In the Matter of

G. “Brand/Generic Settlement Agreement” means a written agreement that settles a Patent Infringement Claim in or affecting Commerce in the United States.

H. “Branded Subject Drug Product” means a Subject Drug Product marketed, sold, or distributed in the United States under the proprietary name identified in the NDA for the Subject Drug Product.

I. “Commerce” has the same definition as it has in 15 U.S.C. § 44.

J. “Control” or “Controlled” means the holding of more than 50% of the common voting stock or ordinary shares in, or the right to appoint more than 50% of the directors of, or any other arrangement resulting in the right to direct the management of, the said corporation, company, partnership, joint venture, or entity.

K. “Drug Product” means a finished dosage form (e.g., tablet, capsule, solution, or patch), as defined in 21 C.F.R. § 314.3(b), approved under a single NDA, ANDA or 505(b)(2) Application, that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients.

L. “Executive and General Counsel Staff” means the Respondent’s Executive Team, including the Chief Executive Officer, the Chief Financial Officer, the General Counsel, the Chief Compliance Officer, Presidents of divisions within Respondent, including the Generics Division and Specialty Pharm Division, and all attorneys in the Respondent’s office of General Counsel.

M. “Generic Entry Date” means the date in a Brand/Generic Settlement Agreement, whether certain or contingent, on or after which a Generic Filer is authorized by the NDA Holder to begin manufacturing, using, importing, or Marketing the Generic Subject Drug Product.

N. “Generic Filer” means a party to a Brand/Generic Settlement who controls an ANDA or 505(b)(2) Application for the Subject Drug Product or has the exclusive right under such ANDA or 505(b)(2) Application to distribute the Subject Drug Product.

O. “Generic Product” means a Drug Product manufactured and/or sold under an ANDA or pursuant to a 505(b)(2) Application.

P. “Market,” “Marketed,” or “Marketing” means the promotion, offering for sale, sale, or distribution of a Drug Product.

Q. “NDA” means a New Drug Application filed with the United States Food and Drug Administration pursuant to Section 505(b) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(b), including all changes or supplements thereto that do not result in the submission of a new NDA.

R. “NDA Holder” means a party to a Brand/Generic Settlement that controls the NDA for the Subject Drug Product or has the exclusive right to distribute the Branded Subject Drug Product in the United States.

S. “No-AG Commitment” means any agreement with, or commitment or license to, the Generic Filer that prohibits, prevents, restricts, requires a delay of, disincentivizes, or imposes a condition precedent upon the research, development, manufacture, regulatory approval, or Marketing of an Authorized Generic.

T. “Oxymorphone ER Manufacturer or Applicant” means any company that has an Oxymorphone ER NDA or ANDA, has filed an Oxymorphone ER NDA or ANDA, or is preparing to file an Oxymorphone ER NDA or ANDA.

U. “Oxymorphone ER Product” means any extended-release tablet containing oxymorphone that is the subject of an NDA, ANDA, or 505(b)(2) Application.

V. “Patent Infringement Claim” means any allegation threatened in writing or included in a complaint filed with a court of law that a Generic Product may infringe one or more U.S. Patents held by, or licensed to, an NDA Holder.

W. “Payment by the NDA Holder to the Generic Filer” means a transfer of value by the NDA Holder to the Generic Filer (including, but not limited to, a No-AG Commitment, money, goods, or services), regardless of whether the Generic Filer purportedly transfers value in return, where such transfer is either (i) expressly contingent on entering a Brand/Generic Settlement Agreement, or (ii) agreed to during the 90 day period starting 45 days before executing a Brand/Generic Settlement Agreement and ending 45 days after executing a Brand/Generic Settlement Agreement. The following, however, are not Payment by the NDA Holder to the Generic Filer:

1. compensation for the NDA Holder’s saved future litigation expenses, but only if the total compensation the NDA Holder agrees to provide to the Generic Filer during the 90 day period starting 45 days before and ending 45 days after executing the Brand/Generic Settlement Agreement does not exceed a

5. a continuation or renewal of a pre-existing agreement between an NDA Holder and a Generic Filer but only if: (i) the pre-existing agreement was entered into at least 90 days before the relevant Brand/Generic Settlement Agreement, (ii) the terms of the renewal or continuation, including the duration and the financial terms, are substantially similar to those in the existing agreement, and (iii) entering into the continuation or renewal is not expressly contingent on agreement to a Brand/Generic Settlement.

X. "Subject Drug Product" means the Drug Product for which one or more Patent Infringement Claims are settled under a given Brand/Generic Settlement. For purposes of this Order, the Drug Product of the NDA Holder and the Generic Filer to the same Brand/Generic Settlement shall be considered to be the same Subject Drug Product.

Y. "U.S. Patent" means any patent issued by the United States Patent and Trademark Office, including all divisions, reissues, continuations, continuations-in-part, modifications, or extensions thereof.

II. Prohibited Agreements

IT IS FURTHER ORDERED that:

A. Respondent is prohibited from entering into any Brand/Generic Settlement that includes:

1. (i) a No-AG Commitment and (ii) an agreement by the Generic Filer not to research, develop, manufacture, distribute, Market, or sell the Subject Drug Product for any period of time; or

2. (i) any Payment by the NDA Holder to the Generic Filer and (ii) an agreement by the Generic Filer not to research, develop, manufacture, distribute, Market, or sell the Subject Drug Product for any period of time.

B. Respondent shall not enter any agreement with another Oxymorphone ER Manufacturer or Applicant that prevents or restricts competition between Oxymorphone ER Products.

III. Compliance Program

IT IS FURTHER ORDERED that Respondent shall design, maintain, and operate an Antitrust Compliance Program that sets forth the policies and procedures Respondent has implemented to comply with this Order and with the antitrust laws. The Antitrust Compliance Program shall include

A. Designation and retention of an antitrust compliance officer or director to supervise the design, maintenance, and operation of the program;

B. Training regarding Respondent's obligations under this Order and the antitrust laws for Executive and General Counsel Staff within 30 days after this Order becomes final and at least annually thereafter;

C. Certification by each Executive and General Counsel Staff member that he or she has received the training required in Paragraph III.B;

D. Policies and procedures for employees and representatives of Respondents to ask questions about, and report violations of, this Order and the antitrust laws confidentially and without fear of retaliation of any kind;

E. Policies and procedures for disciplining employees and representatives of Respondents for failure to comply with this Order and the antitrust laws; and

F. The retention of documents and records sufficient to record Respondents' compliance with its obligations under this Paragraph III of this Order, including but not limited to records showing that employees and representatives of Respondents have received all trainings required under this Order during the preceding two years.

IV. Reporting Requirements

IT IS FURTHER ORDERED that

A. Respondent shall file a verified written report to the Commission ("compliance report"):

1. 90 days after the date this Order is issued; and
2. One

verified in the manner set forth in 28 U.S.C. § 1746. Commission Rule 2.41(a), 16 C.F.R. § 2.41(a), requires that the Commission receive an original and two copies of each compliance report. A paper original of each compliance report shall be filed with the Secretary of the Commission and electronic copies shall be transmitted to the Secretary at ElectronicFilings@ftc.gov, and the Compliance Division at bccompliance@ftc.gov.

D. This Order does not alter the reporting requirements of Respondent pursuant to Section 1112 of the Medicare Prescriptions Drug, Improvement, and Modernization Act of 2003.

V. Change of Corporate Control

IT IS FURTHER ORDERED that

A. Respondent shall notify the Commission at least 30 days prior to:

1. Any proposed dissolution of Impax Laboratories LLC;
2. Any proposed acquisition of, or merger or consolidation involving Impax Laboratories LLC; or
3. Any other change in Respondent, including assignment or the creation, sale, or dissolution of subsidiaries, if such change may affect compliance obligations arising out of this Order.

B. Respondent shall submit any notice required under this paragraph electronically to the Secretary of the Commission at ElectronicFilingsi(c)4 (t)-2 9<</MCID 9.97 0 Td Span1 (io)2 (n32
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