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

In the Matter of **Impax Laboratories, Inc.,** **a corporation,** **Respondent.**	**PUBLIC** **Docket No. 9373**

SECOND SET OF JOINT STIPULATIONS

Complaint Counsel and Respondent Impax Laboratories, Inc., stipulate to the following terms and events:

I. Key Events

1. In 1960, the United States Food and Drug Administration ("FDA") first approved oxymorphone, a semi-synthetic opioid used to relieve pain.
2. In June 2006, the FDA approved Endo's extended-release oxymorphone product, Opana ER (NDA No. 021610) ("Original Opana ER"), "for the relief of moderate to severe pain in patients requiring continuous, around-the-clock opioid treatment for an extended period of time."
3. In July 2006, Endo announced the commercial availability of Original Opana ER. Endo ultimately offered Original Opana ER in seven dosage strengths (5, 7.5, 10, 15, 20, 30 and 40 mg). At the time of launch in 2006, Original Opana ER was the only extended-release version of oxymorphone on the market.
4. In June 2007, Impax filed an Abbreviated New Drug Application ("ANDA") (No. 79-087) for a generic version of Original Opana ER ("generic oxymorphone ER"). Impax

included a Paragraph III certification for the ’143 patent, meaning that its ANDA would be eligible for FDA approval upon the patent’s expiration in September 2008. As of June 2007, the ’143 patent was the only patent covering Opana ER listed in the FDA publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations (*commonly known as the “Orange Book”). The ’143 patent expired in September 2008.

5. Several other generic companies subsequently filed ANDAs for Opana ER, including Actavis South Atlantic LLC (“Actavis”).

6. In October 2007, Endo listed three additional patents in the Orange Book as covering Original 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 ’250, ’933, and ’456 patents all pertain to the controlled-release mechanism of the oxymorphone formulation. The ’456 and ’933 patents expired on September 9, 2013.

7. 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. 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 hydrochloride extended-release tablets for which” Impax’s ANDA had been submitted. Impax was eligible for first-filer exclusivity for the 5, 10, 20, 30 and 40 mg dosages, which comprised over 95% of Endo’s Opana ER sales. So long as Impax maintained its eligibility, this meant that the FDA could not approve another ANDA for a generic version of Opana ER in those dosages until 180 days after Impax began selling its product. Endo, however, as the

holder of the approved NDA for Opana ER, could market its own "authorized generic" version of Original Opana ER during Impax's exclusivity period.

8. 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 ANDA product did not infringe these patents.

9. On January 25, 2008, Endo and Penwest sued Impax alleging that Impax's ANDA for the 5, 10, 20, 30, and 40 mg dosages of generic oxymorphone ER infringed the '456 and '933 patents. Endo's lawsuit triggered a statutory 30-month stay, meaning that the FDA could not approve Impax's ANDA for generic oxymorphone ER until the earlier of the expiration of 30 months or resolution of the patent dispute in Impax's favor. The 30-month stay was set to expire on June 14, 2010.

10. Endo and Penwest initially filed their suit against Impax in the District of Delaware.

11. Impax successfully transferred the case to the District of New Jersey to avoid delay.

12. Actavis was the first to file an ANDA with Paragraph IV certifications for the two remaining strengths of Opana ER (7.5mg and 15mg), although its ANDA covered all dosage strengths.

13. In March 2008, Endo sued Actavis alleging that Actavis's ANDA covering the 5, 10, 20, and 40 mg dosages of generic oxymorphone ER infringed the '456 and '933 patents.

14. 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's ANDA for those dosages also infringed the '456 and '933 patents.

15. In February 2009, Endo and Actavis settled their then-pending patent litigation relating to Actavis's generic oxymorphone ER product.
16. In September 2009, Endo and Impax initiated discussions on a potential settlement of the '456 and '933 patent infringement litigation.
17. In December 2009, Endo and Impax ended their discussions on a potential settlement of the '456 and '933 patent infringement litigation.
18. On December 21, 2009, and March 19, 2010, the district court presiding over the Endo-Impax litigation held claim construction hearings.
19. On April 5, 2010, the Court in the *Endo v. Impax* litigation on the '456 and '933 patents 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."
20. On May 13, 2010, FDA granted tentative approval for Impax's ANDA for a generic version of Original Opana ER.
21. On May 17, 2010, Endo and Impax resumed discussions on the potential settlement of the '456 and '933 patent infringement litigation.
22. On May 19, 2010, the court scheduled the *Endo v. Impax* patent infringement trial on the '456 and '933 patents to begin on June 3, 2010 and continue through June 17, 2010.
23. On May 20, 2010, Impax advised the court it would not launch generic oxymorphone ER "through and including the last day of trial as presently scheduled."
24. On June 3, 2010, the *Endo v. Impax* patent infringement trial on the '456 and '933 patents began.

25. The trial was set to conclude on June 17, 2010.

26. On June 8, 2010, Impax and Endo entered into the Settlement and License Agreement and the Development and Co-Promotion Agreement. At the time of the settlement, the outcome of the patent infringement suit was uncertain.

27. On June 14, 2010, upon expiry of the 30-month stay under 21 U.S.C. § 355(j)(5)(B)(iii), the FDA granted Impax's ANDA final approval for generic oxymorphone ER for the 5, 10, 20, and 40 mg dosage strengths.

28. On June 24, 2010, Endo paid Impax the $10 million "Upfront Payment" in accordance with Section 3.1 of the Development and Co-Promotion Agreement.

29. In July 2010, Endo filed a supplemental New Drug Application (No. 201655) for a reformulated version of Opana ER ("Reformulated Opana ER").

30. On July 22, 2010, the FDA granted final approval to Impax's ANDA for the 30 mg dosage of generic oxymorphone ER.

31. On December 14, 2010, Patent No. 7,851,482 ("the '482 patent") was issued to Johnson Matthey. The '482 patent covered a process for producing the active pharmaceutical ingredient of oxymorphone ER meeting a certain limit of impurities.

32. In December 2011, the FDA approved Endo's supplemental New Drug Application for Reformulated Opana ER without labeling changes.

33. In March 2012, Endo stopped distributing Original Opana ER and launched Reformulated Opana ER.

34. On May 31, 2012, Endo requested that the FDA move Original Opana ER to the Orange Book Discontinued List.

35. In August 2012, Endo submitted a Citizen Petition to the FDA seeking the FDA's withdrawal of approved generic oxymorphone ER (Docket No. FDA-2012-P-0895).
36. In 2012, Endo acquired the '482 patent from Johnson Matthey.
37. On November 13, 2012, the Patent and Trademark Office issued Patent Nos. 8,309,060 ("the '060 patent") and 8,309,122 ("the '122 patent") to Endo. The '122 patent expires on February 4, 2023. The '060 patent expires on November 20, 2023.
38. On December 11, 2012, the Patent and Trademark Office issued Patent No. 8,329,216 ("the '216 patent") to Endo. The '216 patent expires on February 4, 2023.
39. 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.
40. In January 2013, Impax launched generic oxymorphone ER in the 5, 10, 20, 30, and 40 mg dosage strengths per terms of the Settlement and License Agreement.
41. On January 18, 2013, Impax provided Endo with written documentation supporting its demand for payment of the Endo Credit in the amount of $102,049,199.64, pursuant to Section 4.4 of the Settlement and License Agreement.
42. On April 18, 2013, Impax received a payment from Endo in the amount of $102,049,199.64 via wire transfer pursuant to Section 4.4 of the Settlement and License Agreement.
43. On May 10, 2013, the FDA denied Endo's Citizen Petition (Docket No. FDA-2012-P-0895).
44. On December 19, 2013, the '482 patent was partially invalidated following interference proceedings with the '779 patent owned by Mallinkrodt.

45. On August 19, 2014, the Patent and Trademark Office issued U.S. Patent No. 8,808,737 ("the '737 patent") to Endo. The '737 patent was scheduled to expire on June 21, 2027.

46. On October 28, 2014, the Patent and Trademark Office issued U.S. Patent No. 8,871,779 to Mallinkcrodt ("the '779 patent"). Endo acquired an exclusive field-of-use license to the '779 patent in the U.S. The '779 patent expires on November 22, 2029.

47. In August 2015, the U.S. District Court for the Southern District of New York held that the '122 and '216 patents were not invalid and were infringed by other companies' generic versions of Original Opana ER and by generic versions of Reformulated Opana ER, including Impax's.

48. In November 2015, the U.S. District Court for the District of Delaware held that the '737 patent was invalid. The ruling is currently on appeal to the Federal Circuit.

49. On December 23, 2015, Impax and Endo terminated the Development and Co-Promotion Agreement "by mutual agreement." At the time of termination, Impax had not received additional milestone payments from Endo and had not met any of the milestones that would have required additional payment from Endo.

50. On April 29, 2016, the U.S District Court for the Southern District of New York issued an "Omnibus opinion" enjoining all defendants from making or selling generic oxymorphone ER products before the expiration of the '122 and '216 patents. This decision is on appeal at the Federal Circuit, and oral arguments are scheduled for December 4, 2017. This decision does not apply to Impax's generic version of Original Opana ER.

51. On May 4, 2016, Endo sued Impax in the U.S. District Court for the District of New Jersey for breach of the Settlement and License Agreement, breach of implied duty of good faith and fair dealing, and infringement of the ’122, ’216, and ’737 patents by Impax’s generic version of Original Opana ER.
52. On July 11, 2016, Impax moved to dismiss Endo’s complaint for breach of contract, breach of good faith and fair dealing, and patent infringement.
53. In October 2016, the U.S. District Court for the District of Delaware held that the ’779 patent was not invalid and was infringed by a generic version of Reformulated Opana ER. The ruling is currently on appeal to the Federal Circuit.
54. On October 25, 2016, the U.S. District Court for the District of New Jersey denied Impax’s motion to dismiss Endo’s claims for breach of contract, breach of good faith and fair dealing, and infringement of the ’122 and ’216 patents. The court granted Impax’s motion to dismiss Endo’s claim for infringement of the ’737 patent.
55. On June 8, 2017, the FDA publicly requested that Endo voluntarily withdraw its Reformulated Opana ER product (NDA No. 201655) from the marketplace.
56. On August 30, 2017, the U.S. District Court for the District of Delaware held that the ’779 patent was not invalid. The ruling is currently on appeal to the Federal Circuit.
57. On September 1, 2017, Endo ceased sales of Reformulated Opana ER.
58. On September 15, 2017, the U.S. District Court for the District of Delaware entered a final judgment and permanent injunction precluding Actavis and Teva from selling generic oxymorphone ER products until after the expiration of the ’779 patent.
59. As of December 20, 2017, Impax is the only drug company selling any version of Opana ER.

II. Other Facts

60. The Settlement and License Agreement granted Impax a license to sell its generic version of Opana ER beginning on January 1, 2013, or the earlier of the following two events:

    (i) a final federal court decision holding all asserted and adjudicated claims of the patents at issue to be invalid, unenforceable, or not infringed by a generic version of Opana ER; or

    (ii) the withdrawal of the patents at issue from the Orange Book.

61. Section 4.1(a) of the Settlement and License Agreement granted Impax a license to the "Opana ER Patents" (meaning the '933, '456, and '250 patents) 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 . . . ." The Settlement and License Agreement identifies "the patent applications (and any patents issued thereunder)" as the "Pending Applications."

62. At the time of settlement in June 2010, Endo had pending applications for patents relating to Opana ER, but it was uncertain whether any additional patents would ultimately issue or whether any patents that Endo might obtain in the future would cover Impax's ANDA product..

63. The Settlement and License Agreement also grants Impax an "Exclusivity Period" for the dosages for which Impax was the first-filer. Endo agreed not to "sell, offer to sell, import, or distribute any generic version of products that are the subject of the Opana®

NDA" during Impax's 180-day exclusivity period or to license or authorize a third party to do the same.

64. Under a provision called the "Endo Credit," Endo agreed it would pay Impax a cash amount, determined by a formula included in the Settlement and License Agreement, if certain market changes occurred.

65. Specifically, if, by the fourth quarter of 2012, sales of Opana ER sold under NDA No. 021610 (Original Opana ER) fell by more than 50% from the peak quarterly sales between the third quarter of 2010 and the third quarter of 2012, Endo would pay Impax a cash amount determined by the formula included in the agreement.

66. Under the Settlement and License Agreement, Impax also agreed to pay Endo a royalty on all Net Sales of Original Opana ER if Endo Net Sales of Endo products for three months from October 1, 2012 to December 31, 2012 exceeded a specific sales threshold.

67. Under the Development and Co-Promotion Agreement, Impax and Endo entered a deal concerning a potential treatment for Parkinson's disease using a combination of a levodopa-ester and carbidopa.

68. Endo agreed to pay Impax an "Upfront Payment" of $10 million within five days of the Development and Co-Promotion Agreement's effective date. Endo also agreed to pay Impax up to $30 million in additional "Milestone Payments" for achieving events in the development and commercialization of the product.

69. The Settlement and License Agreement incorporates the Development and Co-Promotion Agreement.

70. At the time Impax and Endo entered the Settlement and License Agreement and the Development and Co-Promotion Agreement, the Impax Board of Directors had not been asked to vote on whether or not to launch generic oxymorphone at risk.

71. Margaret Snowden has never been asked to give a recommendation to the Board of Directors on whether or not Impax should launch a product at risk where Impax held first-to-file exclusivity.

72. 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.

Dated: December 19, 2017

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on December 19, 2017, I filed the foregoing documents on behalf of Complaint Counsel and Respondent using the FTC's E-Filing System, which will send notification of such filing to:

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The Honorable D. Michael Chappell
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I also certify that I delivered via electronic mail a copy of the foregoing documents to:

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Dated: December 19, 2017

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CERTIFICATE FOR ELECTRONIC FILING

I certify that the electronic copy sent to the Secretary of the Commission is a true and correct copy of the paper original is available for review by the parties and the adjudicator.

December 19, 2017 By: /s/ Rebecca E. Weinstein
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Notice of Electronic Service

I hereby certify that on December 19, 2017, I filed an electronic copy of the foregoing Second Set of Joint Stipulations, with:

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I hereby certify that on December 19, 2017, I served via E-Service an electronic copy of the foregoing Second Set of Joint Stipulations, upon:

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I hereby certify that on December 19, 2017, I served via other means, as provided in 4.4(b) of the foregoing Second Set of Joint Stipulations, upon:

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