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IntelGenx Corp.

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

INTELGENX CORP., Plaintiff, v. WOCKHARDT BIO, AG; WOCKHARDT LIMITED; and WOCKHARDT USA, LLC, Defendants.	Civil Action No. _____ **COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiff, IntelGenx Corp. ("IntelGenx"), by its undersigned attorneys, for its Complaint against defendants Wockhardt Bio AG, Wockhardt Limited, and Wockhardt USA, LLC (collectively, "Wockhardt"), alleges as follows:

THE 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 to commercially market a generic version of IntelGenx's FORFIVO XL® drug product

prior to the expiration of United States Patent No. 7,674,479 (the '479 patent) (the patent-in-suit) owned by IntelGenx.

THE PARTIES

2. IntelGenx is a Canadian corporation, having its principal place of business at 6425 Abrams, Ville Saint-Laurent, Quebec H4S 1X9, Canada. IntelGenx is wholly owned by IntelGenx Technologies Corp., which is a publicly traded company and is incorporated in Delaware.

3. On information and belief, Wockhardt Limited is a company organized and existing under the laws of India, having a principal place of business at Bandra-Kurla Complex, Bandra East, Mumbai 400 051, India. On information and belief, Wockhardt Limited, itself and through its subsidiaries Wockhardt Bio AG and Wockhardt USA, LLC, is in the business of making and selling generic pharmaceutical products, which it distributes in the State of New Jersey and throughout the United States.

4. On information and belief, Wockhardt Bio AG, a wholly-owned subsidiary of Wockhardt Limited, is a company organized and existing under the laws of Switzerland, having a principal place of business at Baarerstrasse 43, 6300 Zug, Switzerland. On information and belief, Wockhardt Bio AG, itself and through Wockhardt USA, LLC, is in the business of making and selling generic pharmaceutical products, which it distributes in the State of New Jersey and throughout the United States.

5. On information and belief, Wockhardt USA, LLC, a wholly-owned subsidiary of Wockhardt Limited, is a corporation 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. On information and belief, Wockhardt USA, LLC, with the assistance and/or direction of Wockhardt Bio AG and/or Wockhardt Limited, develops, manufactures, markets, imports, offers to sell, and/or sells generic drug products for sale and use in the State of New Jersey and throughout the United States.

6. Upon information and belief, Wockhardt USA, LLC, Wockhardt Bio AG, and Wockhardt Limited act in concert with one another and hold themselves out as an integrated unit for purposes of developing, manufacturing, distributing, marketing, importing, and selling generic drug products throughout the United States, including in this judicial district.

7. Upon information and belief, Wockhardt USA, LLC, Wockhardt Bio AG, and Wockhardt Limited acted collaboratively and in concert in the preparation and submission of ANDA No. 205079.

8. Upon information and belief, following any FDA approval of ANDA No. 205079, Wockhardt Limited, Wockhardt Bio AG, and Wockhardt USA, LLC will act in concert with one another, and/or with other Wockhardt Limited subsidiaries, to make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 205079 throughout the United States, and/or import such generic drug products into the United States, including in this judicial district.

JURISDICTION AND VENUE

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

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

11. This Court has personal jurisdiction over Wockhardt USA, LLC because it has availed itself of the legal protections of the State of New Jersey by, among other things, maintaining its principal place of business in Piscataway, New Jersey.

12. This Court also has personal jurisdiction over Wockhardt USA, LLC because, among other things, as described above, it manufactures, distributes, markets, and sells generic drug products throughout the United States and within New Jersey. Furthermore, upon information and belief, Wockhardt USA, LLC derives substantial revenue from such conduct in New Jersey. Accordingly, Wockhardt USA, LLC has persistent, systematic and continuous contacts with New Jersey and has therefore purposefully availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court in this district.

13. This Court also has personal jurisdiction over Wockhardt USA, LLC because it has availed itself of the legal protections of the State of New Jersey by, among other things, admitting jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of New Jersey (*e.g.*, *Aventis Pharms. Inc. v. Wockhardt Limited*., C.A. No. 07-5647, Answer and Counterclaims of Defendants Wockhardt Limited and Wockhardt USA,

LLC at 3 (D.N.J. June 4, 2010); *Sanofi Aventis U.S. LLC v. Wockhardt Limited*., C.A. No. 10-1471, Answer and Counterclaims of Defendants Wockhardt Limited and Wockhardt USA, LLC at 3-4 (D.N.J. Apr. 22, 2010); *Nautilus Neurosciences, Inc. v. Wockhardt USA, LLC*, C.A. No. 11-1997, Defendants Wockhardt USA, LLC's and Wockhardt Limited's Answer and Counterclaims at 4 (D.N.J. Apr. 29, 2011)).

14. This Court also has personal jurisdiction over Wockhardt Limited because, among other things, as described above it manufactures, distributes, markets, and sells generic drug products throughout the United States and within New Jersey. Furthermore, upon information and belief, Wockhardt Limited derives substantial revenue from such conduct in New Jersey. Accordingly, Wockhardt Limited has persistent, systematic and continuous contacts with New Jersey and therefore purposefully availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court in this district.

15. This Court also has personal jurisdiction over Wockhardt Limited because it has availed itself of the legal protections of the State of New Jersey by, among other things, creating a subsidiary with its principal places of business in New Jersey (*i.e.*, Wockhardt USA, LLC).

16. This Court also has personal jurisdiction over Wockhardt Limited because it has availed itself of the legal protections of the State of New Jersey by, among other things, admitting jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of New Jersey (*e.g.*, *Aventis Pharms. Inc. v. Wockhardt Limited*., C.A. No. 07-5647, Answer and Counterclaims of Defendants Wockhardt Limited and Wockhardt USA, LLC at 3 (D.N.J. June 4, 2010); *Sanofi Aventis U.S. LLC v. Wockhardt Limited*., C.A. No. 10-

1471, Answer and Counterclaims of Defendants Wockhardt Limited and Wockhardt USA, LLC at 3-4 (D.N.J. Apr. 22, 2010); *Nautilus Neurosciences, Inc. v. Wockhardt USA, LLC*, C.A. No. 11-1997, Defendants Wockhardt USA, LLC's and Wockhardt Limited's Answer and Counterclaims at 4 (D.N.J. Apr. 29, 2011)).

17. This Court also has personal jurisdiction over Wockhardt Bio AG because, among other things as described above, it manufactures, distributes, markets, and sells generic drug products throughout the United States and within New Jersey. Furthermore, upon information and belief, Wockhardt Bio AG derives substantial revenue from such conduct in New Jersey. Accordingly, Wockhardt Bio AG has persistent, systematic and continuous contacts with New Jersey and therefore purposefully availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court in this district.

THE PATENT-IN-SUIT

18. On March 9, 2010, the United States Patent and Trademark Office ("USPTO") duly and lawfully issued the '479 patent, entitled "Sustained-Release Bupropion and Bupropion/Mecamylamine Tablets" to inventors Horst G. Zerbe and Nadine Paiement. A copy of the '479 patent is attached hereto as Exhibit A.

THE FORFIVO XL® Product

19. IntelGenx was granted approval for its New Drug Application ("NDA") under Section 505(b)(2) of the Federal Food Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(b)(2), for bupropion hydrochloride 450 mg extended-release tablets (NDA No. 022497), which is sold under the trade name FORFIVO XL®. Pursuant to the License and Asset Transfer

Agreement dated February 3, 2012, IntelGenx transferred the NDA to Edgemont Pharmaceuticals, LLC. The claims of the patent-in-suit cover, *inter alia,* pharmaceutical compositions containing bupropion hydrochloride (450 mg). IntelGenx owns the patent-in-suit.

20. Pursuant to 21 U.S.C. § 355(b) and attendant FDA regulations, '479 patent is listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to FORFIVO XL®.

ACTS GIVING RISE TO THIS SUIT

21. Pursuant to Section 505 of the FFDCA, Wockhardt filed ANDA No. 205079 ("Wockhardt's ANDA") seeking approval to engage in the commercial manufacture, use, sale, offer for sale or importation of bupropion hydrochloride ER 450 mg tablets ("Wockhardt's Proposed Product") before the patent-in-suit expires.

22. 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, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Wockhardt's Paragraph IV Certification"), alleging that the claims of the patent-in-suit are invalid, unenforceable, and/or will not be infringed by the activities described in Wockhardt's ANDA.

23. No earlier than July 9, 2013, IntelGenx received written notice of Wockhardt's Paragraph IV Certification ("Wockhardt's Notice Letter") pursuant to 21 U.S.C. § 355(j)(2)(B). Wockhardt's Notice Letter alleged that the claims of the patent-in-suit are invalid, unenforceable, and/or will not be infringed by the activities described in Wockhardt's ANDA. Wockhardt's

Notice Letter evinces its intent to seek approval to market Wockhardt's Proposed Product before the patent-in-suit expire.

COUNT I: INFRINGEMENT OF THE '479 PATENT

24. Plaintiff repeats and re-alleges the allegations of paragraphs 1-23 as though fully set forth herein.

25. Wockhardt, through its submission of its Paragraph IV Certification as part of its ANDA to the FDA, has indicated that it seeks approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of bupropion hydrochloride (450 mg) tablets prior to the expiration of the '479 patent.

26. Wockhardt's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of bupropion hydrochloride (450 mg) tablets, prior to the expiration of the '479 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

27. Wockhardt Limited, Wockhardt Bio AG, and Wockhardt USA, LLC are jointly and severally liable for any infringement of the '479 patent. This is so because, upon information and belief, Wockhardt Limited, Wockhardt Bio AG, and Wockhardt USA, LLC participated in, contributed to, aided and abetted and/or induced the submission of ANDA No. 205079 and its §505(j)(2)(A)(vii)(IV) allegations to the FDA. Additionally, upon information and belief, Wockhardt Limited and Wockhardt Bio AG will, without authority, import the Generic Products

into the United States for subsequent commercial sale by Wockhardt USA, LLC, Wockhardt Limited and Wockhardt Bio AG under ANDA No. 205079.

28. Wockhardt Limited, Wockhardt Bio AG, and Wockhardt USA, LLC's participation in, contributing to, aiding, abetting and/or inducement of the submission of ANDA No. 205079 and its § 505(j)(2)(A)(vii)(IV) allegations regarding the '479 patent to the FDA constitutes infringement under 35 U.S.C. § 271(e)(2)(A). Moreover, if Wockhardt Limited and/or Wockhardt Bio AG import any of the Generic Products into the United States, or induce or contribute to any such conduct, they would further infringe the '479 patent under 35 U.S.C. § 271(a), (b), and/or (c).

29. There is a justiciable controversy between the parties hereto as to the infringement of the '479 patent.

30. Unless enjoined by this Court, upon FDA approval of Wockhardt's ANDA, Wockhardt will infringe the '479 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.

31. Unless enjoined by this Court, upon FDA approval of Wockhardt's ANDA, Wockhardt will induce infringement of the '479 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 '479 patent and knowledge that its acts are encouraging infringement.

32. Unless enjoined by this Court, upon FDA approval of Wockhardt's ANDA, Wockhardt will contributorily infringe the '479 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 '479 patent and that there is no substantial non-infringing use for Wockhardt's Proposed Product.

33. IntelGenx will be substantially and irreparably damaged and harmed if Wockhardt's infringement of the '479 patent is not enjoined.

34. IntelGenx does not have an adequate remedy at law.

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiff IntelGenx respectfully requests the following relief:

(A) A Judgment be entered that Wockhardt has infringed the patent-in-suit by submitting ANDA No. 205079;

(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 patent-in-suit;

(C) An Order that the effective date of FDA approval of ANDA No. 205079 be a date which is not earlier than the later of the expiration of the patent-in-suit, or any later expiration of exclusivity to which Plaintiff is or becomes 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 patent-in-suit, or any later expiration of exclusivity to which Plaintiff is or becomes 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 actively inducing or contributing to the infringement of any claim of the patent-in-suit, until after the expiration of the patent-in-suit, or any later expiration of exclusivity to which Plaintiff is or becomes 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 patent-in-suit;

(G) To the extent that Wockhardt has committed any acts with respect to the compositions claimed in the patent-in-suit, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), that Plaintiff IntelGenx be awarded damages for such acts;

(H) 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 patent-in-suit, a Judgment awarding damages to Plaintiff IntelGenx resulting from such infringement, together with interest;

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

(J) Costs and expenses in this action; and

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

Dated: August 23, 2013

/s/ Thomas Curtin

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CERTIFICATION PURSUANT TO L. CIV. R. 11.2

I hereby certify that there are no other matters related to the matter in controversy here involving the same Plaintiff and same patent.

I further certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: August 23, 2013

/s/ Thomas Curtin

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