

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

AVANIR PHARMACEUTICALS, INC.,  
AVANIR HOLDING COMPANY, and  
CENTER FOR NEUROLOGIC STUDY,

Plaintiffs,

v.

WOCKHARDT, LTD. AND WOCKHARDT  
USA, LLC,

Defendants.

C.A. No. \_\_\_\_\_

**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiffs Avanir Pharmaceuticals, Inc. (“Avanir Pharmaceuticals”), Avanir Holding Company, and Center for Neurologic Study (“CNS”), by their undersigned attorneys, for their Complaint against defendants Wockhardt USA, LLC. and Wockhardt, Ltd. (collectively, “Wockhardt”), allege as follows:

**Nature of the Action**

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. §100, *et seq.*, arising from Wockhardt’s filing of an Abbreviated New Drug Application (“ANDA”) with the United States Food and Drug Administration (“FDA”) seeking approval commercially to market a generic version of Avanir Pharmaceuticals’ NUEDEXTA<sup>®</sup> drug product prior to the expiration of United States Patent Nos. 7,659,282 (the “282 patent”) and RE38,115 (the “115 patent”).

**The Parties**

2. Plaintiff Avanir Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 20 Enterprise, Suite 200, Aliso Viejo, California 92656.

3. Plaintiff Avanir Holding Company is a corporation organized and existing under the laws of the State of California, having a principle place of business at 20 Enterprise, Suite 200, Aliso Viejo, California 92656. Avanir Holding Company is a wholly-owned subsidiary of Avanir Pharmaceuticals, Inc.

4. Plaintiff Center for Neurologic Study is a not-for-profit corporation organized and existing under the laws of the State of California, having a principle place of business at 9850 Genese Avenue, Suite 320, La Jolla, California 92037.

5. On information and belief, defendant Wockhardt USA, LLC is a limited liability company organized and existing under the laws of the State of Delaware, having a principal place of business at 20 Waterview Boulevard, Parsippany, New Jersey 07054.

6. On information and belief, defendant Wockhardt, Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at Wockhardt Tower, Bandra-Kurla Complex, Bandra (East), Mumbai, Maharashtra 400 051, India. On information and belief, defendant Wockhardt Ltd. manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district, through its wholly-owned subsidiary and agent Wockhardt USA, LLC.

7. On information and belief, Wockhardt USA, LLC and Wockhardt, Ltd. acted collaboratively in the preparation and submission of ANDA No. 203-060 to the FDA. On information and belief, following any FDA approval of ANDA No. 203-060, Wockhardt USA,

LLC and Wockhardt, Ltd. will work in concert with one another to make, use, offer to sell, and/or sell the generic products that are the subject of ANDA No. 203-060 throughout the United States, and/or import such generic products into the United States..

### **Jurisdiction and Venue**

8. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

9. This Court has personal jurisdiction over Wockhardt USA, LLC because it is a company organized and existing under the laws of the State of Delaware and, by virtue of, *inter alia*, having availed itself of the rights and benefits of Delaware law, and having engaged in systematic and continuous contacts with the State of Delaware.

10. This Court has personal jurisdiction over Wockhardt, Ltd. by virtue of, *inter alia*, (1) having availed itself of the rights and benefits of Delaware law, including through its subsidiary and agent Wockhardt USA, LLC; and (2) having engaged in systematic and continuous contacts with the State of Delaware, including through its subsidiary and agent Wockhardt USA, LLC.

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

### **The Patents-in-Suit**

12. On February 9, 2010, the United States Patent and Trademark Office (“USPTO”) duly and lawfully issued the ’282 patent, entitled “Pharmaceutical Compositions Comprising Dextromethorphan and Quinidine for the Treatment of Neurological Disorders” to inventors Gerald Yakatan, James Berg, Laura Pope, and Richard Smith. A copy of the ’282 patent is attached hereto as Exhibit A.

13. On May 6, 2003, the USPTO duly and lawfully issued the '115 patent, entitled "Dextromethorphan and an Oxidase Inhibitor for Treating Intractable Conditions" to inventors Richard Smith and Jonathan Licht. A copy of the '115 patent is attached hereto as Exhibit B.

**The NUEDEXTA<sup>®</sup> Drug Product**

14. Avanir Pharmaceuticals holds an approved New Drug Application ("NDA") under Section 505(a) of the Federal Food Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(a), for dextromethorphan hydrobromide/quinidine sulfate capsules (NDA No. 21-879), which it sells under the trade name NUEDEXTA<sup>®</sup>. The claims of the patents-in-suit cover, *inter alia*, pharmaceutical formulations containing dextromethorphan hydrobromide/quinidine sulfate or methods of using same. Avanir Pharmaceuticals is the assignee of the '282 patent. CNS is the assignee of the '115 patent. Avanir Holding Company is an exclusive licensee of the '115 patent, and Avanir Pharmaceuticals is an exclusive sub-licensee of the '115 patent.

15. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the '282 and '115 patents are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to NUEDEXTA<sup>®</sup>.

**Acts Giving Rise to this Suit**

16. Pursuant to Section 505 of the FFDCA, Wockhardt filed ANDA No. 203-060 ("Wockhardt's ANDA") seeking approval to engage in the commercial use, manufacture, sale, offer for sale or importation of 20 mg dextromethorphan hydrobromide/10 mg quinidine sulfate capsules ("Wockhardt's Proposed Product") before the patents-in-suit expire.

17. In connection with the filing of its ANDA, as described in the preceding paragraph, Wockhardt has provided a written certification to the FDA, as called for by Section 505 of the FFDCA, alleging that the claims of the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the activities described in Wockhardt's ANDA.

18. No earlier than July 18, 2011, Wockhardt sent written notice of its ANDA certification to Avanir Pharmaceuticals ("Wockhardt's Notice Letter"). Wockhardt's Notice Letter alleged that the claims of the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the activities described in Wockhardt's ANDA. Wockhardt's Notice Letter also informed Avanir Pharmaceuticals that Wockhardt seeks approval to market Wockhardt's Proposed Product before the patents-in-suit expire.

**Count I: Infringement of the '282 Patent**

19. Plaintiffs repeat and reallege the allegations of paragraphs 1-18 as though fully set forth herein.

20. Wockhardt's submission of its ANDA to the FDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of dextromethorphan hydrobromide/quinidine sulfate capsules, prior to the expiration of the '282 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

21. There is a justiciable controversy between the parties hereto as to the infringement of the '282 patent.

22. Unless enjoined by this Court, upon FDA approval of Wockhardt's ANDA, Wockhardt will infringe the '282 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Wockhardt's Proposed Product in the United States.

23. Unless enjoined by this Court, upon FDA approval of Wockhardt's ANDA, Wockhardt will induce infringement of the '282 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Wockhardt's Proposed Product in the United States. On information and belief, upon FDA approval of Wockhardt's ANDA, Wockhardt will intentionally encourage acts of direct infringement with knowledge of the '282 patent and knowledge that its acts are encouraging infringement.

24. Unless enjoined by this Court, upon FDA approval of Wockhardt's ANDA, Wockhardt will contributorily infringe the '282 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Wockhardt's Proposed Product in the United States. On information and belief, Wockhardt has had and continues to have knowledge that Wockhardt's Proposed Product is especially adapted for a use that infringes the '282 patent and that there is no substantial non-infringing use for Wockhardt's Proposed Product.

25. Plaintiffs will be substantially and irreparably damaged and harmed if Wockhardt's infringement of the '282 patent is not enjoined.

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

27. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

#### **Count II: Infringement of the '115 Patent**

28. Plaintiffs repeat and reallege the allegations of paragraphs 1-27 as though fully set forth herein.

29. Wockhardt's submission of its ANDA to the FDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of dextromethorphan hydrobromide/quinidine sulfate capsules, prior to the expiration of the '115 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

30. There is a justiciable controversy between the parties hereto as to the infringement of the '115 patent.

31. Unless enjoined by this Court, upon FDA approval of Wockhardt's ANDA, Wockhardt will infringe the '115 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Wockhardt's Proposed Product in the United States.

32. Plaintiffs will be substantially and irreparably damaged and harmed if Wockhardt's infringement of the '115 patent is not enjoined.

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

34. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

### **PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs respectfully request the following relief:

(A) A Judgment be entered that Wockhardt has infringed the '282 and '115 patents by submitting ANDA No. 203-060 to the FDA;

(B) A Judgment be entered that Wockhardt has infringed, and that Wockhardt's making, using, selling, offering to sell, or importing Wockhardt's Proposed Product will infringe one or more claims of the '282 and '115 patents;

(C) An Order that the effective date of FDA approval of ANDA No. 203-060 be a date which is not earlier than the later of the expiration of the '282 and '115 patents, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

(D) Preliminary and permanent injunctions enjoining Wockhardt and its officers, agents, attorneys and employees, and those acting in privity or concert with them, from making, using, selling, offering to sell, or importing Wockhardt's Proposed Product until after the expiration of the '282 and '115 patents, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

(E) A permanent injunction be issued, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Wockhardt, its officers, agents, attorneys and employees, and those acting in privity or concert with them, from practicing any methods claimed in the '282 patent, or from actively inducing or contributing to the infringement of any claims of the '282 patent, until

after the expiration of the '282 patent, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

(F) A Declaration that the commercial manufacture, use, importation into the United States, sale, or offer for sale of Wockhardt's Proposed Product will directly infringe, induce and/or contribute to infringement of the '282 and '115 patents;

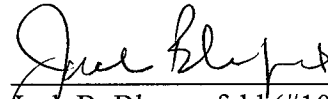
(G) If Wockhardt engages in the commercial manufacture, use, importation into the United States, sale, or offer for sale of Wockhardt's Proposed Product prior to the expiration of the '282 and '115 patents, a Judgment awarding damages to Plaintiffs resulting from such infringement, together with interest;

(H) Attorneys' fees in this action as an exceptional case pursuant to 35 U.S.C. § 285;

(I) Costs and expenses in this action; and

(J) Such further and other relief as this Court may deem just and proper.

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