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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. AMNEAL PHARMACEUTICALS LLC, *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 Amneal Pharmaceuticals LLC ("Defendant" or "Amneal"), 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. 9,132,110 ("the '110 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 Amneal is a limited liability company organized under the laws of the state of Delaware, having its principal place of business at 400 Crossing Boulevard, 3rd Floor, Bridgewater, New Jersey 08807.

6. On information and belief, Amneal 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, Amneal is registered with the State of New Jersey as a manufacturer and wholesale drug distributor under Registration Number 5002991.

8. On information and belief, Amneal is registered with the State of New Jersey, Division of Revenue and Enterprise Services, as Entity No. 0600211542.

9. On information and belief, Amneal has a transdermal, topicals & complex oral solids manufacturing and R&D facility in Piscataway, New Jersey.

10. On information and belief, Amneal submitted to the FDA ANDA No. 208198 ("the Amneal ANDA") for diclofenac sodium topical solution 2% w/w ("the Amneal 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 Amneal Product throughout the United States, including in the State of New Jersey, in the event the FDA approves Amneal's ANDA.

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

12. On information and belief, Amneal has admitted to, consented to or has not contested, the jurisdiction of this Court in at least five prior District of New Jersey actions: *Otsuka Pharm. Co., Ltd. v. Amneal Pharms. LLC et al.*, 1:15-cv-01585; *Jazz Pharmaceuticals, Inc. et al. v. Amneal Pharmaceuticals LLC*, Civil Action No. 2:10-cv-01043, *Roxane Laboratories, Inc. v. Amneal Pharmaceuticals, LLC*, Civil Action No. 2:14-cv-05420, *Boehringer Ingelheim Pharma GmbH & Co. KG et al. v. Amneal Pharmaceuticals LLC*, Civil Action No. 1:14-cv-04726, *Jazz Pharmaceuticals, Inc. et al. v. Amneal Pharmaceuticals LLC*, Civil Action No. 2:14-cv-03235, and *Novo Nordisk Inc. et al. v. Amneal Pharmaceuticals LLC et al.*, Civil Action No. 3:13-cv-04915.

13. On information and belief, Amneal has availed itself of the rights, benefits and privileges of this Court by asserting counterclaims in at least five prior District of New Jersey actions: *Otsuka Pharm. Co., Ltd. v. Amneal Pharms. LLC et al.*, 1:15-cv-01585; *Jazz Pharmaceuticals, Inc. et al. v. Amneal Pharmaceuticals LLC*, Civil Action No. 2:10-cv-01043, *Roxane Laboratories, Inc. v. Amneal Pharmaceuticals, LLC*, Civil Action No. 2:14-cv-05420, and *Boehringer Ingelheim Pharma GmbH & Co. KG et al. v. Amneal Pharmaceuticals LLC*, Civil Action No. 1:14-cv-04726, *Jazz Pharmaceuticals, Inc. et al. v. Amneal Pharmaceuticals LLC*, Civil Action No. 2:14-cv-03235, and *Novo Nordisk Inc. et al. v. Amneal Pharmaceuticals LLC et al.*, Civil Action No. 3:13-cv-04915.

JURISDICTION AND VENUE

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

15. This Court has personal jurisdiction over Amneal 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, previously submitting to personal jurisdiction in this Court, availing itself of the jurisdiction of this Court (*e.g.*, by the assertion of counterclaims), 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 Amneal products, within this judicial district, and through its intent to market and sell the Amneal Product, if approved, to residents of this judicial district.

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

THE PATENT-IN-SUIT

17. On September 15, 2015, the U.S. Patent and Trademark Office ("USPTO") duly and legally issued the '110 patent entitled "Treatment of Pain with Topical Diclofenac."

18. HZNP Limited is the sole assignee and owner of all right, title and interest in and to the '110 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 '110 patent is attached hereto as Exhibit A.

PENNSAID® 2%

19. 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®.

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

21. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '110 patent was submitted to FDA for listing on September 16, 2015, and is listed, in the FDA publication entitled Approved Drug Products and Therapeutic Equivalence Evaluations ("the Orange Book") for the PENNSAID® 2% NDA.

22. The '110 patent covers PENNSAID® 2% and FDA-approved uses.

AMNEAL'S ANDA

23. On information and belief, Amneal submitted the Amneal 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 Amneal ANDA seeks approval to market the Amneal Product for the relief of pain of osteoarthritis of the knees.

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

25. HZNP Limited received from Amneal a letter, dated April 2, 2015 ("the April 2nd Letter"), stating that Amneal had included a certification in the Amneal ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that, *inter alia*, U.S. Patent 8,563,613 ("the '613 patent") is invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of the Amneal Product (the "Paragraph IV Certification").

26. The Amneal 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. 9,132,110

27. Plaintiffs re-allege and incorporate by reference the allegations of paragraphs 1-26 of this Complaint.

28. The '110 patent issued on September 15, 2015, and will expire no earlier than October 17, 2027.

29. Defendants have previously filed a Paragraph IV Certifications in the Amneal ANDA seeking approval to market the Amneal Product prior to the expiration of, *inter alia*, the '613 patent, which expires on October 17, 2027. Because the '110 patent expires no earlier than October 17, 2027, Defendants seek approval of the Amneal ANDA, and to market the Amneal Product, prior to the expiration of the '110 patent.

30. By submitting and seeking approval of the Amneal ANDA, and also seeking approval to engage in the commercial manufacture, use, offer to sell, sale or importation of the Amneal Product, prior to date on which the '110 patent expires, Defendants have infringed the '110 patent pursuant to 35 U.S.C. § 271(e)(2)(A).

31. Defendants' commercial manufacture, use, offer to sell, or sale of the Amneal Product within the United States, or importation of the Amneal Product into the United States, during the term of the '110 patent, also would infringe the '110 patent under 35 U.S.C. § 271(a), (b) and/or (c).

32. Upon approval of the Amneal ANDA, and commercialization of the Amneal Product, Defendants will actively induce and/or contribute to infringement of the '110 patent.

33. Upon information and belief, Defendants had actual and constructive notice of the '110 patent as of its issue date, and Defendants' infringement of the '110 patent is willful.

34. 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 Amneal's ANDA be a date that is not earlier than the expiration of the '110 patent, or any later expiration of any exclusivity or extension of the '110 patent to which Plaintiffs or the patent may become entitled.

35. Plaintiffs will be substantially and irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to the infringement of the '110 patent.

36. Plaintiffs have no adequate remedy at law.

37. 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. 9,132,110

38. Plaintiffs re-allege and incorporate by reference the allegations of paragraphs 1-37 of this Complaint.

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

40. 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.

41. Defendants' commercial manufacture, use, offer to sell, or sale of the Amneal Product within the United States, or importation of the Amneal Product into the United States, during the term of the '110 patent, would infringe the '110 patent.

42. Defendants seek approval of the Amneal ANDA, and to market the Amneal Product, prior to the expiration of the '110 patent.

43. Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, offer to sell, sell and/or import the Amneal Product prior to the expiration of the '110 patent.

44. Plaintiffs are entitled to a declaratory judgment that the commercial manufacture, use, offer for sale, sale and/or importation of the Amneal Product prior to the expiration of the '110 patent by Defendants would constitute direct infringement, contributory infringement, and/or active inducement of infringement of the '110 patent.

45. Plaintiffs will be substantially and irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to the infringement of the '110 patent.

46. Plaintiffs have no adequate remedy at law.

47. 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. 9,132,110;

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 Amneal Product within the United States, or import the Amneal Product into the United States, prior to the expiration date of the '110 patent, it will constitute an act of infringement of the '110 patent;

C. If Defendants commercially manufacture, use, offer to sell, or sell the Amneal Product within the United States, or import the Amneal Product into the United States, prior to the expiration of the '110 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 Amneal ANDA shall be a date not earlier than the expiration date of the '110 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: September 17, 2015

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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:

- *Mallinckrodt LLC, et al. v. Zydus Pharmaceuticals (USA) Inc.*, Civil Action No. 14-cv-04901-NLH-AMD (D.N.J.);
- *Horizon Pharma Ireland Limited, et al. v. Actavis Laboratories UT, Inc.*, Civil Action No. 14-cv-07992-NLH-AMD (D.N.J.) (Civil Action Nos. 1:15-cv-5025 is consolidated for all purposes with this action);
- *Horizon Pharma Ireland Limited, et al. v. Actavis Laboratories UT, Inc.*, Civil Action No. 14-cv-06131-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-NLH-AMD (D.N.J.);
- *Horizon Pharma Ireland Limited, et al. v. Taro Pharmaceuticals USA, Inc. et al.*, Civil Action No. 1:15-cv-05021-NLH-AMD (D.N.J.);
- *Horizon Pharma Ireland Limited, et al. v. Taro Pharmaceuticals USA, Inc. et al.*, Civil Action No. 1:15-cv-06135-NLH-AMD (D.N.J.);
- *Horizon Pharma Ireland Limited, et al. v. IGI Laboratories, Inc.*, Civil Action No. 1:15-cv-03508-NLH-AMD (D.N.J.);
- *Horizon Pharma Ireland Limited, et al. v. IGI Laboratories, Inc.*, Civil Action No. 1:15-cv-05022-NLH-AMD (D.N.J.);
- *Horizon Pharma Ireland Limited, et al. v. IGI Laboratories, Inc.*, Civil Action No. 1:15-cv-06134-NLH-AMD (D.N.J.);
- *Horizon Pharma Ireland Limited, et al. v. Lupin Limited, et al.*, Civil Action No. 15-cv-03051-NLH-AMD (D.N.J.);
- *Horizon Pharma Ireland Limited, et al. v. Lupin Limited, et al.*, Civil Action No. 15-cv-05027-NLH-AMD (D.N.J.); and
- *Horizon Pharma Ireland Limited, et al. v. Amneal Pharms. LLC*, Civil Action No. 15-cv-03367-NLH-AMD (D.N.J.) (Civil Action Nos. 15-cv-05024 and 15-cv-06132 are consolidated for all purposes with this action).

Date: September 17, 2015

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