

v.
AMNEAL PHARMACEUTICALS LLC
Defendant.

Civil Action No. _____

COMPLAINT

Plaintiff Hospira, Inc. (“Hospira”), for its Complaint against Defendant Amneal Pharmaceuticals LLC (“Defendant”), hereby alleges as follows:

PARTIES

1. Hospira is a Delaware corporation with its principal place of business at 275 North Field Drive, Lake Forest, Illinois 60045.

2. On information and belief, Defendant is a corporation organized and existing under the laws of the State of Delaware with its principal place of business at 400 Crossing Boulevard, Third Floor, Bridgewater, New Jersey 08807.

NATURE OF THE ACTION

3. This is a civil action for infringement of U.S. Patent Nos. 8,242,158 (the “158 patent”) (D.I. 1, Ex. A); 8,338,470 (the “470 patent”) (D.I. 1, Ex. B); 8,455,527 (the “527 patent”) (D.I. 1, Ex. C); and 8,648,106 (the “106 patent”) (D.I. 1, Ex. D) (collectively, the “Patents-in-suit”).

4. This action is based upon the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.* and arises out of the Defendant’s filing of Abbreviated New Drug Application

JURISDICTION AND VENUE

5. This action arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*

6. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. Defendant is subject to personal jurisdiction in this District by virtue of, *inter alia*, its incorporation under the laws of the State of Delaware, and its conduct of business in this District. On information and belief, Defendant develops, formulates, manufactures, markets, and sells drug products throughout the United States, including Delaware, and Delaware is a likely destination of Defendant's products. On information and belief, Defendant has purposely availed itself of the rights and benefits of the laws of the State of Delaware, and has engaged in substantial and continuous contacts with the State of Delaware.

8. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

THE PATENTS-IN-SUIT

9. The '158 patent, entitled "Dexmedetomidine Premix Formulation," was duly and legally issued by the USPTO on August 14, 2012. Hospira is the assignee and owner of the '158 patent.

Dexmedetomidine Premix Formulation,” was duly and legally issued by the USPTO on June 4, 2013. Hospira is the assignee and owner of the ‘527 patent.

12. The ‘106 patent, entitled “Dexmedetomidine Premix Formulation,” was duly and legally issued by the USPTO on February 11, 2014. Hospira is the assignee and owner of the ‘106 patent.

13. The Patents-in-suit are duly listed in the Orange Book as covering PRECEDEX™. The claims of the Patents-in-suit cover various presentations of PRECEDEX™ and methods of using PRECEDEX™.

14. Hospira is the holder of New Drug Application (“NDA”) No. 21-038 for dexmedetomidine hydrochloride injection, sold in the United States under the trademark PRECEDEX™. The United States Food and Drug Administration (“FDA”) originally approved NDA No. 21-038 on December 17, 1999. On March 13, 2013 and November 14, 2014, the FDA approved amendments to Hospira’s NDA No. 21-038 for an alternate premix formulation of PRECEDEX™.

ACTS GIVING RISE TO THIS ACTION

15. On information and belief, Defendant reviewed the Patents-in-suit and certain commercial and economic information regarding Hospira’s PRECEDEX™ and decided to file an ANDA seeking approval to market the Proposed Amneal Dexmedetomidine Product.

16. On June 30, 2015, Hospira received a letter dated June 26, 2015, from Defendant, notifying Hospira that Defendant had filed ANDA No. 207551 with the FDA under

207551 included a certification under 21 U.S.C. § 355(j)(2)(a)(vii)(IV) (“Paragraph IV Certification”) that the claims of the ‘158 patent, the ‘470 patent, the ‘527 patent, and the ‘106 patent are invalid and/or will not be infringed by Defendant.

18. Included in the June 26, 2015 letter was a “detailed statement” of the factual and legal basis for Defendant’s Paragraph IV Certification.

19. On information and belief, Defendant was aware of the Patents-in-suit when it filed ANDA No. 207551 with a Paragraph IV Certification.

20. Hospira received the June 26, 2015, letter on June 30, 2015. Hospira commenced this action within 45 days of receipt of the letter.

COUNT I FOR INFRINGEMENT OF PATENT NO. 8,242,158

21. Paragraphs 1 through 20 are incorporated herein as set forth above.

22. Defendant submitted ANDA No. 207551 with a Paragraph IV Certification to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Proposed Amneal Dexmedetomidine Product prior to the expiration of the ‘158 patent. By submitting this ANDA, Defendant committed an act of infringement under 35 U.S.C. § 271(e)(2).

23. Moreover, any commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Proposed Amneal Dexmedetomidine Product described

25. Defendant was aware of the existence of the '158 patent prior to the filing of ANDA No. 207551, and took such action knowing it would constitute infringement of the '158 patent.

26. Hospira will be irreparably harmed if Defendant is not enjoined from infringing the '158 patent.

COUNT II FOR INFRINGEMENT OF PATENT NO. 8,338,470

27. Paragraphs 1 through 20 are incorporated herein as set forth above.

28. Defendant submitted ANDA No. 207551 with a Paragraph IV Certification to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Proposed Amneal Dexmedetomidine Product prior to the expiration of the '470 patent. By submitting this ANDA, Defendant committed an act of infringement under 35 U.S.C. § 271(e)(2).

29. Moreover, any commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Proposed Amneal Dexmedetomidine Product described in ANDA No. 207551 by Defendant would infringe the '470 patent under 35 U.S.C. § 271(a), (b), and/or (c).

30. Defendant's actions and conduct will encourage direct infringement of the '470 patent by others.

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