IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

HOSPIRA, INC., Plaintiff, v. PAR STERILE PRODUCTS, LLC, Defendant.	Civil Action No. 16-879 (RGA)

FIRST AMENDED COMPLAINT

Plaintiff Hospira, Inc. ("Hospira"), hereby files its First Amended Complaint against Defendant Par Sterile Products, LLC ("Par Sterile" or "Defendant") adding U.S. Patent No. 9,320,712 pursuant to Par Sterile's October 28, 2016, Notice of Paragraph IV certification. Hospira files its First Amended Complaint within 21 days of service of Par Sterile's Answer, in accordance with Fed. R. Civ. P. 15(a)(1)(B). Hospira 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, Par Sterile is a limited liability company organized and existing under the laws of the State of Delaware, having a place of business at One Upper Pond Road; Morris Corporate Centre 2; Building D; 3rd Floor; Parsippany, NJ 07054. On information and belief, Par Sterile is registered with the Delaware Department of State: Division of Corporations under file number 4352249, and has appointed The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801, as its registered agent for service of process in Delaware.

3. On information and belief, Par Sterile is a wholly owned subsidiary of Par Pharmaceutical Companies, Inc. On information and belief, Par Sterile develops, manufactures and markets branded and generic aseptic injectable products throughout the United States, including the State of Delaware, and provides contract manufacturing services to the biopharmaceutical and pharmaceutical industry.

NATURE OF THE ACTION

4. This is a civil action for infringement of U.S. Patent Nos. 8,242,158 (the "'158 patent") (Ex. A); 8,338,470 (the "'470 patent") (Ex. B); 8,455,527 (the "'527 patent") (Ex. C); 8,648,106 (the "'106 patent") (Ex. D); and 9,320,712 (the "'712 patent") (Ex. E) (collectively, the "Patents-in-suit").

5. 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. 208266 seeking approval to market dexmedetomidine hydrochloride products ("Proposed Par Dexmedetomidine Products") 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

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

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

8. Defendant is subject to personal jurisdiction in this District by virtue of, *inter alia*, its incorporation in the State of Delaware and conduct of business in this District. Defendant has purposely availed itself of the privilege of doing business in this Judicial District.

Defendant maintains extensive systematic contacts with the State of Delaware, including the marketing, distribution, and/or sale of generic pharmaceutical drugs to Delaware residents.

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

THE PATENTS-IN-SUIT

10. 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.

11. 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.

12. 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.

13. 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.

14. The '712 patent, entitled "Dexmedetomidine Premix Formulation," was duly and legally issued by the USPTO on April 26, 2016. Hospira is the assignee and owner of the '712 patent.

15. 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™.

16. 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 a premix formulation of PRECEDEX™.

ACTS GIVING RISE TO THIS ACTION

17. On August 16, 2016, Hospira received a letter dated August 15, 2016, on behalf of Par Sterile ("the First Notice Letter"), notifying Hospira that Par Sterile had filed ANDA No. 208266 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 Par Dexmedetomidine Products prior to the expiry of the '158, '470, '527, and '106 patents.

18. On October 28, 2016, Hospira received a letter dated October 28, 2016, on behalf of Par Sterile ("the Second Notice Letter"), notifying Hospira that Par Sterile had filed ANDA No. 208266 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 Par Dexmedetomidine Products prior to the expiry of the '712 patent.

19. The stated purpose of the First Notice Letter and Second Notice Letter was to notify Hospira that ANDA No. 208266 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, the '106 patent, and '712 patent are invalid and/or that certain claims will not be infringed by Defendant.

20. Included in the First Notice Letter and Second Notice Letter was a "detailed statement" of the alleged factual and legal basis for Defendant's Paragraph IV

Certification. The sole basis set forth in the detailed statement for Defendant's Paragraph IV Certification is alleged invalidity.

21. As described in the First Notice Letter and Second Notice Letter, the Proposed Par Dexmedetomidine Products are Dexmedetomidine Hydrochloride, 200 mcg/50mL and 400mcg/100ml, for injection.

22. On information and belief, Defendant was aware of the Patents-in-suit when it filed ANDA No. 208266 with a Paragraph IV Certification.

23. Hospira received the First Notice Letter on August 16, 2016. Hospira commenced this action within 45 days of receipt of the Notice Letter.

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

24. The foregoing paragraphs are incorporated herein as set forth above.

25. Defendant submitted ANDA No. 208266 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 Par Dexmedetomidine Products 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).

26. Moreover, any commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Proposed Par Dexmedetomidine Products described in ANDA No. 208266 would infringe the '158 patent under 35 U.S.C. § 271(a). The Proposed Par Dexmedetomidine Products meet each limitation of at least one claim of the '158 patent. The First Notice Letter does not allege non-infringement of any claim of the '158 patent.

27. In addition, Defendant's actions and conduct, including providing information and instructions for use of its products in the proposed package insert to accompany

the products, will also encourage direct infringement of the '158 patent by others. Thus, Defendant would infringe the '158 patent under 35 U.S.C. § 271(b), and/or (c).

28. On information and belief, Defendant was aware of the existence of the '158 patent prior to the filing of ANDA No. 208266, and took such action knowing it would constitute infringement of the '158 patent.

29. 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

30. The foregoing paragraphs are incorporated herein as set forth above.

31. Defendant submitted ANDA No. 208266 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 Par Dexmedetomidine Products 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).

32. Moreover, any commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Proposed Par Dexmedetomidine Products described in ANDA No. 208266 would infringe the '470 patent under 35 U.S.C. § 271(a). The Proposed Par Dexmedetomidine Products meet each limitation of at least one claim of the '470 patent. The First Notice Letter does not allege non-infringement of any claim of the '470 patent.

33. In addition, Defendant's actions and conduct, including providing information and instructions for use of its products in the proposed package insert to accompany the products, will also encourage direct infringement of the '470 patent by others. Thus, Defendant would infringe the '470 patent under 35 U.S.C. § 271(b), and/or (c).

34. On information and belief, Defendant was aware of the existence of the '470 patent prior to the filing of ANDA No. 208266, and took such action knowing it would constitute infringement of the '470 patent.

35. 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

36. The foregoing paragraphs are incorporated herein as set forth above.

37. Defendant submitted ANDA No. 208266 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 Par Dexmedetomidine Products 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).

38. Moreover, any commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Proposed Par Dexmedetomidine Products described in ANDA No. 208266 would infringe the '527 patent under 35 U.S.C. § 271(a). The use of the Proposed Par Dexmedetomidine Products meets each limitation of at least one claim of the '527 patent. The First Notice Letter does not allege non-infringement of any claim of the '527 patent.

39. In addition, Defendant's actions and conduct, including providing information and instructions for use of its products in the proposed package insert to accompany the products, will also encourage direct infringement of the '527 patent by others. Thus, Defendant would infringe the '527 patent under 35 U.S.C. § 271(b), and/or (c).

40. On information and belief, Defendant was aware of the existence of the '527 patent prior to the filing of ANDA No. 208266, and took such action knowing it would constitute infringement of the '527 patent.

41. 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

42. The foregoing paragraphs are incorporated herein as set forth above.

43. Defendant submitted ANDA No. 208266 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 Par Dexmedetomidine Products 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).

44. Moreover, any commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Proposed Par Dexmedetomidine Products described in ANDA No. 208266 would infringe the '106 patent under 35 U.S.C. § 271(a). The Proposed Par Dexmedetomidine Products meet each limitation of at least one claim of the '106 patent. The First Notice Letter does not allege non-infringement of any claim of the '106 patent.

45. In addition, Defendant's actions and conduct, including providing information and instructions for use of its products in the proposed package insert to accompany the products, will also encourage direct infringement of the '106 patent by others. Thus, Defendant would infringe the '106 patent under 35 U.S.C. § 271(b), and/or (c).

46. On information and belief, Defendant was aware of the existence of the '106 patent prior to the filing of ANDA No. 208266, and took such action knowing it would constitute infringement of the '106 patent.

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

COUNT V FOR INFRINGEMENT OF PATENT NO. 9,320,712

48. The foregoing paragraphs are incorporated herein as set forth above.

49. Defendant submitted ANDA No. 208266 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 Par Dexmedetomidine Products prior to the expiration of the '712 patent. By submitting this ANDA, Defendant committed an act of infringement under 35 U.S.C. § 271(e)(2).

50. Moreover, any commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Proposed Par Dexmedetomidine Products described in ANDA No. 208266 would infringe the '712 patent under 35 U.S.C. § 271(a). The Proposed Par Dexmedetomidine Products meet each limitation of at least one claim of the '712 patent. The Second Notice Letter does not allege non-infringement of any claim of the '712 patent.

51. In addition, Defendant's actions and conduct, including providing information and instructions for use of its products in the proposed package insert to accompany the products, will also encourage direct infringement of the '712 patent by others. Thus, Defendant would infringe the '712 patent under 35 U.S.C. § 271(b), and/or (c).

52. On information and belief, Defendant was aware of the existence of the '712 patent prior to the filing of ANDA No. 208266, and took such action knowing it would constitute infringement of the '712 patent.

53. Hospira will be irreparably harmed if Defendant is not enjoined from infringing the '712 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment as follows:

A. An order decreeing that the submission to the FDA of ANDA No. 208266 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 Par Dexmedetomidine Products 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 Par Dexmedetomidine Products 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 Par Dexmedetomidine Products 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 Par Dexmedetomidine

Products prior to the expiration of the '106 patent, including any regulatory extensions, will infringe, directly and/or indirectly, the '106 patent;

F. An order decreeing that Defendant's commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Proposed Par Dexmedetomidine Products prior to the expiration of the '712 patent, including any regulatory extensions, will infringe, directly and/or indirectly, the '712 patent;

G. An order pursuant to 21 U.S.C. § 355(c)(3)(C) that the effective date of any approval of ANDA No. 208266 shall be no earlier than thirty months after the date on which Hospira received the First Notice Letter, and, if the Court rules that the Proposed Par Dexmedetomidine Products infringe any Patent-in-suit, shall be no earlier than the expiration date of the infringed Patent(s)-in-suit, including any applicable extensions;

H. 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 Proposed Par Dexmedetomidine Products described in ANDA No. 208266, or any other ANDA not colorably different from ANDA No. 208266, until the expiration of the Patents-in-suit, including any applicable extensions;

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

J. Costs and expenses in this action; and

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

Dated: November 14, 2016 Respectfully Submitted,

HOSPIRA, INC.

By: */s/ Arthur G. Connolly, III*

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