development and Co-Promotion Agreement

a. Overview of relevant provisions

- 244. On June 7, 2010, Endo and Impax executed a Development and Co-Promotion Agreement ("DCA") with respect to a Parkinson's disease treatment known internally at Impax as IPX-203. (Snowden, Tr. 397-99; Nestor, Tr. 2935; RX365 (executed DCA)).

Initial Decision

245. The DCA was executed simultaneously with the SLA and is incorporated into the SLA. (RX312; CX0326; Second Set of Joint Stipulations, JX003 ¶ 69).
246. Under the DCA, Impax and Endo agreed to collaborate with respect to the development and marketing of a potential treatment for Parkinson's disease using an extended release, orally administered product containing a combination of levodopa and carbidopa. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-010 ¶ 37).
247. Endo agreed to pay Impax an "Upfront Payment" of \$10 million within five days of the agreement's effective date. The \$10 million payment was guaranteed and non-refundable. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-010 ¶ 39; Snowden, Tr. 399-400).
248. The DCA contained the possibility that Endo would make up to \$30 million in additional "Milestone Payments" for achieving specified milestone events in the development and commercialization of the product. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-010 ¶ 40; Snowden, Tr. 408).
249. Under the DCA, Impax and Endo agreed to share promotional responsibilities, with Impax promoting IPX-203 to its network of neurologists, and Endo promoting IPX-203 to its network of non-neurologists, including primary care physicians who prescribe Parkinson's disease medications. (RX365).
250. If the target product, IPX-203, was successfully commercialized, Endo would be entitled to a share of the profits. Specifically, Endo would receive a co-promotion fee equal to 100% of gross margins on sales resulting from prescriptions by non-neurologists. (RX365 ¶ 3.4).
251. On June 24, 2010, Endo wired a payment of \$10 million to Impax in accordance with section 3.1 of the DCA. (Joint

Initial Decision

Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-011 ¶ 44).

- 252. Upon receipt of Endo's \$10 million payment, Impax deferred the accounting of the money, attributing it as an investment related to research and development work that would be accomplished in the future. (Reasons, Tr. 1242-43).
- 253. Impax and Endo terminated the DCA by mutual agreement effective December 23, 2015. At the time of termination, the development had not met any of the milestones that would have required additional payment from Endo and Endo made no additional payments to Impax. (Joint Stipulations of Jurisdiction, Law, and Fact, and Authenticity, JX001-011 ¶ 43; Snowden, Tr. 461).

b. Background to the DCA

i. Endo's reliance on collaboration agreements

- 254. Endo generally does not research or discover new drug molecules on its own. Instead, it acquires and licenses drugs from other pharmaceutical companies. This means that Endo enters many collaboration agreements with other pharmaceutical companies. (Cobuzzi, Tr. 2513-15).
- 255. Endo's collaboration agreements with other pharmaceutical companies can relate to drugs at every stage of the development lifecycle, including early-stage development agreements. Because Endo had "no discovery pipeline . . . in place," Endo would enter "very early, very speculative agreements." (Cobuzzi, Tr. 2516).
- 256. In connection with a collaboration agreement, Endo identifies therapeutic areas of interest and companies that own promising drug molecules in those areas and enters into early-stage development deals. Endo also regularly licenses technology from and collaborates with other companies for more developed products. For Opana ER, Endo licensed the necessary technology to make both

Initial Decision

original and reformulated Opana ER. (Cobuzzi, Tr. 2516-17).

ii. Endo's interests in neurology products and Parkinson's disease treatments

257. In 2005, the areas of significant interest to Endo were pain, neurology, areas of movement disorders, including Parkinson's disease, and gastroenterology. (Cobuzzi, Tr. 2518).
258. By 2010, although Endo's focus had shifted away from pain and neurology to urology, endocrinology, and oncology, Endo's sales force still had a focus on pain and neurology and Endo was interested in products that were compatible with Endo's existing products and sales efforts. (Cobuzzi, Tr. 2518-19).
259. In 2010, Endo was selling Frova, which Endo marketed to neurologists and primary care physicians who treat migraine sufferers. (Cobuzzi, Tr. 2519-21).
260. For a number of years, Endo sold an immediate-release Parkinson's disease drug known as Sinemet, which was the original formulation of carbidopa and levodopa. (Cobuzzi, Tr. 2524; Nestor, Tr. 2938; CX1007 at 001).
261. In the 2010 timeframe, Endo evaluated collaborations with other companies related to treatments for Parkinson's disease. This included exploring potential Parkinson's disease collaboration opportunities with an Italian company called Newron, which had multiple Parkinson's disease products, and conducting due diligence on a Parkinson's disease product with a novel mechanism of action that was owned by a Finnish company. (Cobuzzi, Tr. 2520-22).

Initial Decision

iii. Impax's efforts to develop Parkinson's disease treatments

262. Impax, formed in 1995, is a manufacturer of generic pharmaceutical drugs. Impax created a separate brand division to manufacture and sell its own branded drugs in 2006. (Koch, Tr. 219-20; Nestor, Tr. 2926, 2929; CX4014 (Hsu Dep. at 9)).
263. When Impax's brand division was founded in 2006, it focused its efforts on central nervous system and neurology products, with a specific focus on improved treatments for Parkinson's disease. As part of this focus, Impax's brand division also concentrated on developing a network of relationships with neurology physicians. (Nestor, Tr. 2929-31).
264. Impax promoted other companies' products to the neurology community, including Carbitol, an epilepsy product, and licensed Zoming, a migraine drug created by AstraZeneca. Impax did so because it "wanted to begin the process of developing those relationships with the neurology physicians." (Nestor, Tr. 2931-32).
265. The "gold standard" treatment for Parkinson's disease is a combination of carbidopa and levodopa molecules. (Nestor, Tr. 2929).
266. The majority of carbidopa-levodopa medications are available only in immediate-release formulations. (Nestor, Tr. 2929).
267. Immediate release carbidopa-levodopa requires frequent dosing and often results in patients losing control of their motor skills as they experience rapid increases and decreases in the concentration of medicine in their bodies, especially as the disease progresses. (Nestor, Tr. 2929-30, 2939).
268. Impax's first attempt to develop an extended-release carbidopa-levodopa treatment for Parkinson's disease was

Initial Decision

known as Vadova. That product was intended to combine carbidopa-levodopa with controlled-release technology to give a much smoother effect to the amount of medication in Parkinson's patients' blood, providing for more control over motor symptoms. Vadova was never fully developed or marketed. (Nestor, Tr. 2926-27, 2929-30).

269. Impax's second attempt to develop an extended-release Parkinson's disease medication was IPX-066. (Nestor, Tr. 2930-31).
270. IPX-066 was a combination of carbidopa and levodopa that had been formulated to extend the release profile of Parkinson's disease drugs. (Cobuzzi, Tr. 2524; see Reasons, Tr. 1236).
271. As with Vadova, IPX-066 was intended to better treat Parkinson's patients by allowing for less frequent and more consistent dosing of up to six hours, as well as more consistent motor symptom control. (Nestor, Tr. 2930-31; see RX247).
272. By significantly extending the absorption of the drug, IPX-066 would provide "significant improvement of the patient's quality of life." (CX4014 (Hsu, IHT at 38-39)).
273. IPX-066 had reached Phase III clinical trials¹¹ in 2010 and was marketed under the name Rytary in 2015. (Snowden, Tr. 401; Nestor, Tr. 2930-31).
274. By 2010, Impax had begun efforts to develop a "next generation" of IPX-066. The goal of the next-generation product, which was first designated as IPX-066a and later became known as IPX-203, was to further improve treatment to Parkinson's patients by extending dosing time even longer than IPX-066. (Cobuzzi, Tr. 2599; Nestor, Tr. 2935-36; see RX247).

¹¹ Phase III of clinical development is the last stage of development before submitting a drug application for approval to the FDA. (Nestor, Tr. 3003).

Initial Decision

c. Negotiations of the DCA**i. Background to the negotiations**

275. In early 2009, Impax approached Endo about a collaboration with respect to Endo's central nervous system drug Frova, which treats migraine headaches. (RX393 at 0014; see Nestor, Tr. 2932; Koch, Tr. 318-19; CX4036 (Fatholahi, Dep. at 51-52)).
276. Impax was interested in collaborating with Endo on Frova because the product fit with Impax's focus on central nervous system and neurology products. (Snowden, Tr. 453-54; Nestor, Tr. 2929).
277. Endo rejected Impax's proposal to collaborate on Frova in the early 2009 discussions (F. 275). (Nestor, Tr. 2932).
278. In late 2009, after Endo and Impax began discussions relating to the settlement of the Opana ER patent litigation (F. 112), Shawn Fatholahi, the head of sales and marketing for Impax's brand division, contacted Ms. Snowden to express his interest in a co-development arrangement with Endo on Frova. (Snowden, Tr. 346, 454-55).
279. In October 2009, Impax and Endo discussed a potential business collaboration on Frova and executed a non-disclosure agreement in connection with those discussions. (Snowden, Tr. 455-56; RX359; CX1816).
280. The discussions between Impax and Endo relating to Frova did not result in a collaboration agreement. (Snowden, Tr. 495).
281. In the fall of 2009, in the course of Endo's and Impax's discussions relating to the settlement of the Opana ER patent litigation, Endo became aware of Impax's efforts to develop drugs for Parkinson's disease and expressed an interest. (Koch, Tr. 323-24).

Initial Decision

282. In December 2009, Endo and Impax ended their discussions on a potential settlement of the '456 and '933 patent infringement litigation. (Second Set of Joint Stipulations, JX003 ¶ 17).

ii. Negotiations resume in May 2010

283. On May 17, 2010, Endo and Impax resumed discussions on the potential settlement of the '456 and '933 patent infringement litigation. (Second Set of Joint Stipulations, JX003 ¶ 21).
284. After discussions relating to settlement of the Opana ER litigation resumed on May 17, 2010, Impax and Endo began discussing a potential joint development agreement and Endo expressed an interest in marketing IPX-066. (CX0310 at 004; CX4003 (Snowden, IHT at 89-90); Koch, Tr. 320, 323-24).
285. On May 19, 2010, in conjunction with the discussion of a potential collaboration agreement, Mr. Donatiello of Endo confirmed to Ms. Snowden and Mr. Mengler of Impax that the confidential disclosure agreement Endo and Impax had entered as part of negotiations in October 2009 (F. 279) was still in effect. (CX2966 at 002; CX1816 at 001).
286. Between May 17 and 26, 2010, Impax and Endo held two conference calls and exchanged numerous emails and materials regarding IPX-066. (CX2966; RX272 at 0001-03, 0005-08; CX1301 at 112-13; CX0310 at 004-05).
287. At Endo, the senior vice president of corporate development, Dr. Robert Cobuzzi, and his team of employees were responsible for evaluating potential pharmaceutical business deals for further development. Dr. Cobuzzi first learned about a potential collaboration with Impax on IPX-066 from Endo's chief financial officer, Mr. Levin, who was not part of the corporate development group. Dr. Cobuzzi was not involved in the SLA negotiations, and was only vaguely aware of them. (Cobuzzi, Tr. 2513, 2567-68, 2584).

Initial Decision

288. On May 19, 2010, David Paterson, Impax's vice president of business development, provided initial written materials on IPX-066 to Dr. Cobuzzi, including a presentation entitled "IPX066: Licensing Opportunity For Parkinson's Disease." The presentation touted the clinical benefits of IPX-066 over Sinemet, the leading carbidopa-levodopa brand product, and projected a launch of IPX-066 in the United States in the second half of 2012. (CX2966 at 001, 003, 038, 040-45, 73).
289. On May 20, 2010, Dr. Cobuzzi directed his team of employees to work on an opportunity evaluation worksheet ("OEWS") to assess a potential collaboration with Impax on IPX-066. Dr. Cobuzzi noted that IPX-066 will be positioned with Frova, that it is a known molecule, that Endo has looked at the space before, and that it fits with Frova. (CX1006 at 001).
290. On May 21, 2010, Endo asked an outside consulting firm to provide guidance about the potential value of IPX-066, stating: "There 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!!) No detailed proposal is needed at this point given the extremely tight timelines" (RX072; Cobuzzi, Tr. 2587).
291. On May 22, 2010, Dr. Paterson of Impax provided Dr. Cobuzzi and a number of additional Endo employees access to a "data room" with "a large amount of IPX-066 related documents." The documents covered: (i) intellectual property/legal; (ii) chemistry, manufacturing, and controls; (iii) commercial; (iv) regulatory; (v) clinical; (vi) clinical pharmacology; and (vii) Impax's unredacted confidential presentation on IPX-066. (RX272 at 0001).
292. On May 25, 2010, the outside consulting firm hired by Endo (F. 290), informed Dr. Cobuzzi that: its best estimate of peak U.S. revenue for IPX-066 was [REDACTED]; the data suggest that IPX-066 will be superior to a comparator drug; and although the current market is heavily

Initial Decision

genericized, “we think that if the final data continue to show a [REDACTED], neurologists will push through payer barriers to the drug for at least some of their patients.” (RX072, *in camera*).

293. On May 25, 2010, Dr. Cobuzzi directed his staff to help in the assessment of IPX-066, stating: “It is a controlled-release formulation of carbidopa-levodopa for Parkinson’s disease that benefits by [REDACTED]. We have very little time for this evaluation All of the information is available in an e-dataroom As this is an area we know well as a company both in terms of past evaluations, and by virtue of the fact that we previously held the rights to IR Sinemet, this should not be a difficult evaluation.” (CX1007 at 001, *in camera*).
294. On May 26, 2010, Mr. Donatiello of Endo sent to Mr. Mengler and Ms. Snowden of Impax two term sheets.¹² The initial term sheet for what evolved into the DCA proposed an option agreement concerning IPX-066 “and all improvements, modifications, derivatives, formulations and line extensions thereof.” The term sheet gave Endo the option to receive either the right to co-promote the product to non-neurologists within the United States or to purchase an exclusive license to the product in the United States. 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. If Endo exercised the option to co-promote, Endo would receive a fee of 50% “on the net sales” from prescriptions by non-neurologists in the United States. If Endo exercised the option for a license, Endo would pay Impax a one-time license fee based on projected sales. (RX565 at 0002; CX320 at 002-05).
295. On May 27, 2010, Mr. Mengler responded to the May 26, 2010 term sheet (F. 294) that any collaboration would be “for a product I will designate as [IPX]-066a. This is our

¹² The May 26, 2010 term sheet relating to the SLA is discussed in F. 131.

Initial Decision

next generation of [IPX]-066. We have significant data and can name the product at signing.” Impax set out milestone payments for the collaboration, beginning with a payment at signing of \$3 million, and followed by up to six additional payments of increasing amounts based on reaching specified milestones, for a total of \$60 million. (RX318 at 0001 (Impax’s response to Endo’s initial term sheet) (proposed milestones as follows: signing (\$3 million); Phase II initiation (\$4 million); Phase II completion (\$6 million); Phase III initiation (\$8 million); Phase III completion (\$11 million); application filing (\$13 million); FDA approval (\$15 million)).

296. Following a June 1, 2010 in-person meeting between Endo and Impax, internal Impax emails referred to the deal structure for the co-development of IPX-066a. (RX387 at 0001; CX0406 at 001; CX1011).
297. In an internal Impax email dated June 1, 2010, Mr. Mengler described the “current proposal . . . [w]ith regard to the R&D collaboration” for “project 066a: milestone funding totaling 40M” including \$5 million at signing. Mr. Mengler stated his opinion that he “like[s] the 40M. 5M guaranteed and the rest is success based. A lot of this depends on how successful we think this program will be – and how much the program will cost.” (RX387 at 0001).
298. On June 2, 2010, Mr. Levin of Endo clarified to Impax that Endo’s offer for IPX-066a was for an upfront payment of \$10 million and a single additional milestone payment of \$5 million upon successful completion of Phase II. If Endo elected to exclusively in-license the compound, Endo would pay Impax five times 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).
299. In an internal Impax email dated June 3, 2010, Mr. Mengler stated that the current proposal for the R&D

Initial Decision

collaboration was a total of \$20 million, with half (\$10 million) upfront. (CX0114 at 001).

300. On June 3, 2010, Mr. Mengler of Impax and Mr. Levin of Endo reached an agreement in principle on the SLA and the DCA. (CX3334 at 001; CX0412 (Donatiello, IHT at 139)).
301. After Endo rejected Impax's June 4, 2010 proposal for a simple settlement with a July 15, 2011 entry date for Impax's generic version of Opana ER and no compensation terms (F. 155-156), Impax dropped its request for such a settlement and sought Endo's agreement to an increase in the milestone payments under the DCA. (F. 302, 306; Snowden, Tr. 378-80; CX4032 (Snowden, Dep. at 197-99)).
302. On June 4, 2010, Mr. Koch proposed to Endo new terms for the IPX-066a development agreement, 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 ten years on the market. (CX0410 at 001-02).
303. In a June 4, 2010 email, Impax informed Endo that IPX-203 was the product that had been designated as IPX-066a and provided Endo with additional information on IPX-203. (CX1311).
304. In an internal Endo email dated June 4, 2010, Mr. Levin stated that he received a call from Impax "looking to recut the economics on the R&D collaboration." (CX1311).
305. In an internal Impax email dated June 4, 2010, Mr. Koch expressed his belief that Mr. Mengler had "dropped" the milestones for the product collaboration too dramatically from the prior proposal of \$40 million. Mr. Koch agreed with the proposal's including a \$10 million upfront payment. (CX407 at 001).

Initial Decision

306. On June 4, 2010, Impax and Endo exchanged first drafts of the SLA and the DCA. After exchanging the first drafts, Impax and Endo continued to negotiate the language of the documents, exchanging numerous drafts and holding at least ten teleconferences between June 4 and June 7, 2010. (CX4003 (Snowden, IHT at 137-38); RX406 at 0001; CX1301 at 114-18; CX0310 at 006-11).
307. On June 7, 2010, Dr. Cobuzzi provided the final opportunity evaluation worksheet on IPX-203 to Endo's executive team, stating: "I believe this OEW provides adequate and fair representation of what I would define as a good deal for Endo." (CX2748).
308. On June 7, 2010, an execution version of the DCA was circulated. (CX0326).

d. Relationship between IPX-066 and IPX-203

309. In 2010, Impax was not looking for a partner in the United States for IPX-066 because Impax planned to market the product domestically on its own, utilizing its established neurologist network. (Snowden, Tr. 456-57; Koch, Tr. 319-20; CX4036 (Fatholahi, Dep. at 77, 80) (Impax "could effectively market [IPX-]066 here in the U.S. ourselves and didn't need any assistance.")).
310. In 2010, Impax had already shouldered all development risks and development costs of IPX-066. Therefore, it made little sense to Impax to share potential profits from the drug with a partner. (Nestor, Tr. 2941-42).
311. Dr. Michael Nestor, the head of Impax's brand division,¹³ was "absolutely not" willing to consider an agreement with Endo regarding IPX-066. (Nestor, Tr. 3054-55).
312. Impax ultimately engaged GlaxoSmithKline ("Glaxo") as a partner for marketing IPX-066 outside the United States

¹³ As president of the brand division, Dr. Nestor had to approve any co-development and co-promotion agreement. (Nestor, Tr. 3054-55).

Initial Decision

and Taiwan. Glaxo would assist with the regulatory and infrastructure hurdles associated with commercializing a product outside the United States and Taiwan and could ensure the commercialization process proceeded in non-U.S. markets. (Nestor, Tr. 2942-43).

313. In response to Endo's May 26, 2010 proposal for an agreement concerning IPX-066 and all improvements, modifications, derivatives, and line extensions thereof (F. 294), Impax countered on May 27, 2010 that any collaboration would be for IPX-066a. (F. 295; *see also* Snowden, Tr. 405-06 (testifying that "Endo was interested in the Parkinson's space and wanted the deal to cover both products, the original IPX-066 and the follow-on product, but Impax wasn't interested in doing the deal on IPX-066. So there wasn't actually . . . a switch as much as Endo was trying to negotiate for both product rights and Impax was only interested in doing product rights on the one product.")).
314. IPX-066a, which later became known as IPX-203 (F. 303), was Impax's "next generation" version of IPX-066 and was a planned carbidopa-levodopa-based product that Impax hoped would improve the treatment of Parkinson's disease symptoms and also have favorable dosing over IPX-066. (Reasons, Tr. 1236; *see* Koch, Tr. 320; Nestor, Tr. 2935).
315. At the time of the DCA negotiations, IPX-203 was in the beginning of the formulation stage. Impax had not landed on a final formulation for the product, but, based on the opinion of Dr. Suneel Gupta, the chief scientific officer at Impax in 2010, Impax believed that the product concept for IPX-203 would be "doable." (Nestor, Tr. 2946, 3030-31; RX387 at 0001).
316. Dr. Gupta had expertise in reformulating existing chemical compounds to create commercial and clinical improvements through reformulation and "is renowned for taking existing compounds and reformulating them and turning those products into very successful drugs in the

Initial Decision

marketplace that meet significant medical need[s].” When Dr. Gupta tells Impax management that a product concept is “doable,” they believe him and rely on his judgment. (CX4033 (Nestor, Dep. at 80-83)).

317. Impax’s expertise has long been the development of extended-release technologies, which gives it “the basis of knowledge to know what kinds of things to look for in a formulation that would give you” longer effective time for a Parkinson’s disease medication. Such expertise is “a very important asset for” Impax and allows it to regularly “take advantage of that [controlled-release] technology” to compete successfully. (Nestor, Tr. 2955-56; see CX4014 (Hsu, IHT at 10, 30) (Impax is “a company specialized in the controlled release” of medications.)).
318. Impax was already planning to withdraw promotion and sampling of IPX-066 (Rytary) once IPX-203 reached the market, allowing patients to continue successful use of IPX-066 while avoiding any division of Impax’s sales force between multiple Parkinson’s disease products. This was consistent with the commercial goal of extending the IPX-066 franchise. (Nestor, Tr. 2935-37).
319. The ultimate goal of IPX-203 was to further extend the amount of time patients have control over their motor symptoms after taking the medication. (Nestor, Tr. 2935 (“the whole idea behind this product . . . is to be able to even extend more the effective time that a patient is on IPX-203, meaning that they have a longer period of time when their motor control symptoms are under control”); CX4014 (Hsu, IHT at 39)).
320. IPX-203 would also employ a “much more simplified” dosing regimen than IPX-066, making it more intuitive for neurologists to prescribe the product. (Nestor, Tr. 2994).
321. Impax projected that the total cost of development for IPX-203 would be between \$80 and \$100 million. The projected costs were a “natural extrapolation” of the

Initial Decision

development costs incurred in connection with IPX-066. (Nestor, Tr. 2944-45; Koch, Tr. 321; RX387 at 0001).

e. Due diligence efforts by Endo

i. Review of information regarding IPX-203

322. Impax provided Endo with information regarding Impax's research into the IPX-203 product concept and about how IPX-203 would improve upon existing Parkinson's disease therapies, including IPX-066. (RX377; Cobuzzi, Tr. 2525-26, 2602).
323. The information Impax provided on IPX-203 made clear that IPX-066 and IPX-203 were intended to be [REDACTED]. (Cobuzzi, Tr. 2530, *in camera*).
324. IPX-203 was intended to be a modification of carbidopa and levodopa, a well-known combination treatment for Parkinson's disease. (CX1209 at 003; Nestor, Tr. 3004; Cobuzzi, Tr. 2524).
325. Levodopa generally is not well absorbed in the colon. (Cobuzzi, Tr. 2535).
326. IPX-203 would have [REDACTED]. (Nestor, Tr. 2950-51, 2957, *in camera*; Cobuzzi, Tr. 2529-30, 2538, *in camera*).
327. The information Impax provided on IPX-203 [REDACTED]. (Cobuzzi, Tr. 2530, 2534-35, *in camera*; see RX377 at 0031, 0040-41, *in camera*).

Initial Decision

ii. Review of information regarding IPX-066

328. Impax sent IPX-066 materials to Endo to “help [Endo] frame their evaluation of the market environment into which IPX-203 could be launched as a successor to IPX-066.” (Cobuzzi, Tr. 2539; RX376 at 0001; see RX272 at 0001; RX080 at 0006 (“IPX-066 affords a reasonable surrogate for IPX-203 given the anticipated similarities in constituents and formulation.”)).
329. Impax sent IPX-066 materials to Endo because (1) Impax had already established a data room regarding IPX-066 when it sought a partner to market the product outside the United States, and (2) IPX-203 was a follow-on product to IPX-066; therefore “the foundational aspects of what was in the data room about IPX-066 were relative to the kind of product we envisioned IPX-203 ultimately to be, which is an extended release carbidopa-levodopa formulation that would offer clinically meaningful benefit[s] over and above what the current standard of care was.” (Nestor, Tr. 3055-56).
330. The materials Impax provided regarding IPX-066 aided Endo’s assessment of IPX-203 “tremendously.” Dr. Cobuzzi explained that IPX-066 was relevant to his assessment of IPX-203 because, among other reasons, both products would contain carbidopa and levodopa, and the only difference was [REDACTED], [REDACTED], “which we viewed as being relatively simple, although it does change the chemistry.” (Cobuzzi, Tr. 2625, 2539-40, *in camera*).
331. Julie McHugh, Endo’s chief operating officer at the time of settlement and the individual responsible for assessing the commercial opportunity of any product, deemed IPX-066 an appropriate commercial proxy for assessing IPX-203. (CX2772 at 001; Cobuzzi, Tr. 2541-42).
332. The IPX-066 materials, as well as Endo’s experience with other Parkinson’s disease treatments, suggested that the successful development of IPX-203 would more

Initial Decision

effectively treat Parkinson's disease symptoms. (Cobuzzi, Tr. 2634-35).

333. The materials Impax provided regarding IPX-066 showed that IPX-066 was forecasted to have [REDACTED] in sales by 2019. (RX376 at 0050, *in camera*).
334. Endo used those forecasts (F. 333) to calculate "conservative estimates" for IPX-203 sales. (CX2780 at 001; see RX080 at 0011-12; CX2533 at 001 ("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.")).
335. Endo's reliance on information about a related drug when evaluating IPX-203 was not unusual. Endo relies on information about one pharmaceutical asset to assess another, related pharmaceutical asset "all the time." (Cobuzzi, Tr. 2624).
336. When information about related pharmaceutical assets is available, it is "much easier" to evaluate a proposed drug than it is to evaluate a new chemical entity on its own. (Cobuzzi, Tr. 2625).

iii. Sufficiency of time and information

337. Dr. Robert Cobuzzi was the head of Endo's corporate development group as well as the lead scientist on the team that evaluated the commercial and scientific merits of the DCA with Impax. (Cobuzzi, Tr. 2523).
338. Dr. Cobuzzi and his team conducted Endo's due diligence review of the DCA. (Cobuzzi, Tr. 2547-48).
339. Dr. Cobuzzi holds a Ph.D. in molecular and cellular biochemistry and wrote his dissertation on Parkinson's disease. (Cobuzzi, Tr. 2511-12).
340. Dr. Cobuzzi's team included at least one other scientist with a background in Parkinson's disease treatments. Dr.

Initial Decision

Kevin Pong, who was in charge of evaluating Endo's scientific licenses, had a "significant amount of experience" in the area of Parkinson's disease treatments. (Cobuzzi, Tr. 2512-13).

- 341. Endo also employed an outside consulting firm to provide guidance about the potential value of IPX-066. (RX072).
- 342. Dr. Cobuzzi believes that Endo had sufficient time to assess IPX-203 before entering into the DCA, particularly in light of Dr. Cobuzzi's and Endo's familiarity with Parkinson's disease treatments (F. 257-261, 293) and the detailed nature of the information Impax provided on IPX-066 (F. 328-332). (Cobuzzi, Tr. 2543, 2563, 2625).
- 343. In his May 25, 2010 email to the Endo team performing due diligence on a potential Parkinson's disease treatment collaboration with Impax, Dr. Cobuzzi wrote: "this is an area we know well as a company both in terms of past evaluations, and by virtue of the fact that we previously held the rights to IR Sinemet [another Parkinson's disease treatment], this should not be a difficult evaluation." (CX1007 at 001; Cobuzzi, Tr. 2547-48).
- 344. Endo knew "the underlying molecules, the carbidopa and levodopa, and we looked at a number of Parkinson's opportunities in the past, so we knew the general landscape of the area in which we were looking at this as a commercial opportunity." (Cobuzzi, Tr. 2548-49).
- 345. Taken together, Dr. Cobuzzi believed that Endo had adequate time and "the information [it] needed" to evaluate the DCA properly. (Cobuzzi, Tr. 2563).

f. Endo's valuation of IPX-203

- 346. Any time Endo considers a pharmaceutical collaboration, it completes an OEW (opportunity evaluation worksheet), which is Endo's standard method of assessing the science, medical information, commercial opportunity, and related

Initial Decision

financial considerations behind a potential collaboration project. (Cobuzzi, Tr. 2540-41, 2546-47).

347. In Endo's OEW on IPX-203, Dr. Cobuzzi and his team concluded that Endo should enter the DCA. Dr. Cobuzzi made that recommendation to Endo's CEO, CFO, and board of directors. (Cobuzzi, Tr. 2544, 2561; CX2748 at 001).

i. Commercial aspects

348. Endo's OEW on IPX-203 stated that the DCA was "a good deal for Endo." (CX2748 at 001; see Cobuzzi, Tr. 2545-46, 2554; CX4017 (Levin, Dep. at 166-67)).
349. Dr. Cobuzzi recommended the DCA as "an exciting opportunity for Endo" because it "further builds our product pipeline for the future with a drug candidate that fits with our commercial footprint." (CX1209 at 001; Cobuzzi, Tr. 2549-50).
350. In 2010, Endo did not have many products in its commercial pipeline and did not have the capacity to develop new products in-house. (Cobuzzi, Tr. 2515, 2562).
351. Endo's OEW on IPX-203 stated: "[m]arket research provided by Impax is similar to work done several years ago by Endo in evaluating other [Parkinson's disease] related opportunities." (CX1209 at 011).
352. Endo also analyzed the net present value of its initial investment under the DCA. Endo generally requires a 10% rate of return on its investment before agreeing to a development and co-promotion deal. (Cobuzzi, Tr. 2561).
353. Endo determined that the DCA and IPX-203 had a "very reasonable rate of return" of [REDACTED]. (Cobuzzi, Tr. 2560, *in camera*; CX1209 at 018, *in camera* (estimating net present value of the DCA

Initial Decision

to be [REDACTED]);
RX080 at 0017, *in camera*).

354. Endo thought it could realize the type of return referenced in F. 353, even though the market for Parkinson's disease treatments was heavily genericized, because IPX-203 would offer a superior product. (CX2748 at 0012; Cobuzzi, Tr. 2622-23).
355. Dr. Cobuzzi explained that "the better [a product] is for the patient or the end user, the more likely they are to want it, need it, or use it," and the more likely that doctors will prescribe the new compound. (Cobuzzi, Tr. 2536-37).

ii. Medical aspects

356. Endo's OEW on IPX-203 stated that market research "indicate[d] that most physicians who treat [Parkinson's] patients are generally satisfied by existing treatment options with two exceptions: 1) existing treatments do not modify the course of the disease, they only palliate symptoms; and, 2) existing drugs begin to lose effectiveness within 10-15 years after initiation of therapy due to the development of feedback inhibition and other biochemical mechanisms that can be classified loosely as 'resistance.' Other unmet needs include a need for better control of efficacy over time" (CX1209 at 011).
357. IPX-203 was intended to address the second exception described in F. 356. Specifically, it would extend the period of time over which the drug is absorbed, which would allow doctors to lower the doses needed for effective treatment. Over time, lower doses would also prevent the drug from losing effectiveness in patients. (Cobuzzi, Tr. 2555; *see* Nestor, Tr. 2935 ("the whole idea behind this product . . . is to be able to even extend more the effective time that a patient is on IPX-203, meaning that they have a longer period of time when their motor control symptoms are under control"))).

Initial Decision

358. Endo's OEW on IPX-203 (F. 356) explained that "IPX066 has been developed by Impax to address physician[s'] desire for a superior long-acting carbidopa-levodopa product, and IPX-203 represents a still greater improvement in pharmaceutical profile with a value proposition that includes faster onset of action, superior management of motor fluctuations and convenient oral dosing in a simplified regimen that could require no more than twice-daily administration, and in some cases even once-daily administration." (CX1209 at 012).
359. Taking the drug less frequently would be particularly beneficial for Parkinson's patients, who can have trouble "even picking up the pill." (Cobuzzi, Tr. 2557).
360. Dr. Cobuzzi and his team concluded that the attributes ascribed in F. 357-359 (to lower doses and taking drugs less frequently) would make IPX-203 a "greater improvement in disease control and ease of use relative to" IPX-066. (RX080 at 0011).
361. Dr. Cobuzzi and his team concluded that IPX-203 "had the opportunity to move very quickly through development" and "was an exciting compound in that it was made up of . . . two compounds that have already been approved by the FDA" (CX4017 (Levin, Dep. at 166-67)).
362. Dr. Cobuzzi and his team concluded that there was "a higher than average probability that we might be able to get this drug approved if they were able to make the modification" envisioned in the IPX-203 product concept. (Cobuzzi, Tr. 2537-38).
363. Dr. Cobuzzi believed that IPX-203 had a path to approval that would successfully bring IPX-203 to the market. (Cobuzzi, Tr. 2552).

iii. Allocation of risk

364. Endo's OEW analysis on IPX-203 explained to Endo's board of directors that the DCA's "deal structure

Initial Decision

acceptably mitigates Endo's exposure despite the early development stage." (CX1209 at 003; Cobuzzi, Tr. 2543-44 (noting that most of the risk under the DCA was borne by Impax)).

365. One way in which the DCA mitigated risks to Endo is that Endo had to make a single contribution to Impax's development work and would make additional payments only if the "risk associated with proving the concept would have been retired" through successful completion of development milestones such as Phase II clinical trials. Thus, Endo knew its maximum development costs up front even though "[d]rug development is extremely expensive." (Cobuzzi, Tr. 2543-44, 2558; see CX1209 at 003).
366. A second way in which the DCA mitigated risks to Endo is that it did not require Endo to perform any development work or otherwise expend internal resources. (Cobuzzi, Tr. 2558-59, 2627-28).
367. A third way in which the DCA mitigated risks to Endo is that Endo retained the same profit-sharing rights no matter how much time or money Impax expended on IPX-203's development. (Cobuzzi, Tr. 2564, 2627-28).
368. These factors (F. 365-367) left Endo "comfortable" with the collaboration from the perspective of risk. (Cobuzzi, Tr. 2543-44).
369. Dr. Cobuzzi believed that the profit-sharing rights Endo received under the DCA justified Endo's payment obligations. (Cobuzzi, Tr. 2564).
370. Compared to other collaboration agreements, Endo's \$10 million investment to buy into the IPX-203 opportunity was "not an uncharacteristically large amount of money." (Cobuzzi, Tr. 2559).

Initial Decision

g. Impax's valuation of IPX-203 and the DCA

371. Dr. Michael Nestor, president of Impax's brand division, noted in 2010 that he "would hate to have to sell" IPX-203 since the product was envisioned as a better product than, and "a potential franchise extender for," IPX-066. (RX387 at 0001).
372. In negotiating the DCA, Impax initially wanted to retain any profits flowing from prescriptions written by high-prescribing non-neurologists – which were the profits Endo sought under the DCA – because of the "significant" amount of money those prescriptions represented. (RX405 at 0001; see CX4033 (Nestor, Dep. at 123); CX1009 at 008 (non-neurologists "manage about 40%" of Parkinson's patients)).
373. Impax knew that there were at least "a couple of thousand physicians who were primary care physicians that prescribed Parkinson's patients, somewhat like a neurologist. So that was the audience that we had envisioned promoting IPX-203 to." (Nestor, Tr. 2948).
374. With the DCA, Impax "got a partner who would fund some of the costs to get [IPX-203] approved." (Koch, Tr. 321).
375. In 2010, Impax did not have the money to begin working on the clinical research for IPX-203. Impax could not fund the IPX-203 project internally because its shareholders did not "want to see large sums of money being spent over an extended time period on a single product. They were accustomed to R&D investments being made on many individual products that you bring to market as a generic." (Nestor, Tr. 3052-53).
376. Impax needed external funding to move the IPX-203 product forward in development and explored a number of possible funding approaches, including seeking money from venture capital firms. (Nestor, Tr. 2941, 3052-53).

Initial Decision

377. When the idea was raised of obtaining funding for IPX-203 through a co-development program with Endo, Impax's brand drug development team was "very excited about that." (Nestor, Tr. 2941).

h. Impax's efforts to develop IPX-203

378. As early as November 2009, Impax had reviewed [REDACTED]. (Nestor, Tr. 2952-53, *in camera*; RX247, *in camera*).
379. Following execution of the DCA, Impax devoted substantial efforts to IPX-203's development. Impax personnel have spent over [REDACTED] working on IPX-203 since June 2010. (Nestor, Tr. 2970-71, *in camera*; RX241, *in camera*).
380. In 2010, Impax commissioned preclinical pharmacokinetic studies testing several relevant compounds and began laboratory research. (RX241; RX242).
381. In the course of its development efforts, Impax explored various IPX-203 formulations in an effort to achieve the desired clinical outcome. This involved multiple rounds of pharmacokinetic studies of various formulations to assess their pharmacokinetic profiles, a metric that spoke directly to the clinical improvement Impax was seeking to achieve with the program. (Nestor, Tr. 2961-62; CX0310 at 26-27; RX242; CX3166 at 039-42).
382. Impax completed pharmacokinetic studies of IPX-203 no later than 2012. Impax then conducted additional pharmacokinetic studies and completed Phase I clinical trials. (RX242 (Tab 2012); CX3166 at 039-42; Nestor, Tr. 2957; RX157 at 0020).
383. Impax manufactured a clinical supply of IPX-203, developed protocols for Phase II clinical trials, submitted those protocols to the FDA, and secured FDA approval for

Initial Decision

efficacy and safety studies in November 2014. (RX157 at 0020).

384. Further development work on IPX-203 was delayed after Impax experienced delays in the development of IPX-066, the brand drug IPX-203 was intended to extend and improve upon. (Reasons, Tr. 1237-38; CX4021 (Ben-Maimon, Dep. at 145) (IPX-066 development was delayed for a “[c]ouple years”); CX4033 (Nestor, Dep. at 135-36)).
385. Bryan Reasons, Impax’s current chief financial officer, explained that when IPX-066 was delayed, “resources were put to focus on the approval of Rytary [IPX-066] so that we could get that to market, grow that . . . commercially, and it would also be beneficial to . . . when we launched the next generation of [IPX]-203.” (Reasons, Tr. 1237-38).
386. Further development work on IPX-203 was also delayed after Impax received an FDA Warning Letter in 2011 relating to Impax’s manufacturing processes, which caused Impax to direct its scientific staff to spend their time helping the operations people correct the deficiencies that the FDA noted in its last inspection. (Nestor, Tr. 2968, 2985-86).
387. Impax’s research and development team “worked to help remediate” any issues identified by the FDA and to prepare for “the FDA to come in and do their re-inspection,” which meant that “nothing was going to go forward until such time as we got over that hurdle.” (Nestor, Tr. 2985-88).
388. Notwithstanding the delays (F. 387) and the DCA’s termination (F. 389), Impax has continued development work on IPX-203. (Nestor, Tr. 2970).
389. IPX-203 is currently Impax’s “lead compound on the brand side of [its] R&D programs. It’s really our strategy to continue to grow and extend the duration of our Parkinson’s franchise.” (Reasons, Tr. 1238).

Initial Decision

390. Impax has now completed Phase II clinical trials for IPX-203 and plans to begin Phase III clinical trials at the beginning of 2018. (Nestor, Tr. 2978; Reasons, Tr. 1238).
391. Phase II clinical trials of IPX-203 revealed a statistically significant improvement in treatment over IPX-066 and other existing treatments, reducing the amount of time Parkinson's patients are without control over their motor symptoms. (Nestor, Tr. 2978).
392. The Phase II clinical trials of IPX-203 suggest that it will offer an improvement of over two hours in motor symptom control when compared to immediate-release carbidopa-levodopa treatments and one hour of improvement over IPX-066. (Nestor, Tr. 2984-85; *see also* RX208 at 0015-16).
393. An improvement of over two hours in motor symptom control over existing medications is a "terrific result" that is "highly statistically significant" and "clinically meaningful." (Nestor, Tr. 2978-79, 2984-85).
394. The Phase II clinical results of IPX-203 suggest that Parkinson's patients will have "their symptoms . . . under control for a longer time period," which is "a very important thing" for patients. (Nestor, Tr. 2937, 2966).
395. Impax also sought, and the FDA granted, a special protocol assessment for further clinical trials of IPX-203 in 2017. A special protocol assessment is an agreement between a pharmaceutical company and the FDA regarding the design of clinical trials. When a special protocol assessment is in place, the FDA will not question the trial designs in Phase III clinical trials, which "takes an element of risk out of a new drug application review." (Nestor, Tr. 3001-02).

i. Termination of the DCA

396. Impax's IPX-203 development efforts revealed that the formulation of IPX-203 contemplated by the DCA could

Initial Decision

not achieve the intended clinical benefits. (Snowden, Tr. 459-60; *see* Nestor, Tr. 2960-61).

397. Between 2014 and 2015, Impax's research team determined it could not achieve the desired product profile with a [REDACTED] formulation. Impax consequently began pursuing alternative approaches to an extended-release formulation of carbidopa and levodopa. (Snowden, Tr. 459-60; Nestor, Tr. 2960-61).
398. After extensive research and testing, [REDACTED]
[REDACTED]
[REDACTED].
(Nestor, Tr. 2961-62, *in camera*).
399. In 2014, Impax filed an Investigational New Drug Application with the FDA regarding [REDACTED]
[REDACTED], which the FDA accepted. (Nestor, Tr. 2963, *in camera*).
400. Although the specific formulation of IPX-203 changed, Impax still viewed [REDACTED]
[REDACTED] it had been developing since 2009 "[b]ecause it was all towards the same end. It still involved carbidopa-levodopa. It was just a variation in formulation." (Nestor, Tr. 2962, *in camera*).
401. Under the terms of the DCA, Impax and Endo formed a joint development committee that was to meet four times a year. These meetings were intended to be "[e]ssentially a progress report on clinical development by Impax." (Nestor, Tr. 3036-37; RX365 at 0016-17 (DCA §§ 7.2, 7.3); CX3345 at 006).
402. As of 2014, the joint development committee had not met. Michael Nestor, the president of Impax's brand division, explained that Impax really had nothing to discuss with Endo until the formulation work was settled. Once

Initial Decision

Impax's formulation work had reached that point, Impax met with Endo in 2015 regarding the status of Impax's IPX-203 development work. (CX3165; Nestor, Tr. 2963-64, 2967-69; CX4033 (Nestor, Dep. at 163-64)).

403. In April 2015, Impax approached Endo to update it on the status of Impax's IPX-203 development work, including the change in formulation strategy. Impax made a presentation describing Impax's formulation testing and results and [REDACTED]. (Nestor, Tr. 2963-64, *in camera*; RX208, *in camera*).
404. Impax viewed the presentation (F. 403) as a "precursor" to the joint development committee meetings called for by the DCA. (Nestor, Tr. 2967; CX4033 (Nestor, Dep. at 164)).
405. Endo and Impax "had not had a meeting of the joint development committee" before 2015 "because, quite frankly, we really had nothing to discuss with them" until the formulation work was settled. (Nestor, Tr. 2967-69; *see* CX4033 (Nestor, Dep. at 163-64)).
406. Indeed, Impax "had to make sure we had a formulation first and that we were ready to go into the clinic" before meetings of the joint development committee "would be relevant." (CX4033 (Nestor, Dep. at 163-64); *see* Nestor, Tr. 2967-68).
407. By 2015, Impax had sufficient formulation research, as well as [REDACTED], to report to Endo. (Nestor, Tr. 2963, *in camera*).
408. During the parties' April 2015 discussion (F. 403), Impax offered to amend the DCA so that the DCA would cover the [REDACTED] to IPX-203. (Nestor, Tr. 3057, *in camera*; CX2928 at 013, *in camera*).
409. Impax was prepared to amend the DCA to include the new formulation of IPX-203 because it wanted to work with

Initial Decision

Endo in order to move the drug forward and Impax believed the new formulation would give it “an avenue through which we could continue the development of IPX-203.” (Nestor, Tr. 3056-57).

410. Endo initially agreed to the proposed amendment (F. 408), noting that it “would like to maintain or even increase [its] involvement with the development program . . . as [it] remain[ed] optimistic this will be a successfully differentiated product, which Endo looks forward to the opportunity to co-promote . . . with Impax.” (RX218 at 0001; *see* Snowden, Tr. 459-60).
411. Following Endo’s initial agreement (F. 410), Impax consequently prepared an amendment to the DCA and expected the parties to continue collaborating on IPX-203. (Snowden, Tr. 458-59; *see* CX2747).
412. Endo subsequently informed Impax that Endo had “decided not to amend the existing agreement” and would no longer “participat[e] in [the] program,” but did not provide any explanation. (CX2747).
413. Endo’s decision surprised Impax because “fairly recently” Endo “had said the opposite, that they were interested in continuing forward with the program and amending the agreement.” (Snowden, Tr. 460-61; RX221 at 0001 (Endo’s decision not to amend DCA was “a surprise”)).
414. Because Endo retracted its initial expression of interest in amending the DCA to cover the new formulation for IPX-203, Impax and Endo terminated the DCA by mutual agreement effective December 23, 2015. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-011 ¶ 43); Snowden, Tr. 407; RX219 at 0001-02; RX198 at 0005-07 (termination agreement)).

j. Complaint Counsel’s experts’ opinions

415. Complaint Counsel’s expert in pharmaceutical business development agreements, Dr. John Geltosky, has worked

Initial Decision

on a handful of development deals in their early stages and has never negotiated a development and co-promotion agreement similar to the DCA. The majority of Dr. Geltosky's experience with pharmaceutical collaboration agreements relates to his employment with large pharmaceutical companies and Dr. Geltosky admitted that he could not speak to how the universe of small or mid-sized pharmaceutical companies approach partnerships for early-stage products. (Geltosky, Tr. 1141-45).

416. Dr. Geltosky acknowledged that Endo's senior vice president of corporate development (Dr. Cobuzzi) is better qualified to assess the strategic fit of the DCA for Endo than he is. (Geltosky, Tr. 1163).

i. Bona fide product collaboration

417. Dr. Geltosky did not offer an opinion regarding whether the DCA was a bona fide scientific collaboration or whether Endo exercised good business judgement in entering the DCA. (Geltosky, Tr. 1125-28).
418. Dr. Geltosky acknowledged that the DCA was a way for Impax and Endo to share both risks and costs associated with developing IPX-203. (Geltosky, Tr. 1135).
419. Dr. Geltosky did not offer an opinion regarding whether Endo or Impax bore more of the risk under the DCA and did not quantify any risk related to the DCA or opine what the appropriate payment would be to reflect that risk. (Geltosky, Tr. 1138, 1147).
420. Dr. Geltosky acknowledged that at the time of settlement, Impax estimated costs for the development of IPX-203 to be between \$80 and \$100 million, that Impax had to cover all development costs in excess of Endo's specified milestone contributions, no matter how much the development work cost, and that Endo's risks and costs associated with developing IPX-203 were limited to the milestone payments. (Geltosky, Tr. 1136-38).

Initial Decision

421. Dr. Geltosky's opinion that IPX-203 did not fit within Endo's strategic area of focus was based on his review of certain Endo documents provided to him by Complaint Counsel, which did not list Parkinson's disease as an area of interest, and one of which stated that Endo was interested in near-term revenue generators. In reaching that opinion, Dr. Geltosky did not consider other deals contemplated or completed by Endo. Dr. Geltosky did not have contact with the individuals involved in evaluating the DCA. (Geltosky, Tr. 1159-61).
422. Dr. Geltosky acknowledged that Endo has entered into very-early, discovery-stage pharmaceutical partnership deals and that pharmaceutical companies enter early-stage development deals "all the time." (Geltosky, Tr. 1145-46).
423. Dr. Geltosky offered no criticism of Impax's behavior with regard to the DCA. (Geltosky, Tr. 1183).

ii. Due diligence

424. Dr. Geltosky reached an opinion of Endo's due diligence efforts in evaluating the DCA based on one document provided to him by Complaint Counsel. (Geltosky, Tr. 1159).
425. Dr. Geltosky admits that Impax provided Endo with comprehensive information regarding IPX-066, including clinical information regarding safety and efficacy, intellectual property, technical due diligence, and financial analysis. (Geltosky, Tr. 1156-58; RX272 at 0005-08).
426. Dr. Geltosky admits that information about IPX-066 provides useful information for IPX-203 because IPX-203 was a follow-on drug, because the two products could compete, and because, in modeling how IPX-203 might perform in the market, Impax and Endo needed to use IPX-066 as a benchmark. (Geltosky, Tr. 1153-56).

Initial Decision

427. Dr. Geltosky did not offer an opinion on whether Endo exercised good business judgment in its due diligence of the DCA. (Geltosky, Tr. 1128).

iii. Valuation

428. Dr. Geltosky has never performed a financial valuation of a pharmaceutical collaboration. (Geltosky, Tr. 1179-80).
429. Dr. Geltosky did not conduct any valuation analysis of the DCA, did not calculate a net present value of the DCA at the time it was executed, and did not conduct any other form of empirical analysis regarding the DCA. (Geltosky, Tr. 1125, 1133).
430. Dr. Geltosky did not offer any opinion about the actual value of the DCA to Endo. (Geltosky, Tr. 1125).
431. Dr. Geltosky did not compare the payment terms in the DCA to the payment terms in other pharmaceutical collaboration agreements. (Geltosky, Tr. 1139-40).
432. Dr. Geltosky did not address the actual value of the profit-sharing rights acquired by Endo or whether Endo's profit-sharing rights justified its DCA payment obligations. (Geltosky, Tr. 1124-25).
433. Dr. Geltosky agreed that Endo's profit-sharing rights remained the same regardless of the development costs incurred by Impax. (Geltosky, Tr. 1137-38).
434. Dr. Geltosky did not offer an opinion regarding whether the profit-sharing provisions in the DCA favored Impax or Endo. (Geltosky, Tr. 1138).
435. Complaint Counsel's economic expert, Professor Noll, acknowledged that, if a payment from a brand company to a generic company is used to purchase a bundle of rights at a fair market price, the payment is justified. (Noll, Tr. 1620).

Initial Decision

436. Professor Noll did not independently analyze the DCA to determine whether it was justified, had value to either party, or represented an overpayment. (Noll, Tr. 1456, 1581-82).
437. Professor Noll relied on Dr. Geltosky's "analysis of the degree to which the \$10 million payment and co-development deal represented the acquisition of an asset that was approximately valued at a \$10 million price." (Noll, Tr. 1582).
438. Professor Noll agreed that if Dr. Geltosky did not offer an opinion regarding the actual value of the DCA to Endo at the time it was executed, then Professor Noll "would not include the \$10 million as part of the large payment that was unjustified." (Noll, Tr. 1585-86).
439. Professor Noll agreed that if Dr. Geltosky did not provide a "sufficiently well-documented rationale for the conclusion that the payment [under the DCA] was unjustified, then you would pull [the DCA] out of the case." (Noll, Tr. 1582-83).

D. Anticompetitive Effects**1. Harm to competition**

440. A basic economic principle is that consumers benefit from increased competition in the form of lower prices and increased choice. (CX5000 (Noll Expert Report at 011 ¶ 24, *see also* at 109-10 ¶ 250)).
441. Harm to competition occurs when the conduct of firms on one side of a market (usually sellers) inflict harm on participants on the other side of the market (usually consumers). Harm to competition is not limited to the certain elimination of competition, but also 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 (Noll Expert Report at 011 ¶ 24)).

Initial Decision

442. Normally when a generic drug launches, the competition between the brand-name firm and the generic firm causes the price of the drug to drop, which is a benefit to consumers. Reverse payment settlements can harm consumers, to the extent that the settlement extends the period in which the brand-name firm is the only seller of a drug, by requiring the generic firm to forego entering at an earlier date. (CX5000 (Noll Expert Report at 118, 132 ¶¶ 268, 300); Noll, Tr. 1425-27).
443. A reverse payment settlement replaces the possibility of successful generic entry with a certainty. To this extent, the brand-name firm is buying an insurance policy by which it pays the generic firm a premium in exchange for the generic firm guaranteeing it will not compete prior to the date specified in the settlement of the patent litigation. (CX5000 (Noll Expert Report at 118 ¶ 268); Noll, Tr. 1427-28).
444. Payment to an alleged patent infringer, in exchange for a certain entry date, converts the possibility of substantial loss of profits for the patent-holder, due to generic competition, into the certainty that it will continue to earn profits as the sole seller of the drug until the entry date agreed to in the settlement of the patent litigation. (CX5000 (Noll Expert Report at 104 ¶ 239)).
445. By eliminating the possibility of generic competition for a period of time, reverse payment settlements interfere with the competitive process and can harm consumers by depriving them of the possible benefits of increased competition in the period prior to the entry date provided under the settlement agreement. (Noll, Tr. 1422-23; CX5000 (Noll Expert Report at 119 ¶ 269)).
446. A large reverse payment can imply that the market entry date in the settlement agreement is later than the date that the patent holder expected the alleged patent infringer would enter the market since it is unlikely that a patent holder would agree by a settlement to pay an alleged patent infringer anything more than saved litigation costs,

Initial Decision

only to obtain entry on the date the alleged patent infringer would have entered anyway. (CX5000 (Noll Expert Report at 103-04 ¶ 238); *see also* Bazerman, Tr. 873-74; CX5001 (Bazerman Expert Report at 006 ¶ 10) (“[L]itigation costs to the parties increase the viability of a negotiated agreement, as both parties save these costs if they can negotiate an agreement.”)).

447. A brand-name pharmaceutical firm has an economic incentive to pay the generic firm as part of a settlement if the payment is less than the profits the brand firm would earn during the period before the agreed-upon entry date of the generic product. (CX5000 (Noll Expert Report at 124-26 ¶¶ 280, 284-85); CX5001 (Bazerman Expert Report at 023 ¶ 46) (stating that it is a “common pattern” in the pharmaceutical industry that the brand company’s gains from not facing generic competition are greater than the costs to the generic for agreeing not to sell a generic product)).
448. A generic pharmaceutical firm has an economic 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. However, if the brand-name firm compensates the generic firm with a sufficiently large payment, the generic firm will be willing to postpone its launch until a later date. (CX5000 (Noll Expert Report at 128-29 ¶¶ 290-92)).
449. The Hatch-Waxman regulatory framework creates additional incentives for pharmaceutical companies to enter into reverse payments. Because of the 180-day exclusivity period granted to first filers (*see* F. 21), by settling with the first filer, the brand company not only eliminates the possibility of entry by the first filer during the period before the generic firm’s product’s entry date in the agreement, but also eliminates the possibility of market entry for six months beyond this period by other potential generic drug competitors. (CX5000 (Noll Expert Report at 104 ¶ 239)).

Initial Decision

2. At-risk launch

450. Impax would not have launched its generic Opana ER at risk. (F. 451-548).

a. At-risk launches generally

451. Launching a generic product before a non-appealable decision in patent litigation is commonly known as an “at-risk launch.” (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-008 ¶ 23; *see* Koch, Tr. 246; Bingol, Tr. 1282; Hoxie, Tr. 2831).
452. 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) after a Federal Circuit opinion if the case is remanded or otherwise continues. (Hoxie, Tr. 2810-11; CX4021 (Ben-Maimon, Dep. at 133-34); CX4026 (Nguyen, Dep. at 47-48)).
453. If a generic company launches a product before a non-appealable court decision or patent expiration, brand companies can be awarded damages, as measured by the brand seller’s own lost profits rather than by the generic seller’s earned profits. Lost profits are measured by the profits the patent owner would have made on sales of its branded product but for the launch of the generic product. Damages can be trebled if the infringement is found to be willful, for instance, if the generic product was launched before a district court ruled on the patent dispute. (Koch, Tr. 286-87; Figg, Tr. 1921-23; Hoxie, Tr. 2782; CX4030 (Hsu, Dep. at 48-49)).
454. Generic companies often risk far more in infringement liability than they earn from each sale when launching at risk. (Koch, Tr. 286-87; CX4021 (Ben-Maimon, Dep. at 159) (at-risk launches could result in generic “pay[ing] more to the brand company than [generic] made”); *see also* CX4039 (Noll, Dep. at 74)).

Initial Decision

455. The risk of damages for launching at risk represent “bet-the-company” stakes and can “take [away] the solvency of the company entirely.” Damages can be in the billions of dollars if the sales of the branded drug are high enough. The profits that the brand company loses would almost always be greater than the total revenues that the generic company receives. (Koch, Tr. 287; Hoxie, Tr. 2782; Figg, Tr. 1922-23; *see* CX4030 (Hsu, Dep. at 43) (“the risk can be huge depending on the size of the product and depending on whether we’re first to file”)).
456. A first filer’s launch of a generic product triggers the beginning of the 180-day exclusivity period, which is “extremely valuable.” If the generic launches at risk and is enjoined from making sales, the generic forfeits some of its 180-day exclusivity because the 180-day time period would continue to run during the period the generic is enjoined. Even if the injunction was eventually lifted or the infringer prevailed in the underlying patent litigation, the patent infringer could never recover the forfeited part of its 180-day exclusivity period. (Snowden, Tr. 503-04; Figg, Tr. 1923-24; Hoxie, Tr. 2754, 2778-80; CX4021 (Ben-Maimon, Dep. at 164-65)).
457. If the branded company wins its action against a generic company that has launched at risk and the generic’s actions are deemed “exceptional,” courts may award attorney’s fees to the brand company. (Figg, Tr. 1924).
458. At-risk launches are fairly uncommon across the entire pharmaceutical industry. (Figg, Tr. 1924-26).
459. At-risk launches are most common when there are multiple ANDA filers who have received approval from the FDA, no ANDA filer has exclusivity, and there subsequently is a race to the market by generic firms. (Hoxie, Tr. 2704-05).
460. When at-risk launches do occur, they generally are undertaken by large pharmaceutical companies that can

Initial Decision

absorb significant financial risk in the event they are found to infringe. (Figg, Tr. 1925).

- 461. Complaint Counsel's expert, Professor Noll, identified 48 at-risk launches over a 15-year period (August 2001 thru April 2015). Twenty-one of those forty-eight at-risk launches were conducted by Teva, which Professor Noll explains, "is by far the most likely company to do at-risk launches." (Noll, Tr. 1607-09; CX5004 (Noll Rebuttal Expert Report at 92-99)).
- 462. Teva is a "very large pharmaceutical company" and, as a result, can undertake at-risk launches more regularly. (Figg, Tr. 1925; *see also* Hoxie, Tr. 2820 (Complaint Counsel's expert noting that Teva has "a high willingness to take risks" and "a greater appetite for risk than others.")).
- 463. Of the 48 at-risk launches identified by Professor Noll (F. 461), only 4 were conducted by companies with less than \$1 billion in revenue. (Noll, Tr. 1609).
- 464. Mr. Hoxie agreed with industry analysts who empirically analyzed at-risk launches between 2003 and 2009 that, generally, "at-risk launches are fairly uncommon." (Hoxie, Tr. 2827-28).

b. Impax's history of at-risk launches

- 465. Impax is a small pharmaceutical company. In 2010, Impax's revenues were less than \$1 billion. (Koch, Tr. 275, 287; *see* Figg, Tr. 1925; CX3278 at 45 (Impax 2010 Annual Report)).
- 466. Impax is "incredibly conservative" with respect to at-risk launches. (CX4021 (Ben-Maimon, Dep. at 34); *see* Koch, Tr. 287).
- 467. Mr. Koch, Impax's CFO at the time of the Endo-Impax Settlement, explained that "being a small company," Impax "could not bet the company on any one product."

Initial Decision

(Koch, Tr. 275; *see* CX4018 (Koch, Dep. at 97) (describing risks as “huge”)).

468. Impax only “infrequently” considers the possibility of an at-risk launch. (Koch, Tr. 246-47).
469. Prior to the Endo-Impax patent litigation, Impax had launched a product at risk only once. That at-risk launch was for one dosage strength of a generic version of oxycodone. Impax limited its risk of damages by capping its potential sales at \$25 million. Impax launched at risk only after it received a favorable district court decision holding the relevant patents unenforceable and after Teva, the first ANDA filer for the relevant dosage, had launched at risk six months earlier. (Koch, Tr. 274-75; Snowden, Tr. 425-26).
470. The risks to a second generic company launching at risk are lower than the risks associated with an initial at-risk launch because (1) the second generic company does not have first-filer exclusivity at stake, and (2) the patent holder may have a harder time arguing that damages are the result of any one particular generic company’s sales. (Hoxie, Tr. 2817-18).
471. Since the Endo-Impax Settlement in 2010, Impax has considered possible at-risk launches. Only one of those launches occurred, and only in a limited manner. (Snowden, Tr. 466-67; CX2927 at 014-19).
472. Impax’s one post-settlement at-risk launch involved a drug called azelastine, a nasal spray antihistamine. Impax and Perrigo, the ANDA holder and marketer of azelastine, entered a partnership agreement through which Impax would share development costs and litigation expenses in return for a share of the drug’s profits. In 2014, Perrigo notified Impax that it intended to launch azelastine at risk. Under the terms of the Impax-Perrigo partnership agreement, Impax could participate in the launch and earn a share of the profits or could not participate, in which case Perrigo would receive all azelastine profits. Impax

Initial Decision

participated in Perrigo's at-risk launch, but limited its exposure to potential damages by capping its participation at 150,000 units. (Snowden, Tr. 462-65; CX4021 (Ben-Maimon, Dep. at 37-39, 153); CX2689 (minutes of special meeting of Impax Board)).

c. Impax's process for approval of an at-risk launch

- 473. It is an absolute prerequisite for Impax's board of directors to formally approve any at-risk launch. (Koch, Tr. 276-77 ("every at-risk launch is a board-level decision"); Snowden, Tr. 426; CX4030 (Hsu, Dep. at 128); CX4021 (Ben-Maimon, Dep. at 160)).
- 474. Many steps take place before an at-risk launch is formally approved by Impax's board of directors. F. 474-483.
- 475. Impax's process for evaluating a possible at-risk launch starts with Impax's new product committee, which evaluates the science, marketing opportunity, and legal issues related to the drug under consideration for an at-risk launch. If Impax's new product committee recommends an at-risk launch, Impax's research and development team conducts further due diligence regarding the drug. (Koch, Tr. 276).
- 476. When evaluating whether to launch a product at risk, Impax's in-house legal team conducts an analysis regarding the specifics, including any pending patent litigation between Impax and the brand company, and the strength of the underlying patents. (Koch, Tr. 276; CX4021 (Ben-Maimon, Dep. at 166)).
- 477. When evaluating whether to launch a product at risk, Impax's division heads, including those from the legal, marketing, and operations departments, and from the generics division, meet with Impax's CFO to formulate a risk analysis profile. Impax's CFO must present a risk analysis profile to Impax's executive committee, which has to approve any at-risk launch. (Koch, Tr. 276-77).

Initial Decision

478. Impax's CEO must approve any decision to launch at risk. (CX4030 (Hsu, Dep. at 127); CX4021 (Ben-Maimon, Dep. at 167-68)).
479. If Impax's CEO and executive committee approve a possible at-risk launch, a presentation is made to Impax's board of directors by Impax's CFO, legal department, president of the generics division, and the manufacturing department ("Board presentation"). (Koch, Tr. 277; see CX2689; CX3223).
480. The Board presentation includes background on the product, the basis for the executive committee's decision to propose an at-risk launch, and a resolution seeking the Board's vote on the matter. (Koch, Tr. 277).
481. Impax's board of directors must formally authorize any at-risk launch. (Koch, Tr. 276-77 ("every at-risk launch is a board-level decision"); Snowden, Tr. 426; CX4021 (Ben-Maimon, Dep. at 160)).
482. For an at-risk launch, Impax has "to have sign off from the Board, because we're such a small company, and a launch at risk would . . . potentially cause our company problems if we were hit with damages, big damages." (CX4026 (Nguyen, Dep. at 55-56)).
483. If the Board formally authorizes an at-risk launch, the Board approval is recorded in the board of director's minute book. (Koch, Tr. 286).
484. In the case of azelastine, the nasal spray antihistamine that Impax did launch at risk (F. 472), Impax's senior management, including the president of Impax's generics business, Impax's general counsel, and Impax's in-house attorney responsible for intellectual property, made a presentation and recommendation regarding a limited at-risk launch at a special board of directors meeting. A resolution was then placed before the Board, and the Board voted to approve the resolution. (Snowden, Tr. 463-66; CX4021 (Ben-Maimon, Dep. at 153-54); CX2689

Initial Decision

(minutes of special meeting of Impax Board regarding azelastine)).

485. Impax would not launch a product at risk if it did not have Board approval. (Snowden, Tr. 470).

d. Impax did not seek or receive Board approval for an at-risk launch of generic Opana ER

486. Impax did not seek or receive Board approval for an at-risk launch of Opana ER. (F. 487-502).
487. Impax's senior management never decided to pursue an at-risk launch of generic Opana ER. (Mengler, Tr. 547-48, 584; Koch, Tr. 299, 324-25; Snowden, Tr. 470-71).
488. In 2010, senior management was looking at possible scenarios and modeled an at-risk launch to forecast how that might impact Impax's budget if the decision to launch at risk were made. (Koch, Tr. 299-300; *see* CX4014 (Hsu, IHT at 129-30) ("We could settle, we could launch at risk, we could do many other things, and as the job of CEO, I just have to, you know, lay out everything, get prepared so I don't get accused by the board and say, well, wait a minute, how come you didn't prepare for plan B?")).
489. On May 9, 2010, Impax's CEO, Dr. Hsu, informed Mr. Koch, Impax's CFO, that "[i]t's unlikely we will launch Opana ER this year (I actually prefer not to launch this year for obvious reason[s])." (RX297 at 0002).
490. In response to an internal Impax email reporting that on May 13, 2010, the FDA granted tentative approval to Impax's ANDA for generic Opana ER (F. 64), Dr. Hsu stated that Impax would most likely "make launch decision based on court decision on the PI." (CX2929 at 001; Koch, Tr. 310).
491. After the FDA granted tentative approval to Impax's ANDA for generic Opana ER (F. 64), when customers inquired about the status of Impax's Opana ER product, on

Initial Decision

May 17, 2010, Todd Engle, a senior member of Impax's sales and marketing team, told members of the Impax sales team that "[a] launch decision has not been made yet. There is nothing we can tell the customers yet." (Engle, Tr. 1778-79; RX323 at 0001).

492. Impax told the court presiding over the Endo-Impax patent litigation on May 20, 2010 that Impax would not launch at risk during trial. (Snowden, Tr. 471-72; RX251).
493. Mr. Mengler, president of Impax's generics division, created a presentation for the May 2010 board of directors meeting, in which he listed an at-risk launch of oxymorphone as a "current assumption" for the purpose of projecting sales of oxymorphone ER. Mr. Mengler's assumptions with respect to possible sales numbers did not "imply or mean that any legal decision ha[d] been made to clear the way for a launch." (CX2662 at 012; Koch, Tr. 337-38; Mengler, Tr. 552-53).
494. The minutes of the meeting of the board of directors meeting on May 25 and 26, 2010 note that Mr. Mengler "expressed the view that [o]xymorphone was a good candidate for an at-risk launch." (CX2663 at 001).
495. Mr. Mengler raised oxymorphone ER at the May 2010 Board meeting to put oxymorphone ER "on the radar" of the Board and to "alert the board as to the product being out there that might get to the point of an at-risk launch." Mr. Mengler discussed potential revenues from oxymorphone ER and told the Board that he thought oxymorphone ER "was a great market opportunity" because it was a "very rapidly growing product." (Mengler, Tr. 584-85; Koch, Tr. 294-95, 300-01).
496. Mr. Koch, who wrote the minutes of the meeting of the board of directors meeting on May 25 and 26, 2010, explained that Mr. Mengler was communicating his evaluation of the oxymorphone market and sharing that information with the Board because senior management was unsure of what direction it would "ultimately take and

Initial Decision

. . . [did not] want to come back to the board seeking an at-risk launch with them never having heard of it before.” (Koch, Tr. 301).

497. Dr. Hsu explained that senior management “want[s] to alert the board that we are considering this [as] one of the scenario[s] so that if we do come up with a final recommendation to the board, there will be no surprise. . . . [T]his is very typical.” (CX4030 (Hsu, Dep. at 82)).
498. Impax’s senior management did not make a recommendation to the Board for an at-risk launch, did not discuss the risk or benefits of an at-risk launch, and did not ask the Board to approve an at-risk launch at the May 25 and 26, 2010 Board meeting. (Koch, Tr. 295, 299; Mengler, Tr. 584-85; Snowden, Tr. 470-71; CX4030 (Hsu, Dep. at 85)).
499. There was no substantive discussion of an at-risk launch at the May 2010 board of directors meeting. (Koch, Tr. 295; Mengler, Tr. 584).
500. If a recommendation, discussion, or approval to launch at risk had been made to or by the board of directors, it would have been “very carefully” recorded in detailed Board meeting minutes, and would include the at-risk launch discussion, the resolution regarding the possible launch, a formal request for a vote, and the actual Board vote about the at-risk launch. No such meeting minutes exist. (Koch, Tr. 289-90, 297-98 (“I would have written the resolution, and there was no resolution for oxymorphone.”)).
501. As of June 8, 2010, the Impax board of directors had not been asked to vote on whether or not to launch generic oxymorphone ER at risk. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-009 ¶ 29; Koch, Tr. 299; CX4030 (Hsu, Dep. at 85)).

Initial Decision

502. The board of directors never voted on or approved an at-risk launch of generic oxymorphone ER. (CX4030 (Hsu, Dep. at 85); Koch, Tr. 298-99).

e. Impax's launch preparedness efforts

i. Impax's general preparedness practices

503. Impax generally strives to have its products that have been filed with Paragraph IV certifications ready to launch after the expiration of the Hatch-Waxman Act's 30-month stay. (Engle, Tr. 1768-69).
504. Impax's supply chain department is responsible for producing and packaging Impax's products. Joseph Camargo was Impax's vice president of the supply chain group from 2006 through 2011. (Camargo, Tr. 950-51).
505. Each month, the supply chain group receives from Impax's marketing department a product forecast for the next 18 months which the supply chain group uses to begin routine launch planning. (Camargo, Tr. 958; CX4023 (Hildenbrand, Dep. at 78-79)).
506. When a product is 18 months away from its earliest theoretical launch, the supply chain group begins prelaunch preparation activities. (Camargo, Tr. 958; CX4023 (Hildenbrand, Dep. at 9-12, 79)).
507. Impax uses a computer system called Enterprise Resource Planning ("ERP") and a product launch checklist to plan and track product production projects within the 18-month planning horizon. The ERP system tracks the purchasing of materials, shop floor activities, financials associated with paying suppliers, and other planning activities based on projected batch sizes, necessary materials, and how the product is produced. (Camargo, Tr. 959-61).
508. Once a product is uploaded into the ERP system, the supply chain group undertakes the following tasks: requests a quota from the U.S. Drug Enforcement Agency

Initial Decision

(“DEA”) to purchase any active pharmaceutical ingredients (“API”) that are controlled substances; purchases the API and other unique materials necessary to produce the finished product; conducts “process validation” (F. 510) to prove that Impax’s manufacturing process is repeatable and makes the product in a satisfactory manner; and produces a “launch inventory build” to ensure that Impax has enough product to meet expected demand on the launchable date. (Camargo, Tr. 964-68).

509. The supply chain group holds monthly meetings called “launch coordination meetings” to assess the status of any products in the 18-month planning horizon, which are chaired by Impax’s vice president of supply chain and attended by representatives of all departments who have responsibilities related to the planning of a product launch, including the marketing, purchasing, and regulatory departments. (Camargo, Tr. 962-63).
510. Process validation is an FDA requirement imposed on all pharmaceutical manufacturers to prove that their manufacturing processes are satisfactory and repeatable. Every product must undergo successful process validation before it can be launched. (Camargo, Tr. 966-67; Koch, Tr. 270).
511. Impax’s practice is to begin process validation six months before FDA approval of the relevant drug is expected, even if the product is the subject of active litigation. (Koch, Tr. 269-70; CX3278 at 101 (Impax’s 2010 10-K report: “When the Company concludes FDA approval is expected within approximately six months, the Company will generally begin to schedule manufacturing process validation studies as required by the FDA to demonstrate the production process can be scaled up to manufacture commercial batches.”)).
512. Impax may build pre-launch quantities of the products in its planning pipeline before either FDA approval is granted or a formal launch decision is made. (CX3278 at

Initial Decision

101 (Impax's 2010 10-K report: "the Company may build quantities of pre-launch inventories of certain products pending required final FDA approval and/or resolution of patent infringement litigation, when, in the Company's assessment, such action is appropriate to increase the commercial opportunity, FDA approval is expected in the near term, and/or the litigation will be resolved in the Company's favor.")).

- 513. Impax generally builds pre-launch quantities of products because it takes months to build up launch inventory. (CX4030 (Hsu, Dep. at 42); Koch, Tr. 270-71).
- 514. Impax considers its production of pre-launch quantities "routine" and consistent with industry practice. (Koch, Tr. 271; CX3278 at 100-01).
- 515. By having pre-launch quantities ready, Impax is able to "increase the commercial opportunity" for its drugs and have the option of launching if the decision to launch is made. (CX3278 at 100-01; CX4030 (Hsu, Dep. at 86)).
- 516. Because Impax's operations team prepares products for launch before FDA approval or a formal decision about launch timing, it is not unusual for Impax to discard and write off some of the products and raw materials in its inventory. (Camargo, Tr. 1020-21, 1033 (discarding of products or materials was "a matter of course pretty much every month"); Koch, Tr. 273 (writing off and destroying product is a routine and "small cost" of doing business in the generic industry)).

**ii. Impax's launch preparedness efforts for
generic Opana ER**

- 517. Impax's operations team sought to be ready to launch its generic oxymorphone ER product at the expiration of the Hatch-Waxman Act's 30-month stay, June 14, 2010. (Mengler, Tr. 558; Engle, Tr. 1769).

Initial Decision

518. To meet a June 2010 launch date, Impax began planning oxymorphone ER production in 2009. (Camargo, Tr. 969).
519. The supply chain group created master data for oxymorphone ER in its ERP system to manage production capacity and materials planning and put oxymorphone ER on its product launch checklist to coordinate all launch-related activities. (Camargo, Tr. 1006).
520. In June 2009, the supply chain group acknowledged that the “odds of launching [oxymorphone in June 2010] when the 30-month stay expires may be low.” Mr. Camargo explained that “it didn’t seem likely to me that we would actually launch” in mid-2010 because the company “tended to shy away from” at-risk launches and oxymorphone ER would have been an at-risk launch given the ongoing litigation. (RX181; Camargo, Tr. 1009-10).
521. Impax undertook its normal launch preparations for oxymorphone ER to be prepared for a potentially “very lucrative” situation, even if the odds of an actual launch in June 2010 were low because the “upside [was] substantial and . . . we may want to plan for” it. (RX181; see Camargo, Tr. 1008-10).
522. Because oxymorphone, the API for generic Opana ER, is a controlled substance, purchasing oxymorphone is regulated by the DEA. (Camargo, Tr. 965; CX4027 (Anthony, Dep. at 13-14, 150-51)).
523. Impax requested a procurement quota from the DEA for oxymorphone, a necessary step before it could purchase oxymorphone API for any reason, including to conduct process validation of its oxymorphone ER product. (Camargo, Tr. 974, 1013).
524. Impax was initially allotted 9.0 kg (of anhydrous base) of procurement quota for oxymorphone for 2010 by the DEA. The initial allotment of oxymorphone quota was for product development manufacturing. (Joint Stipulations

Initial Decision

of Jurisdiction, Law, Fact, and Authenticity, JX-001-008 ¶ 24; CX4027 (Anthony, Dep. at 145-48)).

525. On January 18, 2010, Impax submitted a request for additional oxymorphone procurement quota to the DEA, which was approved. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX-001-008 ¶¶ 25-26).
526. On April 15, 2010, Impax submitted another request for additional oxymorphone procurement quota to the DEA, which was approved. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX-001-008-009 ¶¶ 27, 30).
527. Impax conducted process validation for oxymorphone ER in 2010. (Camargo, Tr. 1011-12).
528. Impax used a matrix approach for conducting process validation for its generic Opana ER product. A matrix approach to process validation takes less time, reduces the amount of product produced during the validation process, and ultimately reduces the costs incurred by Impax. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX-001- 009 ¶ 31; Camargo, Tr. 1012-13).
529. As of May 20, 2010, Impax had completed process validation for the 5 mg, 10 mg, 20 mg, and 40 mg dosages of generic oxymorphone ER. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX-001-008 ¶ 28).
530. The process validation batches that Impax had built were not sufficient to meet the market demand for a full launch. (Koch, Tr. 292-93).
531. As a general practice, after process validation is complete, the Impax operations team does not build launch inventory without management approval. (Camargo, Tr. 1015-16; RX186 at 0004).
532. In the case of oxymorphone ER, the Impax operations team never received instructions from senior management

Initial Decision

to begin a launch inventory build. (Camargo, Tr. 1016-17, 1020; CX2898-001 (internal Impax email from Mr. Camargo on May 12, 2010: “[W]e will not commence the launch inventory build until we receive direction to do so from senior mgmt.”); RX186 at 0004 (we “await management decision to proceed with 8-lot launch inventory build.”); Engle, Tr. 1778-79; RX323 at 0001 (internal Impax email from Mr. Engle on May 17, 2010: “There has been no decision yet to complete the launch build.”)).

533. Impax never actually completed a launch inventory build in support of an oxymorphone ER launch. (Camargo, Tr. 1020).
534. By May 28, 2010, Impax’s operations team had still not produced enough oxymorphone ER to support a product launch. (Engle, Tr. 1783; CX0006 at 001 (internal Impax email from Todd Engle, Impax’s vice president of sales and marketing for the generics division, to Impax’s operations team that Impax would need at least one additional lot of 20 mg and three additional lots of 40 mg oxymorphone ER to meet sales estimates for even one month of sales)).
535. Having less than one month’s worth of product would have prohibited a product launch because Impax would “rapidly run out of product, and most likely . . . would have started to incur penalties from [its] customers for not delivering on time.” (Engle, Tr. 1784-85).
536. The time required to produce the necessary amount of oxymorphone ER would have made a product launch soon after FDA approval in mid-June 2010 impossible. (Engle, Tr. 1780).
537. Impax had solicited letters of intent from four customers asking customers for their good faith estimate of how much product they likely would buy if generic oxymorphone ER came on the market, but Impax did not have any pricing contracts or agreements to purchase with

Initial Decision

those customers. (CX2868 at 001; CX2882; Engle, Tr. 1780-81, 1797-98).

538. Prior to the Endo-Impax Settlement, Impax's inventory included finished goods of generic oxymorphone ER, including three lots of 10 mg, as well as bright stock¹⁴ of generic oxymorphone ER, including three lots of 5 mg, one lot of 20 mg, and two lots of 40 mg dosage strengths. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX-001-009 ¶ 32).
539. Based on the cost of materials and labor, the total value of Impax's manufactured oxymorphone ER at the time of Endo-Impax Settlement was \$1,387,883. (Camargo, Tr. 994-95).
540. Following the Endo-Impax Settlement in June 2010, Impax accounted for the oxymorphone ER product as likely to be rejected because the product could not be used and the finished goods eventually were destroyed. (Camargo, Tr. 998; Koch, Tr. 273).
541. In June 2010, Impax also possessed oxymorphone API that had not been incorporated into any finished products which may have been used later to manufacture other products. (Camargo, Tr. 1022; CX2928 at 015).
542. Because Impax seeks to be prepared for all possible outcomes, discarding product "falls under the category of cost of doing business in weighing all your options." (CX4004 (Engle, IHT at 181); *see also* Engle, Tr. 1785-86 ("Throwing away product or discarding product in about a 1.5 million range happens frequently and it – it's not unusual."); Camargo, Tr. 1020-21, 1033 (discarding products or materials was "a matter of course pretty much every month"); Koch, Tr. 273 (discarding and writing off product is a routine and "small cost" of doing business)).

¹⁴ Bright stock is product that has been manufactured and placed in bottles, but has not been labeled yet. (Koch, Tr. 253).

Initial Decision

543. Impax wrote off over \$1 million worth of non-oxymorphone ER products in April 2010, and \$560,000 worth of non-oxymorphone ER product in June 2010. Impax also discarded and wrote off roughly \$25 million in finished product in 2017. (CX2905 at 003; CX2896 at 002-03; Camargo, Tr. 1023-24; Engle, Tr. 1786).

f. Economic disincentives

544. Had Impax launched a generic version of Opana ER at risk, Impax's potential liability for damages would have exceeded any profits Impax realized from the launch. (Addanki, Tr. 2379-80; F. 545-546).
545. Impax projected a total of \$28 million in potential oxymorphone ER sales over six months in 2010 following an at-risk launch. (CX2662 at 015).
546. Based on Endo documents indicating that at the time of the Endo-Impax Settlement Endo's Opana ER net sales were \$20 million per month and an assumption that Endo had a 90% profit margin on those sales such that Endo's profits were \$18 million per month, if Impax sold a month's worth of Opana ER at risk, and if Impax took 50% of Endo's sales, Impax could be risking as much as \$9 million per month or \$54 million for six months of sales. If Endo showed that Impax's infringement was willful and was awarded treble damages, Impax could be risking as much as \$162 million for six months of sales. (CX1106 at 005; Hoxie, Tr. 2784-92).
547. The 180-day exclusivity period starts from the day of launch. If Impax launched at risk and then was subsequently enjoined, the 180-day exclusivity period would continue to run and Impax would forfeit that part of the 180-day exclusivity period. (Addanki, Tr. 2380-81).
548. Because of these economic disincentives for an at-risk launch by Impax (F. 544-547), it "was perfectly reasonable for Impax to view a launch at risk as a losing proposition." (Addanki, Tr. 2380).

Initial Decision

g. Complaint Counsel's experts

549. Although Mr. Hoxie identified risks to Impax of an at-risk launch, he did not quantify the risk to Impax from an at-risk launch, conduct a risk-benefit analysis for an at-risk launch by Impax, or evaluate the magnitude of potential lost-profit damages that Impax would have faced if it launched at risk. (Hoxie, Tr. 2760, 2769-70, 2782-83, 2910).
550. Mr. Hoxie did not opine that an at-risk launch would have been a reasonable risk from Impax's perspective. (Hoxie, Tr. 2808).
551. Professor Noll, Complaint Counsel's economic expert, did not analyze Impax's economic incentives to determine whether it was economically rational for Impax to launch at risk. (Noll, Tr. 1601-02).
552. Professor Noll testified that an at-risk launch was a hypothetical possibility, but did not offer an opinion about whether Impax would have launched at risk or when it would have done so, and did not conduct any economic analysis to determine if a launch at risk would have been good, bad, or economically rational for Impax. (Noll, Tr. 1600-06).

3. Launch after litigation

553. At the time of the Endo-Impax Settlement, the outcome of the Endo-Impax patent litigation was uncertain. (RX548 (Figg Expert Report at 0030-31 ¶ 69)).
554. 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 (Hoxie Rebuttal Expert Report at 043 ¶ 79)).
555. If Impax and Endo had not entered into the Endo-Impax Settlement, the trial in the patent litigation would have continued. (Snowden, Tr. 400-01).

Initial Decision

556. Following a trial in the Endo-Impax patent litigation, the parties would have had to wait for the district court to issue findings of fact, conclusions of law, and an order. Based on a review of Hatch-Waxman cases from the district court of New Jersey conducted by Impax's patent litigation expert, Mr. Figg, a decision would have been issued approximately four to five months after completion of trial, in or around November 2010. (Figg, Tr. 1906-07, 2027-28).
557. Mr. Figg is an attorney specializing in intellectual property, primarily involving the chemical, pharmaceutical, healthcare and biotechnology industries. Mr. Figg has practiced patent law since 1978 and his principal emphasis is patent litigation. He has served as lead counsel in numerous complex patent litigation matters, including Hatch-Waxman litigation, in federal district court and the Federal Circuit Court of Appeals.. (Figg, Tr. 1810; RX548 (Figg Expert Report at 006-08 ¶¶ 6-10)).
558. Regardless of when the district court would have issued its decision in the Endo-Impax litigation, an appeal was likely, and would take 30 days to be docketed in the Federal Circuit Court of Appeals. (Figg, Tr. 1908).
559. Based on statistics maintained by the Federal Circuit and reviewed by Mr. Figg, the median time from docketing to final decision was approximately eleven months in 2010 and 2011. Applying these statistics, Mr. Figg estimated that an appellate decision in the Endo-Impax patent litigation would have been issued in November 2011. This estimate is "very conservative" because the median time from docketing to a final decision includes settlements and summary affirmances. (Figg, Tr. 1908-09).
560. The Federal Circuit is generous with briefing extensions, which increases the time it takes to receive a decision. (Figg, Tr. 1909-10).

Initial Decision

561. If Impax had lost at the trial level, the “centerpiece” of the appeal would have been the trial court’s claim construction ruling. Impax would have had “substantial arguments” regarding that ruling on appeal. (Figg, Tr. 1911-12; Hoxie, Tr. 2694).
562. If the appellate court agreed with Impax’s arguments regarding the district court’s claim construction, it is likely that the appellate court would remand to the trial court for further development of the evidentiary issues. This is because the parties would need to litigate infringement and validity under Impax’s construction of the claims. Because the trial court’s claim construction ruling was in favor of Endo, Endo never developed a record that Impax infringed its patents under Impax’s construction of the claims. Absent a record on the issue of infringement and validity, the Federal Circuit would not decide these issues itself, but would instead direct such decision to the trial court via remand. (Figg, Tr. 1912-13).
563. If the appellate court ruled in favor of Impax and remanded the case to the trial court, the evidentiary proceedings on remand would likely have taken up to 18 months to complete, and therefore would not be concluded until a date close to January 2013. (Figg, Tr. 1914-15, 1973).
564. If Impax had lost in the Federal Circuit, Impax would be enjoined and would not have been able to launch its oxymorphone ER product until the expiration of the patents in September 2013. (Figg, Tr. 1915, 1973).

E. Procompetitive Benefits**1. Broad license agreement**

565. 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, in order to provide Impax with as much flexibility as possible. In any negotiation where the brand

Initial Decision

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 155-58)).

566. For Impax, every “agreement has to cover all the patent[s], not just the patent [at issue] today, but cover all future patent[s] as well . . . [O]therwise you end up with [a] launch [of] the product and still have to be under the [patent] risk, and that doesn’t really help [Impax].” (CX4014 (Hsu, IHT at 116)).
567. The SLA contains a broad license agreement and a covenant not to sue that covered all patents “that would ever be owned by [Endo and Penwest] that would cover the Impax product, so the patents that existed at the time as well as future patents” were covered. (Snowden, Tr. 439; RX364 at 009).
568. Section 4.1(a) of the SLA grants Impax a license both to the “Opana ER Patents” (defined in the SLA as the ’933, ’456, and ’250 patents and any reissuances thereof) and to “any patents and patent applications owned by Endo or Penwest . . . that cover or could potentially cover the manufacture, use, sale, offer for sale, importation, marketing or distribution of products . . . that are the subject of the Impax ANDA . . .” (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-009-10 ¶ 35).
569. The Settlement and License Agreement identified “the patent applications (and any patents issued thereunder)” as the “Pending Applications.” (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-010 ¶ 36).
570. In section 4.1(b) of the SLA, Endo provided Impax with a covenant not to sue, which prohibited Endo and its affiliates from suing Impax for patent infringement on any of the patents licensed pursuant to section 4.1(a) (F. 568-

Initial Decision

569). This provision meant that Endo could not sue Impax for infringement of Endo's patents listed in the Orange Book at the time of settlement, as well as any continuations, continuations in part, or divisions of those patents, or patent applications owned or controlled by Endo that could cover the product described in Impax's ANDA for original Opana ER. (RX364 at 0010 (SLA); *see also* Figg, Tr. 1964; Hoxie, Tr. 2885).

2. Endo's additional patents and patent litigation

571. After entering into the SLA, Endo obtained additional patents and patent licenses that it has asserted cover both original and reformulated Opana ER (the "after-acquired patents"). (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-012 ¶ 55).
572. At the time of the Endo-Impax Settlement, some of the after-acquired patents (F. 571) were pending and it was uncertain whether any new patents would issue. (Snowden, Tr. 440, 442-43; CX3455 at 022-23).

a. The Johnson Matthey Patent

573. Endo acquired its first post-settlement patent – U.S. Patent No. 7,851,482 – from Johnson Matthey in March 2012 (the "Johnson Matthey patent"). (Snowden, Tr. 442-43; RX127; Addanki, Tr. 2362; Figg, Tr. 1949).
574. The Johnson Matthey patent addressed a process for making a purified type of oxymorphone and was issued in December 2010. (Snowden, Tr. 443; CX4017 (Levin, Dep. at 150-51); CX3329 at 006).

b. The '060, '122, and '216 patents and New York litigation

575. The Patent and Trademark Office issued U.S. Patent Nos. 8,309,060 and 8,309,122 to Endo on November 13, 2012 ("the '060 and '122 patents"). (Joint Stipulations of

Initial Decision

Jurisdiction, Law, Fact, and Authenticity, JX001-012 ¶ 56).

576. The Patent and Trademark Office issued U.S. Patent No. 8,329,216 to Endo on December 11, 2012 (“the ’216 patent”). (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-012 ¶ 57).
577. In December 2012, Endo began asserting the ’060, ’122, and ’216 patents against drug manufacturers seeking to market generic versions of both original and reformulated Opana ER. At that time, Endo did not assert these patents against Impax’s generic version of original Opana ER. Endo did, however, assert these patents against Impax’s generic version of reformulated Opana ER, as to which Impax had filed an ANDA. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-012-13 ¶ 58; Snowden, Tr. 440-41, 444-45).
578. In August 2015, the district court for the southern district of New York held that the ’122 and ’216 patents were not invalid and were infringed by other companies’ generic versions of original Opana ER and by generic versions of reformulated Opana ER, including Impax’s version of reformulated Opana ER. The court issued an injunction barring all defendants except Impax from selling their generic versions of original Opana ER until 2023. That ruling is currently on appeal to the Federal Circuit. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-013 ¶ 62; Snowden, Tr. 444-45).

c. The ‘737 and ‘779 patents and Delaware litigation

579. The U.S. Patent and Trademark Office issued U.S. Patent No. 8,808,737 to Endo on August 19, 2014 (“the ’737 patent”). (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-013 ¶ 59).
580. The U.S. Patent and Trademark Office issued U.S. Patent No. 8,871,779 on October 28, 2014 (“the ’779 patent”).

Initial Decision

(Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-013 ¶ 60).

581. Endo also acquired an exclusive field-of-use license to U.S. Patent No. 8,871,779 from Mallinckrodt. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-013 ¶ 61).
582. The '779 patent specifies the maximum levels of impurity that can be contained in the active pharmaceutical ingredient for generic Opana ER. (Figg, Tr. 1965).
583. Endo asserted the '737 and '779 patents in litigation in the district court of Delaware against drug manufacturers seeking to market both original and reformulated Opana ER. (Snowden, Tr. 450-51).
584. Endo did not assert these patents (F. 583) against Impax's generic version of original Opana ER because of the SLA's broad license provision, but did assert them with respect to Impax's ANDA for a generic version of reformulated Opana ER. (Snowden, Tr. 450).
585. In November 2015, the federal district court in Delaware held that the '737 patent was invalid. The ruling is currently on appeal to the Federal Circuit. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-013 ¶ 63).
586. In October 2016, the federal district court in Delaware held that the '779 patent was not invalid and was infringed by a generic version of reformulated Opana ER. That ruling is currently on appeal to the Federal Circuit. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-013 ¶ 64; see Snowden, Tr. 441).
587. In August 2017, the district court in Delaware ruled that the '779 patent was not invalid following a bench trial against certain ANDA filers. In September 2017, Judge Andrews entered a final order, enjoining all defendants from selling generic Opana ER until the patents expire in

Initial Decision

2029. (Second Set of Joint Stipulations, JX003 ¶¶ 56, 58; RX544; RX575).

588. The '779 patent expires in 2029. (Snowden, Tr. 451).

d. The Endo v. Impax New Jersey litigation

589. On May 4, 2016, Endo filed a lawsuit against Impax in federal district court in New Jersey, alleging that Impax was in breach of the SLA for failing to negotiate with Endo in good faith a royalty for three after acquired patents – the '122, '216 and '737 patents. Endo included claims for patent infringement in its complaint, predicated on the alleged breach and termination of the contract, which would have terminated Impax's license under the SLA. (CX2976; Figg, Tr. 2050-51).

590. On August 5, 2017, Endo and Impax resolved the New Jersey litigation (F. 589) regarding the breach of the SLA by entering into a Contract Settlement Agreement. (CX3275).

591. The August 5, 2017 Contract Settlement Agreement (F. 590) includes [REDACTED]. (CX3275 at 011-15, *in camera*).

3. Effect of the broad license agreement

592. The broad patent license and covenant not to sue provided in the SLA (collectively, the “broad patent license” or “broad license agreement”) gave Impax freedom to operate “[u]nder both the litigated patents as well as future patents that Endo might obtain in this area.” (Figg, Tr. 1936-37).

593. The broad license agreement in the SLA gave Impax protection against any future patents being asserted against Impax and potentially preventing continued sales of

Initial Decision

Impax's generic version of original Opana ER. (Addanki, Tr. 2376).

594. The January 2013 entry date and the broad license agreement in the SLA allowed Impax to launch its product eight months before the original patents expired and sixteen years before the after-acquired patents expired, and to "continue with the sale of that product right up to the present day because . . . Endo did not sue Impax for infringement of the second wave patents or the third wave patents for the original Opana ER product." (Figg, Tr. 1971-72; *see* Noll, Tr. 1674).
595. Although every other Opana ER ANDA filer settled patent claims asserted by Endo related to Opana ER, no other drug manufacturer negotiated rights to future Opana ER patents similar to the broad license agreement that Impax obtained in the SLA. (RX441; RX442; RX443; CX3192; *see* Snowden, Tr. 440; Figg, Tr. 1939-40, 1947; Hoxie, Tr. 2714, 2886).
596. Taken together, Endo's acquisition and litigation of additional patents (F. 575-588) has led to all generic manufacturers other than Impax being enjoined from selling a generic version of Opana ER until Endo's patents expire. Impax's product is the only generic Opana ER available to consumers. (Snowden, Tr. 440-42).
597. Impax has sold generic Opana ER without interruption since launching its product in January 2013. (Snowden, Tr. 476).
598. Impax's product is now the only oxymorphone ER product available to consumers. (Second Set of Joint Stipulations, JX003 ¶ 59; Figg, Tr. 1972).
599. Complaint Counsel's economic expert, Professor Noll, admits that consumers are better off today because Impax is selling oxymorphone ER. (Noll, Tr. 1669).

Initial Decision

600. The “real-world effect” of the SLA is that “there is a product on the market and available to consumers today that would not be there had Impax not had the foresight to negotiate licenses to future patents.” (Figg, Tr. 1975-76).

III. ANALYSIS

A. Overview of the Case

This is the FTC’s first administrative enforcement action challenging an alleged reverse payment patent settlement agreement since the Supreme Court’s decision in *FTC v. Actavis*, 133 S. Ct. 2223 (2013). A reverse payment settlement refers to when a patent holder sues another company for patent infringement and the patent litigation is settled with a payment from the patent holder to the claimed infringer and an agreement from the claimed infringer to stay out of the market until a certain date. *In re Lipitor Antitrust Litig.*, 2018 U.S. App. LEXIS 93, *5-6 (3rd Cir. Jan. 3, 2018). A distinguishing feature of a reverse payment settlement is that the period in which the patent challenger agrees to stay out of the market falls within the term of the patent at issue, when the patent holder would normally enjoy a government-conferred monopoly. *Id.* at *6. “[M]ost if not all reverse payment settlement agreements arise in the context of pharmaceutical drug regulation, and specifically in the context of suits brought under statutory provisions allowing a generic drug manufacturer (seeking speedy marketing approval) to challenge the validity of a patent owned by an already-approved brand-name¹⁵ drug owner.” *Actavis*, 133 S. Ct. at 2227.

Prior to 2013, the federal courts of appeal disagreed as to how to assess the legality of reverse payment settlement agreements. Some circuits followed the “scope-of-the-patent” test, which held that “absent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent.” *FTC v. Watson Pharms., Inc.*, 677 F.3d 1298, 1312 (11th Cir. 2012); accord *In re*

¹⁵ The terms “brand-name drugs,” “branded drugs,” or “brand drugs” are used interchangeably by the courts and the parties and in this Initial Decision.

Initial Decision

Ciprofloxacin Hydrochloride Antitrust Litig. (“Cipro”), 544 F.3d 1323, 1336 (Fed. Cir. 2008); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 212-13 (2d Cir. 2006). The Third Circuit, in *In re K-Dur Antitrust Litigation*, held that reverse payment settlement agreements were presumed unlawful, although the presumption could be rebutted by showing that the payment (1) was for a purpose other than delayed entry or (2) offered some pro-competitive benefit. 686 F.3d 197, 218 (3d Cir. 2012), *vacated by, remanded by Merck & Co. v. La. Wholesale Drug Co.*, 133 S. Ct. 2849 (2013), *Upsher-Smith Labs., Inc. v. La. Wholesale Drug Co.*, 133 S. Ct. 2849 (2013). The Supreme Court, in *FTC v. Actavis*, resolved the split in the circuit courts, holding that reverse payment patent settlements are not immune from antitrust scrutiny, anticompetitive effects should not be presumed from the presence of a reverse payment alone, and that reverse payment settlements are to be evaluated under the rule of reason, as more fully explained in Section III.B.2, below.

Antitrust inquiries “must always be attuned to the particular structure and circumstances of the industry at issue.” *Verizon Commc’ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 411 (2004). The distinctive features of the pharmaceutical industry provide the context for assessing the agreement challenged in this case.

1. The Hatch-Waxman Act

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 (the “Hatch-Waxman Act”) and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, 21 U.S.C. §§ 355(b)(2) and 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.

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. 21 U.S.C. § 355. Pursuant to the Hatch-Waxman Act, the FDA requires a company seeking to

Initial Decision

market a new pharmaceutical product to identify any patents that the company 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 titled, “Approved Drug Products with Therapeutic Equivalence Evaluations” (commonly known as the “Orange Book”). See *King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.*, 791 F.3d 388, 395 (3d Cir. 2015).

A company seeking to market a generic version of a branded drug may file an Abbreviated New Drug Application (“ANDA”) with the FDA. 21 U.S.C. § 355(j); *Actavis*, 133 S. Ct. at 2228. 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. *Id.* 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. *Id.* If a company makes a Paragraph IV certification, it must notify the patent holder of the filing of its ANDA. *King Drug*, 791 F.3d at 395 n.7.

If the brand-name drug company initiates a patent infringement suit within 45 days of an ANDA filing, the FDA must withhold approval of the generic drug for at least 30 months while the parties litigate the validity or infringement of the patent. *In re Lipitor Antitrust Litig.*, 868 F.3d 231, 241 (3d Cir. 2017), *cert. denied*, 138 S. Ct. 983, 984 (2018) (citing *Actavis*, 133 S. Ct. at 2228; 21 U.S.C. § 355(j)(5)(B)(iii)). If a court decides the infringement claim within this 30-month period, then the FDA will follow that determination. *Id.* However, if the litigation is still proceeding at the end of the 30-month period, the FDA may give its approval to the generic drug manufacturer to begin marketing a generic version of the drug. *Id.* The generic manufacturer then has the option to launch “at risk,” meaning that, if the ongoing court proceeding ultimately determines that the patent was valid and infringed, the generic manufacturer will

Initial Decision

be liable for the brand-name manufacturer's lost profits despite the FDA's approval. *Id.* (citing *King Drug*, 791 F.3d at 396 n.8).

The Hatch-Waxman framework grants the first company to file a Paragraph IV certification ("first filer") a 180-day period of market exclusivity, beginning on the first day of its commercial marketing. *Actavis*, 133 S. Ct. at 2229. The FDA may not grant final approval to any subsequent ANDA filer until the first filer's exclusivity period expires or is forfeited. *Id.* "If the first-to-file generic manufacturer can overcome any patent obstacle and bring the generic to market, this 180-day period of exclusivity can prove valuable, possibly 'worth several hundred million dollars.'" *Id.* (citation omitted).

Although the 180-day exclusivity period enables the first filer to sell its product without competition from other generic companies, it does not prevent the brand-name drug manufacturer from selling its own "authorized generic." *King Drug*, 791 F.3d at 393. An authorized generic, or "AG," is a non-branded version of a brand-name drug that is produced by the brand-name company itself. *In re Wellbutrin XL Antitrust Litig.*, 868 F.3d 132, 158 n.37 (3d Cir. 2017). Brand-name companies often introduce AGs to recoup some of the losses they face once a generic drug has entered the market. *See King Drug*, 791 F.3d at 405.

2. Generic drug competition

Generic drugs are unique sources of competition for their brand-name drug counterparts. *See New York v. Actavis PLC*, 787 F.3d 638, 655-56 (2nd Cir. 2015). Generic drugs that are "therapeutically equivalent" to their brand-name counterpart receive an "AB" rating from the FDA. 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. F. 14. A generic drug must also contain identical amounts of the same active ingredient(s) as the brand-name drug, although its inactive ingredients may vary. F. 14.

An AB-rated generic drug may be automatically substituted for the brand-name drug at the pharmacy counter. F. 29. All 50

Initial Decision

states and the District of Columbia have enacted laws that either permit or require a pharmacist to substitute an AB-rated generic drug for the brand-name drug, unless a physician directs or the patient requests otherwise. F. 29.

Generic manufacturers typically charge lower prices than branded drug sellers. F. 31 (The first one or two generic products are typically offered at a 10% to 25% discount to the branded product. Subsequent generic entry creates greater price competition, which typically leads to discounts between 50% to 80% off the brand price). Automatic substitution of the generic drug for the branded drug is the primary way that generic drug companies make their sales. F. 32. Because of the price advantages of generic drugs over branded drugs, many third-party payors 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. F. 30.

3. Endo-Impax patent litigation and settlement

The FTC's Complaint challenges the agreement entered into between Respondent Impax Laboratories, Inc. ("Impax" or "Respondent") and Endo Pharmaceuticals Inc. ("Endo") to settle patent litigation brought by Endo against Impax ("Endo-Impax patent litigation"). The Endo-Impax patent litigation arose in connection with Endo's branded product, Opana ER.

Opana ER is an extended release form of oxymorphone hydrochloride marketed for the relief of moderate to severe pain. F. 46. Endo's NDA for Opana ER was approved by the FDA in June 2006, and Endo launched the product the following month.¹⁶ F. 46-47. In October 2007, 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"). F. 51-53.

¹⁶ When Endo launched Opana ER in 2006, it only listed a single patent in the Orange Book as covering Opana ER, U.S. Patent No. 5,128,143 ("the '143 patent"). F. 49. The '143 patent was set to expire in September 2008. F. 50.

Initial Decision

In November 2007, Impax filed an ANDA seeking to market a generic version of Opana ER and submitted a Paragraph IV certification certifying that Endo's patents were not valid and/or would not be infringed by Impax's generic drug. F. 58-59. Impax was the first to file an ANDA for the 5, 10, 20, 30, and 40 milligram ("mg") dosage strengths of Opana ER. F. 173. Thus, Impax was entitled, upon obtaining FDA approval, to a 180-day period of exclusivity for those dosage strengths without competition from other ANDA filers. F. 174.

On January 25, 2008, Endo sued Impax, alleging that Impax's ANDA for generic oxymorphone ER infringed Endo's '456 and '933 patents. F. 61. This suit triggered the statutory 30-month stay, meaning that the FDA could not approve Impax's ANDA until the earlier of the expiration of 30 months or resolution of the patent dispute in Impax's favor. F. 62. The 30-month stay was set to expire on June 14, 2010. F. 63.

After Impax filed its ANDA, other generic companies, including Actavis South Atlantic LLC ("Actavis"), filed ANDAs seeking to market generic versions of Opana ER before the expiration of Endo's patents. F. 82, 84. Endo sued each ANDA filer for alleged patent infringement. F. 83, 85-86.

On May 13, 2010, a month before the 30-month stay was set to expire, the FDA granted tentative approval to Impax's ANDA. F. 63-64. Impax received final approval on the 5, 10, 20, and 40 mg dosage strengths of generic Opana ER on June 14, 2010, upon expiration of the statutory 30-month stay, and was granted final approval by the FDA for the 30 mg dosage strength on July 22, 2010. F. 66-67. Pursuant to the Hatch-Waxman framework, once Impax received final approval from the FDA, Impax had the option to launch its generic oxymorphone ER product "at risk." F. 66-67, 451-452.

On June 3, 2010, the trial in the patent litigation between Endo and Impax began. F. 73. The parties settled the patent litigation on June 8, 2010 by entering into two agreements: a Settlement and License Agreement ("SLA") and (2) a Development and Co-Promotion Agreement ("DCA") (collectively, the "Endo-Impax Settlement" or the "Challenged

Initial Decision

Agreement”). F. 74. The DCA was executed simultaneously with the SLA and is incorporated into the SLA. F. 75, 245.

In summary, pursuant to the SLA, Endo granted Impax a license to the '933, '456, and '250 patents, as well as any additional patents then pending or subsequently issued that could cover Impax's generic oxymorphone ER product (“licensed patents”), and Impax agreed not to launch its generic oxymorphone product before January 1, 2013. F. 124-125. Endo also agreed not to sue Impax for patent infringement with respect to any of the licensed patents. F. 126. In addition, Endo agreed in the SLA that Impax's license to sell generic Opana ER would be exclusive during Impax's 180-day first-filer exclusivity period, meaning that Endo agreed not to sell an authorized generic for Opana ER (in the five dosage strengths covered by Impax's ANDA) until Impax's 180-day exclusivity period ended (the “no-AG provision”). F. 127. Furthermore, pursuant to a provision titled “Endo Credit,” Endo would be obligated to make a cash payment to Impax in the event Endo's Opana ER dollar sales fell by more than 50% of their quarterly peak, prior to Impax's entering the market with its generic drug. F. 129. In addition, the SLA obligated Impax to pay Endo a 28.5% royalty on Impax's generic Opana ER sales during Impax's 180-day exclusivity period in the event that sales of Opana ER grew by a specific percentage. F. 128.

Under the DCA, Impax and Endo agreed to collaborate with respect to the development and marketing of a potential treatment for Parkinson's disease, IPX-203. F. 244, 246. Endo agreed to make an upfront payment to Impax of \$10 million and to make additional “milestone payments” for achieving specified milestone events in the development and commercialization of the product. F. 247-248. If the product was successfully commercialized, Endo would be entitled to a share of the profits resulting from prescriptions by non-neurologists. F. 250. While Endo agreed to take on some of the costs for the development of IPX-203, with a cap on its contributions based on accomplished milestones, Impax was responsible for all IPX-203 development work. F. 248, 365-366.

Initial Decision

B. Overview of Applicable Law**1. Introduction**

The Complaint charges that the Endo-Impax Settlement constitutes an agreement to restrain competition and is an unfair trade practice in violation of Section 5(a) of the FTC Act. Complaint ¶¶ 101, 102.¹⁷ The FTC Act’s prohibition of unfair methods of competition encompasses violations of Section 1 of the Sherman Act. *Cal. Dental Ass’n v. FTC*, 526 U.S. 756, 762 & n.3 (1999). “[T]he analysis under § 5 of the FTC Act is the same . . . as it would be under § 1 of the Sherman Act.” *Polygram Holding, Inc. v. FTC*, 416 F.3d 29, 32 (D.C. Cir. 2005); *see also FTC v. Indiana Fed’n of Dentists*, 476 U.S. 447, 451-52 (1986). Accordingly, Sherman Act jurisprudence is appropriately relied upon in determining whether challenged conduct violates Section 5 of the FTC Act. *Cal. Dental Ass’n*, 526 U.S. at 762 n.3; *Realcomp II, Ltd. v. FTC*, 635 F.3d 815, 824 (6th Cir. 2011).

Section 1 of the Sherman Act prohibits “[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States” 15 U.S.C. § 1.¹⁸ Despite its broad language, the ban on contracts in

¹⁷ Section 5(a)(2) of the FTC Act gives the Commission jurisdiction “to prevent persons, partnerships, or corporations . . . from using unfair methods of competition in or affecting commerce” 15 U.S.C. § 45(a)(2); *Kaiser Aluminum & Chem. Corp. v. FTC*, 652 F.2d 1324, 1327 n.2 (7th Cir. 1981). Respondent develops, manufactures, and markets pharmaceutical drugs. F. 3. Respondent is a corporation, as “corporation” is defined in Section 4 of the FTC Act, 15 U.S.C. § 44, and Respondent’s challenged activities relating to the sale of pharmaceutical drugs are in or affect commerce in the United States, as “commerce” is defined in Section 4 of the FTC Act, 15 U.S.C. § 44. F. 1-5. The parties have stipulated that the FTC has jurisdiction over the subject matter of this proceeding and over Respondent Impax. (Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity, JX001-002 ¶ 7). Thus, the Commission has jurisdiction over Respondent and the subject matter of this proceeding, pursuant to Section 5 of the FTC Act.

¹⁸ There is no dispute in this case that there was a contract, combination, or conspiracy. The patent litigation between Endo and Impax relating to Impax’s generic Opana ER was settled by agreement of the parties on June 8, 2010. F. 74. “[C]oncerted action may be amply demonstrated by an express agreement.” *United States v. Delta Dental*, 943 F. Supp. 172, 175 (D.R.I. 1996).

Initial Decision

restraint of trade extends only to unreasonable restraints of trade, i.e., restraints that unreasonably restrain competition. *State Oil Co. v. Khan*, 522 U.S. 3, 10 (1997).

**2. Antitrust scrutiny of reverse payment settlements:
*Actavis***

In *Actavis*, the Supreme Court held that reverse payment patent settlements are not immune from antitrust scrutiny, can sometimes violate the antitrust laws, and are to be evaluated under the rule of reason. By way of background, the FTC's complaint in *Actavis* had alleged that the defendants violated Section 5 of the FTC Act "by unlawfully agreeing 'to share in [the brand-name drug manufacturers'] monopoly profits, abandon their patent challenges, and refrain from launching their low-cost generic products to compete with [the brand-name drug] for nine years.'" *Actavis*, 133 S. Ct. at 2230 (citation omitted). The district court held that the allegations did not set forth an antitrust law violation, and dismissed the complaint. *In re Androgel Antitrust Litig.*, (No. II), 687 F. Supp. 2d 1371, 1379 (N.D. Ga. 2010).

On appeal by the FTC, the Court of Appeals for the Eleventh Circuit affirmed. *Watson Pharms.*, 677 F.3d 1298. The appellate court held that patent holders have a "lawful right to exclude others from the market," and that a patent "conveys the right to cripple competition." *Id.* at 1307, 1310 (internal quotation marks omitted). The appellate court further reasoned that the public policy in favor of settling litigation weighs against requiring parties to continue to litigate in order to avoid any antitrust liability. *Id.* at 1313-14. *See also e.g., Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1072 (11th Cir. 2005) (stating that "[t]he general policy of the law is to favor the settlement of litigation, and the policy extends to the settlement of patent infringement suits"); *Cipro*, 544 F.3d at 1333 (highlighting the "long-standing policy in the law in favor of settlements, . . . [which] extends to patent infringement litigation").

The Supreme Court reversed the lower court's dismissal of the FTC's complaint, holding that "reverse payment settlements . . .

Initial Decision

can sometimes violate the antitrust laws.” *Actavis*, 133 S. Ct. at 2227. It rejected the appellate court’s scope-of-the-patent test, reasoning that “to refer . . . simply to what the holder of a valid patent could do does not by itself answer the antitrust question. The patent . . . may or may not be valid, and may or may not be infringed.” *Id.* at 2230-31. Thus, even though a patent, if valid and infringed, would confer a right to charge supracompetitive prices and exclude competitors, this fact does not “immunize the agreement from antitrust attack.” *Id.* at 2230. Rather, “patent and antitrust policies are both relevant in determining the ‘scope of the patent monopoly’ – and consequently antitrust law immunity – that is conferred by a patent.” *Id.* at 2231. The question of antitrust legality can be answered by “considering traditional antitrust factors such as likely anticompetitive effects, redeeming virtues, market power, and potentially offsetting legal considerations present in the circumstances, such as here those related to patents.” *Id.* at 2231. Furthermore, the Supreme Court held that the fear “that antitrust scrutiny of a reverse payment agreement would require the parties to litigate the validity of the patent in order to demonstrate what would have happened to competition in the absence of the settlement,” should not be determinative. *Id.* at 2234.

The Court stated that “five sets of considerations lead [the Court] to conclude that the FTC should have been given the opportunity to prove its antitrust claim”: (1) reverse payment settlements have the “potential for genuine adverse effects on competition”; (2) such anticompetitive consequences “will at least sometimes prove unjustified”; (3) patent holders often possess market power; (4) litigating patent validity may not be necessary in order to determine whether a settlement is legal under antitrust laws, as “large and unexplained” reverse payment settlements indicate that the patent holder has doubts about the patent’s ability to withstand scrutiny; and (5) parties can still settle patent litigation, despite the risk of antitrust scrutiny, by avoiding reverse payment settlements. *Actavis*, 133 S. Ct. at 2234-37.

Regarding the “potential for genuine adverse effects on competition,” the Court explained that a reverse payment settlement can amount to “a purchase by the patentee of the exclusive right to sell its product, a right it already claims but

Initial Decision

would lose if the patent litigation were to continue and the patent were held invalid or not infringed by the generic product.” *Id.* at 2234. In such case, the patent holder loses any supracompetitive profits it would have obtained for the remaining life of the patent, which “then would flow in large part to consumers in the form of lower prices.” *Id.*

However, a settlement that provides a “payment in return for staying out of the market – simply keeps prices at patentee-set levels, . . . while dividing that return between the challenged patentee and the patent challenger.” *Id.* at 2234-35. In that instance, “[t]he patentee and the challenger gain; the consumer loses.” *Id.* at 2235. The Court was clear that the relevant anticompetitive harm potentially posed by reverse payment settlements is that the payment is used by the patent holder to avoid the risk of patent invalidation and the resulting generic competition that such patent invalidation would enable. *Id.* at 2236. *See also id.* (stating that the relevant “anticompetitive consequence” is the patent holder’s agreement to share supracompetitive profits with the patent challenger, “rather than face what might have been a competitive market . . .”).

In addition, the Court reasoned that a large and unexplained payment suggests that “the patentee has serious doubts about the patent’s survival.” *Id.* at 2236. The Court therefore rejected the notion that it would necessarily be required to litigate the validity of the patent in order to resolve the antitrust claim, stating that “the size of the unexplained reverse payment can provide a workable surrogate for a patent’s weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself.” *Id.* at 2236-37 (citing 12 *Areeda* ¶ 2046, at 350-52).

The Court summarized the considerations supporting antitrust scrutiny of reverse payment settlements as follows:

In sum, a reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects; one who makes such a payment may be unable to explain and to justify it; such a firm or individual may well possess market power derived from the patent; a court, by examining the size of the payment, may well be

Initial Decision

able to assess its likely anticompetitive effects along with its potential justifications without litigating the validity of the patent; and parties may well find ways to settle patent disputes without the use of reverse payments. In our view, these considerations, taken together, outweigh the single strong consideration – the desirability of settlements – that led the Eleventh Circuit to provide near-automatic antitrust immunity to reverse payment settlements.

Id. at 2237.

Finally, the Court expressly rejected the FTC’s argument that reverse payment settlement agreements “are presumptively unlawful and that courts reviewing such agreements should proceed via a ‘quick look’ approach, rather than applying a ‘rule of reason.’” *Id.* at 2237. “That is because 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.*

3. Rule of reason framework generally

Actavis holds that the rule of reason applies to evaluating the legality of a reverse payment settlement agreement. 133 S. Ct. at 2237. The rule of reason inquiry asks “whether under all the circumstances of the case the restrictive practice imposes an unreasonable restraint on competition.” *Arizona v. Maricopa County Med. Soc’y*, 457 U.S. 332, 343 (1982). A full rule of reason analysis may include an analysis of “the facts peculiar to the business, the history of the restraint, and the reasons why it was imposed.” *Realcomp*, 635 F.3d at 825 (citations omitted).

“‘[T]here is always something of a sliding scale in appraising reasonableness,’ [and] ‘the quality of proof required should vary with the circumstances.’” *Cal. Dental Ass’n*, 526 U.S. at 780 (quoting 7 Areeda ¶ 1507, at 402 (1986)); *Actavis*, 133 S. Ct. at 2237-38. *See also Cal. Dental Ass’n*, 526 U.S. at 781 (holding that rule of reason analysis looks to “the circumstances, details, and logic of a restraint”). As the Court indicated in *Actavis*, trial

Initial Decision

courts should “structure antitrust litigation so as to avoid, on the one hand, the use of antitrust theories too abbreviated to permit proper analysis, and, on the other, consideration of every possible fact or theory irrespective of the minimal light it may shed on the basic question – that of the presence of significant unjustified anticompetitive consequences.” *Actavis*, 133 S. Ct. at 2238.

Under the traditional burden-shifting framework of the rule of reason, the plaintiff bears the initial burden of proving that the challenged agreement “produced adverse, anti-competitive effects within the relevant product and geographic markets.” *United States v. Brown Univ.*, 5 F.3d 658, 668 (3d Cir. 1993). *See also Cipro*, 544 F.3d at 1331-32 (The first step in a rule of reason analysis is for the plaintiff to show that the challenged action has had an actual adverse effect on competition in the relevant market.); *Geneva Pharms. Tech. Corp. v. Barr Labs., Inc.*, 386 F.3d 485, 506-07 (2d Cir. 2004) (same).

The burden of proving anticompetitive effects in a traditional rule of reason case may be met by proving actual anticompetitive effects in the relevant market, or by “an indirect showing based on a demonstration of defendant’s market power, which when combined with the anticompetitive nature of the restraints, provides the necessary confidence to predict the likelihood of anticompetitive effects.” *In re Realcomp II, Ltd.*, 2009 FTC LEXIS 250, at *90 (Oct. 30, 2009) (citing *Tops Mkts., Inc. v. Quality Mkts., Inc.*, 142 F.3d 90, 96 (2d Cir. 1998) (plaintiff has “two independent means by which to satisfy the adverse-effect requirement” – direct proof of “actual adverse effect on competition” or “indirectly by establishing . . . sufficient market power to cause an adverse effect on competition”); *Law v. NCAA*, 134 F.3d 1010, 1019 (10th Cir. 1998) (“[P]laintiff may establish anticompetitive effect indirectly by proving that the defendant possessed the requisite market power within a defined market or directly by showing actual anticompetitive effects.”).

If the plaintiff meets its burden of demonstrating anticompetitive effects, the burden shifts to the defendant to prove procompetitive justifications for the challenged restraint. *Realcomp*, 635 F.3d at 825; *Polygram*, 416 F.3d at 36. “If the defendant is able to demonstrate procompetitive effects, the

Initial Decision

plaintiff then must prove that the challenged conduct is not reasonably necessary to achieve the legitimate objectives or that those objectives can be achieved in a substantially less restrictive manner.” *Law*, 134 F.3d at 1019. “Ultimately, if these steps are met, the harms and benefits must be weighed against each other in order to judge whether the challenged behavior is, on balance, reasonable.” *Id.* The plaintiff bears the overall burden of establishing that the challenged restraints “engendered a net harm” to competition in the relevant market. *Cal. Dental Ass’n v. FTC*, 224 F.3d 942, 957-58 (9th Cir. 2000).

4. Reverse payment cases

A number of courts have addressed the structure for a rule of reason analysis in the reverse payment context, but with somewhat inconsistent results. *In re Aggrenox Antitrust Litig.*, 199 F. Supp. 3d 662, 669 (D. Conn. 2016) (noting that “[v]arious district courts have struggled to fill the gaps that *Actavis* left open, and not always with consistent results.”) Moreover, these courts have opined on a rule of reason framework in the context of motions to dismiss and motions for summary judgment, but have not been called upon to apply the rule of reason to a complete evidentiary record developed after trial.¹⁹

The Court of Appeals for the Third Circuit described a rule of reason framework in *King Drug*, stating:

The *Actavis* Court provided initial guidance on how to structure rule-of-reason litigation in the reverse payment context. The Court explained that such antitrust questions must be answered “by considering traditional antitrust factors such as likely anticompetitive effects, redeeming

¹⁹ *In re Nexium (Esomeprazole) Antitrust Litigation*, which was a private cause of action, appears to be the first post-*Actavis* case to be submitted to a jury. See *Am. Sales Co., LLC v. AstraZeneca LP (In re Nexium (Esomeprazole) Antitrust Litig.)*, 842 F.3d 34, 39 (1st Cir. 2016). The appellate court’s review of the special verdict form provided to the jury does not clearly address the elements of a rule of reason analysis, for purposes of the instant case. *Nexium*, 842 F.3d at 50, 60 (holding that jury’s answers to special verdict form questions on market power, “large and unjustified” payment, and anticompetitive effects, indicated jury found an antitrust violation).

Initial Decision

virtues, market power, and potentially offsetting legal considerations present in the circumstances, such as here those related to patents.” *Actavis*, 133 S. Ct. at 2231.

First, to prove anticompetitive effects, the plaintiff must prove payment for delay, or, in other words, payment to prevent the risk of competition. “[T]he 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.” *Actavis*, 133 S. Ct. at 2237.

Second, the burden then shifts to the defendant to show “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.” *Id.* at 2235-36. The reverse payment, for example, may amount to no more than a rough approximation of the litigation expenses saved through the settlement. That payment may reflect compensation for other services that the generic has promised to perform – such as distributing the patented item or helping to develop a market for that item. There may be other justifications. *Id.* at 2236. The Court does not foreclose other justifications, and we need not decide today what those other justifications might be.

Finally, the plaintiff will have the opportunity to rebut the defendant’s explanation.

791 F.3d at 412. The court remanded to the district court “to proceed with the litigation under the traditional rule of reason, tailored, as necessary, to the circumstances of th[e] case.” *Id.*

In *In re K-Dur Antitrust Litigation*, 2016 U.S. Dist. LEXIS 22982 (D.N.J. Feb. 25, 2016), after examining *Actavis* and subsequent cases, the court adopted the following burden-shifting framework:

Initial Decision

“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”

Id. at *46 (quoting *In re Cipro Cases I & II*, 348 P.3d 845, 871 (Cal. 2015)). See also *K-Dur*, 2016 U.S. Dist. LEXIS 22982, at *44 (“[T]he burden must be on Plaintiffs to show that the settlement delayed the generic company’s entry onto the market, that the brand-name company paid the generic company consideration of some kind, and that the consideration exchanged in the settlement exceeded the estimated cost of litigation and the costs of other services and products, in order to establish a prima facie case.”).

The approach in *In re Nexium*, 42 F. Supp. 3d 231, 262-63 (D. Mass 2014), is somewhat similar to that of *K-Dur*. The court in *Nexium*, evaluating a motion for summary judgment, held that, for the initial burden, the plaintiff must present evidence that the brand-name manufacturer “made a payment to a generic manufacturer that exceeded anticipated future litigation costs, exceeded the costs of other services, and lacked ‘any other convincing justification.’” *Id.* at 262 (quoting *Actavis*, 133 S. Ct. at 2237). Once this showing is made, the burden then shifts to the defendant to show a justification for the payment, “such as avoided litigation costs or fair value for services” *Id.* (quoting *Actavis*, 133 S. Ct. at 2236). If the defendant justifies the payment, then “the burden shifts back to the [p]laintiff[] to

Initial Decision

establish, under the rule of reason, that the settlement is nevertheless anticompetitive on balance.” *Id.* at 262-63.

Incorporating elements of both *King Drug* and *Nexium*, the district court in *In re Loestrin 24 Fe Antitrust Litigation*, 261 F. Supp. 3d 307 (D.R.I. Aug. 8, 2017), held that the rule of reason in a reverse payment case is applied in a three-step process:

[A] plaintiff must first “prove anticompetitive effects,” by demonstrating “a payment for delay, or, in other words, payment to prevent the risk of competition.” *King Drug Co. of Florence v. Smithkline Beecham Corp.*, 791 F.3d 388, 412 (3d Cir. 2015) (“*Lamictal*”), cert. denied, 137 S. Ct. 446, 196 L. Ed. 2d 328 (2016) (citing *Actavis*, 133 S. Ct. at 2235-36). “[T]he 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.” *Actavis*, 133 S. Ct. at 2237. Second, if the plaintiffs satisfy the first step, “the burden then shifts to the [d]efendants to show that a challenged payment was justified by some precompetitive objective”; and third, “the burden shifts back to the [p]laintiffs to establish, under the rule of reason, that the settlement is nevertheless anticompetitive on balance.” *In re Nexium (Esomeprazole) Antitrust Litig.*, 42 F. Supp. 3d 231, 262-63 (D. Mass. 2014) (“*Nexium II*”).

Id. at 329.

The district court in *King Drug Company of Florence v. Cephalon, Inc.* (“*Cephalon*”), 88 F. Supp. 3d 402 (E.D. Pa. 2015), adopted a somewhat different approach. There, the court held that in order to meet the initial burden of proving anticompetitive effects, the plaintiff must demonstrate that the brand-name company made a “large” payment in the settlement agreement and that the brand-name company had market power. *Id.* at 414. The court held that, for purposes of avoiding summary judgment, a payment is sufficiently “large” if there is evidence that the payment exceeded saved litigation costs and a reasonable jury

Initial Decision

could find that the payment was significant enough to induce the generic company to stay off the market. *Id.* at 417. If the plaintiff meets this burden, the burden shifts to the defendant to demonstrate procompetitive justifications for the reverse payment. *Id.* at 416. The plaintiff “must then rebut those justifications and establish that the ‘restraint is not reasonably necessary to achieve the stated objective.’” *Id.* “If the plaintiff provides evidence to rebut the defendant’s justifications, the fact-finder will then weigh the anticompetitive and procompetitive effects, as in other rule of reason cases.” *Id.*

5. Contentions of the parties as to structure for rule of reason analysis

Complaint Counsel acknowledges that it has the initial burden of proving anticompetitive effects. CCB at 21. Complaint Counsel contends that it meets its initial burden by proving that Endo induced Impax to accept a share of Endo’s monopoly profits in exchange for staying out of the market. Complaint Counsel urges that this is demonstrated by proof that: (1) Endo made a large reverse payment to Impax; and (2) Endo possessed market power. CCB at 23-24, citing *Cephalon*. According to Complaint Counsel, if it proves a large payment and market power, the burden then shifts to Respondent to prove a “legitimate, cognizable justification” for the payment. CCB at 28. Complaint Counsel contends next that if Respondent fails to justify the reverse payment, the antitrust inquiry ends and the agreement is condemned. If Respondent justifies the reverse payment, according to Complaint Counsel, Complaint Counsel may prevail by showing that the reverse payment was not reasonably necessary to achieve the stated objectives, and only if Complaint Counsel fails to make this showing is there any weighing of anticompetitive and procompetitive effects.

Complaint Counsel further asserts that it has no obligation to show that the Challenged Agreement resulted in increased prices for consumers or other payors, or caused an actual delay in the onset of generic competition. Complaint Counsel argues that under *Actavis*, the relevant anticompetitive harm is paying the generic challenger to drop its patent challenge and stay out of the market, thereby avoiding the risk of competition from a finding of

Initial Decision

patent invalidation or non-infringement. Complaint Counsel further contends that such an agreement harms the competitive process.

Respondent contends that for Complaint Counsel to prove that the Challenged Agreement constitutes an unreasonable restraint under the rule of reason, Complaint Counsel must prove: (1) that the alleged reverse payment was both “large” and “unjustified”; (2) that Endo had monopoly power in a properly defined relevant market; (3) that the Challenged Agreement caused actual anticompetitive effects; and (4) that any alleged less restrictive alternative to the Challenged Agreement was actually feasible. Respondent further contends that the assessment of procompetitive justifications is not limited to justifications for the payment itself, but that the rule of reason considers procompetitive benefits arising from the Challenged Agreement as a whole. Moreover, Respondent asserts, in order to prevail, Complaint Counsel must prove that the asserted anticompetitive effects outweigh the procompetitive benefits.

6. Relevant market

In a traditional rule-of-reason case, the relevant market must be defined to allow a court “to determine the effect that an allegedly illegal act has on competition.” *Southeast Mo. Hosp. v. C.R. Bard, Inc.*, 642 F.3d 608, 613 (8th Cir. 2011); *see also Reifert v. S. Cent. Wis. MLS Corp.*, 450 F.3d 312, 320 (7th Cir. 2006).²⁰ However, several post-*Actavis* cases have evaluated anticompetitive effects of reverse payment agreements without a separate determination of the relevant market. *E.g.*, *King Drug*, 791 F.3d at 410 (describing the “market the agreement is said to have protected”); *Wellbutrin*, 868 F.3d 132 at 165 (no mention of relevant market other than stating that the branded drug company’s patent prevented market entry by the generic); *Lipitor*, 868 F.3d at 250, 258 (referring only to the “patentee’s market”).

²⁰ An antitrust market is comprised of a relevant geographic market and a relevant product market. *Brown Shoe Co. v. United States*, 370 U.S. 294, 324 (1962). The parties have stipulated that the relevant geographic market is the United States. Joint Stipulations of Jurisdiction, Law, and Fact, and Authenticity, JX001-002 ¶ 10.

Initial Decision

As explained in *In re Cipro Cases I & II*, although “[p]roving that a restraint has anticompetitive effects often requires the plaintiff to “‘delineate a relevant market and show that the defendant plays enough of a role in that market to impair competition significantly,’” i.e., has market power [P]roof of a sufficiently large payment is a surrogate” in reverse payment settlement cases. 348 P.3d at 869 (citations omitted).

In *King Drug*, the Court of Appeals for the Third Circuit, after stating that *Actavis* explained that antitrust questions must be answered “‘by considering traditional antitrust factors such as likely anticompetitive effects, redeeming virtues, market power, and potentially offsetting legal considerations present in the circumstances, such as here those related to patents,’” *Actavis*, 133 S. Ct. at 2231, laid out its own rule of reason framework to use in a reverse payment case. *King Drug*, 791 F.3d at 412. Nowhere in the *King Drug* framework for determining the likelihood of anticompetitive effects, summarized above, does the appellate court direct the district court to define the relevant market. *Id.* Instead, it invited the district court to “proceed with the litigation under the traditional rule of reason, tailored, as necessary, to the circumstances of this case.” *Id.* at 412.

As stated by one district court in a reverse payment settlement case, evidence of market power will be available “even without an express articulation of the relevant market definition.” *Aggrenox Antitrust Litig.*, 199 F. Supp. 3d at 665.²¹ “[A]s a practical matter, the only ‘relevant’ market in this case, and in similar cases brought under *FTC v. Actavis*, will be the market in which the challenged settlement agreement allegedly acted as an anticompetitive restraint: that is, in this case, it will be implicitly defined by the scope of the disputed patent.” *Id.* at 665-66. It is also noteworthy that while *Actavis* itself did not expressly identify the relevant market, it did refer to patent settlements as “allowing

²¹ The district court certified the ruling regarding the relevance of evidence pertaining to the substitutability of other drugs for the product at issue for interlocutory appeal. *Aggrenox*, 199 F. Supp. 3d at 670. The court of appeals declined to provide interlocutory review. *In re Aggrenox Antitrust Litig.*, Case 3:14-md-02516-SRU (2nd Cir. Jan. 9, 2017).

Initial Decision

the generic manufacturer to enter *the patentee's market*.” *Actavis*, 133 S. Ct. at 2237 (emphasis added).

Thus, in the context of a settlement of patent litigation arising under the peculiar framework of the Hatch-Waxman Act, which promotes generic competition and facilitates patent challenges, and where a valid patent gives the brand holder a legal monopoly, the appropriate market in which to assess the anticompetitive effects of a reverse payment settlement agreement is the market that is the subject of that agreement – the branded pharmaceutical product and its generic equivalents. Accordingly, in the instant case, the relevant market is the market for oxymorphone ER, branded and generic, which is the market that mattered to Impax and Endo, the parties to the Challenged Agreement.

7. Conclusion

Having fully considered *Actavis*, subsequent court decisions, and the parties’ arguments, the rule of reason analysis to be applied in the instant case will proceed as set forth below.

First, in order to determine whether the evidence shows any anticompetitive effect in connection with the Challenged Agreement, the analysis will determine whether the Endo-Impax Settlement provided “payment for delay, or, in other words, payment to prevent the risk of competition.” *King Drug*, 791 F.3d at 412. The analysis will consider direct evidence from the parties’ settlement negotiations, as well as inferences reasonably drawn from the payment’s “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.” *Actavis*, 133 S. Ct. at 2237; *King Drug*, 791 F.3d at 412. See Aaron Edlin, *The Actavis Inference*, 67 Rutgers U. L. Rev. 585, 587, 592 (2015) (stating that under *Actavis*, a “reasonable inference of harm to consumers from lessened competition . . . can be established by identifying a large and otherwise unexplained payment of cash or something else of value made by the patent holder to the alleged infringer in exchange for that firm’s agreement not to enter the market for some period of time. . . . [An antitrust plaintiff may also] prove by direct evidence that “the patent holder paid the alleged infringer to

Initial Decision

delay its entry into the market and thereby restrict competition . . . e.g., if there is other contemporaneous evidence indicating that the purpose and effect of a reverse payment was to delay entry.”).

The formulation of the initial burden set forth in *Cephalon*, upon which Complaint Counsel relies, to the extent it holds that anticompetitive effects can be demonstrated solely by proof of a large payment and market power, has not been adopted by any other court²² and presents an unduly truncated burden of proof. See *Actavis*, 133 S. Ct. at 2238 (noting that trial courts should avoid “the use of antitrust theories too abbreviated to permit proper analysis”). *Realcomp* states that the rationale for substituting proof of market power for proof of actual anticompetitive effects is that proof of market power “when combined with the anticompetitive nature of the [challenged] restraints, provides the necessary confidence to predict the likelihood of anticompetitive effects.” 2009 FTC LEXIS 250, at *90. However, *Actavis* does not hold that a “large” reverse payment is anticompetitive “by nature.” Rather, it is a large *and unjustified* reverse payment that “can bring with it the risk of significant anticompetitive effects.” *Actavis*, 133 S. Ct. at 2237 (emphasis added). Furthermore, in the context of a reverse payment patent settlement, proof of market power adds little in the way of burden because, as explained further in Section III.D. below, a large payment is already a strong indicator of market power.²³ *Actavis*, 133 S. Ct. at 2236. Accordingly, the formulation of the initial burden set forth in *Cephalon* is rejected.

For the second step of the rule of reason inquiry, the analysis will consider evidence of procompetitive effects arising from the Endo-Impax Settlement. Consistent with the traditional rule of reason framework, the burden of proving such effects is properly placed on Respondent. *Realcomp*, 635 F.3d at 825; *Polygram*,

²² Although the Third Circuit in *King Drug* cited the *Cephalon* case in a footnote, it is unclear for what proposition. Furthermore, *King Drug*’s articulation of the initial burden of proving anticompetitive effects is clearly different than that set forth in *Cephalon*.

²³ It is noteworthy that market power was not even at issue in *Cephalon*, as the defendants there had “not challenged [p]laintiffs’ ability to demonstrate market power.” *Cephalon*, 88 F. Supp. 3d at 419.

Initial Decision

416 F.3d at 36 (holding that if the plaintiff meets its burden of demonstrating anticompetitive effects, the burden shifts to the defendant to prove procompetitive justifications for the challenged restraint).

Complaint Counsel's position that the only relevant procompetitive justifications are those that justify the reverse payment, thereby barring all other evidence of procompetitive benefits from the settlement and condemning the settlement on the basis of the reverse payment alone, is inconsistent with *Actavis* and the rule of reason generally. *Actavis* expressly identified "redeeming virtues" of a patent settlement as among the "traditional antitrust factors" that can be considered in evaluating antitrust legality. *Actavis*, 133 S. Ct. at 2231. See also *K-Dur*, 2016 U.S. Dist. LEXIS 22982, at *46 ("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 . . ."); see also *In re Impax Labs, Inc.*, 2017 FTC LEXIS 130, at *29-32 (Oct. 27, 2017) (refusing to bar evidence and argument concerning post-settlement events). Focusing only on the reverse payment, without any consideration of offsetting procompetitive benefits arising from the settlement, conflates the initial burden of proving anticompetitive effects with the ultimate burden of proving that an agreement is, on the whole, an unreasonable restraint of trade. The "restraint" in a reverse payment settlement agreement is not the payment alone, but the use of the payment to restrain potential generic competition. Simply put, to condemn an agreement based on the reverse payment term alone is an approach that is "too abbreviated to permit proper analysis." *Actavis*, 133 S. Ct. at 2238.

Third, the analysis will consider whether the evidence proves that the demonstrated procompetitive benefits of the Endo-Impax Settlement could have been achieved with a less restrictive agreement.

Fourth, the analysis will weigh the demonstrated anticompetitive effects against the demonstrated procompetitive

Initial Decision

effects to determine whether the Challenged Agreement is anticompetitive on balance. Such balancing properly considers the extent to which the Endo-Impax Settlement delayed generic competition. See *Impax Labs*, 2017 FTC LEXIS 130, at *29. As recognized in *In re Cipro Cases I & II*, under *Actavis*, “the relevant benchmark in evaluating reverse payment patent settlements should be no different from the benchmark in evaluating any other challenged agreement: What would the state of competition have been without the agreement?” 348 P.3d at 863.

The analysis now turns to the application of the foregoing principles to the record in this case.

C. Anticompetitive Harm

Actavis explains that a brand patent holder’s use of a payment to induce a generic challenger to drop its patent challenge and agree to stay out of the market, rather than face the risk of patent invalidation and resulting generic competition, is an anticompetitive harm. *Actavis*, 133 S. Ct. at 2236 (for shorthand purposes, alternatively referred to as payment to “prevent” or to “eliminate” the risk of competition). See also *King Drug*, 791 F.3d at 403 (holding that, under *Actavis*, harm occurs when the payment’s objective is to maintain supracompetitive prices to be shared among the patentee and the challenger, rather than face what might have been a competitive market). Complaint Counsel has the initial burden of proving anticompetitive harm which, as noted above, in the reverse-payment context, means the burden of proving that the Endo-Impax Settlement included payment to prevent the risk of competition. Complaint Counsel has met this initial burden, as explained below.

1. Economic theory of anticompetitive harm

A basic economic principle is that consumers benefit from increased competition in the form of lower prices and increased choice. F. 440. Harm to competition is not limited to the certain elimination of competition, but also includes eliminating the possibility that participants on the other side of the market will

Initial Decision

have the opportunity to experience the benefits of competition, such as lower prices. F. 441.

Normally, when a generic drug manufacturer launches a generic version of a branded drug, the competition between the brand-name firm and the generic firm causes the price of the drug to drop, which is a benefit to consumers. F. 442. Reverse payment settlements can harm consumers, to the extent that, by requiring the generic company to forego the possibility of entering at an earlier date, the settlement extends the period in which the brand-name manufacturer is the only seller of a drug. F. 442.²⁴ Moreover, a large reverse payment can imply that the market entry date in the settlement agreement is later than the date that the patent holder expected the alleged patent infringer to enter the market. This is based on the theory that it is unlikely that a patent holder would agree by settlement to pay an alleged patent infringer anything more than saved litigation costs, only to obtain entry on the date the alleged patent infringer would have entered anyway. F. 446.

A reverse-payment settlement replaces the possibility of entry by the generic drug with the certainty that generic competition will not occur prior to an agreed date. F. 443. To this extent, the brand-name firm is buying an insurance policy, by which it pays the generic company a premium in exchange for the generic firm's guaranteeing it will not compete prior to the date specified in the settlement. F. 443. Payment to an alleged infringer, in exchange for a certain entry date, converts the possibility of substantial loss of profits for the patent-holder, due to generic competition, into the certainty that the brand manufacturer will continue to earn profits as the sole seller of the drug, until the agreed entry date set by the settlement. F. 444. By eliminating the possibility of generic competition for a period of time, reverse-payment settlements interfere with the competitive process and can harm consumers by depriving them of the possible benefits of increased competition in the period prior to the entry date provided under the settlement. F. 445.

²⁴ This theory of economic harm assumes that issues of patent validity and/or infringement were pending and unresolved at the time of settlement.

Initial Decision

A brand-name pharmaceutical firm has an economic incentive to pay the generic firm as part of a settlement, to the extent that the payment is less than the profits the brand firm would earn during the period before the agreed-upon generic entry date. F. 447. A generic pharmaceutical firm also has an economic incentive to enter into reverse-payment settlements. F. 448. While the generic firm stands to lose profits it would have earned by launching prior to the agreed-upon date, a sufficiently large payment can compensate for that loss and thereby induce the generic company to forego the opportunity to launch earlier than the agreed-upon date. F. 448.

2. Size of the payment**a. Applicable legal principles**

Under *Actavis*, the size of the reverse payment is central to the antitrust inquiry, and therefore the reviewing court or factfinder must measure the value of the payment. *Rochester Drug Co-Operative, Inc. v. Warner Chilcott Co. (In re Loestrin 24 Fe Antitrust Litig.)*, 814 F.3d 538, 551-52 (1st Cir. 2016). While *Actavis* refers to “large” and “unexplained,” or “unjustified,” payments as being material to the evaluation of a reverse payment settlement, the Court did not specify what makes a payment “large.” *Cephalon*, 88 F. Supp. 3d at 416 (“*Actavis* did not identify any specific formula for determining whether a reverse payment is sufficiently large.”).

The fact-finder must determine the value of the reverse payment in order to determine the payment’s size. *Loestrin*, 814 F.3d at 551-52. Valuing the payment is particularly important in the case of non-cash payments, such as the no-AG provision challenged in the instant case. Although it is settled that *Actavis* applies to non-cash payments, *see, e.g., King Drug*, 791 F.3d at 403; *Loestrin*, 814 F.3d at 549-50, there must be a reliable calculation of the payment’s value. *Lipitor*, 868 F.3d at 255 (upholding complaint based on plausible allegations that non-monetary payment was worth “hundreds of millions of dollars,” noting that “more detailed, advanced calculations related to those allegations” come later in the proceeding); *In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d 224, 244 (D. Conn. 2015).

Initial Decision

(“[C]ourts interpreting *Actavis*, while holding that reverse ‘payments’ are not limited to cash transfers, have observed the importance of the court’s ability to calculate the value of any nonmonetary payments . . .”). Furthermore, the value of the payment must be assessed at the time the parties entered into the settlement. *Loestrin 24 Fe Antitrust Litig.*, 261 F. Supp. 3d at 337 (“The deal must be valued at the time the parties entered the deal . . .”).

In addition, the size of a reverse payment is properly determined by considering the total compensation provided under the settlement, as a whole, rather than examining each component of the settlement in a piecemeal fashion. *Loestrin*, 261 F. Supp. 3d at 331. See also *In re Opana ER Antitrust Litig.*, 162 F. Supp. 3d 704, 718 (N.D. Ill. 2016) (refusing to assess components of the settlement in a “piecemeal fashion” to determine whether “each individual payment fails to rise to the level of a large and unjustified payment” in favor of “determin[ing] whether, when taken as a whole, the total payment . . . was large and unjustified”). This is particularly true where, as here, the Challenged Agreement consists of both the SLA and the DCA, executed the same day. See *In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735, 752 (E.D. Pa. 2014) (“[D]efendants may not improperly ‘dismember’ [the complaint] by examining each of the three settlement agreements in isolation. Rather, the Licensing Agreement must be read in conjunction with the Co-Promotion and Manufacturing Agreements executed that same day.”).

The fact that a payment exceeds saved litigation costs is a relevant benchmark in assessing whether a payment is “large,” but it is not dispositive. Even if a payment exceeds saved litigation costs, “the *Actavis* factors – the size of the payments, their scale in relation to litigation costs, their independence from other services for which they might be fair consideration, and any other convincing justification – still matter.” *Aggrenox*, 94 F. Supp. 3d at 243.

Actavis noted that a large payment may provide “strong evidence that the patentee seeks to induce the generic challenger to abandon its claim with a share of its monopoly profits” 133 S. Ct. at 2235. Interpreting *Actavis*, a number of courts have

Initial Decision

considered whether the payment induced the patent challenger to drop its patent challenge and stay out of the market until the agreed date. *See King Drug*, 791 F. 3d at 411 (upholding allegations of anticompetitive harm, noting that the promise of no authorized-generic competition during the generic's 180-day exclusivity period was alleged to have induced the generic to drop the patent challenge and thereby enabled the brand to avoid the risk of patent invalidation); *Loestrin*, 814 F.3d at 550 (holding that *Actavis* applies to payments that "induce the generic to abandon a patent challenge"). *See also Cephalon*, 88 F. Supp. 3d at 417 (holding that, in addition to considering whether a payment exceeded saved litigation costs, determination of "large" payment must also consider whether the payment was sufficiently large to induce the generic to forfeit its claim and agree to stay off the market).

With the foregoing principles in mind, the analysis now assesses the value of the reverse payment provided under the Endo-Impax Settlement.

b. Valuation

The Endo-Impax Settlement provided a cash payment in the amount of \$10 million, pursuant to the terms of the DCA. F. 247. In addition to the \$10 million cash payment under the DCA, pursuant to the terms of the SLA, as further explained below, the Endo-Impax Settlement included a non-cash payment, in the form of a no-AG provision, under which Endo agreed not to compete with Impax during Impax's 180-day exclusivity period by launching an authorized generic. In addition, the Endo-Impax Settlement provided Impax with security for the value conveyed by the no-AG provision in the form of the Endo Credit.

i. No-AG provision

Impax was the first company to file an ANDA with Paragraph IV certifications for the 5, 10, 20, 30, and 40 mg dosage strengths of oxymorphone ER. F. 58. As the first filer on these dosages, Impax would be entitled to a 180-day exclusivity period as to the five most popular dosages of Opana ER, comprising 95% of Endo's Opana ER sales. F. 173-174. However, Impax's 180-day

Initial Decision

exclusivity period was not a bar to Endo's launching an authorized generic during that exclusivity period because the Hatch-Waxman Act does not prevent a brand-name drug company from launching an authorized generic. F. 21-22, 176. At the time Endo and Impax reached a settlement of their patent litigation, Impax did not know whether or not, absent the settlement, Endo would launch an authorized generic. F. 186. The no-AG provision guaranteed to Impax that Impax would be the only seller of generic Opana ER during its first 180 days on the market and would not face competition from an Endo authorized generic. F. 187.

The no-AG provision was valuable to Impax. Impax would generally seek a no-AG provision as part of a settlement agreement with a brand-name drug manufacturer. F. 182. Indeed, along with obtaining the earliest possible entry date, a no-AG agreement is among the more important things that Impax would seek in a negotiation. F. 183. A first-filer generic manufacturer makes a substantial portion of its profits during the 180-day exclusivity period, 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. F. 172.

Impax witnesses acknowledged that the absence of an authorized generic means more control for the generic company, which can often lead to higher profits for the generic company. F. 182. Conversely, the introduction of an authorized generic during the exclusivity period reduces the value of the 180-day exclusivity period, by causing lower prices and fewer sales for the first filer. F. 172. Specifically, as Impax witnesses testified, an authorized generic competitor during the 180-day exclusivity period generally results in a price decrease of approximately 30 to 35%, and reduces the generic company's share of generic sales. F. 177. Impax executives estimated that if Endo launched an authorized generic when Impax entered the market, Endo's authorized generic would capture as much as half of the sales of generic Opana ER and cause substantially lower generic prices during the exclusivity period than would be the case if Impax was the only generic seller. F. 181.

Initial Decision

In May 2010, Todd Engle, of Impax's sales and marketing team, prepared an analysis that projected lost profits in the amount of \$24.5 million if an Endo AG entered within two to four weeks after Impax's launch of generic oxymorphone ER. F. 191. In addition, in 2010, Impax forecasted the effect of an Endo AG on Impax's expected generic sales. F. 189. In what Impax referred to as the "upside" scenario, Impax assumed that Endo's authorized generic Opana ER would enter the market about two months after Impax's launch of generic Opana ER. F. 189. Under the upside scenario, Impax's share of generic sales was estimated to fall to 60% and Impax's average price was estimated to fall by 36%. F. 189. In what Impax referred to as its "base" scenario, Impax assumed that Endo's authorized generic Opana ER would enter the market simultaneously with Impax. Under the base scenario, it was estimated that Endo would capture half of the market and that prices would fall by the same 36%. F. 189.

Employing the figures from Impax's 2010 forecasts, Complaint Counsel's economic expert witness, Professor Roger Noll, calculated that: (1) under Impax's upside scenario, market entry by an authorized generic during Impax's 180-day exclusivity period would cause Impax's revenues to fall by approximately \$23 million; and (2) under Impax's base assumptions, market entry by an authorized generic during Impax's 180-day exclusivity period would cause Impax's revenues to fall by approximately \$33 million. F. 190.

Respondent contends that, notwithstanding the value to Impax, the no-AG provision had little value to Endo because Endo offered the no-AG agreement as part of its initial settlement offer to Impax. *See* F. 131. However, this fact does not compel the inference that the no-AG agreement was worthless to Endo. Moreover, evidence contemporaneous to the parties' negotiations shows that Endo estimated that, if Impax launched at risk, Endo could recoup \$25 million in lost revenues by launching an authorized generic to compete with Impax. F. 192; *see also* F. 175.

Respondent also contends that it was not guaranteed to receive the value of the no-AG agreement because Endo was planning to reformulate Opana ER and remove original Opana ER from the

Initial Decision

market, which could render the no-AG agreement illusory and potentially defeat Impax's generic market opportunity entirely. However, the evidence shows that Endo agreed to compensate Impax for this possibility, and to insure the value of the no-AG provision, by agreeing to the Endo Credit, as further explained in subsection 2.b.ii below.

Based on the foregoing, the no-AG provision in the SLA was worth between \$23 and \$33 million in projected sales revenue to Impax at the time Impax entered into the SLA. F. 193. By agreeing not to compete with Impax through launching an authorized generic, Endo was promising to provide Impax with a monopoly on generic sales of Opana ER during Impax's 180-day exclusivity period, which would enable Impax to charge a higher price for generic Opana ER compared to a market that had two companies selling generic products. F. 187-189, 191. *See also* F. 190 (expert opinion that the no-AG provision provided substantial value to Impax when the SLA was executed by ensuring that Impax would face no generic competition during its 180-day exclusivity period and would thereby earn greater profits on its generic sales).

ii. Endo Credit

Under section 4.4 of the SLA, titled "Endo Credit," Endo agreed to make a cash payment to Impax in the event that Endo's Opana ER sales fell by more than 50% from the "Quarterly Peak" (defined as the highest sales quarter between the third quarter of 2010 and the third quarter of 2012) to the fourth quarter of 2012 (the last quarter before the agreed generic entry date of January 2013). F. 195. The formula for calculating the Endo Credit incorporates a number of factors that relate to Impax's sales of generic Opana ER, multiplied by the market opportunity for the generic product in the quarter of peak sales. F. 196. Specifically, the agreement relies on Impax's "Market Share Profit Value," defined 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

Initial Decision

Opana ER during the period from the third quarter of 2010 to the third quarter of 2012, divided by 100.²⁵ F. 196.

(a) Purpose of Endo Credit

As further explained below, the intent and the design of the Endo Credit were to provide Impax with a payment approximating the profits Impax would lose if, during the two and a half year time period between the June 2010 settlement and the agreed January 2013 Impax entry date, Endo launched a reformulated version of Opana ER in such a way as to substantially eliminate the market for original Opana ER. In this scenario, Impax stood to lose the value of its 180-day exclusivity period, including the generic monopoly during this period that Endo promised to Impax in the no-AG provision. The Endo Credit was designed to make Impax whole for this potential loss. To understand the role of the Endo Credit in the reverse payment conferred to Impax under the Endo-Impax Settlement, a review of the parties' negotiations is helpful.

Endo sent Impax an initial term sheet for the SLA on May 26, 2010. F. 131. The initial term sheet for the SLA included, among other things, a no-AG provision and a generic entry date of March 2013. F. 131-132. Impax accepted the no-AG offer, but counter-offered a generic entry date of January 1, 2013, plus "certain acceleration triggers, including market degradation to any alternate product." F. 136-137. An acceleration trigger for market degradation would have allowed 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. F. 138.

Impax wanted a market acceleration trigger as "protection in case Endo had any intentions of moving the market to a next-generation product." F. 139. Impax had included similar provisions in other patent settlements with brand companies. F. 139. Although Impax did not have specific information about

²⁵ Although in 2013, the Endo Credit formula yielded a payment to Impax in the amount of \$102 million, this is not the appropriate measure of the value of the Endo Credit, for the reasons explained in subsection b.ii.(c) below.

Initial Decision

Endo's plans to reformulate Opana ER, Impax had seen analyst reports suggesting that Endo was working on crush-resistant drugs generally.²⁶ F. 140-141. Impax was aware that the FDA had been encouraging opioid manufacturers to make opioids tamper-resistant, which companies were accomplishing primarily by manufacturing tablets that could not be crushed. F. 142. Impax was also aware that Purdue Pharma, L.P., the manufacturer of the brand-name drug OxyContin, had introduced a reformulated, crush-resistant version of its product and was withdrawing its original formulation. F. 143.

Pharmacists are allowed or sometimes required to dispense an AB-rated generic version of a drug instead of the more expensive branded drug, unless a physician directs or the patient requests otherwise. F. 29. Automatic substitution of the generic drug for the branded drug is the primary way that generics make their sales. F. 32. When brand companies introduce a reformulated drug, they often cease marketing and selling the original product. F. 198. They can also withdraw the original product's reference-listed drug designation, preventing generic products from having AB-rated status. F. 198. By introducing a reformulated drug, the brand company can greatly reduce the ability of generic companies to sell generic versions of the original drug because those generic products are no longer bioequivalent to – and not subject to automatic substitution in place of – the reformulated product. F. 199. For a generic drug to be sold where there is no branded drug for which it is automatically substituted, doctors must actually write out a prescription for the generic product. F. 202-203.

If Endo reformulated Opana ER, Impax's generic Opana ER would not be AB-rated to the reformulated Opana ER product. F. 200. To the extent that original Opana ER disappeared or became insignificant, Impax's opportunity to sell a generic Opana ER would be significantly reduced or even eliminated. F. 204. Impax was concerned that Endo would be able to “subvert the

²⁶ At the time of settlement, Endo had not filed any supplemental NDAs for a reformulated version of Opana ER. F. 226. Relevant facts regarding Endo's launching of a reformulated Opana ER are further addressed in subsection b.ii.(c) below.

Initial Decision

value of the deal” being negotiated by introducing a reformulated version of Opana ER. F. 205.

Endo rejected the concept of accelerated entry for Impax and rejected Impax’s demand for a market acceleration trigger. F. 147. This increased Impax’s concern that Endo was going to switch the market to a crush-resistant version of Opana ER, notwithstanding Endo’s denial of such a plan. F. 148. When Endo insisted to Impax that Endo was not planning to move the market to a crush-resistant version of Opana ER, Impax told Endo, “if you’re not telling me the truth, you’re going to pay me what I would have made anyway.” F. 150. If Endo did destroy the market for Impax’s generic Opana ER, Impax wanted “to be made whole for the profits that [it] would have otherwise achieved.” F. 206. *See also e.g.*, F. 207, 213 (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”); F. 151-152 (describing the then-current proposal as including a “make good” payment). Once Endo refused to agree to an acceleration trigger, and agreed instead to the concept of a make-whole payment, Impax stopped pursuing an acceleration trigger. F. 153. Thereafter, Endo and Impax proceeded instead to finalize the terms of this “make-good” or “make-whole” provision, which eventually became the Endo Credit. F. 154, 160-165. In addition, Endo agreed to a January 2013 generic entry date for Impax. F. 154.

As Impax’s then-CFO, Arthur Koch, explained, Impax was “worried about the control” Endo would have during the two and a half year time period before the agreed launch date of January 2013, and was “looking for a way to gain – take back some of that control away from the brand.” F. 149. Impax’s goal was, “if the market changed substantially before the date that the parties agreed that Impax could launch, there would be a way of making Impax whole” by providing Impax with the profits that Impax otherwise would have achieved during its 180-day exclusivity period. F. 213.

Impax described the make-whole provision as “protect[ing] the downside.” F. 154; *see also* F. 208. If Endo’s obligation to pay the Endo Credit were triggered, based on declining sales of

Initial Decision

Opana ER prior to Impax's generic entry, the calculations of the Endo Credit were designed to approximate the net profits Impax would have expected to make during its six-month exclusivity period, with no AG. F. 212; *see also* F. 214. Getting this downside protection for Impax in the event Endo reformulated Opana ER was "super, super important" to Impax's primary negotiator, Mr. Mengler, who testified that "something that didn't protect us from the downside was . . . a deal-breaker." F. 208.

If the market for Opana ER did not decline, the value of the no-AG provision would be higher. F. 210. A sharp decline in the sales of original Opana ER before Impax's generic launch, however, would decrease the value of the no-AG provision, because the total market potential for generic Opana ER would decrease. F. 209. The Endo Credit would then "correct for the loss in the value of the market that had occurred before the generic entry date." F. 209. In this way, the Endo Credit was designed as insurance against the risk of Endo reformulating Opana ER, and thereby degrading the market for Impax's generic drug. F. 211. *See also* F. 213 (The Endo Credit provision "was intended to insulate" Impax from the risk of a substantial decrease in Opana ER sales prior to the agreed generic entry date.).

In summary, the Endo Credit was designed to "back-up" the value of the no-AG provision and provide value to Impax regardless of whether Endo reformulated Opana ER. F. 197. *See also* F. 215 (Impax CFO Mr. Koch in 2011 characterizing the settlement as having "protection [against reformulation] built into the agreement so we should have a reasonable outcome almost no matter what happens").

(b) Monetary value of Endo Credit

The evidence shows that the monetary value of the Endo Credit was uncertain at the time of settlement and was contingent on unknown future events that were outside of Impax's control, such as the figure for quarterly peak sales for Opana ER prior to generic entry, which was the biggest "input" in the Endo Credit formula. F. 216.

Initial Decision

Complaint Counsel's economic expert witness, Professor Noll, devised four scenarios to approximate the value of the no-AG provision and the Endo Credit at the time of the settlement, and opined that the value ranged from \$16.5 to \$62 million, depending on his assumptions regarding the sales of Opana ER in the years after the settlement. *See* CX5000 at 240 (Noll Expert Report Appendix F). Professor Noll failed to adequately describe or explain the bases for his assumptions or his calculations, either in his expert report, or in his testimony. Without an understandable and verifiable basis for his estimates, the estimates are unsupported, are conclusory at best, and are, thus, rejected.

Respondent contends that the Endo Credit should be deemed to have added no value to the Endo-Impax Settlement because, by virtue of the contingent nature of the Endo Credit, the Endo Credit did not actually "guarantee" a payment to Impax. Respondent asserts that it was possible that Endo could time the introduction of reformulated Opana ER so as to avoid any payment obligation under the Endo Credit, while still diluting Impax's sales of generic original Opana ER (referred to by Respondent as a "late switch" strategy). Respondent relies on evidence that, prior to the settlement, Impax's director of market planning, Ted Smolenski, told Chris Mengler, Impax's principal negotiator, that there were certain circumstances under which the Endo Credit would not result in a payment to Impax, including a situation in which Endo would withdraw its NDA for original Opana ER and time the elimination of sales in such a way that the Endo Credit would result in zero payment. F. 221. *See also* F. 220 (preliminary calculations by Mr. Cuca of Endo included potential for zero payment under Endo Credit). However, Mr. Smolenski considered this "downside" scenario unlikely to occur. Moreover, Mr. Mengler decided not to pursue the issue further because he did not deem the potential to be likely enough to try to correct for it. F. 221.

Even if there was a theoretical possibility of a zero payment under the Endo Credit, the notion that Impax bargained to obtain a zero payment under the Endo Credit is implausible. It is also against the weight of the evidence, including evidence that the Endo Credit formula was designed to provide an approximation of the net profits Impax would have expected to make during its six-

Initial Decision

month exclusivity period, with no AG; Impax viewed the Endo Credit provision as “super, super important” and a “deal-breaker”; Impax viewed the Endo Credit as insurance; and Impax expected a “reasonable outcome almost no matter what happens.” F. 208, 212, 214-215. Moreover, Impax gave up its request for an acceleration trigger in exchange for the Endo Credit. F. 150-154. In summary, the facts belie the assertion that Impax bargained to obtain nothing.

In addition, the evidence does not support Respondent’s assertion that Endo was in fact planning the above-mentioned “late switch” strategy for introducing reformulated Opana ER in order to avoid payment under the Endo Credit. Respondent points to evidence that Endo’s 2012 budget contemplated a launch date for reformulated Opana ER of August 2012, with a full conversion of the market from original Opana ER to reformulated Opana ER within two to three months, while continuing sales of original Opana ER into the last quarter of 2012. RX094 at 0003. However, the Endo document cited by Respondent clearly states that “significant uncertainties existed around manufacturing capabilities, market acceptance and our ability to transition to the new formulation.” *Id.* The document notes that Endo was “particularly concerned with [transition time], as [Endo] knew that Purdue’s OxyContin transition took 6 months.” *Id.* In fact, an orderly transition from original Opana ER to reformulated Opana ER was expected to take about six to nine months. F. 106.

Moreover, even if sales of original Opana ER continued into the fourth quarter of 2012, it does not follow that this would enable Endo to avoid any payment under the Endo Credit. A cash payment under the Endo Credit was to be triggered if Endo’s original Opana ER dollar sales in the fourth quarter of 2012 fell by more than 50% from the “Quarterly Peak” (the highest sales quarter between the third quarter of 2010 and the third quarter of 2012). F. 129, 195. Having some sales of original Opana ER in the fourth quarter of 2012 would not necessarily be sufficient to avoid triggering an Endo Credit payment. Rather, to avoid triggering an Endo Credit payment, the total dollar sales of original Opana ER in the fourth quarter of 2012 would need to be at least 50% of the Quarterly Peak sales.

Initial Decision

The weight of the evidence is that, at the time of the settlement, Endo's principal interest in the timing of the launch of reformulated Opana ER was to launch as soon as possible, and sufficiently ahead of entry of a generic for original Opana ER to maximize the value of its reformulated product. F. 99-104. The assertion that Endo's priority was instead to avoid payment under the Endo Credit is unsupported and unconvincing, and is, therefore, rejected.

(c) 2013 payment under Endo Credit

On April 18, 2013, Impax received a payment pursuant to the Endo Credit in the amount of \$102 million. F. 237. This amount is not, however, the proper measure of the value of the Endo Credit, which must be measured as of the date of settlement. *Loestrin*, 261 F. Supp. 3d at 337. To the extent that any of Professor Noll's estimates of the value of the Endo Credit at the time of settlement are based upon discounting the value of the Endo Credit payment made in 2013 (F. 239) such valuation would be improper and provides an additional reason to reject those estimates.

Furthermore, the evidence shows that the amount of money that Endo eventually paid under the Endo Credit was a function of a number of unforeseen factors that were outside of Impax's control. F. 216, 227-235. At the end of 2011, after discovering manufacturing deficiencies, the FDA shut down the plant where Novartis Consumer Health, Inc. ("Novartis"), another pharmaceutical company, manufactured original Opana ER for Endo. F. 227. The shutdown of the Novartis plant caused a supply chain crisis for Opana ER. F. 228. Thereafter, in or about February 2012, the FDA ordered Endo to cease selling original Opana ER in order to avoid consumer confusion with Endo's reformulated Opana ER, which had just been approved by the FDA in December 2011. F. 225-226, 229. Accordingly, Endo stopped distributing original Opana ER and launched reformulated Opana ER in March 2012. F. 230.²⁷ It was not until

²⁷ Endo also took steps to have original Opana ER removed from the market. In August 2012, Endo filed multiple citizen petitions with the FDA, in which Endo argued that the FDA should (1) determine that original Opana ER was discontinued for safety reasons and could no longer serve as a reference-listed

Initial Decision

after the Novartis supply disruption in late 2011, the FDA's order to stop selling original Opana ER in February 2012, and the launching of reformulated (crush-resistant) Opana ER in March 2012, that Endo first concluded that it would have to make a payment under the Endo Credit provision. In fact, the first time Endo knew that its sales of Opana ER would be zero was in the last quarter of 2012, after the supply interruption caused by the Novartis plant shutdown. F. 231. There is no basis in the record for concluding that anyone at the time of settlement did foresee, or reasonably could have foreseen, the occurrence of all these events.

Although \$102 million is not the appropriate measure of the value of the Endo Credit at the time of settlement, the fact that a payment was made confirms the purpose of the Endo Credit. As noted above in Section III.C.2.b.ii.(b), the purpose of the Endo Credit was to provide Impax the profits it would have received as the sole seller of generic Opana ER during its 180-day exclusivity period, with no AG, in the event of a sharp decline in the market. To the extent that the 2013 Endo Credit payment includes the value of such profits, the Endo Credit payment fulfilled its purpose.

c. Conclusion as to valuation of reverse payment

Based on the foregoing, the evidence proves that, at the time of settlement, the value of the no-AG provision, as secured by the Endo Credit, was between \$23 and \$33 million in projected sales, and the actual value of the cash payment under the DCA was \$10 million, for a total reverse payment under the SLA and DCA of between \$33 and \$43 million.

drug for any ANDA; (2) refuse to approve any ANDA pending for original Opana ER; and (3) withdraw any already-granted approvals for original Opana ER ANDAs. F. 233. Impax formally responded to the petition and offered scientific evidence that the discontinuation of Endo's original Opana ER was unrelated to safety or effectiveness. F. 234. The FDA concluded that Endo did not withdraw original Opana ER for safety or efficacy reasons. F. 235.

Initial Decision

3. Scale in relation to litigation costs

Although litigation costs vary substantially among cases, a survey by the American Intellectual Property Lawyers Association estimated that the median litigation cost for all patent cases with more than \$25 million at stake averages about \$5.5 million for each party. F. 77. When such a case is handled by a large firm (with more than 76 attorneys), the median litigation cost average is somewhat higher, at approximately \$7 million for each party. F. 77.

The top end of the range that Impax uses in its budgeting process to estimate costs for generic patent litigation is about \$3 to \$4 million per case. This \$3 to \$4 million estimate represents total expenses from the start of litigation to completion and is based primarily on expenses for outside counsel, such as hourly attorneys' fees. F. 79. In November 2011, Impax represented in a public earnings conference call that it was saving \$3 million in litigation expenses because of recent settlements, including the Endo settlement. F. 80. At the time of the Endo-Impax Settlement, which occurred during the patent trial, Endo had spent between \$6 and \$7 million and Impax had spent about \$4.7 million on litigation in the infringement case. F. 78.

Based on the foregoing, 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. F. 81. As set forth above, the value of the no-AG provision, secured by the Endo Credit, was between \$23 and \$33 million, based on projected sales revenue to Impax, and the actual value of the cash payment under the DCA was \$10 million, for a total reverse payment under the SLA and DCA of between \$33 and \$43 million. Therefore, the value of the reverse payment substantially exceeded the estimated saved litigation costs.

4. Justifications for reverse payment**a. Legal principles**

Actavis holds that a reverse payment can be justified as “compensation for other services that the generic has promised to

Initial Decision

perform – such as distributing the patented item or helping to develop a market for that item. There may be other justifications.” *Actavis*, 133 S. Ct. at 2236. *See also id* at 2237 (holding that likelihood of anticompetitive effects in connection with reverse payment settlement depends on, among other things, “independence from other services for which it might represent payment, *and the lack of any other convincing justification*”) (emphasis added). Clearly, *Actavis* did not limit the types of justifications for a reverse payment that can be asserted. *See also King Drug*, 791 F.3d at 412 (“The Court does not foreclose other justifications.”).

The parties dispute who has the burden of proof on the issue of justification, with each party placing the burden of proof on the other party. Complaint Counsel points to language in *Actavis* stating that “[a]n antitrust defendant may show . . . 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,” 133 S. Ct. at 2236, and argues this shows that the defendant bears the burden of proving that a payment was justified. However, *Actavis* also cites “the lack of any . . . convincing justification” as an element of proving anticompetitive effects, 133 S. Ct. at 2237, which indicates that the burden of proving that a payment was unjustified should fall on the plaintiff.

Post-*Actavis* cases have held that the plaintiff challenging a reverse patent settlement must allege plausible facts to support a conclusion that an alleged reverse payment was large and unjustified. *Loestrin*, 814 F.3d at 552. In addition, it has been held that when a defendant comes forward with evidence of justifications for the payment, the burden is on the plaintiff to prove that the asserted justifications are unsupported. *Cipro Cases I & II*, 348 P.3d at 871 (citing *Polygram*, 416 F.3d at 37-38). *See also K-Dur*, 2016 U.S. Dist. LEXIS 22982, at *46 (holding that plaintiff must “dispel” justifications offered by defendant). As the court in *In re Cipro Cases I & II* explained, if a plaintiff dispels all justifications explaining the reverse payment, “the conclusion follows that the settlement payment must include, in part, consideration for additional delay in entering the market.” 348 P.3d at 871. *See also In re Aggrenox Antitrust Litig.*, 2015 U.S. Dist. LEXIS 94516, at *37 (D. Conn.

Initial Decision

July 21, 2015) (holding that an antitrust violation requires proof, among other things, “that the settlement included a large and unjustified reverse payment giving rise to an inference of payment in order to avoid the risk of competition”). Other post-*Actavis* cases have held that the burden is on the defendant to prove the justifications for the payment. See, e.g., *King Drug*, 791 F.3d at 412; *Cephalon*, 88 F. Supp. 3d at 416. See also *Lipitor*, 868 F.3d at 256-57 (rejecting the argument that the complaint’s allegations of lack of justification were insufficient, stating that *Actavis* “clearly placed the onus of explaining or justifying a large reverse payment on antitrust defendants”).

In the instant case, the parties have vigorously litigated the question of justification for the reverse payment and have developed a complete record on the issue. Notwithstanding Complaint Counsel’s assertion that the burden of proving justification is on Respondent, Complaint Counsel nevertheless asserts that the reverse payment was unjustified, and offers evidence and argument in an effort to support that claim (see, e.g., CCB at 27-31, CCF Section XII). Regardless of which party has the ultimate burden of proof on the issue of justification for the payment, as discussed in detail below, the evidence proves that, of the total payment provided to Impax under the Endo-Impax Settlement: (1) the payment conferred to Impax by the no-AG and Endo Credit provisions of the SLA was unjustified; and (2) the \$10 million payment to Impax pursuant to the DCA was justified.

b. Payment under the SLA**i. Contentions of the parties**

Respondent argues that, even if the no-AG and Endo Credit provisions of the SLA conferred a large reverse payment to Impax, the payment was not unjustified because the payment was not provided “in return for staying out of the market.” RB at 60.²⁸ Respondent points to evidence that the no-AG provision was

²⁸ Respondent does not assert that the reverse payment conferred to Impax by the no-AG and Endo Credit provisions of the SLA reflects compensation for services provided to Endo by Impax.

Initial Decision

included in Endo's initial offer and that during negotiations, the entry date moved back from Endo's initial proposed entry date of March 2013, to the agreed entry date in the settlement of January 2013. Respondent further argues that the Endo Credit was not tied to the negotiation of the entry date, but rather was coupled with a royalty provision in the SLA designed to (1) encourage Endo to support sales of Opana ER in the time period between the date of the settlement and the date set for entry of Impax's generic product, and (2) discourage Endo from transitioning to a reformulated Opana ER product. Respondent refers to this as a "carrot and stick." RB at 61.

Complaint Counsel contends that the no-AG and Endo Credit provisions are unjustified. Complaint Counsel argues that these provisions were directly linked to the January 2013 entry date provided under the Endo-Impax Settlement, and the fact that the entry date in the settlement was slightly earlier than the March 2013 entry date initially proposed by Endo does not justify these provisions. Further, Complaint Counsel argues, Respondent's assertion that the Endo Credit was part of a "carrot and stick" designed to discourage Endo from transitioning to a reformulated product is legally non-cognizable and factually unsupported.

ii. Analysis

Evidence from the parties' negotiations readily supports the conclusion that the reverse payment conferred to Impax by the no-AG provision, secured by the Endo Credit, was directly linked to negotiation of the generic entry date as compensation to Impax for giving up its patent challenge and committing not to launch a generic Opana ER until January 2013. Endo's initial offer included a no-AG provision, but this initial offer was not sufficient to induce Impax to settle the patent litigation and agree to the March 2013 entry date proposed by Endo. F. 131-132. Impax accepted the no-AG provision, but counter-proposed a January 2013 entry date, plus an acceleration trigger that would allow for entry prior to January 2013 in the event of a degradation of the market for Opana ER prior to Impax's entry. F. 136-139. Endo would not agree to an acceleration trigger, but agreed instead to pay Impax a "make-good" payment, the Endo-Credit, and further agreed to the January 2013 entry date requested by

Initial Decision

Impax. F. 147, 151, 154. Once Endo and Impax agreed on the concept of a make-good payment, the parties reached an agreement in principle on the SLA. F. 147-154.

When weighed against the foregoing evidence, the facts that the no-AG provision was included in Endo's initial offer, and that the January 2013 entry date ultimately agreed to was two months earlier than the March 2013 date Endo initially offered, are not significant. Moreover, the issue is not whether the January 2013 entry date in the settlement was earlier than the date Endo initially offered, but whether the no-AG provision, as secured by the Endo Credit, was effectively payment by Endo to Impax for agreeing to drop its patent challenge and commit to staying out of the market prior to January 2013. See *Actavis*, 133 S. Ct. at 2237 (noting that parties may settle with an agreed entry date "without the patentee paying the challenger to stay out prior to that point"). See also *King Drug*, 791 F.3d at 408 (holding that the question is whether entry might have been earlier, and/or the risk of competition not eliminated, had the reverse payment not been tendered). Viewed as a whole, the evidence supports the conclusion that the reverse payment conferred to Impax by the no-AG provision, secured by the Endo Credit, was unjustified.

Respondent's contention that the Endo Credit is not unjustified because it was part of a "carrot and stick" strategy is without merit for several reasons. First, the evidence does not support Respondent's assertion that the Endo Credit and the royalty provision were "coupled." The evidence shows that a royalty proposal was made by Endo, as part of its initial term sheet for the SLA on May 26, 2010. F. 135. The proposal for a "make-good" payment did not occur until on or about June 1, 2010, and was not reduced to writing until June 4, 2010. F. 151, 160. Second, the assertion that the Endo Credit was part of a "carrot and stick" design is against the weight of the evidence, which shows that the Endo Credit was intended as a "make-whole" provision, to provide Impax with the profits Impax would have earned during its 180-day exclusivity period, with no AG, if Endo switched the market to a reformulated Opana ER. See Section III.C.2.b.ii.(a) above. While Respondent points to deposition and trial testimony to support the characterization of the Endo Credit as part of a "carrot and stick," see RFF 195-198,

Initial Decision

the phrase does not appear in contemporaneous documents from the parties' negotiations. Third, the assertion that the royalty provision was a "carrot" is unconvincing because the royalty imposed costs on Endo in the form of lost sales from its agreement not to launch an authorized generic. Under the SLA, Impax would be obligated to pay Endo a 28.5% royalty on Impax's generic Opana ER sales during Impax's 180-day exclusivity period only in the event that sales of Opana ER in the calendar quarter prior to Impax's entry grew by a specific percentage. F. 128, 194. However, if sales grew enough to require a royalty payment to Endo, the no-AG provision operated to prevent Endo from selling an AG into this increased market. See F. 127. Thus, while pursuant to the royalty provision, Endo would receive 28.5% of profits from Impax's generic sales, pursuant to the no-AG provision, Endo still would lose 100% of profits it could have earned from sales of an Endo AG. Moreover, even if Opana ER sales reached a sufficiently high level prior to Impax's generic entry to trigger royalty payments, Impax would be the only seller of a generic oxymorphone ER product, pursuant to the no-AG provision. F. 127-128, 194. Impax stood to gain more in sales of generic oxymorphone ER than Impax would lose in royalty payments. F. 194. For all these reasons, Respondent's contention that the Endo Credit is not unjustified because it was part of a "carrot and stick" strategy is rejected.²⁹

iii. Conclusion

As explained above, the evidence supports the conclusion that the reverse payment conferred to Impax under the SLA by the no-AG provision, secured by the Endo Credit, was unjustified. The analysis now examines justification for the payment made to Impax under the DCA.

²⁹ Because Respondent's "carrot and stick" justification is contrary to the weight of the evidence, it is not necessary to address Complaint Counsel's argument that such justification is not legally cognizable.

Initial Decision

c. Payment under the DCA**i. Overview**

On June 7, 2010, Endo and Impax executed a Development and Co-Promotion Agreement with respect to a Parkinson's disease treatment known internally at Impax as IPX-203. F. 244. The DCA was executed simultaneously with the SLA and is incorporated into the SLA. F. 245. Under the DCA, Impax and Endo agreed to collaborate with respect to the development and marketing of a potential treatment for Parkinson's disease using an extended release, orally administered product containing a combination of levodopa and carbidopa. F. 246.

The DCA provided for an upfront payment of \$10 million by Endo to Impax, and the possibility of payment of up to \$30 million more, based on achieving specified milestone events in the development and commercialization of the product. F. 247-248. Impax and Endo agreed to share promotional responsibilities, with Impax promoting IPX-203 to its network of neurologists, and Endo promoting IPX-203 to its network of non-neurologists, including primary care physicians who prescribe Parkinson's disease medications. F. 249. If the target product was successfully commercialized, Endo would be entitled to a share of the profits. F. 250. Specifically, Endo would receive a co-promotion fee equal to 100% of gross margins on sales resulting from prescriptions by non-neurologists. F. 250. Endo paid Impax the \$10 million upfront payment on June 24, 2010. F. 250.

Respondent contends that the \$10 million payment by Endo to Impax under the DCA was justified as fair value for profit-sharing rights Endo received under the DCA.³⁰ Respondent asserts that

³⁰ Respondent makes a single assertion in its brief that the \$10 million paid under the DCA reflected fair value compensation for services by Impax. RB at 42. However, Respondent does not expand on the assertion, articulate what services it was to provide to Endo in exchange for the \$10 million payment, or point to any evidence supporting the assertion. Accordingly, the assertion has not been sufficiently raised to warrant consideration. See *United States v. Zannino*, 895 F.2d 1, 17 (1st Cir. 1990) (“[I]ssues adverted to in a perfunctory manner, unaccompanied by some effort at developed argumentation, are deemed waived.”).

Initial Decision

the evidence shows that Endo was interested in Parkinson's disease treatments; Endo's team was familiar with Parkinson's disease treatments; Endo analyzed the merits of the product collaboration; and Endo concluded that the DCA had financial and commercial merit for Endo. In addition, Respondent asserts that, among other things, the DCA entitled Endo to a share of profits without obligating Endo to perform any resource-intensive formulation or development work, the DCA capped Endo's total financial obligations, and, beyond the \$10 million investment, Endo's obligations were contingent on Impax achieving specific milestones, regardless of how much it cost Impax to achieve those milestones.

Complaint Counsel contends that the \$10 million payment from Endo to Impax under the DCA was not justified by Endo's profit-sharing rights. According to Complaint Counsel, the evidence demonstrates that the payment was not part of a bona fide product collaboration, but was instead payment for Impax's agreement under the SLA not to enter the market with its generic Opana ER until January 2013. In support of this argument, Complaint Counsel relies on expert opinion to contend that the DCA and the SLA were not independent agreements, because they were negotiated and executed together, and because, as adversaries, Endo and Impax would be unlikely to collaborate, but for the settlement discussions. In addition, Complaint Counsel asserts that the evidence shows that Endo did not have a genuine interest in developing the drug that was the subject of the collaboration.

Furthermore, relying on expert opinion, Complaint Counsel argues that the negotiation process was unusual in comparison to industry standards, particularly with regard to Endo's due diligence. Complaint Counsel asserts that the evidence shows that Endo offered the same \$10 million upfront payment at the beginning of negotiations of the DCA, despite a change in the product under discussion. Complaint Counsel further asserts that \$10 million was an unusually large payment to make upfront, in light of the drug's early stage of development at the time the DCA was signed.

Initial Decision

ii. Summary of facts

The detailed facts concerning the DCA are set forth in Section II.C.3 and are summarized below.

(a) Background facts

Endo has entered into many collaboration agreements with other pharmaceutical companies. F. 254. These include early-stage development deals, and potentially speculative deals. F. 255. This is because Endo generally does not research or discover new drug molecules on its own and instead acquires and licenses drugs from other pharmaceutical companies. F. 254. In connection with a collaboration agreement, Endo identifies therapeutic areas of interest and companies that own promising drug molecules in those areas and enters into early-stage development deals. F. 256. Endo also regularly licenses technology from and collaborates with other companies for more developed products. F. 256. For example, for Opana ER, Endo licensed the necessary technology to make both original and reformulated Opana ER. F. 256. Endo's collaboration agreements with other pharmaceutical companies could relate to drugs at every stage of the development lifecycle, including early-stage development agreements. F. 255. Because Endo had no pipeline in place to discover new drugs on its own, Endo would enter into "very early, very speculative agreements." F. 255.

Beginning in 2005, Endo's significant areas of interest included pain, neurology, and movement disorders, including Parkinson's disease treatments. F. 257. In the 2010 timeframe, Endo evaluated collaborations with other companies related to treatments for Parkinson's disease. These included exploring potential Parkinson's disease collaboration opportunities with an Italian company called Newron, which had multiple Parkinson's disease products, and conducting due diligence on a Parkinson's disease product with a novel mechanism of action that was owned by a Finnish company. F. 261. For a number of years, Endo sold an immediate-release Parkinson's disease drug known as Sinemet, which was the original formulation of carbidopa and levodopa.³¹

³¹ A combination of carbidopa and levodopa molecules is the "gold standard" treatment for Parkinson's disease. F. 265.

Initial Decision

F. 260. Thus, the evidence demonstrates that Endo had both an interest in Parkinson's disease treatments and knowledge about such treatments through its experience with Sinemet.

Impax also had a long-standing interest in Parkinson's disease treatments. When Impax's brand division was founded in 2006, it focused its efforts on central nervous system and neurology products, with a specific focus on improved treatments for Parkinson's disease. F. 263. As part of its focus on central nervous system and neurology products, Impax's brand division also concentrated on developing a network of relationships with neurology physicians. F. 263. In addition, in furtherance of its interest in Parkinson's disease treatment, Impax had undertaken attempts to develop an extended release drug for treatment of Parkinson's disease. F. 268-276. The majority of carbidopa-levodopa medications are available only in immediate-release formulations, which requires frequent dosing and often results in patients' losing control of their motor skills as they experience rapid increases and decreases in the concentration of medicine in their bodies, especially as the disease progresses. F. 266-267.

Impax's first attempt to develop an extended-release carbidopa-levodopa treatment for Parkinson's disease was known as Vadova. F. 268. That product was intended to combine carbidopa-levodopa with controlled-release technology to give a much smoother effect to the amount of medication in Parkinson's disease patients' blood, providing for more control over motor symptoms. F. 268. Vadova was never fully developed or marketed. F. 268.

Impax's second attempt to develop an extended-release Parkinson's disease medication was known as IPX-066, which was a combination of carbidopa and levodopa that had been formulated to extend the release profile of Parkinson's disease drugs. F. 269-270. As with Vadova, IPX-066 was intended to better treat Parkinson's disease patients by allowing for less frequent and more consistent dosing of up to six hours, as well as more consistent motor symptom control. F. 271. By significantly extending the absorption of the drug, IPX-066 would provide

Initial Decision

“significant improvement of the patient’s quality of life.” F. 272. IPX-066 had reached Phase III clinical trials in 2010 and was marketed under the name Rytary in 2015. F. 273.

By 2010, Impax had also begun efforts to develop a “next generation” of IPX-066. F. 274. The goal of the next-generation product, which was originally designated by Impax as IPX-066a and later designated as IPX-203, was to further improve treatment for Parkinson’s disease patients by extending dosing time even longer than IPX-066. F. 274.

(b) Negotiations

In early 2009, Impax approached Endo about a collaboration with respect to Endo’s central nervous system drug Frova, which treats migraine headaches. F. 275-276. Endo declined. F. 277. Although Endo and Impax again discussed a potential product collaboration on Frova in late 2009, in connection with discussions about settlement of the Endo-Impax patent litigation, these discussions did not result in a collaboration agreement. F. 278-280. However, in the course of these discussions, Endo became aware of Impax’s efforts to develop drugs for Parkinson’s disease and expressed an interest. F. 281. Subsequently, in May 2010, after discussions regarding settlement of the Endo-Impax patent litigation resumed, Impax and Endo began discussing a potential joint development agreement and Endo expressed an interest in marketing IPX-066. F. 283-284.

At Endo, the senior vice president of corporate development, Dr. Robert Cobuzzi, and his team of employees were responsible for evaluating potential pharmaceutical business deals for further development. F. 287. Between May 17 and 26, 2010, the date of Endo’s initial term sheet for the DCA (F. 294), Impax and Endo held two conference calls and exchanged numerous emails and materials regarding IPX-066, including a presentation on the clinical benefits of IPX-066 over Sinemet, which at that time was the leading carbidopa-levodopa brand product. F. 286, 288.

On May 20, 2010, Dr. Cobuzzi directed his team to work on an opportunity evaluation worksheet (“OEW”) to assess a potential collaboration with Impax on IPX-066. F. 289. An OEW

Initial Decision

is Endo's standard method of assessing the science, medical information, commercial opportunity, and related financial considerations behind a potential collaboration project. F. 346. Any time Endo considers a pharmaceutical collaboration, it completes an OEW. F. 346.

On May 21, 2010, Endo asked an outside consulting firm to provide guidance about the potential value of IPX-066. F. 290. In addition, on May 22, 2010, Dr. Paterson, Impax's vice president of business development, provided Dr. Cobuzzi and a number of additional Endo employees access to a "data room" with a large amount of IPX-066 related documents, covering: (i) intellectual property/legal; (ii) chemistry, manufacturing, and controls; (iii) commercial; (iv) regulatory; (v) clinical; (vi) clinical pharmacology; and (vii) Impax's unredacted confidential presentation on IPX-066. F. 291.

On May 26, 2010, Endo sent Impax an initial term sheet for an option agreement concerning IPX-066 "and all improvements, modifications, derivatives, formulations and line extensions thereof." F. 294. Under this proposal, Endo would have the option to receive either the right to co-promote the product to non-neurologists within the United States or to purchase an exclusive license to the product in the United States. F. 294. 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. F. 294. If Endo exercised the option to co-promote the product, Endo would receive a fee of "50% on the net sales" from prescriptions by non-neurologists in the United States. F. 294. If Endo exercised the option for a license, Endo would pay Impax a fee based on projected sales. F. 294.

Endo's May 26 proposal was not acceptable to Impax. As Impax's vice president of intellectual property litigation and licensing, Margaret Snowden, explained: "Endo was interested in the Parkinson's space and wanted the deal to cover both products, the original IPX-066 and the follow-on product, but Impax wasn't interested in doing the deal on IPX-066." F. 313. Dr. Michael Nestor, the head of Impax's brand division, was "absolutely not" willing to consider an agreement with Endo regarding IPX-066.

Initial Decision

F. 311. In 2010, Impax had already shouldered all development risks and development costs for IPX-066 and it made little sense to Impax to share potential profits from the drug with a partner. F. 310. Furthermore, in 2010, Impax was not looking for a partner in the United States for IPX-066 because Impax planned to market the product domestically on its own, utilizing its established neurologist network. F. 309.

Accordingly, Impax made a counter-offer to Endo on May 27, 2010 for a research and development collaboration for what Impax referred to as IPX-066a, its “next generation” of IPX-066. F. 295, 313-314. Impax advised Endo that Impax would name this product “at signing.” F. 295. IPX-066a, which later became known as IPX-203, was a planned carbidopa-levodopa-based product that Impax hoped would improve the treatment of symptoms and also have more favorable dosing as compared to IPX-066. F. 314.

Contrary to the inferences urged by Complaint Counsel, designation of IPX-066a was not a “late switch” by Impax from IPX-066, but a rejection by Impax of Endo’s proposal for a deal for both IPX-066 and IPX-066a, and a counterproposal by Impax for a collaboration for IPX-066a only. Impax had initially sent IPX-066 materials to Endo to review in order to “help [Endo] frame their evaluation of the market environment into which IPX-203 could be launched as a successor to IPX-066.” F. 328. When Impax sought a partner to market the product outside the United States, it had already established a data room regarding IPX-066. F. 329. Because IPX-203 was a follow-on product to IPX-066, the foundational information in the data room regarding IPX-066 was relevant to show Impax’s plans for IPX-203. F. 329.

Impax’s May 27, 2010 counter-offer for a collaboration for IPX-066a included an upfront payment at signing of \$3 million, and six additional milestone payments, tied to the initiation and completion of Phases II and III development and final FDA approval, for a total of \$60 million. F. 295. Over the next ten days, Endo and Impax traded proposals regarding the timing and total amount of the payments under the DCA, which culminated in the final DCA terms, summarized above. F. 296-308. On June 4, 2010, Impax named IPX-203 as the product previously

Initial Decision

designated as IPX-066a. F. 303. Impax also provided additional information to Endo regarding Impax's research into the IPX-203 product concept, and about how IPX-203 would improve upon existing Parkinson's disease therapies, including IPX-066. F. 322.

(c) Relationship between IPX-066 and IPX-203

IPX-203 was intended to be a modification of carbidopa and levodopa, a well-known combination treatment for Parkinson's disease. F. 324. Levodopa generally is not well absorbed in the colon. F. 325. The information Impax provided on IPX-203 made clear that IPX-066 and IPX-203 were intended to be [REDACTED]. F. 323. IPX-203 would have [REDACTED]. F. 326. The information Impax provided Endo on IPX-203 [REDACTED]. F. 327.

Although IPX-203 was in the beginning of the formulation stage, Impax reasonably relied on Dr. Suneel Gupta, the chief scientific officer at Impax in 2010, who believed that the product concept for IPX-203 was "doable." F. 315-316. As early as November 2009, Impax had reviewed [REDACTED]. F. 378. Dr. Gupta had expertise in reformulating existing chemical compounds to create commercial and clinical improvements through reformulation and "is renowned for taking existing compounds and reformulating them and turning those products into very successful drugs in the marketplace that meet significant medical need[s]." F. 316. When Dr. Gupta tells Impax management that a product concept is "doable," Impax's senior management believes him and relies on his judgment. F. 316. Moreover, Impax's expertise has long been the development of extended-release technologies. F. 317.

Initial Decision

The ultimate goal of IPX-203 was to further extend the amount of time patients have control over their motor symptoms after taking the medication. F. 319. IPX-203 would also employ a “much more simplified” dosing regimen than IPX-066, making it more intuitive for doctors to prescribe the product. F. 320. Impax projected that the total cost of development for IPX-203 would be between \$80 and \$100 million by 2017, based on a “natural extrapolation” of the development costs incurred by IPX-066. F. 321.

Impax was planning to withdraw promotion and sampling of IPX-066 (Rytary) once IPX-203 reached the market. F. 318. This would allow patients to continue successful use of IPX-066 while avoiding any division of Impax’s sales force between multiple Parkinson’s disease products, which was consistent with the commercial goal of extending the IPX-066 franchise. F. 318.

**(d) Endo’s evaluation of product
collaboration for IPX-203**

Endo carefully evaluated the commercial, medical, and risk allocation aspects of the DCA. On June 7, 2010, Dr. Cobuzzi provided the final OEW on IPX-203 to Endo’s executive team. F. 307. In terms of the commercial aspects of the DCA, Endo’s OEW on IPX-203 stated that the DCA was “a good deal for Endo.” F. 307. Endo analyzed the net present value of its initial investment under the DCA and determined that the DCA and IPX-203 had a “very reasonable rate of return” of [REDACTED] under base case assumptions, and a net present value of [REDACTED]. F. 352-353. Such a return would exceed Endo’s general requirement of a 10% rate of return on a development and co-promotion deal. F. 352. Endo thought it could realize this return, notwithstanding that Parkinson’s disease treatments were heavily genericized, because IPX-203 would offer a superior product to other generics. F. 354. In addition, Dr. Cobuzzi recommended the DCA as “an exciting opportunity for Endo” because it “further builds [Endo’s] product pipeline for the future with a drug candidate that fits with [Endo’s] commercial footprint.” F. 349. Endo did not have many products in its commercial pipeline in 2010, and did not have the capacity to develop new products in-house. F. 350.

Initial Decision

Endo's evaluation of the medical aspects of IPX-203 concluded that IPX-203 would extend the period of time over which the drug is absorbed, which would allow doctors to lower the doses needed for effective treatment. F. 357. This would provide an opportunity to address doctor dissatisfaction with existing drugs that tend to begin to lose effectiveness within 10 to 15 years after initiation of therapy, and would meet a need for better control of efficacy over time. F. 356. Endo's OEW for IPX-203 also noted that IPX-203 represented a further improvement over IPX-066, including "faster onset of action, superior management of motor fluctuations and convenient oral dosing in a simplified regimen that could require no more than twice-daily administration, and in some cases even once-daily administration." F. 358. Taking the drug less frequently would be particularly beneficial for Parkinson's disease patients, who can have trouble "even picking up the pill." F. 359. Endo's evaluation team concluded that IPX-203 could move very quickly through development and "was an exciting compound in that it was made up of . . . two compounds that have already been approved by the FDA." F. 361. Endo reasonably believed that there was a path to obtaining FDA approval and bringing IPX-203 to market. F. 361-363.

Endo also evaluated how risk was allocated under the DCA. Endo's analysis in the OEW on IPX-203 explained to Endo's board of directors that the DCA's "deal structure acceptably mitigates Endo's exposure despite the early development stage." F. 364. Endo was entitled to share in the profits from IPX-203 without performing any development work or otherwise expending internal resources. F. 365-366. Moreover, Endo retained the same profit-sharing rights no matter how much Impax spent on IPX-203's development, which Impax had projected could amount to \$100 million by 2017. F. 321, 367. In addition, Endo was obligated to make only a single contribution (\$10 million) to Impax's development work. Endo would be required to make any additional milestone payments only to the extent that there was successful completion of development milestones, such as Phase II clinical trials. F. 365. Furthermore, the \$10 million single investment to buy into the IPX-203 opportunity was "not an uncharacteristically large amount of money" to Endo, compared to other collaboration agreements. F. 370.

Initial Decision

Accordingly, Endo was “comfortable” with the collaboration from the perspective of risk. F. 368.

Dr. Cobuzzi believed that the profit-sharing rights Endo received under the DCA justified Endo’s payment obligations. F. 369. Dr. Cobuzzi and his team concluded that Endo should enter into the DCA and Dr. Cobuzzi made that recommendation to Endo’s CEO, CFO, and board of directors. F. 347.

(e) Value to Impax of collaboration for IPX-203

In 2010, Impax did not have the money to begin working on the clinical research for IPX-203. F. 375. Impax could not fund the project internally because its shareholders did not “want to see large sums of money being spent over an extended time period on a single product. They were accustomed to [research and development] investments being made on many individual products that you bring to market as a generic.” F. 375. Thus, Impax needed external funding to move the development of IPX-203 forward, and explored a number of options, including seeking money from venture capital firms. F. 376. Impax’s brand drug development team was “very excited” about the idea of funding IPX-203 through a co-development program with Endo. F. 377.

In negotiating the DCA, Impax initially wanted to retain any profits flowing from prescriptions written by high-prescribing non-neurologists – which were the profits Endo sought and eventually obtained under the DCA – because of the “significant” amount of money those prescriptions represented. F. 372. Impax envisioned promoting IPX-203 to at least “a couple of thousand physicians who were primary care physicians that prescribed [medications to] Parkinson’s patients” F. 373. Nevertheless, in order to get funding through a co-development program with Endo, Impax agreed to give up a share of the profits for IPX-203.

(f) Impax’s continued efforts to develop IPX-203

Since executing the DCA in June 2010, Impax has devoted substantial efforts to IPX-203’s development, including over

Initial Decision

██████████ in employee hours spent working on IPX-203. F. 379. In 2010, Impax commissioned preclinical pharmacokinetic studies testing several relevant compounds and began laboratory research. F. 380. Impax undertook multiple rounds of pharmacokinetic studies to test various IPX-203 formulations in an effort to assess clinical improvements, which were completed as of 2012. F. 381. Since then, Impax conducted additional pharmacokinetic studies and completed Phase I clinical trials. F. 382. Impax manufactured a clinical supply of IPX-203, developed protocols for Phase II clinical trials, submitted those protocols to the FDA, and secured FDA approval for efficacy and safety studies in November 2014. F. 383.

Further development work on IPX-203 was delayed for approximately two years after Impax experienced delays in the development of IPX-066, the drug IPX-203 was intended to extend and improve upon. F. 384. When IPX-066 was delayed, resources were shifted to getting IPX-066 approved and to market. F. 385. Growing the market for IPX-066 would benefit IPX-203. F. 385. Further development work on IPX-203 was also delayed after Impax received an FDA Warning Letter in 2011 relating to Impax's manufacturing processes, which caused Impax to direct its scientific staff to spend their time helping the operations people correct the deficiencies that the FDA noted in its last inspection. F. 386. IPX-203 development was not going to go forward until Impax "got over that hurdle." F. 387.

Notwithstanding the delays and the DCA's termination (discussed below), Impax has continued development work on IPX-203. F. 388. IPX-203 is currently the leading compound in research and development in Impax's brand division. F. 389. Impax has completed Phase II clinical trials for IPX-203, which showed a statistically significant improvement in treatment over IPX-066 and other existing treatments, reducing the amount of time Parkinson's disease patients are without control over their motor symptoms, as compared to both immediate-release carbidopa-levodopa treatments and IPX-066. F. 390-391. Phase II trials suggest that IPX-203 will offer an improvement of over two hours in motor symptom control when compared to immediate-release carbidopa-levodopa treatments and one hour of improvement over IPX-066. F. 392. An improvement of over

Initial Decision

two hours in motor symptom control over existing medications is a “terrific result” that is “highly statistically significant” and “clinically meaningful.” F. 393. Having symptoms under control for a longer time period is “a very important thing” for patients. F. 394. Impax plans to begin Phase III clinical trials in 2018. F. 390.

Impax’s IPX-203 development efforts revealed that the formulation of IPX-203 contemplated by the DCA could not achieve the intended clinical benefits. F. 396. Between 2014 and 2015, Impax’s research team determined that it could not achieve the desired product profile with a [REDACTED] formulation. F. 397. Impax consequently began pursuing alternative approaches to an extended-release formulation of carbidopa and levodopa. F. 397.

After extensive research and testing, [REDACTED] [REDACTED]. F. 398. In April 2015, Impax approached Endo to update it on the status of Impax’s IPX-203 development work, including the change in formulation strategy, and made a presentation describing Impax’s formulation testing and results and [REDACTED]. F. 403.³²

(g) Termination of the DCA

Although the specific formulation of IPX-203 changed, Impax still viewed [REDACTED] [REDACTED] it had been developing since 2009 “[b]ecause it was all towards the same end. It still involved carbidopa-levodopa. It was just a variation in formulation.” F. 400. During the April 2015 meeting between Impax and Endo at which Impax updated Endo on the change in formulation strategy, Impax offered to amend the DCA so that the DCA would cover the [REDACTED]. F. 403, 408.

³² In 2014, Impax filed an Investigational New Drug Application with the FDA regarding [REDACTED], which the FDA accepted. F. 399.

Initial Decision

Impax was prepared to amend the DCA to include the new formulation of IPX-203 in the DCA because it wanted to work with Endo in order to move the drug forward and believed the new formulation would give it “an avenue through which we could continue the development of IPX-203.” F. 409. Endo initially agreed to the proposed amendment, noting that it “would like to maintain or even increase [its] involvement with the development program . . . as [it] remain[ed] optimistic this will be a successfully differentiated product, which Endo looks forward to the opportunity to co-promote . . . with Impax.” F. 410. However, Endo subsequently informed Impax that Endo had decided not to amend the existing agreement and would no longer participate in co-development program, which surprised Impax. F. 412. Endo did not provide an explanation. F. 412.

Because Endo retracted its initial expression of interest in amending the DCA to cover the new formulation for IPX-203, Impax and Endo terminated the DCA by mutual agreement, effective December 23, 2015. F. 414.

iii. Conclusion

The evidence, summarized above and detailed in Section II.C.3, proves that the DCA was a bona fide product development collaboration, and that the \$10 million payment was justified by the profit-sharing rights given to Endo under the DCA. The product collaboration for IPX-203 was consistent with Endo’s and Impax’s business interests. Both Endo and Impax had a history of interest in Parkinson’s disease treatments, and Endo had entered into many collaboration agreements with other pharmaceutical companies, including risky early stage development collaborations. Impax required outside funding to advance the development of IPX-203, which Impax projected could cost between \$80 and \$100 million by 2017. Moreover, Impax continued its development efforts regarding IPX-203 for years after executing the DCA, which further indicates that the DCA was a bona fide agreement.

In addition, substantial weight is properly given to the fact that Endo analyzed the commercial and medical merits of co-promoting IPX-203, as well as the risk allocation under the DCA,

Initial Decision

and concluded that the DCA was a “good deal” for Endo. The record supports Endo’s conclusion, including the facts that Endo would receive its share of the profits without performing any development work; Endo did not consider the upfront payment of \$10 million to be uncharacteristically large; and the projected rate of return [REDACTED] was nearly [REDACTED] Endo’s minimum requirements for a co-development deal.

iv. Complaint Counsel’s arguments as to lack of justification

All of Complaint Counsel’s arguments in support of a conclusion that the \$10 million payment was unjustified have been fully reviewed, and have been rejected as either contrary to the weight of the evidence or insufficiently supported.³³ Only a few of Complaint Counsel’s arguments require further elaboration, and are discussed below.

(a) Asserted “switch” from IPX-066 to IPX-203

Complaint Counsel asserts that the evidence shows that the \$10 million upfront payment in the DCA was the same as the amount of the payment in Endo’s initial offer, despite a “switch”

³³ For example, Complaint Counsel contends that Endo and Impax “understood” the DCA to be a payment for the Opana settlement, relying on two documents. Neither document warrants the inference urged by Complaint Counsel. The first document, an internal Endo document drafted by Dr. Cobuzzi, listed the “license deal completed with Impax” as adding “topline revenue for Opana.” CX1701 at 005. However, although given the opportunity, Complaint Counsel did not elicit any testimony from Dr. Cobuzzi on the meaning of this document. The second document, an internal Impax document, listed \$10 million as cash flow from the “Endo Settlement.” However, when this document was shown to Impax’s former CFO, Mr. Koch, he testified that he did not recognize the document, that it did not appear to be an accounting document, that other aspects of the document were inconsistent with Impax’s common budgeting practices, and that it could have been referring to the research and development collaboration. CX2701 at 004; CX4018 (Koch, Dep. at 147-48). Furthermore, Complaint Counsel’s assertion that the parties “understood” the DCA to be a payment for delay is not only unsupported, but is also against the weight of the evidence, which, as set forth above, demonstrates that the DCA was a bona fide product collaboration.

Initial Decision

from IPX-066 to IPX-203, which, according to Complaint Counsel, reduced the value of the deal to Endo. Thus, Complaint Counsel argues, the \$10 million upfront payment was not in fact an exchange for value received by Endo under the DCA. However, the evidence shows that, while Endo's initial term sheet included a \$10 million upfront payment for a proposed deal on IPX-066, it also contained more limited profit-sharing terms than those agreed upon in the DCA. Under Endo's May 26, 2010 initial term sheet co-promote proposal, Endo would receive 50% of the profits from sales generated by non-neurologists. F. 294. Under the final DCA, Endo received a right to 100% of those profits. F. 250. Moreover, as explained in Section III.C.4.c.ii.(b) above, designation of IPX-066a (IPX-203) was not a "switch" by Impax from IPX-066, but a rejection by Impax of Endo's proposal for a deal regarding both IPX-066 and IPX-203, and a counterproposal by Impax for a collaboration on IPX-203 only. The evidence shows that Impax was never interested in partnering on IPX-066. Thus, Complaint Counsel's assertion that this "switch" shows the payment was unjustified is rejected.

(b) Due diligence

Complaint Counsel contends that Endo did not perform appropriate due diligence as to the merits of IPX-203 or the DCA. However, the evidence shows that Impax provided Endo with information regarding Impax's research into the IPX-203 product concept and about how IPX-203 would improve upon existing Parkinson's disease therapies, including IPX-066. F. 322. Impax had provided information to Endo about IPX-066, and the information Impax provided on IPX-203 made clear that IPX-066 and IPX-203 were intended to be [REDACTED]. F. 323.

In addition, the materials Impax sent to Endo to review regarding IPX-066 were, as stated by Dr. Cobuzzi, "tremendously" helpful to Endo in assessing IPX-203. F. 330. As Dr. Cobuzzi explained, both IPX-066 and IPX-203 were based on carbidopa and levodopa. The only difference in IPX-203 [REDACTED], which Endo viewed as "relatively simple," notwithstanding that this was a change in the chemistry. F. 330. Endo's chief operating officer at the time of

Initial Decision

settlement and the individual responsible for assessing the commercial opportunity of any product, also deemed IPX-066 an appropriate commercial proxy for assessing IPX-203. F. 331. The IPX-066 materials, as well as Endo's experience with other Parkinson's disease treatments, including Sinemet, suggested to Endo that the successful development of IPX-203 would more effectively treat Parkinson's disease symptoms. F. 260, 332, 343. Endo's reliance on information about a related drug when evaluating IPX-203 was not unusual. F. 335. Rather, the evidence shows that Endo routinely relied on information about one pharmaceutical asset to assess another, related pharmaceutical asset. F. 335. Indeed, when information about related pharmaceutical assets is available, it is "much easier" to evaluate a proposed drug than it is to evaluate a new chemical entity on its own. F. 336.

Finally, as noted above, Dr. Cobuzzi was the lead scientist on the team that evaluated the commercial and scientific merits of the DCA for Endo. F. 337. Dr. Cobuzzi holds a Ph.D. in molecular and cellular biochemistry and wrote his dissertation on Parkinson's disease. F. 339. In addition, Dr. Cobuzzi's team included at least one other scientist with a background in Parkinson's disease treatments, Dr. Kevin Pong. F. 340. Dr. Pong, who was in charge of evaluating Endo's scientific licenses, had a "significant amount of experience" in the area of Parkinson's disease treatments. F. 340. Endo knew the underlying molecules, the carbidopa and levodopa, had looked at a number of Parkinson's disease opportunities in the past, and knew the general commercial landscape. F. 344. Dr. Cobuzzi's belief that Endo had sufficient time to assess IPX-203 before entering into the DCA is entitled to substantial weight, given his qualifications, his and Endo's familiarity with Parkinson's disease treatments, and the detailed nature of the information Impax provided on IPX-066. F. 342-345. Accordingly, Complaint Counsel's assertion that Endo did not perform proper due diligence with regard to the DCA is rejected.

(c) Expert opinions

Complaint Counsel's argument that the \$10 million payment under the DCA was unjustified because it was negotiated as part

Initial Decision

of the patent litigation settlement discussions, not as a standalone agreement, is based largely on the opinion of its proffered expert in negotiations, Professor Max Bazerman. Professor Bazerman opined that 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 (Bazerman Expert Report at 021-22 ¶ 43). This opinion ignores the significant facts that Impax and Endo had discussed a potential collaboration on Frova (another central nervous system drug) in early 2009, months before settlement discussions began (F. 275), that Endo had been looking for an opportunity in the Parkinson's disease area for a number of years (F. 257-261), and that Impax had been exploring a number of approaches to get external funding to move the IPX-203 product forward in development (F. 376). Even though the evidence shows that the DCA was negotiated and executed contemporaneously with the SLA and is incorporated into the SLA (F. 123, 245), this neither compels the conclusion that the \$10 million payment under the DCA was unjustified, nor precludes the conclusion that the \$10 million payment under the DCA was justified as fair value for the profit-sharing rights Endo received under the DCA.

Complaint Counsel's argument that the \$10 million payment under the DCA should be deemed unjustified because the DCA was not consistent with Endo's, or the industry's, usual business development practice, is based largely on the opinion of its proffered expert in pharmaceutical business development, Dr. John Geltosky.³⁴ Although he opined that Endo did not perform a comprehensive and integrated due diligence analysis of IPX-203 before agreeing to the terms of the DCA (CX5003 (Geltosky Expert Report at 023-24 ¶ 37)), Dr. Geltosky did not offer an opinion regarding whether Endo exercised good business judgement in its due diligence. F. 427. Furthermore, Dr.

³⁴ Dr. Geltosky has worked on a handful of development deals in their early stages and has never negotiated a development and co-promotion agreement similar to the DCA. The majority of Dr. Geltosky's experience with pharmaceutical collaboration agreements relates to his employment with large pharmaceutical companies and Dr. Geltosky admitted that he could not speak to how the universe of small or mid-sized pharmaceutical companies approach partnerships for early-stage products. F. 415.

Initial Decision

Geltosky admitted that information about IPX-066 provided useful information for IPX-203 and that Impax provided Endo with comprehensive information regarding IPX-066, including clinical information regarding safety and efficacy, intellectual property, technical due diligence, and financial analysis. F. 425-426. The opinion offered by Dr. Geltosky is outweighed by documentary evidence and fact witness testimony summarized above showing the sufficiency of the due diligence steps taken by Endo.

In addition, although Dr. Geltosky testified that the DCA was not consistent with the normal practice in the pharmaceutical industry, he did not offer an opinion regarding whether the DCA was a bona fide scientific collaboration or whether Endo exercised good business judgement in entering the DCA. F. 417. Indeed, Dr. Geltosky acknowledged that Endo's senior vice president of corporate development (Dr. Cobuzzi) is better qualified to assess the strategic fit of the DCA for Endo than he is. F. 416.

Expert opinion that a process was unusual for the industry, even if accepted, does not warrant the inference that the DCA was a pretext, and not a bona fide side deal for value, because such inference would be contrary to the weight of the evidence showing that the DCA was justified as fair value for profit-sharing rights. See *Schering*, 402 F.3d at 1069-71; *In re Schering-Plough Corp.*, 2002 FTC LEXIS 40 at **254-55 (June 27, 2002), *rev'd by In re Schering-Plough Corp.*, 2003 FTC LEXIS 187 (2003), *rev'd by Schering-Plough*, 402 F.3d 1056. In *Schering*, the FTC argued that a \$60 million payment from a branded drug manufacturer to a generic drug manufacturer, pursuant to a patent litigation settlement agreement through which the branded drug company obtained licenses for the generic company's products, was not a bona fide royalty payment, but instead was an inducement for the agreement by the generic to delay generic entry. 402 F.3d at 1068. Complaint Counsel in the administrative litigation had relied on expert opinion that the parties' diligence was "strikingly superficial," *Schering*, 2002 FTC LEXIS 40, at **254-55, and "fell astonishingly short of industry standards." *Schering*, 402 F.3d at 1069. The Court of Appeals in *Schering* rejected these arguments, and held that "substantial and overwhelming

Initial Decision

evidence” weighed against the conclusion that the licenses were not worth the payment made and were exchanged for delay. *Id.* at 1070-71.

The evidence presented in *Schering* is analogous to the evidence in the instant case. Similar to the brand drug manufacturer in *Schering*, Endo had a demonstrated, ongoing interest in the type of product that was the subject of the collaboration, F. 257-261; see *Schering*, 402 F.3d at 1069, and was well-familiar with the relevant commercial environment. F. 337-345; see *Schering*, 2002 FTC LEXIS 40, at **251-52. And, as in *Schering*, Complaint Counsel’s experts’ criticisms of the diligence process in the instant case did “nothing to refute that [the brand’s] payments [for the licensed products were] a fair price.” F. 428-436; see *Schering*, 402 F.3d at 1071.

Dr. Geltosky also opined that the payment structure of the DCA was unusual because, in his opinion, the DCA payment structure was “frontloaded” with a large upfront payment with decreasing milestone payments, while early-stage development deals are typically “backloaded.” However, Dr. Geltosky did not compare the payment terms in the DCA to the payment terms in other pharmaceutical collaboration agreement agreements. F. 431. Moreover, expert opinion that the payment was “unusual” does not warrant an inference that the payment was unjustified. For purposes of justification, the issue is whether the payment was fair value for what was received. Dr. Geltosky did not opine on that value. F. 430, 432.

Indeed, Dr. Geltosky did not conduct any valuation analysis of the DCA, did not calculate a net present value of the DCA at the time it was executed, and did not conduct any other form of empirical analysis regarding the DCA. F. 429. Dr. Geltosky did not offer any opinion about the actual value of the DCA to Endo and did not address the actual value of the profit-sharing rights acquired by Endo or whether Endo’s profit-sharing rights justified its DCA payment obligations. F. 430, 432. See also F. 417, 419, 421, 427, 434. These shortcomings incurably undermine Dr. Geltosky’s opinions. See *Schering*, 402 F.3d at 1069 (stating that the court was “troubled” by expert opinion that a payment was “grossly excessive” and that Schering’s due diligence fell short of

Initial Decision

industry standards, where the expert had “arrived at his conclusions without performing a quantitative analysis” of the licensed products).

Moreover, Complaint Counsel’s economic expert, Professor Noll, who relied on Dr. Geltosky’s “analysis of the degree to which the \$10 million payment and co-development deal represented the acquisition of an asset that was approximately valued at a \$10 million price,” agreed that if Dr. Geltosky did not offer an opinion regarding the actual value of the DCA to Endo at the time it was executed, then Professor Noll “would not include the \$10 million as part of the large payment that was unjustified.” F. 437-438. Professor Noll also acknowledged that, if a payment from a brand company to a generic company is used to purchase a bundle of rights at a fair market price, the payment is justified. F. 435. Indeed, Professor Noll testified that if Dr. Geltosky did not provide a “sufficiently well-documented rationale for the conclusion that the payment was unjustified, then you would pull [the DCA] out of the case.” F. 439.

(d) Conclusion

As explained above, the evidence proves that the \$10 million payment made by Endo to Impax under the DCA was justified as fair value for profit-sharing rights Endo received under the DCA.

5. Conclusion on initial burden of proof

Of the total reverse payment conferred under the Endo-Impax Settlement, the \$10 million payment under the DCA was justified. However, the value conferred to Impax by the no-AG provision of the SLA, secured by the Endo Credit, totaling \$23 to \$33 million in projected sales revenue for Impax, was an unjustified reverse payment. The value of this unjustified reverse payment substantially exceeded the estimated saved litigation costs. In addition, the evidence supports the inference that Endo and Impax agreed to this reverse payment as an inducement to Impax, to compensate Impax for giving up its patent challenge and committing not to launch a generic Opana ER until January 2013. Therefore, based on the totality of the record, viewed as a whole, the evidence supports the inference that the SLA included a

Initial Decision

payment to prevent the risk of competition. Accordingly, Complaint Counsel has met its initial burden of proving an anticompetitive harm.

D. Market Power

Market power is “the power to control prices or exclude competition.” *United States v. E.I. du Pont de Nemours & Co.*, 351 U.S. 377, 391 (1956). It is unclear whether proof of market power is a necessary element of a reverse payment settlement challenge. Although *Actavis* referred to market power as one of several traditional antitrust considerations, market power is not expressly included among the factors listed in *Actavis* as determining the likelihood of anticompetitive effects. *Actavis*, 133 S. Ct. at 2237 (stating that “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”); see also *King Drug*, 791 F.3d at 412 (same). Regardless of whether proof of market power is mandatory, in the instant case the evidence supports the conclusion that Endo had market power in the relevant oxymorphone ER market at the time of the Endo-Impax Settlement, as explained below.

By their nature, pharmaceutical patents often carry with them market power. *In re Wellbutrin XL Antitrust Litig.*, 133 F. Supp. 3d 734, 755 (E.D. Pa. 2015), *aff’d* 868 F.3d 132 (3d Cir. 2017). As the court explained in *Aggrenox*, a patent “grant[s] the legal right to exclude generic competition and the practical ability to profitably charge higher prices than generic competitors would charge.” 199 F. Supp. 3d at 668. *Accord Lipitor*, 2018 U.S. App. LEXIS 93, at *6 (“A distinguishing feature of a reverse settlement is that the bargained-for abstention period falls within the term of the patent at issue, when the patent holder would normally enjoy a government-conferred monopoly.”).

Actavis recognizes that market power is often associated with a pharmaceutical patent, and further holds that proof of that power, derived from the patent, can be found in the reverse payment settlement itself:

Initial Decision

[W]here a reverse payment threatens to work unjustified anticompetitive harm, the patentee likely possesses the power to bring that harm about in practice. At least, the “size of the payment from a branded drug manufacturer to a prospective generic is itself a strong indicator of power” – namely, the power to charge prices higher than the competitive level. An important patent itself helps to assure such power. Neither is a firm without that power likely to pay “large sums” to induce “others to stay out of its market.”

Id. at 2236 (citations omitted). *Accord Loestrin*, 814 F.3d at 552 n.12 (“*Actavis* explains how to evaluate the market power question: ‘the size of the payment from a branded drug manufacturer to a prospective generic is itself a strong indicator of power.’”). The court in *In re Cipro Cases I & II* further explained:

Logically, a patentee would not pay others to stay out of the market unless it had sufficient market power to recoup its payments through supracompetitive pricing. Consequently, proof of a reverse payment in excess of litigation costs and collateral products and services raises a presumption that the settling patentee has market power sufficient for the settlement to generate significant anticompetitive effects.

348 P.3d at 869. *See also Aggrenox*, 199 F. Supp. 3d at 662 (stating that, while it is conceivable that a patent might be worthless, “[i]t is vanishingly unlikely . . . that a large reverse payment would be made in such a case, which is why a large reverse payment is such a strong indicator of market power”).

In the instant case, as held in Section III.C.2.c above, the evidence proves that Endo made an unjustified reverse payment to Impax that was sufficiently large to induce Impax to drop its patent challenge and agree not to enter the relevant oxymorphone ER market until January 2013. Under *Actavis*, this is strong proof of Endo’s market power in the relevant market.

Initial Decision

Other evidence also supports the conclusion that Endo had market power in the relevant oxymorphone ER market. The evidence shows that in 2010, Endo had a 100% share of the market for oxymorphone ER. F. 90. In addition to the intellectual property barriers to entry associated with Endo's patents, there are regulatory barriers created by the Hatch-Waxman Act. F. 92. For instance, the Hatch-Waxman Act imposes a 30-month stay on FDA approval of an ANDA, if a branded drug company files a patent infringement suit against a Paragraph IV ANDA filer. F. 93. Moreover, the first filer's 180-day exclusivity period provided by the Hatch-Waxman Act serves as a barrier to entry by barring later ANDA filers from entering until the period expires. F. 93. These barriers gave Endo the power to exclude competitors even if its patents eventually were found not to be valid or infringed. F. 95.

Based on the foregoing, the evidence demonstrates that Endo had market power in the relevant market for oxymorphone ER. The analysis next turns to the procompetitive benefits of the SLA.

E. Procompetitive Benefits

1. Overview

Respondent argues that the SLA granted Impax a broad patent license, which enabled Impax to sell its generic Opana ER uninterrupted since Impax entered the market in January 2013, while all other generic manufacturers have been enjoined as a result of patent infringement litigation by Endo. Respondent argues that, therefore, the SLA provided substantial procompetitive benefits.

Complaint Counsel's opposing argument – that Respondent's asserted procompetitive benefits cannot be considered because the only legally cognizable procompetitive effects are those that arise from the reverse payment – is without merit, as explained in Section III.B.7 above. The "restraint" at issue in a reverse payment settlement case is not the payment itself, but the use of the payment in such a way as to restrain the onset of generic competition. Thus, procompetitive benefits arising in connection with the settlement agreement as a whole are properly considered

Initial Decision

as part of a well-structured rule of reason analysis. See *K-Dur*, 2016 U.S. Dist. LEXIS 22982, at *46 (“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.”); *Cipro Cases I & II*, 348 P.3d at 871 (same); see also *In re Impax*, 2017 FTC LEXIS 130, at *27-33 (Commission rejecting Complaint Counsel’s request to preclude consideration of entry prior to termination of patent and effect of post-settlement events as potential procompetitive justifications).

2. Relevant provisions

The SLA granted Impax a broad patent license and a covenant not to sue that covered not just the Opana ER patents owned by Endo at the time of the Endo-Impax patent litigation, but all patents “that would ever be owned by [Endo] that would cover the Impax product.” F. 567. Specifically, pursuant to section 4.1(a) of the SLA, Impax obtained a license to the ’933, ’456, and ’250 patents, and to any pending patents “that cover or could potentially cover the manufacture, use, sale, offer for sale, importation, marketing or distribution of” Impax’s generic Opana ER product (collectively, the “licensed patents”). F. 568-569.

Furthermore, section 4.1(b) of the SLA included a “covenant not to sue,” which prohibited Endo and its affiliates from suing Impax for patent infringement on any of the licensed patents. F. 570. This provision meant that Endo could not sue Impax for infringement based on Endo’s Opana ER patents listed in the Orange Book at the time of settlement, as well as any continuations, continuations in part, or divisions of those patents or patent applications owned or controlled by Endo, that could cover Impax’s generic Opana ER. F. 570. (The broad patent license and covenant not to sue provided in the SLA are at times referred to collectively herein as the “broad license agreement” or “broad patent license.”)

Impax would regularly seek a broad patent license in its settlement negotiations with brand-name drug companies whenever it intended to launch and continue to sell its generic product indefinitely, in order to provide Impax with as much

Initial Decision

flexibility as possible. F. 565. 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.” F. 565. For Impax, every settlement agreement must cover all the patents that could affect the generic product, existing and future, “otherwise you end up with [a] launch [of] the product and still have to be under the [patent] risk, and that doesn’t really help [Impax].” F. 566.

Given the possible effects of Endo’s additional patent applications relating to Opana ER, a reasonable litigant would have been concerned with Endo’s future patents. F. 168. Consistent with Impax’s regular practice, in the Endo-Impax negotiations, Impax proposed broadening the patent license that Endo had offered in the SLA to include “any patents and patent applications owned by or licensed to Endo . . . that cover or could potentially cover” Impax’s generic oxymorphone ER product. F. 169. Endo accepted Impax’s proposed language. F. 170.

3. Post-settlement patents and patent litigation

After entering into the SLA, Endo obtained additional patents and patent licenses that it has asserted cover both original and reformulated Opana ER (the “after-acquired patents”). F. 571. Endo acquired its first post-settlement patent – U.S. Patent No. 7,851,482 – from Johnson Matthey in March 2012 (the “Johnson Matthey patent”). F. 573. In addition, between November 2012 and October 2014, the Patent and Trademark Office issued the following patents to Endo: Patent Nos. 8,309,060 (“the ’060 patent”); 8,309,122 (“the ’122 patent”); Patent No. 8,329,216 (“the ’216 patent”); Patent No. 8,808,737 (“the ’737 patent”); and Patent No. 8,871,779 (“the ’779 patent”). F. 575-576, 579-581.

In December 2012, Endo began asserting the ’060, ’122, and ’216 patents in litigation against drug manufacturers seeking to market generic versions of both original and reformulated Opana ER. F. 577. At that time, Endo did not assert these patents against Impax’s generic version of original Opana ER. F. 577. Endo did, however, assert these patents against a generic version of reformulated (crush-resistant) Opana ER, which was covered

Initial Decision

by an ANDA filed by Impax. F. 577. In August 2015, the district court for the southern district of New York held that the '122 and '216 patents were not invalid and were infringed by other companies' generic versions of original Opana ER and by all companies', including Impax's, generic versions of reformulated Opana ER. F. 578. That court issued an injunction barring all defendants, except Impax, from selling their generic versions of original Opana ER until 2023. That ruling is currently on appeal to the Federal Circuit. F. 578.

In addition, Endo asserted the '737 and '779 patents in litigation in the district court of Delaware against drug manufacturers seeking to market generic versions of both original and reformulated Opana ER. F. 583. Endo did not assert these patents against Impax's generic version of original Opana ER because of the SLA's broad patent license; however, Endo did assert the patents against Impax's ANDA for a generic version of reformulated (crush-resistant) Opana ER. F. 584. In October 2016, the Delaware court held that the '779 patent was not invalid and was infringed by a generic version of reformulated Opana ER. F. 586. That ruling is currently on appeal to the Federal Circuit. F. 586. In August 2017, the Delaware court again ruled that the '779 patent was not invalid, following a bench trial against other ANDA filers. F. 587. In September 2017, the Delaware court entered its final order, enjoining all defendants from selling generic Opana ER until the last of Endo's patents expires in 2029. F. 587-588.

4. Effect of broad license agreement

The broad license agreement gave Impax protection against any of Endo's future patents being asserted against Impax for its generic version of original Opana ER. F. 593. Thus, these provisions gave Impax freedom to sell its generic Opana ER under both the litigated patents and any future patents that Endo might obtain in this product area. F. 592. The January 2013 entry date provided in the SLA, together with the broad license agreement, enabled a generic Opana ER to enter the market eight months before the original patents expired, and sixteen years before Endo's after-acquired patents expired, and to continue with the sale of that product up to the present day, without threat of

Initial Decision

patent infringement litigation relating to original Opana ER. F. 594.

Impax's product is the only generic Opana ER available to consumers. F. 596. Although every other Opana ER ANDA filer settled patent claims asserted by Endo related to Opana ER, no other drug manufacturer negotiated rights to future Opana ER patents similar to the broad license agreement that Impax obtained in the SLA. F. 595. Endo's acquisition and successful litigation of additional patents has led to all generic manufacturers, other than Impax, being enjoined from selling a generic version of Opana ER until the last of Endo's patents expires in 2029. F. 588, 596. Impax, in contrast, has sold generic Opana ER without interruption since launching its product in January 2013. F. 597.

5. Analysis

a. Procompetitive benefits

The Supreme Court has held that "enabl[ing] a product to be marketed which might otherwise be unavailable . . . widen[s] consumer choice . . . and hence can be viewed as procompetitive." *NCAA v. Board of Regents*, 468 U.S. 85, 102 (1984); accord *Brown Univ.*, 5 F.3d at 675 ("Enhancement of consumer choice is a traditional objective of the antitrust laws and has also been acknowledged as a procompetitive benefit.").

The evidence shows that Endo's acquisition of additional patents, and successful assertion of those additional patents in litigation, has led to all generic manufacturers, other than Impax, being enjoined from selling a generic version of Opana ER until the last of Endo's patents expires in 2029. F. 592-598. This is clear evidence of the strength of the after-acquired patents, and supports the inference that, absent the SLA, such after-acquired patents also would have been successfully asserted to enjoin Impax from selling generic Opana ER – even if Impax had gone to trial and won its challenge to the patents at issue in the Endo-Impax patent litigation. Instead, as a result of the broad license agreement in the SLA, Impax has sold generic Opana ER without interruption since launching the product in January 2013. F. 598. This is despite Endo's efforts, through filing FDA citizen petitions

Initial Decision

with the FDA, to have original Opana ER removed from the market for alleged safety reasons. F. 233-235.

The case of *In re Wellbutrin XL Antitrust Litigation* is additional authority supporting the conclusion that the broad patent license in the SLA is procompetitive. In *Wellbutrin*, as part of a reverse payment patent settlement, the brand drug manufacturer, GlaxoSmithKline (“GSK”), granted to the generic manufacturers a sublicense to certain patents (the “Andrx patents”) acquired by GSK in connection with the settlement of a separate patent lawsuit among GSK, Andrx, and the generic manufacturers. 133 F. Supp. 3d at 737, 747. The Andrx patents were not due to expire for 15 more years. *Id.* at 759. The court held that the sublicense provided under the settlement agreement was a cognizable procompetitive justification for the agreement because the sublicense “eliminat[ed] an independent and substantial hurdle to generic entry” and removed “the possibility that Andrx could prevent generic Wellbutrin XL from being marketed for the 15 years remaining on its patent.” *Id.* at 758-59. The court further held that the plaintiffs had failed to present a genuine factual dispute as to this procompetitive justification. *Id.*

In the instant case, as in *Wellbutrin*, Impax negotiated for a broad license agreement in order to ensure that it had the freedom to sell generic Opana ER without concern of patent infringement liability going forward. F. 167, 169, 565-566. In addition, as in *Wellbutrin*, the SLA eliminated a separate, and substantial, hurdle that Endo could have imposed on Impax’s sale of generic Opana ER by asserting after-acquired patents against Impax – patents that Endo successfully did assert against other generic manufacturers. F. 575-587.

In summary, the evidence proves that consumers have benefitted from the SLA by having uninterrupted and continuous access to generic Opana ER since January 2013. The real-world effect of the SLA is that there is a product on the market and available to consumers today that would not be there had Impax not had the foresight to negotiate licenses to future patents. F. 600. This is procompetitive. *See NCAA*, 468 U.S. at 102; *Brown Univ.*, 5 F.3d at 675.

Initial Decision

Furthermore, the Challenged Agreement settled litigation, which is favored in the law. *American Sec. Vanlines, Inc. v. Gallagher*, 782 F.2d 1056, 1060 (D.C. Cir. 1986) (“Few public policies are as well established as the principle that courts should favor voluntary settlements of litigation by the parties to a dispute.”); *TBK Partners, Ltd. v. Western Union Corp.*, 675 F.2d 456, 461 (2d Cir. 1982) (noting “the paramount policy of encouraging settlements”). Although *Actavis* held that the policy in favor of settlement was not a sufficient reason to bar antitrust review, see Section III.B.2 above, nothing in the language of *Actavis* holds that this factor is precluded from consideration. In addition, the fact that the SLA enabled Impax to enter the market prior to the expiration of Endo’s Opana ER patents, while not dispositive, can be considered in assessing the competitive consequences of the Challenged Agreement. See *In re Impax*, 2017 FTC LEXIS 130, at *29. In the instant case, the SLA enabled Impax to enter the market in January 2013, nine months before expiration of the initial Opana ER patents in September 2013, and sixteen years before the expiration of Endo’s after-acquired patents in 2029.

For all the foregoing reasons, Respondent has met its burden of proving that the SLA had procompetitive benefits.

b. Less restrictive alternative

Because Respondent has met its burden of proving that the SLA had procompetitive benefits, the burden shifts to Complaint Counsel to demonstrate that these benefits could have been achieved with a less restrictive settlement agreement. See *Law*, 134 F.3d at 1019. Complaint Counsel contends that Endo and Impax could have entered into a settlement that did not include any payment to stay off the market. However, Complaint Counsel fails to demonstrate that such hypothetical settlement could have, or would have, included the broad patent license.³⁵ Accordingly, Complaint Counsel has failed to meet its burden of proving that

³⁵ With respect to the likelihood of a hypothetical alternative settlement with no reverse payment and an entry date earlier than January 2013, it is noteworthy that Impax twice proposed a simple settlement with a 2011 entry date and no reverse payment, which Endo rejected. F. 116, 155.

Initial Decision

the demonstrated procompetitive benefits of the SLA in this case could have been achieved through a less restrictive settlement agreement.

The final step of the rule of reason analysis, set forth below, weighs the anticompetitive and procompetitive effects of the SLA, to determine whether, on balance, the agreement is anticompetitive.

F. Balancing of Anticompetitive and Procompetitive Effects

Where the evidence proves that an agreement poses both anticompetitive harm and procompetitive benefits, “the harms and benefits must be weighed against each other in order to judge whether the challenged behavior is, on balance, reasonable.” *Law*, 134 F.3d at 1019. Plaintiffs have the burden of establishing that “the settlement is nevertheless anticompetitive on balance.” *Nexium*, 42 F. Supp. 3d at 262-63; *Loestrin*, 261 F. Supp. 3d at 329.

As the court recognized in *In re Cipro Cases I & II*, “the relevant benchmark in evaluating reverse payment patent settlements should be no different from the benchmark in evaluating any other challenged agreement: What would the state of competition have been without the agreement?” 348 P.3d at 863. Regardless of whether Complaint Counsel must prove actual delay in the onset of generic competition to meet its initial burden as to anticompetitive effect, it is appropriate to assess the magnitude and/or extent of delayed generic competition in order to balance anticompetitive harm against demonstrated procompetitive benefits. *See Impax Labs*, 2017 FTC LEXIS 130, at *29-30 (holding that a settlement providing for 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, which “[a]t a minimum . . . affects the magnitude of any anticompetitive effect”). Complaint Counsel bears the overall burden of establishing that the Challenged Agreement “engendered a net harm.” *Cal. Dental Ass’n*, 224 F.3d at 957-58.

Initial Decision

Respondent argues that the Endo-Impax Settlement expedited generic competition, as compared to litigating the Endo-Impax patent dispute, regardless of the eventual outcome of that litigation. Respondent asserts that even if Impax had prevailed, the Endo-Impax patent litigation would have delayed generic competition until as late as January 2013.

Complaint Counsel urges rejection of Respondent's evidence as to the expected duration of the patent litigation. Complaint Counsel further argues that, regardless of when the underlying litigation might have ended, the evidence proves that, absent the Endo-Impax Settlement, Impax might have launched its generic Opana ER "at risk" to compete with Endo as early as June 2010, after Impax received final FDA approval of its generic Opana ER. These arguments are analyzed below.³⁶

1. Entry by at-risk launch

a. Background

As explained in Section III.A.3 above, Endo's patent infringement suit against Impax, filed on January 25, 2008, triggered the Hatch-Waxman 30-month stay on approval of Impax's ANDA for generic oxymorphone ER, meaning that the FDA could not approve Impax's ANDA until the earlier of the expiration of 30 months or resolution of the patent dispute in Impax's favor. F. 61-62. If litigation is still pending at the end of the 30-month period, the FDA may give its approval to the generic drug manufacturer to begin marketing a generic version of the drug. *Lipitor*, 868 F.3d at 241; 21 U.S.C. § 355(j)(5)(B)(iii). Pursuant to the Hatch-Waxman framework, once Impax received final approval from the FDA in June 2010, Impax had the option

³⁶ It is undisputed that the outcome of the Endo-Impax patent litigation was uncertain at the time of settlement. F. 553. The duration of continued litigation, as the alternative to the Endo-Impax Settlement, is relevant to the magnitude and/or extent of the anticompetitive effects of the Endo-Impax Settlement. Such analysis does not require, and does not include, an assessment of the merits of the underlying patent dispute. See *Actavis*, 133 S. Ct. at 2236 (stating that "it is normally not necessary to litigate patent validity to answer the antitrust question").

Initial Decision

to launch its generic oxymorphone ER product “at risk.” F. 66-67, 451-452.

Launching at risk refers to the risk of liability for the brand-name manufacturer’s lost profits, if the generic challenger launches its product prior to a non-appealable decision in the underlying patent litigation and ultimately loses its patent challenge. F. 452-453; *Lipitor*, 868 F.3d at 241; *King Drug*, 791 F.3d at 396 n.8. Lost profits are measured by the profits the patent owner would have made on sales of its branded product, but for the launch of the generic product. F. 453. Damages can be trebled if the infringement is found to be willful, for instance, if the generic product is launched before the district court rules on the patent dispute. F. 453. In addition, if the brand company wins its action against a generic company that has launched at risk and the generic company’s actions are deemed “exceptional,” courts may award attorney’s fees to the brand company. F. 457.

Generic companies often risk far more in infringement liability than they earn from each sale when launching at risk. F. 454. Damages are not measured by the generic’s sales revenue, but by the profits the brand company would have earned on such sales. F. 454. Thus, potential damages for launching at risk can represent “bet-the-company” stakes and can “take [away] the solvency of the company entirely.” F. 455. Damages can be in the billions of dollars, if the sales of the branded drug are high enough, and “would almost always be greater than the total revenues that the generic company receives” from launching at risk. F. 455.

Moreover, launching at risk jeopardizes a first filer’s 180-day exclusivity period, which is “extremely valuable.” F. 456. If the generic company launches at risk and is enjoined from making sales, the generic company forfeits some of its 180-day exclusivity because the 180-day time period continues to run during the period the generic is enjoined. F. 456. Even if the injunction is eventually lifted or the infringer prevails in the underlying patent litigation, the patent infringer can never recover the forfeited part of its 180-day exclusivity period. F. 456.

Initial Decision

At-risk launches are fairly uncommon across the entire pharmaceutical industry. F. 458. At-risk launches are most common when there are multiple ANDA filers who have received approval from the FDA, no ANDA filer has exclusivity, and there subsequently is a race to the market by generic firms. F. 459. When at-risk launches do occur, they generally are undertaken by large pharmaceutical companies that can absorb significant financial risk in the event they are found to infringe. F. 460. Complaint Counsel's expert witness, Professor Noll, identified 48 at-risk launches over a 15-year period (August 2001 thru April 2015). Twenty-one of those forty-eight at-risk launches were conducted by Teva, which, Professor Noll explains, "is by far the most likely company to do at-risk launches." F. 461. Teva is a "very large pharmaceutical company" and, as a result, can undertake at-risk launches more regularly. F. 462. Of the 48 at-risk launches identified by Professor Noll, only 4 were conducted by companies with less than \$1 billion in revenue. F. 463. Impax's revenues in 2010 were less than \$1 billion. F. 465.

b. Analysis

The evidence supports the conclusion that Impax would not have launched its generic Opana ER at risk, as further explained below. F. 451-548.

First, the evidence supports the conclusion that it would have been economically disadvantageous for Impax to launch its generic Opana ER at risk. Unlike the overwhelming majority of companies that Professor Noll identified as undertaking at-risk launches, Impax is a small pharmaceutical company, with revenues in 2010 of less than \$1 billion. F. 463, 465. Mr. Koch, Impax's CFO at the time of the Endo-Impax Settlement, explained that "being a small company," Impax "could not bet the company on any one product." F. 467. The potential liability for damages from launching a generic version of Opana ER at risk would have exceeded any profits Impax realized from the launch. F. 544. Impax's potential liability for Endo's lost profits could total as much as \$54 million for six months of sales. F. 546. If it was ultimately determined that Impax's infringement was willful and Endo was awarded treble damages, Impax could be liable for as much as \$162 million for six months of sales. F. 546. In

Initial Decision

contrast to this potential liability, potential sales of oxymorphone ER over six months in 2010, based on an at-risk launch, as projected by Impax, would total only \$28 million. F. 545. In addition, if Impax launched at risk and was then enjoined, Impax would forfeit part of its 180-day exclusivity period. F. 547. Under these circumstances, it “was perfectly reasonable for Impax to view a launch at risk as a losing proposition.” F. 548.

Second, Impax had no relevant history of at-risk launches. Impax is “incredibly conservative” with respect to at-risk launches and only “infrequently” considers the possibility. F. 466-468. Prior to the Endo-Impax patent litigation, Impax had launched a product at risk only once. F. 469. That at-risk launch was for one dosage strength of a generic version of oxycodone. F. 469. Impax limited its risk of damages by capping its potential sales at \$25 million, which, in turn, limited the lost profits it would have had to pay to the branded drug company. F. 469. In fact, Impax launched at risk only after it received a favorable district court decision holding the relevant patents unenforceable and after Teva, the first ANDA filer for the relevant dosage, had launched at risk six months earlier. F. 469. Since the Endo-Impax Settlement in 2010, Impax has undertaken only one at-risk launch, and did so in a limited manner. F. 471. Specifically, Impax and Perrigo, the ANDA holder and marketer of a nasal spray antihistamine named azelastine, entered a partnership agreement through which Impax would share development costs and litigation expenses in return for a share of the drug’s profits. F. 472. In 2014, Perrigo notified Impax that it intended to launch azelastine at risk. F. 472. Under the terms of the Impax-Perrigo partnership agreement, Impax could participate in the launch and earn a share of the profits or could not participate, in which case Perrigo would receive all azelastine profits. F. 472. Impax participated in Perrigo’s at-risk launch, but limited its exposure to potential damages by capping its participation at 150,000 units. F. 472.

Third, Impax did not seek, or obtain, approval for an at-risk launch from Impax’s board of directors, which was an absolute prerequisite. F. 473, 481, 486. *See, e.g.*, F. 482 (Impax has “to have sign off from the Board, because [Impax is] such a small company, and a launch at risk would . . . potentially cause [the]

Initial Decision

company problems” if found liable for substantial damages). Indeed, Impax has an extensive internal process for evaluating an at-risk launch, including a detailed review of the potential product launch by Impax’s new product committee, legal team, marketing team, operations department, and division heads. F. 474-477. Thereafter, Impax’s CFO must present a risk analysis profile to Impax’s executive committee, which has to approve any at-risk launch. F. 477. Impax’s CEO also must approve any decision to launch at risk. F. 478. If Impax’s CEO and executive committee approve a possible at-risk launch, a presentation is made to Impax’s board of directors by Impax’s CFO, legal department, president of the generics division, and the manufacturing department. F. 479-480. Thus, in the case of azelastine, discussed above, Impax senior management, including the president of Impax’s generics business, Impax’s general counsel, and Impax’s in-house attorney responsible for intellectual property, made a presentation and a recommendation regarding the at-risk launch at a special board of directors meeting. F. 484. A resolution was then placed before the Board, and the Board voted to approve the resolution. F. 484. With respect to generic Opana ER, in contrast, Impax’s senior management never decided to pursue an at-risk launch, and the question was never submitted to the board for approval. F. 486-487.

c. Complaint Counsel’s arguments

The evidence fails to prove Complaint Counsel’s assertion that, absent a settlement of the Endo-Impax patent litigation, Impax would have launched its generic Opana ER at risk, as explained below.

i. Consideration of at-risk launch

Complaint Counsel argues that Impax was “considering” an at-risk launch in 2010. CCB at 45-46. Even if true, however, this fact does not warrant an inference that Impax planned to launch at risk, or was likely to launch at risk. Such an inference is against the weight of the contrary evidence, summarized above, that supports the conclusion that Impax was not going to launch its generic Opana ER at risk.

Initial Decision

Moreover, the evidence upon which Complaint Counsel relies to support its argument lacks probative weight. Complaint Counsel points to evidence that Mr. Mengler, president of Impax's generics division, created a presentation for the May 2010 board of directors meeting, in which he listed an at-risk launch of oxymorphone as a "current assumption" for projecting sales of oxymorphone ER, and that according to the minutes of the meeting, Mr. Mengler "expressed the view that [o]xymorphone was a good candidate for an at-risk launch." F. 493-494. However, Mr. Mengler's assumptions with respect to possible sales numbers did not "imply or mean that any legal decision ha[d] been made to clear the way for a launch." F. 493. There was no substantive discussion of an at-risk launch at the May 2010 board of directors meeting; and Impax's senior management did not make a recommendation to the board for an at-risk launch, did not discuss the risk or benefits of an at-risk launch, and did not ask the board to approve an at-risk launch at the May 2010 board meeting. F. 498-499. In 2010, senior management was looking at various possible scenarios and modeled an at-risk launch to forecast how that might impact Impax's budget if the decision to launch at risk were made. F. 488. Mr. Mengler raised oxymorphone ER at the May 2010 Board meeting to put oxymorphone ER "on the radar" of the Board and to "alert the board as to the product being out there that might get to the point of an at-risk launch." F. 495. As Impax's CEO, Dr. Hsu, explained, senior management "want[s] to alert the board that we are considering this [as] one of the scenario[s] so that if we do come up with a final recommendation to the board, there will be no surprise. . . . [T]his is very typical." F. 497. Impax's then CFO, Mr. Koch, who wrote the minutes of the meeting of the May 2010 board of directors meeting, explained that Mr. Mengler was communicating his evaluation of the oxymorphone market and sharing that information with the Board because senior management was unsure of what direction it would "ultimately take and . . . [did not] want to come back to the board seeking an at-risk launch with them never having heard of it before." F. 496.

Initial Decision

ii. Launch preparedness

Complaint Counsel also argues that Impax prepared a “launch inventory build” in 2010, and argues that such evidence shows that Impax was planning to launch at risk. This argument is not supported by the evidence.

The evidence shows that it was Impax’s general practice to have its products that have been filed with Paragraph IV certifications ready to launch after the expiration of the Hatch-Waxman Act’s 30-month stay. F. 503. When a product is 18 months away from its earliest theoretical launch, Impax’s supply chain group begins prelaunch preparation activities. F. 506. This includes requesting a quota from the U.S. Drug Enforcement Agency (“DEA”) to purchase any active pharmaceutical ingredients (“API”) that are controlled substances; purchasing the API and other unique materials necessary to produce the finished product; conducting “process validation” to prove that Impax’s manufacturing process is repeatable and makes the product in a satisfactory manner; and producing a “launch inventory build,” to ensure that Impax has enough product to meet expected demand on the launchable date. F. 508.

The evidence further shows that Impax’s practice is to begin process validation six months before FDA approval of the relevant drug is expected, even if the product is the subject of active litigation. F. 511. Impax may build pre-launch quantities of products in its planning pipeline before either FDA approval is granted or a formal launch decision is made. F. 512. Impax considers its production of pre-launch quantities “routine” and consistent with industry practice. F. 514. Moreover, because Impax’s operations team prepares products for launch before FDA approval or a formal decision about launch timing, it is not unusual for Impax to discard and write off some of the products and raw materials in its inventory. F. 516, 542-543.

Consistent with Impax’s general practice, Impax’s operations team sought to be ready to launch its generic oxymorphone ER product at the expiration of the Hatch-Waxman Act’s 30-month stay on June 14, 2010. F. 503, 517. Impax requested a procurement quota from the DEA for oxymorphone, which was a

Initial Decision

necessary step before it could purchase oxymorphone API for any reason, including to conduct process validation of its oxymorphone ER product. F. 523. The initial allotment of oxymorphone quota was for product development manufacturing. F. 524. In January 2010 and in April 2010, Impax submitted additional requests for oxymorphone procurement quota, which were approved. F. 525-526. By May 20, 2010, Impax had completed process validation for the 5 mg, 10 mg, 20 mg, and 40 mg dosages of generic oxymorphone ER. F. 529. These process validation batches that Impax had built were not sufficient, however, to meet the market demand for a full launch (“launch inventory”). F. 530. The time required to produce the necessary amount of oxymorphone ER would have made a product launch soon after FDA approval in mid-June 2010 impossible. F. 536.

Moreover, Impax never completed a launch inventory build for its oxymorphone ER product. F. 533. Impax’s operations team does not build launch inventory without management approval. F. 531. In the case of oxymorphone ER, the Impax operations team never even received instructions from senior management to begin a launch inventory build. F. 532. Although Impax had solicited letters of intent from four customers asking customers for their good faith estimate of how much product they likely would buy if generic oxymorphone ER came on the market, Impax did not have any pricing contracts or agreements to purchase with those customers. F. 537.

d. Conclusion regarding at-risk launch

The evidence supports the conclusion that, absent a settlement, Impax would not have launched its generic Opana ER at risk, and fails to prove Complaint Counsel’s assertion that, absent a settlement of the Endo-Impax patent litigation, Impax might have launched its generic Opana ER at risk.

2. Entry after litigation

If Impax and Endo had not settled, their patent litigation would have continued. F. 555. Respondent’s contention as to when the patent litigation would likely have concluded relies on the opinions of its intellectual property expert, E. Anthony Figg.

Initial Decision

Mr. Figg's extensive experience in litigating patent matters in the federal courts makes him well qualified to opine on this issue. Mr. Figg is an attorney specializing in intellectual property, primarily involving the chemical, pharmaceutical, healthcare and biotechnology industries. His principal emphasis is patent litigation. He has served as lead counsel in numerous complex patent litigation matters, including Hatch-Waxman litigation, in federal district court and the Federal Circuit Court of Appeals, among other venues. Mr. Figg has practiced patent law since 1978. F. 557. Accordingly, Mr. Figg's opinions on the likely duration of the Endo-Impax patent litigation are entitled to, and are given, substantial weight. Complaint Counsel's arguments that Mr. Figg's opinions on this issue should be rejected as unreliable and/or against the weight of the evidence (*see, e.g.*, CCRB 73-74; CCRFF 1075-1091) have been considered and have been determined to be without merit.

The evidence shows that, following a trial in the Endo-Impax patent litigation, the parties would have had to wait for the district court to issue findings of fact, conclusions of law, and an order. Based on Mr. Figg's review of Hatch-Waxman cases from the district court in New Jersey, a decision would have been issued approximately four to five months after completion of trial, in or around November 2010. F. 556. Regardless of when the district court would have issued its decision in the Endo-Impax patent litigation, however, an appeal was likely, and would take 30 days to be docketed in the Federal Circuit Court of Appeals. F. 588. Based on Mr. Figg's review of statistics maintained by the Federal Circuit, the median time from docketing an appeal to issuance of a final decision was approximately 11 months in 2010 and 2011. F. 559. Applying these statistics, Mr. Figg estimated that an appellate decision in the Endo-Impax litigation would have been issued in November 2011. F. 559. Mr. Figg's estimate of a November 2011 issuance of an appellate decision is "very conservative," however, because the median time from docketing to a final decision, reported in the Federal Circuit statistics, includes settlements and summary affirmances. F. 559. In addition, the Federal Circuit is generous with briefing extensions, which increases the time it takes to receive a decision. F. 560.

Initial Decision

Moreover, if Impax had lost at the trial level, the “centerpiece” of the appeal would have been the trial court’s claim construction ruling, issued on April 5, 2010, which adopted Endo’s proposed constructions for “hydrophobic material” and “sustained release.” F. 71, 561. Impax would have had substantial arguments regarding this ruling on appeal. F. 561. If the appellate court agreed with Impax’s arguments, it is likely that the appellate court would remand to the trial court for further development of the evidentiary issues. F. 562. This is because the parties would need to litigate infringement and validity under Impax’s construction of the claims. F. 562. Because the trial court’s claim construction ruling was in favor of Endo, Endo never developed a record that Impax infringed its patents under Impax’s construction of the claims. F. 562. Thus, lacking a record on the issue of infringement and validity, the Federal Circuit would not decide these issues itself, but would instead direct such decision to the trial court via remand. F. 562. If the appellate court ruled in favor of Impax and remanded the case to the trial court, the evidentiary proceedings on remand would likely have taken up to 18 months to complete, and therefore would not be concluded until a date close to January 2013. F. 563. If Impax lost the appeal in the Federal Circuit, Impax would have been enjoined and would not have been able to launch its oxymorphone ER product until Endo’s patents expired in September 2013. F. 564.

In conclusion, as explained above, the evidence proves that, absent the settlement, ongoing litigation would have prevented Impax’s entry until November 2011 at the earliest, and more likely until a date close to January 2013, assuming Impax ultimately prevailed. If Impax ultimately lost its patent challenge against Endo, Impax would not have been able to launch its oxymorphone ER product until the litigated patents expired in September 2013.

3. Weighing of anticompetitive effects against procompetitive benefits

As explained in detail in Section III.C., the evidence proves that the Endo-Impax Settlement included payment to prevent the risk of competition, which, under *Actavis*, is an anticompetitive

Initial Decision

harm. Under the facts of the instant case, however, the magnitude or extent of such harm is largely theoretical, based on an inference that Impax's entry date, and therefore generic competition, would have been earlier than January 2013, had the reverse payment not induced the settlement. *See, e.g.*, CCB at 47 (asserting that Challenged Agreement "eliminated risk" of generic competition "for over two years"). Although the Endo-Impax Settlement foreclosed the hypothetical possibility of Impax launching its generic Opana ER earlier than the date set forth in the SLA – either at risk or after litigation – the fact is that such earlier entry was unlikely. Moreover, pursuing litigation, which was the alternative to the Endo-Impax Settlement, would not have guaranteed the continued availability of Impax's generic Opana ER, even if Impax had prevailed on its patent claim, because, as explained in Section III.E., it is likely that Endo would have successfully asserted after-acquired patents to enjoin Impax, as it had against all other sellers of generic Opana ER.

In contrast to the largely theoretical anticompetitive harm asserted by Complaint Counsel, the real world procompetitive benefits of the Endo-Impax Settlement are substantial. As detailed in Section III.E, the January 2013 entry date provided in the SLA, together with the broad patent license provisions, enabled a generic Opana ER to enter the market eight months before Endo's original Opana ER patents expired, and sixteen years before Endo's after-acquired patents expired, and to continue selling generic Opana ER up to the present day, without threat of patent infringement litigation relating to original Opana ER. F. 592-596. Impax has sold generic Opana ER without interruption for more than five years, since launching its product in January 2013. F. 597. Furthermore, Impax's product is not only the sole generic oxymorphone product available to consumers, F. 596, but the only available oxymorphone ER product.³⁷ F. 598. These actual consumer benefits outweigh the theoretical anticompetitive harm demonstrated in this case.

³⁷ In March 2012, after a supply disruption affecting production of original Opana ER, Endo launched reformulated Opana ER and, at the direction of FDA, stopped distributing original Opana ER. F. 227-230. On September 1, 2017, at the request of FDA, Endo also ceased sales of reformulated Opana ER. F. 111.

Initial Decision

Indeed, Complaint Counsel's economic expert witness, Professor Noll, admits that consumers are better off today because Impax is selling oxymorphone ER. F. 599. These actual consumer benefits are even more pronounced if it is accepted, as Complaint Counsel urges, that patients cannot readily switch to an alternative long acting opioid. *See, e.g.*, CCFF Section VIII.E., F.

Even if it is assumed that Impax would have entered the market as early as June 2010, and that the settlement therefore delayed generic entry (and extended Endo's patent monopoly) for two and a half years, the demonstrated consumer benefits of the settlement still outweigh the anticompetitive harm because the settlement enabled and allowed uninterrupted and continuous access to generic Opana ER for more than five years. Similarly, to the extent that Complaint Counsel argues that the no-AG provision of the SLA deprived consumers of the benefit of competition from an Endo authorized generic drug, such harm would be limited to the duration of the 180-day exclusivity period to which the no-AG provision applied, and is far outweighed by the more than five years of uninterrupted and continuous access to generic Opana ER.

Accordingly, having weighed and balanced the anticompetitive effects and the procompetitive benefits of the Endo-Impax Settlement, the evidence fails to prove the "presence of significant unjustified anticompetitive consequences," *Actavis*, 133 S. Ct. at 2238, or that the agreement "engendered a net harm." *Cal. Dental Ass'n*, 224 F.3d at 957-58. Rather, the evidence proves that the Endo-Impax Settlement was, on balance, procompetitive. Thus, the evidence fails to demonstrate that Endo-Impax Settlement constituted an unreasonable restraint of trade.

G. Conclusion

Having fully considered the applicable law, the arguments of the parties, and the entire record in this case, and for all the foregoing reasons, the evidence fails to prove a violation of Section 5 of the FTC Act.

Therefore, the Complaint must be DISMISSED.

Initial Decision

IV. SUMMARY OF CONCLUSIONS OF LAW

1. Complaint Counsel bears the burden of proving jurisdiction and liability by a preponderance of evidence.
2. Respondent is a corporation, as “corporation” is defined in Section 4 of the FTC Act, 15 U.S.C. § 44.
3. Respondent’s challenged activities relating to the sale of pharmaceutical drugs are in or affect commerce in the United States, as “commerce” is defined in Section 4 of the FTC Act, 15 U.S.C. § 44.
4. The Commission has jurisdiction over Respondent and the subject matter of this proceeding, pursuant to Section 5 of the FTC Act.
5. The FTC Act’s prohibition of unfair methods of competition under Section 5 of the FTC Act encompasses violations of Section 1 of the Sherman Act.
6. Section 1 of the Sherman Act prohibits every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States. 15 U.S.C. § 1.
7. Despite its broad language, the ban on contracts in restraint of trade extends only to unreasonable restraints of trade, i.e., restraints that impair competition.
8. The Supreme Court, in *FTC v. Actavis*, 133 S. Ct. 2223 (2013), held that reverse payment patent settlements are not immune from antitrust scrutiny, anticompetitive effects should not be presumed from the presence of a reverse payment alone, and that reverse payment settlements are to be evaluated under the rule of reason.
9. 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 (the “Hatch-Waxman Act”) and the Medicare Prescription Drug,

Initial Decision

Improvement, and Modernization Act of 2003, 21 U.S.C. §§ 355(b)(2) and 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.

10. In a traditional rule-of-reason case, the relevant market must be defined to allow a court to determine the effect that an allegedly illegal act has on competition. However, where a settlement of patent litigation arises in the context of the peculiar framework of the Hatch-Waxman Act, and where a valid patent gives the brand holder a legal monopoly, the appropriate market in which to assess the anticompetitive effects of a reverse payment settlement agreement is the market that is the subject of that agreement – the branded pharmaceutical product and its generic equivalents.
11. The relevant market in which to analyze the effects of the Challenged Agreement in the instant case is the market for oxymorphone ER, branded and generic, which is the market that mattered to Impax and Endo, the parties to the Challenged Agreement.
12. In a rule of reason analysis, Complaint Counsel has the initial burden of proving anticompetitive effects.
13. A brand patent holder's use of a payment to induce a generic challenger to drop its patent challenge and agree to stay out of the market, rather than face the risk of patent invalidation and resulting generic competition, is an anticompetitive harm under *Actavis*.
14. To meet the initial burden of proving anticompetitive effects in a reverse payment case, Complaint Counsel must prove payment for delay, or, in other words, payment to prevent the risk of competition. 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

Initial Decision

other services for which it might represent payment, and the lack of any other convincing justification.

15. Under *Actavis*, a reasonable inference of harm to consumers from lessened competition can be established by identifying a large and otherwise unexplained payment of cash or something else of value made by the patent holder to the alleged infringer in exchange for that firm's agreement not to enter the market for some period of time, or by direct evidence that the patent holder paid the alleged infringer to delay its entry into the market and thereby restrict competition, e.g., evidence indicating that the purpose and effect of a reverse payment was to delay entry.
16. The formulation of the initial burden of proving anticompetitive effects in a reverse payment case set forth in *King Drug Company of Florence v. Cephalon, Inc.*, 88 F. Supp. 3d 402 (E.D. Pa. 2015), upon which Complaint Counsel relies, is rejected, to the extent it holds that anticompetitive effects can be demonstrated solely by proof of a large payment and market power. This formulation has not been adopted by any other court and presents an unduly truncated burden of proof.
17. *Actavis* did not state that a "large" reverse payment is by nature anticompetitive. Under *Actavis*, it is a large *and unjustified* payment that can bring the risk of anticompetitive effects.
18. By their nature, pharmaceutical patents often carry with them market power. A valid patent grants the legal right to exclude generic competition and the practical ability to profitably charge higher prices than generic competitors would charge.
19. If the initial burden of proving anticompetitive effects is met, the Respondent in a reverse payment case may demonstrate that the Challenged Agreement had offsetting procompetitive benefits.

Initial Decision

20. Complaint Counsel's position that the only relevant procompetitive justifications are those that justify the reverse payment, thereby barring all other evidence of procompetitive benefits from the settlement and condemning the settlement on the basis of the reverse payment alone, is inconsistent with *Actavis* and the rule of reason generally.
21. Procompetitive benefits arising in connection with a reverse payment settlement agreement as a whole are properly considered as part of a well-structured rule of reason analysis.
22. Enabling a product to be marketed that might otherwise be unavailable widens consumer choice and is therefore procompetitive.
23. The fact that a reverse payment settlement agreement allows generic entry prior to patent expiration, while not dispositive, can be considered in assessing the competitive consequences of the agreement.
24. Where the evidence proves that an agreement poses both anticompetitive harm and procompetitive benefits, the harms and benefits must be weighed against each other in order to judge whether the challenged behavior is, on balance, reasonable.
25. Where the evidence proves that an agreement poses both anticompetitive harm and procompetitive benefits, Complaint Counsel has the burden of establishing that the settlement is nevertheless anticompetitive on balance.
26. The relevant benchmark in evaluating reverse payment patent settlements should be no different from the benchmark in evaluating any other challenged agreement: What would the state of competition have been without the agreement?
27. It is appropriate to assess the magnitude and/or extent of delayed generic competition attributable to a reverse

Initial Decision

payment settlement agreement in order to balance anticompetitive harm against demonstrated procompetitive benefits.

28. A settlement providing for entry prior to patent expiration might enable generic competition on or prior to the entry date that would have resulted, on average, from litigating the patent suit to conclusion, which at a minimum affects the magnitude of any anticompetitive effect.
29. Based on weighing and balancing the anticompetitive effects and the procompetitive benefits of the Challenged Agreement, the evidence fails to prove the presence of significant unjustified anticompetitive consequences, or that the agreement engendered a net harm.
30. The evidence fails to demonstrate that the Challenged Agreement constituted an unreasonable restraint of trade.
31. The evidence fails to prove a violation of Section 5 of the FTC Act.
32. This Initial Decision makes no findings concerning alleged competitive effects of the 2017 settlement agreement between Endo and Impax, and Endo's arguments as intervenor opposing any remedy that would order the nullification or otherwise affect Endo's rights under that agreement are moot.

ORDER

For the reasons stated above, **IT IS ORDERED** that the Complaint be, and hereby is, **DISMISSED**.

Complaint

IN THE MATTER OF

PAYPAL, INC.CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF
SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT, THE
GRAMM-LEACH-BLILEY ACT, THE PRIVACY RULE, REGULATION P,
AND THE SAFEGUARDS RULE

Docket No. C-4651; File No. 162 3102
Complaint, May 23, 2018 – Decision, May 23, 2018

This consent order addresses PayPal, Inc.’s peer-to-peer payment service, Venmo, that incorporates a social networking component through a social “news feed” that shares information about a consumer’s Venmo transactions. The complaint alleges that PayPal, through its operation of Venmo, has violated Section 5 of the FTC Act and the Gramm-Leach-Bliley Act’s Privacy and Safeguards Rules. The consent order prohibits PayPal from making misrepresentations regarding material restrictions, limitations, or conditions to use any payment and social networking service.

Participants

For the *Commission*: Gregory A. Ashe, Cora Han, Ben Rossen
and Lisa Rothfarb.

For the *Respondent*: Eric Mogilnicki, Covington & Burling
LLP.

COMPLAINT

The Federal Trade Commission, having reason to believe that PayPal, Inc., a corporation, (“Respondent”) has violated Section 5(a) of the Federal Trade Commission Act (“FTC Act”), 15 U.S.C. § 45(a); the Privacy of Consumer Financial Information (“Privacy Rule”), 16 C.F.R. Part 313, recodified at 12 C.F.R. Part 1016 (“Reg. P”), and issued pursuant to the Gramm-Leach-Bliley Act (“GLB Act”), 15 U.S.C. §§ 6801-6803; and the Standards for Safeguarding Customer Information Rule (“Safeguards Rule”), 16 C.F.R. Part 314, issued pursuant to Sections 501(b) and 505(b)(2) of the GLB Act, 15 U.S.C. §§ 6801(b), 6805(b)(2); and it appearing to the Commission that this proceeding is in the public interest, alleges: