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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

NAUTILUS NEUROSCIENCES, INC. and APR APPLIED PHARMA RESEARCH SA,	)	
Plaintiffs,	)	Civil Action No. _____
v.	)	
EDICT PHARMACEUTICALS PVT. LTD.,	)	
Defendant.	)	

COMPLAINT

Plaintiffs Nautilus Neurosciences, Inc. ("Nautilus") and APR Applied Pharma Research SA ("APR") (collectively, "Plaintiffs"), by and through their attorneys, for their Complaint against Defendant Edict Pharmaceuticals Pvt. Ltd. ("Defendant"), hereby allege as follows:

PARTIES

1. Nautilus is a Delaware corporation with its principal place of business at 135 Rte 202/206, Bedminster, New Jersey 07921.

2. APR is a corporation organized under the laws of Switzerland with its principal place of business at Via Corti 5, CH-6828, Balerna, Switzerland.

3. On information and belief, Defendant is a corporation organized and existing under the laws of India with its principal place of business at New No. 1/58, Pudupakkam Main Road, Kelambakkam, Chennai – 603 103, Tamil Nadu, India.

4. On information and belief, Defendant has maintained a U.S. office in this judicial district at 9 Revere Road, Monmouth Junction, New Jersey 08852.

5. On information and belief, Defendant authorized a U.S. agent in this district at 508 Elm Avenue, Moorestown, New Jersey 08057 to act on its behalf in corresponding with the United States Food and Drug Administration ("FDA") regarding Defendant's Abbreviated New Drug Application ("ANDA") No. 202964.

6. On information and belief, Defendant develops and manufactures generic pharmaceutical formulations for sale and use throughout the United States, including in this judicial district.

NATURE OF THE ACTION

7. This is a civil action for infringement of U.S. Patent Nos. 6,974,595 (the "'595 patent"), 7,482,377 (the "'377 patent"), and 7,759,394 (the "'394 patent") (collectively, the "patents-in-suit"), which are attached as Exhibits A, B, and C, respectively.

8. This action is based upon the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and arises out of Defendant's filing of ANDA No. 202964 seeking approval to sell diclofenac potassium for oral solution 50 mg prior to the expiration of the patents-in-suit, which are assigned to and/or exclusively licensed by Plaintiffs and listed in the publication entitled "Orange Book: *Approved Drug Products with Therapeutic Equivalents*."

JURISDICTION AND VENUE

9. This action arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*

10. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), and 2201(a).

11. Defendant is subject to personal jurisdiction in this District by virtue of, *inter alia*, its manufacture of generic pharmaceutical formulations for sale and use in this District, its conduct of business in this District, the location of one of its offices in this District, the location of its U.S. agent in this District, its purposeful availment of the rights and benefits of New Jersey law, including its previous admissions that it is subject to personal jurisdiction in New Jersey, *see, e.g.*, *Orexo AB v. Edict Pharms. Pvt. Ltd.*, No. 3:10-cv-05548 (D.N.J. Oct. 26, 2010), and its substantial and continuing contacts with the state of New Jersey.

12. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(b), (c), and (d) and 1400(b).

THE PATENTS-IN-SUIT

13. The ’595 patent, entitled “Pharmaceutical Compositions Based on Diclofenac,” was duly and legally issued by the United States Patent and Trademark Office (“USPTO”) on December 13, 2005.

14. APR owns the entire right, title, and interest in the ’595 patent. Nautilus is the exclusive licensee of the ’595 patent for the United States.

15. The ’377 patent, entitled “Pharmaceutical Compositions and Methods of Treatment Based on Diclofenac,” was duly and legally issued by the USPTO on January 27, 2009.

16. APR owns the entire right, title, and interest in the '377 patent. Nautilus is the exclusive licensee of the '377 patent for the United States.

17. The '394 patent, entitled "Diclofenac Formulations and Methods of Use," was duly and legally issued by the USPTO on July 10, 2010.

18. APR owns the entire right, title, and interest in the '394 patent. Nautilus is the exclusive licensee of the '394 patent for the United States.

19. Nautilus is the holder of New Drug Application ("NDA") No. 22-165 for diclofenac potassium for oral solution 50 mg, sold in the United States under the trademark CAMBIA. The FDA approved NDA No. 22-165 on June 17, 2009.

20. The patents-in-suit are duly listed in the Orange Book: *Approved Drug Products with Therapeutic Equivalents* for NDA No. 22-165. The claims of the patents-in-suit cover, *inter alia*, various methods of using diclofenac.

ACTS GIVING RISE TO THIS ACTION

21. On information and belief, Defendant reviewed each of the patents-in-suit and certain commercial and economic information regarding CAMBIA and decided to file an ANDA seeking approval to market a generic version of CAMBIA.

22. On information and belief, Defendant submitted ANDA No. 202964 to the FDA to seek approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of generic diclofenac potassium for oral solution 50 mg.

23. Plaintiffs received a letter dated June 8, 2011 from Defendant notifying them that Defendant had filed ANDA No. 202964 with the FDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA") seeking approval to market a generic version of CAMBIA prior to the expiry of the patents-in-suit.

24. The stated purpose of Defendant's June 8, 2011 letter was to notify Plaintiffs that ANDA No. 202964 included a certification under 21 U.S.C. § 355(j)(2)(a)(vii)(IV) ("Paragraph IV Certification") that the claims of the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Defendant's ANDA product.

25. On information and belief, Defendant was necessarily aware of each of the patents-in-suit when Defendant filed ANDA No. 202964 with a Paragraph IV Certification.

26. Attached to the June 8, 2011 letter was a "Detailed Statement" setting forth the factual and legal bases for Defendant's opinion that the patents-in-suit are invalid and/or would not be infringed by the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Defendant's product.

27. Nautilus received the June 8, 2011 letter no earlier than June 13, 2011. APR received the June 8, 2011 letter no earlier than June 13, 2011. Plaintiffs commenced this action within 45 days of the date upon which they received Defendant's June 8, 2011 letter.

FIRST CLAIM FOR RELIEF

(Infringement of the '595 Patent by Defendant)

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

29. Defendant submitted ANDA No. 202964 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 diclofenac potassium for oral solution prior to the expiration of the '595 patent. By submitting this ANDA, Defendant has committed an act of infringement under 35 U.S.C. § 271(e)(2).

30. Unless enjoined by this Court, Defendant, upon FDA approval of ANDA No. 202964, will manufacture, use, sell, offer for sale, and/or import into the United States the proposed generic diclofenac potassium product described in ANDA No. 202964, thereby actively inducing others to infringe or contributing to the infringement of the '595 patent under 35 U.S.C. § 271(b) and/or (c).

31. Plaintiffs will be substantially and irreparably harmed if Defendant is not enjoined from infringing the '595 patent.

32. Plaintiffs do not have an adequate remedy at law.

33. An actual and justiciable controversy exists between the parties with respect to the '595 patent.

34. Defendant was aware of the existence of the '595 patent prior to the filing of ANDA No. 202964 but took such action knowing that it would constitute infringement of the '595 patent.

35. Defendant's actions render this an exceptional case under 35 U.S.C. § 285.

SECOND CLAIM FOR RELIEF

(Infringement of the '377 Patent by Defendant)

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

37. Defendant submitted ANDA No. 202964 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 diclofenac potassium for oral solution prior to the expiration of the '377 patent. By submitting this ANDA, Defendant has committed an act of infringement under 35 U.S.C. § 271(e)(2).

38. Unless enjoined by this Court, Defendant, upon FDA approval of ANDA No. 202964, will manufacture, use, sell, offer for sale, and/or import into the United States the proposed generic diclofenac potassium product described in ANDA No. 202964, thereby actively inducing others to infringe or contributing to the infringement of the '377 patent under 35 U.S.C. § 271(b) and/or (c).

39. Plaintiffs will be substantially and irreparably harmed if Defendant is not enjoined from infringing the '377 patent.

40. Plaintiffs do not have an adequate remedy at law.

41. An actual justiciable controversy exists between the parties with respect to the '377 patent.

42. Defendant was aware of the existence of the '377 patent prior to the filing of ANDA No. 202964 but took such action knowing that it would constitute infringement of the '377 patent.

43. Defendant's actions render this an exceptional case under 35 U.S.C. § 285.

THIRD CLAIM FOR RELIEF

(Infringement of the '394 patent by Defendant)

44. Paragraphs 1 through 43 are incorporated herein as set forth above.

45. Defendant submitted ANDA No. 202964 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 diclofenac potassium for oral solution prior to the expiration of the '394 patent. By submitting this ANDA, Defendant has committed an act of infringement under 35 U.S.C. § 271(e)(2).

46. Unless enjoined by this Court, Defendant, upon FDA approval of ANDA No. 202964, will manufacture, use, sell, offer for sale, and/or import into the United States the proposed generic diclofenac potassium product described in ANDA No. 202964, thereby actively inducing others to infringe or contributing to the infringement of the ’394 patent under 35 U.S.C. § 271(b) and/or (c).

47. Plaintiffs will be substantially and irreparably harmed if Defendant is not enjoined from infringing the ’394 patent.

48. Plaintiffs do not have an adequate remedy at law.

49. An actual justiciable controversy exists between the parties with respect to the ’394 patent.

50. Defendant was aware of the existence of the ’394 patent prior to the filing of ANDA No. 202964 but took such action knowing that it would constitute infringement of the ’394 patent.

51. Defendant’s actions render this an exceptional case under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

A. An order decreeing that, by submitting ANDA No. 202964 to the FDA, Defendant has infringed the patents-in-suit under 35 U.S.C. § 271(e)(2);

B. A declaration that, through the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the proposed generic diclofenac potassium product described in ANDA No. 202964, Defendant will actively induce others to infringe or contribute to the infringement of the patents-in-suit under 35 U.S.C. § 271(b) and (c);

C. An order pursuant to 35 U.S.C. § 271(e)(4)(A) decreeing that the effective date of any approval of ANDA No. 202964 be no earlier than the expiration date of the last to expire of the patents-in-suit, including any applicable extensions;

D. A preliminary and permanent injunction restraining and enjoining Defendant, its officers, agents, attorneys, and employees and those acting in privity or concert with them, from engaging in the commercial manufacture, use, sale, and/or offer for sale within the United States and/or importation into the United States of the diclofenac product described in ANDA No. 202964 or any other product not colorably different from the product of ANDA No. 202964 until the expiration of the last to expire of the patents-in-suit, including any applicable extensions;

E. A declaration that this case is exceptional under 35 U.S.C. § 285;

F. An award of attorney fees, costs, and expenses that Plaintiffs incur in prosecuting this action; and

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

Dated: July 20, 2011

CONNELL FOLEY LLP
Attorneys for Plaintiffs
Nautilus Neurosciences, Inc. and
APR Applied Pharma Research SA

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