IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

HOSPIRA, INC., Plaintiff, v. GLAND PHARMA LTD, Defendant.	C. A. No. _____

COMPLAINT

Plaintiff Hospira, Inc. ("Hospira"), for its Complaint against Defendant Gland Pharma Limited ("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 India. Its principal place of business is located in Hyderabad, India.

NATURE OF THE ACTION

3. This is a civil action for infringement of U.S. Patent Nos. 8,455,527 (the "'527 patent") (Ex. A); 8,648,106 (the "'106 patent") (Ex. B); 9,320,712 (the "'712 patent") (Ex. C); and 9,616,049 (the "'049 patent") (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 submission of Abbreviated New Drug Application ("ANDA") No. 209307 to the United States Food and Drug Administration ("FDA").

Defendant's ANDA seeks approval to market 4 mcg/mL dexmedetomidine hydrochloride products (200 mcg/50 mL and 400 mcg/100 mL) (collectively "Proposed Gland 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™ (80 mcg/20 mL, 200 mcg/50 mL, and 400 mcg/100 mL).

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. On information and belief, this Court has personal jurisdiction over Defendant because, among other things: (1) Defendant filed its ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Proposed Gland Dexmedetomidine Products throughout the United States, including in Delaware; (2) upon any approval of ANDA No. 209307, Defendant will market, distribute, offer for sale, and/or sell the Proposed Gland Dexmedetomidine Products throughout the United States, including in Delaware, and will derive substantial revenue from the use or sale of the products in Delaware; and (3) upon any approval of ANDA No. 209307, the Proposed Gland Dexmedetomidine Products would be prescribed by physicians practicing in Delaware and dispensed by pharmacies located within Delaware.

8. On information and belief, Defendant does not maintain a principal place of business within the U.S. and is not incorporated in the U.S.

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

THE PATENTS-IN-SUIT

10. 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.

11. 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.

12. 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.

13. The ’049 patent, entitled “Dexmedetomidine Premix Formulation,” was duly and legally issued by the USPTO on April 11, 2017. Hospira is the assignee and owner of the ’049 patent.

14. 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™ (80 mcg/20 mL, 200 mcg/50 mL, and 400 mcg/100 mL) and methods of using the presentations of PRECEDEX™.

15. 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

16. 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 Gland Dexmedetomidine Products.

17. On December 21, 2017, Hospira received a letter dated December 20, 2017, from Defendant ("the Notice Letter"), notifying Hospira that Defendant had filed ANDA No. 209307 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 Gland Dexmedetomidine Products prior to the expiry of the Patents-in-suit.

18. The stated purpose of the Notice Letter was to notify Hospira that ANDA No. 209307 included a certification under 21 U.S.C. § 355(j)(2)(a)(vii)(IV) ("Paragraph IV Certification") that the claims of the '527 patent, the '106 patent, the '712 patent, and the '049 patent are invalid and/or that certain claims will not be infringed by Defendant.

19. Included in the Notice Letter was a "detailed statement" of the alleged factual and legal basis for Defendant's Paragraph IV Certification. With the exception of certain claims of the '527 patent, the sole basis set forth in the detailed statement for Defendant's Paragraph IV Certification is alleged invalidity.

20. As described in the Notice Letter, the Proposed Gland Dexmedetomidine Products are Dexmedetomidine Hydrochloride in 0.9% Sodium Chloride Injection, 4 mcg/mL, in 50 mL and 100 mL vials.

21. On information and belief, Defendant was aware of the Patents-in-suit when it filed ANDA No. 209307 with a Paragraph IV Certification.

22. Hospira received the Notice Letter on December 21, 2015. Hospira commenced this action within 45 days of receipt of the Notice Letter.

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

23. Paragraphs 1 through 22 are incorporated herein as set forth above.

24. Defendant submitted ANDA No. 209307 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 Gland 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).

25. Moreover, any commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Proposed Gland Dexmedetomidine Products described in ANDA No. 209307 would infringe the '527 patent under 35 U.S.C. § 271(a), (b), and/or (c). The Proposed Gland Dexmedetomidine Products meet each limitation of at least one claim of the '527 patent. With respect to most claims of the '527 patent, the Notice Letter does not allege non-infringement.

26. 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 induce and/or contribute towards the direct infringement of the '527 patent by others.

27. On information and belief, Defendant was aware of the existence of the '527 patent prior to the filing of ANDA No. 209307, and took such action knowing it would constitute infringement of the '527 patent.

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

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

29. Paragraphs 1 through 22 are incorporated herein as set forth above.

30. Defendant submitted ANDA No. 209307 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 Gland 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).

31. Moreover, any commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Proposed Gland Dexmedetomidine Products described in ANDA No. 209307 would infringe the ’106 patent under 35 U.S.C. § 271(a), (b), and/or (c). The Proposed Gland Dexmedetomidine Products meet each limitation of at least one claim of the ’106 patent. The Notice Letter does not allege non-infringement of any claim of the ’106 patent.

32. 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 induce and/or contribute towards the direct infringement of the ’106 patent by others.

33. On information and belief, Defendant was aware of the existence of the ’106 patent prior to the filing of ANDA No. 209307, and took such action knowing it would constitute infringement of the ’106 patent.

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

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

35. Paragraphs 1 through 22 are incorporated herein as set forth above.

36. Defendant submitted ANDA No. 209307 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 Gland 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).

37. Moreover, any commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Proposed Gland Dexmedetomidine Products described in ANDA No. 209307 would infringe the '712 patent under 35 U.S.C. § 271(a), (b), and/or (c). The Proposed Gland Dexmedetomidine Products meet each limitation of at least one claim of the '712 patent. The Notice Letter does not allege non-infringement of any claim of the '712 patent.

38. 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 induce and/or contribute towards the direct infringement of the '712 patent by others.

39. On information and belief, Defendant was aware of the existence of the '712 patent prior to the filing of ANDA No. 209307, and took such action knowing it would constitute infringement of the '712 patent.

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

COUNT IV FOR INFRINGEMENT OF PATENT NO. 9,616,049

41. Paragraphs 1 through 22 are incorporated herein as set forth above.

42. Defendant submitted ANDA No. 209307 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 Gland Dexmedetomidine Products prior to the expiration of the '049 patent. By submitting this ANDA, Defendant committed an act of infringement under 35 U.S.C. § 271(e)(2).

43. Moreover, any commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Proposed Gland Dexmedetomidine Products described in ANDA No. 209307 would infringe the '049 patent under 35 U.S.C. § 271(a), (b), and/or (c). The Proposed Gland Dexmedetomidine Products meet each limitation of at least one claim of the '049 patent. The Notice Letter does not allege non-infringement of any claim of the '049 patent.

44. 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 induce and/or contribute towards the direct infringement of the '049 patent by others.

45. On information and belief, Defendant was aware of the existence of the '049 patent prior to the filing of ANDA No. 209307, and took such action knowing it would constitute infringement of the '049 patent.

46. Hospira will be irreparably harmed if Defendant is not enjoined from infringing the '049 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment as follows:

A. An order decreeing that the submission to the FDA of ANDA No. 209307 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 Gland Dexmedetomidine Products prior to the expiration of the '527 patent, including any regulatory extensions, will infringe, directly and/or indirectly, the '527 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 Gland Dexmedetomidine Products prior to the expiration of the '106 patent, including any regulatory extensions, will infringe, directly and/or indirectly, the '106 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 Gland Dexmedetomidine Products prior to the expiration of the '712 patent, including any regulatory extensions, will infringe, directly and/or indirectly, the '712 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 Gland Dexmedetomidine Products prior to the expiration of the '049 patent, including any regulatory extensions, will infringe, directly and/or indirectly, the '049 patent;

F. An order pursuant to 21 U.S.C. § 355(c)(3)(C) that the effective date of any approval of ANDA No. 209307 shall be no earlier than thirty months after the date on which Hospira received the Notice Letter, and, if the Court rules that the Proposed Gland 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;

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 Proposed Gland Dexmedetomidine Products described in ANDA No. 209307, or any other ANDA not colorably different from ANDA No. 209307, 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: February 1, 2018

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