IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

HOSPIRA, INC., Plaintiff, 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

("ANDA") No. 207551 seeking approval to market a dexmedetomidine hydrochloride product ("Proposed Amneal Dexmedetomidine Product") prior to the expiration of the Patents-in-suit, which are assigned to Hospira and listed in the publication entitled *Approved Drug Products with Therapeutic Equivalents* (the "Orange Book") as covering PRECEDEX™.

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.

10. The '470 patent, entitled "Dexmedetomidine Premix Formulation," was duly and legally issued by the USPTO on December 25, 2012. Hospira is the assignee and owner of the '470 patent.

11. The '527 patent, entitled "Methods of Treatment using a 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

21 U.S.C. § 355(j) (*i.e.* section 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA")), seeking approval to market the Proposed Amneal Dexmedetomidine Product prior to the expiry of the Patents-in-suit.

17. The stated purpose of the letter was to notify Hospira that ANDA No. 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

in ANDA No. 207551 by Defendant would infringe the '158 patent under 35 U.S.C. § 271(a), (b), and/or (c).

24. Defendant's actions and conduct will encourage direct infringement of the '158 patent by others.

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.

31. Defendant was aware of the existence of the '470 patent prior to the filing of ANDA No. 207551, and took such action knowing it would constitute infringement of the '470 patent.

32. Hospira will be irreparably harmed if Defendant is not enjoined from infringing the '470 patent.

COUNT III FOR INFRINGEMENT OF PATENT NO. 8,455,527

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

34. 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 '527 patent. By submitting this ANDA, Defendant committed an act of infringement under 35 U.S.C. § 271(e)(2).

35. 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 '527 patent under 35 U.S.C. § 271(a), (b), and/or (c).

36. Defendant's actions and conduct will encourage direct infringement of the '527 patent by others.

37. Defendant was aware of the existence of the '527 patent prior to the filing of ANDA No. 207551, and took such action knowing it would constitute infringement of the '527 patent.

38. Hospira will be irreparably harmed if Defendant is not enjoined from infringing the '527 patent.

COUNT IV FOR INFRINGEMENT OF PATENT NO. 8,648,106

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

40. 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 '106 patent. By submitting this ANDA, Defendant committed an act of infringement under 35 U.S.C. § 271(e)(2).

41. 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 '106 patent under 35 U.S.C. § 271(a), (b), and/or (c).

42. Defendant's actions and conduct will encourage direct infringement of the '106 patent by others.

43. Defendant was aware of the existence of the '106 patent prior to the filing of ANDA No. 207551, and took such action knowing it would constitute infringement of the '106 patent.

44. Hospira will be irreparably harmed if Defendant is not enjoined from infringing the '106 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment as follows:

A. An order decreeing that the submission to the FDA of ANDA No. 207551 with a Paragraph IV Certification was an act of infringement by Defendant;

B. An order decreeing that Defendant's 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, including any regulatory extensions, will infringe, directly and/or indirectly, the '158 patent;

C. An order decreeing that Defendant's 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, including any regulatory extensions, will infringe, directly and/or indirectly, the '470 patent;

D. An order decreeing that Defendant's 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 '527 patent, including any regulatory extensions, will infringe, directly and/or indirectly, the '527 patent;

E. An order decreeing that Defendant's 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 '106 patent, including any regulatory extensions, will infringe, directly and/or indirectly, the '106 patent;

F. An order pursuant to 21 U.S.C. § 355(c)(3)(C) that the effective date of any approval of ANDA No. 207551 shall be no earlier than thirty months after the date on which Hospira received the June 26, 2015, letter, and, if the Court rules that the Proposed Amneal Dexmedetomidine Product infringes any Patent-in-suit, shall be no earlier than the expiration date of the infringed Patent(s)-in-suit, including any applicable extensions;

G. A preliminary and permanent injunction pursuant to 35 U.S.C. § 271(e)(4) restraining and enjoining Defendant, its officers, agents, attorneys, and employees, and those

acting in privity or concert with it, from engaging in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the generic dexmedetomidine hydrochloride product described in ANDA No. 207551, or any other ANDA not colorably different from ANDA No. 207551, until the expiration of the Patents-in-suit, including any applicable extensions;

H. A declaration that this case is exceptional and an award of attorneys' fees under 35 U.S.C. § 285;

I. Costs and expenses in this action; and

J. Such other and further relief as the Court may deem just and proper.

Dated: August 10, 2015

Respectfully Submitted,

HOSPIRA, INC.

By: /s/ Arthur G. Connolly III

CONNOLLY GALLAGHER LLP
Arthur G. Connolly III (# 2667)
Ryan P. Newell (# 4744)
The Brandywine Building
1000 West Street, Suite 1400
Wilmington, Delaware 19801
Telephone: (302) 757-7300

Bradford P. Lyerla
Sara T. Horton
Yusuf Esat
JENNER & BLOCK LLP
353 N. Clark Street
Chicago, IL 60654-3456
Telephone: 312 222-9350
Facsimile: 312 527-0484
blyerla@jenner.com
shorton@jenner.com
yesat@jenner.com

Attorneys for Plaintiff Hospira, Inc.