Liza M. Walsh
Rukhsanah L. Lighari
Connell Foley LLP
85 Livingston Avenue
Roseland, New Jersey 07068
Tel.: (973) 535-0500
Fax: (973) 535-9217
Attorneys for Plaintiffs
Nautilus Neurosciences, Inc.
and APR Applied Pharma
Research SA

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.	)	
WOCKHARDT USA LLC, WOCKHARDT LTD., and EDICT PHARMACEUTICALS PVT. LTD.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Nautilus Neurosciences, Inc. ("Nautilus") and APR Applied Pharma Research SA ("APR") (collectively, "Plaintiffs"), by and through their attorneys, for their Complaint against Defendants Wockhardt USA LLC ("Wockhardt USA"), Wockhardt Ltd. (collectively, "Wockhardt"), and Edict Pharmaceuticals Pvt. Ltd. ("Edict"), 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, Wockhardt USA is a Delaware corporation with a principal place of business at 20 Waterview Boulevard, 3rd Floor, Parsippany, New Jersey 07054.

4. On information and belief, Wockhardt Ltd. is a corporation organized and existing under the laws of India with its principal place of business at Wockhardt Towers, Bandra-Kurla Complex, Bandra (East), Mumbai – 400 051, Maharashtra, India.

5. On information and belief, Wockhardt USA is a subsidiary of Wockhardt Ltd. and the two companies have common officers and directors.

6. On information and belief, Wockhardt USA is controlled and/or dominated by Wockhardt Ltd.

7. On information and belief, Wockhardt Ltd. manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district, through its subsidiary and agent, Wockhardt USA.

8. On information and belief, the acts of Wockhardt USA complained of herein were done at the direction of, with the authorization of, and with the cooperation, participation, and awareness of, and at least in part for the benefit of, Wockhardt Ltd.

9. On information and belief, Edict 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.

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

11. On information and belief, Edict 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 Edict's Abbreviated New Drug Application ("Edict's ANDA") No. 20-2964.

12. On information and belief, Edict was acquired by Par Pharmaceutical Companies, Inc. ("Par") on February 17, 2012.

13. On information and belief, Par is a Delaware corporation with a principal place of business at 300 Tice Boulevard, Woodcliff Lake, New Jersey 07677.

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

NATURE OF THE ACTION

15. This is a civil action for infringement of U.S. Patent No. 8,097,651 (the "'651 patent" or the "patent-in-suit"), which is attached as Exhibit A.

16. The '651 patent is assigned to and/or exclusively licensed by Plaintiffs and listed in the publication entitled "Orange Book: *Approved Drug Products with Therapeutic Equivalents*."

17. This action is based upon the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and arises out of Wockhardt's filing of ANDA No. 20-2430 seeking approval for Wockhardt to sell diclofenac potassium for oral solution 50 mg prior to the expiration of the patent-in-suit, and Edict's filing of ANDA No. 20-2964 seeking approval for Edict to sell diclofenac potassium for oral solution 50 mg prior to the expiration of the patent-in-suit.

JURISDICTION AND VENUE

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

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

20. Wockhardt USA is subject to personal jurisdiction in this District by virtue of, *inter alia*, its conduct of business in this District, the location of its place of business in this District, its purposeful availment of the rights and benefits of New Jersey law, and its substantial and continuing contacts with the state of New Jersey.

21. Wockhardt Ltd. is subject to personal jurisdiction in this District by virtue of, *inter alia*, its manufacture of numerous generic drugs for sale and use in this District through Wockhardt USA and its direction and control of the business of Wockhardt USA, through which it conducts business in this District, purposefully avails itself of the rights and benefits of New Jersey law, and has substantial and continuing contacts with the state of New Jersey.

22. Edict 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.

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

24. Wockhardt USA and Wockhardt Ltd. did not contest that they were subject to personal jurisdiction or that venue was appropriate in New Jersey in another action brought against them by Plaintiffs in this Court, *Nautilus Neurosciences, Inc. et al. v. Wockhardt USA LLC et al.*, Civil Action No. 2:11-1997 (ES/CLW) (D.N.J. April 8, 2011).

25. Edict did not contest that it was subject to personal jurisdiction or that venue was appropriate in New Jersey in another action brought against it by Plaintiffs in this Court, *Nautilus Neurosciences, Inc. et al. v. Edict Pharmaceuticals Pvt. Ltd..*, Civil Action No. 2:11-4183 (ES/CLW) (D.N.J. July 20, 2011).

THE PATENT-IN-SUIT

26. The ’651 patent, entitled “Diclofenac Formulations and Methods of Use,” was duly and legally issued by the United States Patent and Trademark Office (“USPTO”) on January 17, 2012.

27. APR owns the entire right, title, and interest in the ’651 patent. Nautilus is the exclusive licensee of the ’651 patent for the United States.

28. 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 United States Food and Drug Administration (“FDA”) approved NDA No. 22-165 on June 17, 2009.

29. The ’651 patent is duly listed in the Orange Book: *Approved Drug Products with Therapeutic Equivalents* for NDA No. 22-165 (the “Orange Book listing”). The claims of the ’651 patent cover, *inter alia*, various methods of using diclofenac.

ACTS GIVING RISE TO THIS ACTION

30. On information and belief, Wockhardt reviewed the Orange Book listing for CAMBIA and certain commercial and economic information regarding CAMBIA and decided to file an ANDA seeking approval to market a generic version of CAMBIA.

31. On information and belief, Wockhardt Ltd. has designated Wockhardt USA as its agent for the purpose of submitting and obtaining approval of ANDA No. 20-2430.

32. On information and belief Wockhardt Ltd. submitted ANDA No. 20-2430 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.

33. Plaintiffs received a letter dated March 1, 2011 from Wockhardt purporting to notify them that Wockhardt had filed ANDA No. 20-2430 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 U.S. Patent Nos. 6,974,595, 7,482,377, and 7,759,394.

34. The stated purpose of Wockhardt's March 1, 2011 letter was to notify Plaintiffs that ANDA No. 20-2430 included a certification under 21 U.S.C. § 355(j)(2)(a)(vii)(IV) ("Wockhardt's Paragraph IV Certification") that the claims of U.S. Patent Nos. 6,974,595, 7,482,377, and 7,759,394 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 Wockhardt's ANDA product.

35. Attached to the March 1, 2011 letter was a "Detailed Statement" setting forth the factual and legal bases for Wockhardt's opinion that U.S. Patent Nos. 6,974,595,

7,482,377, and 7,759,394 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 Wockhardt's product.

36. On April 8, 2011, Plaintiffs filed a complaint for infringement by Wockhardt of U.S. Patent Nos. 6,974,595, 7,482,377, and 7,759,394 in this Court. The case is docketed as Civil Action No. 2:11-cv-01997-ES-CLW.

37. The '651 patent was duly and legally issued by the USPTO on January 17, 2012 and subsequently added to the Orange Book listing.

38. Plaintiffs received a letter dated January 30, 2012 from Wockhardt purporting to notify them that Wockhardt had amended ANDA No. 20-2430 with the FDA under section 505(j) of the FDCA to seek approval to market a generic version of CAMBIA prior to the expiry of the '651 patent.

39. The stated purpose of Wockhardt's January 30, 2012 letter was to notify Plaintiffs that Wockhardt's Paragraph IV Certification was amended to add that the claims of the '651 patent 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 Wockhardt's ANDA product.

40. Attached to the January 30, 2012 letter was a "Detailed Statement" setting forth the factual and legal bases for Wockhardt's opinion that the '651 patent is invalid and/or would not be infringed by the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Wockhardt's product.

41. On information and belief, Edict reviewed the Orange Book listing for CAMBIA and certain commercial and economic information regarding CAMBIA and decided to file an ANDA seeking approval to market a generic version of CAMBIA.

42. On information and belief, Edict submitted ANDA No. 20-2964 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.

43. Plaintiffs received a letter dated June 8, 2011 from Edict notifying them that Edict had filed ANDA No. 20-2964 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 U.S. Patent Nos. 6,974,595, 7,482,377, and 7,759,394.

44. The stated purpose of Edict's June 8, 2011 letter was to notify Plaintiffs that ANDA No. 20-2964 included a certification under 21 U.S.C. § 355(j)(2)(a)(vii)(IV) ("Edict's Paragraph IV Certification") that the claims of U.S. Patent Nos. 6,974,595, 7,482,377, and 7,759,394 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 Edict's ANDA product.

45. Attached to the June 8, 2011 letter was a "Detailed Statement" setting forth the factual and legal bases for Edict's opinion that U.S. Patent Nos. 6,974,595, 7,482,377, and 7,759,394 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 Edict's product.

46. On July 20, 2011, Plaintiffs filed a complaint for infringement by Edict of U.S. Patent Nos. 6,974,595, 7,482,377, and 7,759,394 in this Court. The case is docketed as Civil Action No. 2:11-cv-04183-ES-CLW.

47. The ’651 patent was duly and legally issued by the USPTO on January 17, 2012 and subsequently added to the Orange Book listing.

48. Plaintiffs received a letter dated February 7, 2012 from Edict purporting to notify them that Edict had amended its Paragraph IV Certifications in ANDA No. 20-2964 with the FDA under section 505(j) of the FDCA to seek approval to market a generic version of CAMBIA prior to the expiry of the ’651 patent.

49. The stated purpose of Edict’s February 7, 2012 letter was to notify Plaintiffs that Edict’s Paragraph IV Certification was amended to add that the claims of the ’651 patent 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 Edict’s ANDA product.

50. Attached to the February 7, 2012 letter was a “Detailed Statement” setting forth the factual and legal bases for Edict’s opinion that the ’651 patent is invalid and/or would not be infringed by the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Edict’s product.

FIRST CLAIM FOR RELIEF

(Infringement of the ’651 Patent by Wockhardt)

51. Paragraphs 1 through 50 are incorporated herein as set forth above.

52. Wockhardt submitted ANDA No. 20-2430 with a Paragraph IV Certification, along with a subsequent amendment, 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 ’651 patent. By submitting this ANDA, Wockhardt has committed an act of infringement under 35 U.S.C. § 271(e)(2).

53. Unless enjoined by this Court, Wockhardt, upon FDA approval of the amended ANDA No. 20-2430, will manufacture, use, sell, offer for sale, and/or import into the United States the proposed generic diclofenac potassium product described in ANDA No. 20-2430, thereby actively inducing others to infringe or contributing to the infringement of the '651 patent under 35 U.S.C. § 271(b) and/or (c).

54. Plaintiffs will be substantially and irreparably harmed if Wockhardt is not enjoined from infringing the '651 patent.

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

56. An actual and justiciable controversy exists between the parties with respect to the '651 patent.

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

SECOND CLAIM FOR RELIEF

(Infringement of the '651 Patent by Edict)

58. Paragraphs 1 through 57 are incorporated herein as set forth above.

59. Edict submitted ANDA No. 20-2964 with a Paragraph IV Certification, along with a subsequent amendment, 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 '651 patent. By submitting this ANDA, Edict has committed an act of infringement under 35 U.S.C. § 271(e)(2).

60. Unless enjoined by this Court, Edict, upon FDA approval of the amended ANDA No. 20-2964, will manufacture, use, sell, offer for sale, and/or import into the United

States the proposed generic diclofenac potassium product described in ANDA No. 20-2964, thereby actively inducing others to infringe or contributing to the infringement of the ’651 patent under 35 U.S.C. § 271(b) and/or (c).

61. Plaintiffs will be substantially and irreparably harmed if Edict is not enjoined from infringing the ’651 patent.

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

63. An actual justiciable controversy exists between the parties with respect to the ’651 patent.

64. Edict’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. 20-2430 to the FDA, along with a subsequent amendment, Wockhardt has infringed the '651 patent 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. 20-2430, Wockhardt will actively induce others to infringe or contribute to the infringement of the '651 patent 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. 20-2430 be no earlier than the expiration date of the '651 patent including any applicable extensions;

D. A preliminary and permanent injunction restraining and enjoining Wockhardt, its officers, agents, attorneys, and employees and those acting in privity or concert with it, 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. 20-2430 or any other product not colorably different from the product of ANDA No. 20-2430 until the expiration date of the '651 patent, including any applicable extensions;

E. An order decreeing that, by submitting ANDA No. 20-2964 to the FDA, along with a subsequent amendment, Edict has infringed the '651 patent under 35 U.S.C. § 271(e)(2);

F. 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. 20-2964, Edict will actively induce others to infringe or contribute to the infringement of the'651 patent under 35 U.S.C. § 271(b) and (c);

G. An order pursuant to 35 U.S.C. § 271(e)(4)(A) decreeing that the effective date of any approval of ANDA No. 20-2964 be no earlier than the expiration date of the '651 patent, including any applicable extensions;

H. A preliminary and permanent injunction restraining and enjoining Edict, its officers, agents, attorneys, and employees and those acting in privity or concert with it, 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. 20-2964 or any other product not colorably different from the product of ANDA No. 20-2964 until the expiration date of the '651 patent, including any applicable extensions;

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

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

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

Dated: February 27, 2012

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

By: */s Liza M. Walsh*
Liza M. Walsh
Rukhsanah L. Lighari
85 Livingston Avenue
Roseland, New Jersey 07068
Telephone: (973) 535-0500
Facsimile: (973) 535-9217

Of Counsel:

Thomas J. Meloro
Michael W. Johnson
Ketan Pastakia
Laurie N. Stempler
Willkie Farr & Gallagher LLP
787 Seventh Avenue
New York, NY 10019-6099
(T) 212.728.8000
(F) 212.728.8111