Liza M. Walsh
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**

| | | |
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| NAUTILUS NEUROSCIENCES, INC. and APR APPLIED PHARMA RESEARCH SA, | ) | |
| Plaintiffs, | ) | Civil Action No. _____ |
| v. | ) | |
| WOCKHARDT USA LLC and WOCKHARDT 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") and Wockhardt Ltd. (collectively "Defendants"), 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.

## NATURE OF THE ACTION

9. 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.

10. This action is based upon the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and arises out of Defendants' filing of an Abbreviated New Drug Application ("ANDA") No. 20-2430 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**

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

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

13. 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.

14. 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.

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

## THE PATENTS-IN-SUIT

16. 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.

17. 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.

18. 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.

19. 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.

20. The ’394 patent, entitled “Diclofenac Formulations and Methods of Use,” was duly and legally issued by the USPTO on July 10, 2010.

21. 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.

22. 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.

23. 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

24. On information and belief, Defendants 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.

25. 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.

26. 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.

27. Plaintiffs received a letter dated March 1, 2011 from Defendants purporting to notify them that Defendants 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 the patents-in-suit.

28. The stated purpose of Defendants' 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) ("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 Defendants' ANDA product.

29. On information and belief, Defendants were necessarily aware of each of the patents-in-suit when Wockhardt Ltd. filed ANDA No. 20-2430 with a Paragraph IV Certification.

30. Attached to the March 1, 2011 letter was a "Detailed Statement" purporting to set forth the factual and legal bases for Defendants' 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 Defendants' product.

31. The subject line of Defendants' March 1, 2011 letter reads "Notice of Paragraph IV Certification Regarding ANDA No. 202430 (Diclofenac Potassium Tablets) with respect to U.S. Patent Nos. 6,974,595, 7,482,377, and 7,759,394."

32. Defendants' March 1, 2011 letter states that "Wockhardt's proposed drug product is in the form of a tablet, which contains the equivalent of 50 mg per tablet of Diclofenac Potassium as the active ingredient."

33. The Detailed Statement states that "Wockhardt's diclofenac product is a powder for solution."

34. On information and belief, ANDA No. 20-2430 seeks approval for diclofenac potassium powder for oral solution 50 mg.

35. Nautilus received the March 1, 2011 letter no earlier than March 1, 2011. APR received the March 1, 2011 letter no earlier than March 1, 2011. Plaintiffs commenced this action within 45 days of the date upon which they received Defendants' March 1, 2011 letter.

**FIRST CLAIM FOR RELIEF**

**(Infringement of the '595 Patent by Defendants)**

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

37. Defendants submitted ANDA No. 20-2430 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, Defendants have committed an act of infringement under 35 U.S.C. § 271(e)(2).

38. Unless enjoined by this Court, Defendants, upon FDA approval of 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 '595 patent under 35 U.S.C. § 271(b) and/or (c).

39. Plaintiffs will be substantially and irreparably harmed if Defendants are not enjoined from infringing the '595 patent.

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

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

42. Defendants were aware of the existence of the '595 patent prior to the filing of ANDA No. 20-2430 but took such action knowing that it would constitute infringement of the '595 patent.

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

**SECOND CLAIM FOR RELIEF**

**(Infringement of the '377 Patent by Defendants)**

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

45. Defendants submitted ANDA No. 20-2430 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, Defendants have committed an act of infringement under 35 U.S.C. § 271(e)(2).

46. Unless enjoined by this Court, Defendants, upon FDA approval of 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 '377 patent under 35 U.S.C. § 271(b) and/or (c).

47. Plaintiffs will be substantially and irreparably harmed if Defendants are not enjoined from infringing the '377 patent.

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

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

50. Defendants were aware of the existence of the '377 patent prior to the filing of ANDA No. 20-2430 but took such action knowing that it would constitute infringement of the '377 patent.

51. Defendants' actions render this an exceptional case under 35 U.S.C. § 285.

**THIRD CLAIM FOR RELIEF**

**(Infringement of the '394 patent by Defendants)**

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

53. Defendants submitted ANDA No. 20-2430 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, Defendants have committed an act of infringement under 35 U.S.C. § 271(e)(2).

54. Unless enjoined by this Court, Defendants, upon FDA approval of 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 '394 patent under 35 U.S.C. § 271(b) and/or (c).

55. Plaintiffs will be substantially and irreparably harmed if Defendants are not enjoined from infringing the '394 patent.

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

57. An actual justiciable controversy exists between the parties with respect to the '394 patent.

58. Defendants were aware of the existence of the '394 patent prior to the filing of ANDA No. 20-2430 but took such action knowing that it would constitute infringement of the '394 patent.

59. Defendants' 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, Defendants have 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. 20-2430, Defendants 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. 20-2430 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 Defendants, their 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. 20-2430 or any other product not colorably different from the product of ANDA No. 20-2430 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: April 8, 2011

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

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

Of Counsel:

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

**LOCAL CIVIL RULE 11.2 CERTIFICATION**

I certify that, to the best of my knowledge, the matter in controversy is not the subject of any other pending or anticipated litigation in any court or arbitration proceeding, nor are there any non-parties known to Plaintiffs that should be joined to this action. In addition, I recognize a continuing obligation during the course of this litigation to file and to serve on all other parties and with the Court an amended certification if there is a change in the facts stated in this original certification.

Dated: April 8, 2011 _____/s Liza M. Walsh_____
Liza M. Walsh

**LOCAL CIVIL RULE 201.1 CERTIFICATION**

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that declaratory and injunctive relief is sought.

Dated: April 8, 2011 ___/s Liza M. Walsh_____
Liza M. Walsh