UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

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

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

ORDER SPECIFYING FACTS WITHOUT SUBSTANTIAL CONTROVERSY (CORRECTED)

Pursuant to Section 3.24(a)(5), of the Commission's Rules of Practice, 16 C.F.R. § 3.24(a)(5), the Commission hereby specifies the following statement of facts that appear without substantial controversy. This order corrects and supersedes the Commission's Order of October 27, 2017.

Accordingly,

IT IS ORDERED THAT the following facts shall be deemed established for purposes of this proceeding:

Opana ER & Endo Patents

1. Oxymorphone is a semi-synthetic opioid used to relieve pain.

2. The U.S. Food & Drug Administration ("FDA") first approved oxymorphone in 1960.

3. Opana ER is an extended-release formulation of oxymorphone.

4. 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."

5. Endo Pharmaceuticals Inc. ("Endo") announced commercial availability of Opana ER in July 2006. Endo offered Opana ER in seven dosage strengths (5, 7.5, 10, 15, 20, 30 and 40 mg).

6. [redacted] The '143 patent was set to expire in September 2008.

7. [redacted]

8. The '250, '933, and '456 patents all pertain to the controlled-release mechanism of the oxymorphone formulation.

Impax Application and Endo Lawsuit

9. Impax Laboratories, Inc. ("Impax") filed an Abbreviated New Drug Application ("ANDA") for a generic version of Opana ER (No. 79-087) in June 2007. [redacted] As of June 2007, the '143 patent was the only patent covering Opana ER listed in the Orange Book.

10. Following Endo's listing of the additional patents in the Orange Book in October 2007, Impax amended its ANDA to include Paragraph IV certifications for the '250, '933 and

’456 patents. [redacted]

11. The FDA rescinded its original acceptance of Impax’s ANDA for substantive review. Impax re-submitted its ANDA, which the FDA accepted on November 23, 2007.

12. Impax was the first company to file an ANDA with Paragraph IV certifications for the 5, 10, 20, 30, and 40 mg dosages of Opana ER. [redacted]

13. [redacted] meaning that, if the FDA ultimately granted such exclusivity, the FDA would not be able to 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, would be able to market its own “authorized generic” version of Opana ER during Impax’s exclusivity period.

14. On December 13, 2007, Impax sent Endo notice of its Paragraph IV certifications for the ’250, ’933, and ’456 patents. [redacted]

15. Endo sued Impax on January 25, 2008, alleging that Impax’s ANDA product 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 until the earlier of the expiration of thirty months or resolution of the patent dispute in Impax’s favor. [redacted]

16. The FDA granted tentative approval to Impax's ANDA on May 13, 2010.

17. Trial began in Endo's patent infringement action against Impax on June 3, 2010.

18. Impax and Endo settled the patent dispute on June 8, 2010. At the time of settlement, the outcome of Endo's infringement suit was uncertain.

19. 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. The FDA granted final approval to Impax's ANDA for the 30 mg dosage on July 22, 2010.

The Impax-Endo Agreements

20. On June 8, 2010, Impax and Endo entered into the Settlement and License Agreement and the Development and Co-Promotion Agreement.

21. [redacted]

22. [redacted] At the time of settlement in June 2010, 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. At the time of the settlement, Endo had pending applications for patents relating to Opana ER.

23. [redacted]

24. [redacted]

25. 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.

26. [redacted]

27. [redacted]

28. [redacted]

Reformulated Opana ER

29. In July 2010, Endo filed a supplemental New Drug Application (No. 201655) for a reformulated version of Opana ER ("reformulated Opana ER"). The FDA approved the application in December 2011.

30. In 2012, Endo ceased selling original Opana ER and began selling a "new formulation" of Opana ER (NDA No. 201655).

Post-Settlement Patents and Litigations

31. After entering the Settlement and License Agreement, Endo obtained additional patents and patent licenses that it has asserted cover both original and reformulated Opana ER.

32. The Patent and Trademark Office issued Patent Nos. 8,309,060 and 8,309,122 to Endo on November 13, 2012.

33. The Patent and Trademark Office issued Patent No. 8,329,216 to Endo on December 11, 2012.

34. In December 2012, Endo began asserting the '060, '122, and '216 patents against drug manufacturers seeking to market generic versions of Opana ER. At that time, Endo did not assert these patents against Impax's generic version of original Opana ER.

35. The Patent and Trademark Office issued U.S. Patent No. 8,808,737 to Endo on August 19, 2014. The Patent and Trademark Office issued U.S. Patent No. 8,871,779 on October 28, 2014. Endo acquired an exclusive field-of-use license to the '779 patent from Mallinkcrodt.

36. 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. The court issued an injunction barring all defendants except Impax from selling their generic versions of original Opana ER prior to expiration of the ’122 and ’216 patents. *Endo Pharm. Inc. v. Amneal Pharm.*, LLC, 2015 WL 9459823, at *66 (S.D.N.Y. Aug. 18, 2015), *amended in part*, 2016 WL 1732751 (S.D.N.Y. Apr.29, 2016), *appeal reactivated*, Nos. 2015-2021 *et al*. (Fed. Cir. Aug. 4, 2016). The ruling is currently on appeal to the Federal Circuit.

37. 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.

38. 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.

By the Commission.

Donald S. Clark
Secretary

SEAL:
ISSUED: November 17, 2017