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UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: **Edith Ramirez, Chairwoman**
Maureen K. Ohlhausen
Terrell McSweeny

In the Matter of	**Docket No. 9373**
Impax Laboratories, Inc. **a corporation**	**Public Record Version**

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:

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 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 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 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 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 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 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.

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 [redacted] and [redacted], 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 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 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 oxymorphine [*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.

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 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 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 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 [redacted] 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 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).

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.

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 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: [redacted]

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 [redacted]

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, 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 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.

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.

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.

VII. 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 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 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.

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 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 RELEIF

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.

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.

Donald S. Clark
Secretary

SEAL: