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

HORIZON PHARMA IRELAND LIMITED, HZNP LIMITED and HORIZON PHARMA USA, INC., *Plaintiffs,* v. IGI LABORATORIES, INC., *Defendant.*	CIVIL ACTION No. Document Filed Electronically **COMPLAINT FOR PATENT INFRINGEMENT**

COMPLAINT

Plaintiffs Horizon Pharma Ireland Limited, HZNP Limited and Horizon Pharma USA, Inc. (collectively, "Plaintiffs"), by their undersigned attorneys, bring this action against IGI Laboratories, Inc. ("Defendant" or "IGI"), and hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, arising from Defendant's filing of an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to market a generic version of Plaintiffs' pharmaceutical product PENNSAID® (diclofenac sodium topical solution) 2% w/w ("PENNSAID® 2%") prior to the expiration of United States Patent No. 9,066,913 ("the '913 patent") which covers PENNSAID® 2% and its use.

THE PARTIES

2. Plaintiff Horizon Pharma Ireland Limited is a corporation organized and existing under the laws of Ireland, with a principal place of business at Adelaide Chambers, Peter Street, Dublin 8, Ireland.

3. Plaintiff HZNP Limited is a nonresident Irish company that is a tax resident of Bermuda, with a principal place of business at 21 Laffan St., Hamilton, Pembroke, Bermuda HM09.

4. Plaintiff Horizon Pharma USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 520 Lake Cook Road, Suite 520, Deerfield, Illinois.

5. On information and belief, Defendant IGI is a corporation organized under the laws of the state of Delaware, having its principal place of business at 105 Lincoln Avenue, Buena, New Jersey 08310.

6. On information and belief, IGI is in the business of, *inter alia*, developing, manufacturing, obtaining regulatory approval, marketing, selling, and distributing generic copies of branded pharmaceutical products throughout the United States, including within this judicial district, through its own actions and through the actions of its agents and subsidiaries.

7. On information and belief, IGI is registered with the State of New Jersey, Division of Revenue and Enterprise Services, as Entity No. 0100187002.

8. On information and belief, IGI has offices, laboratory and manufacturing facilities located at 105 Lincoln Avenue, Buena, New Jersey 08310.

9. On information and belief, IGI currently markets within the US, and in this judicial district, generic topical pharmaceutical products.

10. On information and belief, IGI submitted to the FDA ANDA No. 208248 ("the IGI ANDA") for diclofenac sodium topical solution 2% w/w ("the IGI Product"), continues to seek FDA approval of that application, and intends to participate in the commercial manufacture, marketing, offer for sale and sale of the IGI Product throughout the United States, including in the State of New Jersey, in the event the FDA approves IGI's ANDA.

11. On information and belief, should the IGI ANDA be finally approved by FDA, IGI will sell, offer for sale and distribute the AIGI Product throughout the United States, including within this judicial district.

JURISDICTION AND VENUE

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

13. This Court has personal jurisdiction over IGI by virtue of, *inter alia*, the fact that its principal place of business is in New Jersey, having conducted business in New Jersey, having availed itself of the rights and benefits of New Jersey law such that it should reasonably anticipate being haled into court in this judicial district, and having engaged in systematic and continuous contacts with the State of New Jersey through the marketing and sales of generic drugs throughout the United States, and in particular within this judicial district, through the receipt of revenue from the sales and marketing of generic drug products, including IGI products, within this judicial district, and through

its intent to market and sell the IGI Product, if approved, to residents of this judicial district.

14. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c) and § 1400(b).

THE PATENT-IN-SUIT

15. On June 30, 2015, the U.S. Patent and Trademark Office ("USPTO") duly and legally issued the '913 patent entitled "Diclofenac Topical Formulation."

16. HZNP Limited currently is the sole assignee and owner of all right, title and interest in and to the '913 patent, which discloses and claims, inter alia, topical formulations and methods for treating pain in a knee due to osteoarthritis by administering the topical formulation to the knee twice daily. A true and correct copy of the '913 patent is attached hereto as Exhibit A.

PENNSAID® 2%

17. Horizon Pharma Ireland Limited is the owner of FDA-approved New Drug Application No. 204623 ("the PENNSAID® 2% NDA") for diclofenac sodium topical solution 2% w/w (PENNSAID® 2%), which is sold by Horizon Pharma USA, Inc. in the US under the tradename PENNSAID®.

18. The PENNSAID® 2% solution is currently approved by the FDA for the relief of pain of osteoarthritis of the knees.

19. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the'913 patent was submitted to FDA for listing on June 30, 2015, and is listed in the FDA publication entitled Approved Drug Products and Therapeutic Equivalence Evaluations ("the Orange Book") for the PENNSAID® 2% NDA.

20. The '913 patent covers PENNSAID® 2%.

IGI'S ANDA

21. On information and belief, IGI submitted the IGI ANDA to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market diclofenac sodium topical solution 2% w/w. On information and belief, the IGI ANDA seeks approval to market the IGI Product for the relief of pain of osteoarthritis of the knees.

22. On information and belief, the IGI ANDA refers to and relies upon the PENNSAID® 2% NDA and contains data that, according to IGI, demonstrate the bioequivalence of the IGI Product and PENNSAID® 2%.

23. On information and belief, IGI forwarded, via certified mail/registered mail, a letter dated March 24, 2015, to the following sole addressee: "Timothy Patrick Walbert, Director, HZNP Limited, Riverside One, Sir John Rogerson's Quay, Dublin 2, Ireland" ("the March 24th Letter"). The March 24th Letter stated that IGI included a certification in the IGI ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that, *inter alia*, the '613 patent is invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of the IGI Product (the "Paragraph IV Certification").

24. The IGI ANDA seeks approval to engage in the commercial manufacture, use or sale of diclofenac sodium topical solution 2% before the expiration of the '613 patent.

COUNT I FOR INFRINGEMENT OF U.S. PATENT NO. 9,066,913

25. Plaintiffs re-allege and incorporate by reference the allegations of paragraphs 1-24 of this Complaint.

26. The '913 patent issued on June 30, 2015, and will expire on October 17, 2027.

27. Defendants have previously filed a Paragraph IV Certifications in the IGI ANDA seeking approval to market the IGI Product prior to the expiration of, *inter alia*,

the ’613 patent, which expires on October 17, 2027. Because the ’913 patent also expires on October 17, 2027, Defendants seek approval of the IGI ANDA, and to market the IGI Product, prior to the expiration of the ’913 patent.

28. By submitting and seeking approval of the IGI ANDA, and also seeking approval to engage in the commercial manufacture, use, offer to sell, sale or importation of the IGI Product, prior to date on which the ’913 patent expires, Defendants have infringed the ’913 patent pursuant to 35 U.S.C. § 271(e)(2)(A).

29. Defendants’ commercial manufacture, use, offer to sell, or sale of the IGI Product within the United States, or importation of the IGI Product into the United States, during the term of the ’913 patent, also would infringe the ’913 patent under 35 U.S.C. § 271(a), (b) and/or (c).

30. Upon approval of the IGI ANDA, and commercialization of the IGI Product, Defendants will actively induce and/or contribute to infringement of the ’913 patent.

31. Upon information and belief, Defendants had actual and constructive notice of the ’913 patent as of its issue date, and Defendants’ infringement of the ’913 patent is willful.

32. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of IGI’s ANDA be a date that is not earlier than the expiration of the ’913 patent, or any later expiration of any exclusivity or extension of the ’913 patent to which Plaintiffs or the patent may become entitled.

33. Plaintiffs will be substantially and irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to the infringement of the ’913 patent.

34. Plaintiffs have no adequate remedy at law.

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

COUNT II FOR DECLARATION OF INFRINGEMENT OF U.S. PATENT NO. 9,066,913

36. Plaintiffs re-allege and incorporate by reference the allegations of paragraphs 1-35 of this Complaint.

37. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

38. There currently exists an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

39. Defendants' commercial manufacture, use, offer to sell, or sale of the IGI Product within the United States, or importation of the IGI Product into the United States, during the term of the '913 patent, would infringe the '913 patent.

40. Defendants seek approval of the IGI ANDA, and to market the IGI Product, prior to the expiration of the '913 patent.

41. Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, offer to sell, sell and/or import the IGI Product prior to the expiration of the '913 patent.

42. Plaintiffs are entitled to a declaratory judgment that the commercial manufacture, use, offer for sale, sale and/or importation of the IGI Product prior to the expiration of the '913 patent by Defendants would constitute direct infringement, contributory infringement, and/or active inducement of infringement of the '913 patent.

43. Plaintiffs will be substantially and irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to the infringement of the '913 patent.

44. Plaintiffs have no adequate remedy at law.

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for a judgment in their favor and against Defendants, and respectfully request the following relief:

A. A judgment declaring that Defendants have infringed and will infringe one or more claims of U.S. Patent No. 9,066,913;

B. A declaration pursuant to 28 U.S.C. § 2201 that if Defendants, their officers, directors, employees, representatives, agents, parents, subsidiaries, affiliates, customers, distributors, suppliers, and those persons in active concert or participation with any of them, and their successors and assigns, manufacture, use, offer to sell, or sell the IGI Product within the United States, or import the IGI Product into the United States, prior to the expiration date of the '913 patent, it will constitute an act of infringement of the '913 patent;

C. If Defendants commercially manufacture, use, offer to sell, or sell the IGI Product within the United States, or import the IGI Product into the United States, prior to the expiration of the '913 patent, including any extensions, a judgment awarding Plaintiffs monetary relief together with interest;

D. That an order be issued under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of the IGI ANDA shall be a date not earlier than the expiration date of the '913 patent, inclusive of any extensions;

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

F. Costs and expenses in this action; and

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

Date: June 30, 2015

s/ John E. Flaherty
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CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Plaintiffs Horizon Pharma Ireland Limited, HZNP Limited and Horizon Pharma USA, Inc., by their undersigned attorneys, hereby certify pursuant to Local Civil Rule 11.2 that the matter in controversy is the subject of the following pending actions:

- *Horizon Pharma Ireland Limited, et al. v. Watson Laboratories, Inc., et al.*, Civil Action No. 14-cv-07992-NLH-AMD (D.N.J.);
- *Horizon Pharma Ireland Limited, et al. v. Taro Pharmaceuticals USA, Inc. et al.*, Civil Action No. 1:15-cv-02046 (D.N.J.);
- *Horizon Pharma Ireland Limited, et al. v. Lupin Limited, et al.*, Civil Action No. 15-cv-03057-NLH-AMD (D.N.J.);
- *Horizon Pharma Ireland Limited, et al. v. IGI Labs. Inc.*, Civil Action No. 15-cv-03508-NLH-AMD (D.N.J.);
- *Horizon Pharma Ireland Limited, et al. v. Amneal Pharms. LLC*, Civil Action No. 15-cv-03367-NLH-AMD (D.N.J.).

Date: June 30, 2015

s/ John E. Flaherty

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