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Ireland Limited, HZNP Limited and  
Horizon Pharma USA, Inc.*

**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.

TARO PHARMACEUTICALS USA, INC. and  
TARO PHARMACEUTICAL INDUSTRIES,  
LTD.,

*Defendants.*

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 Defendants Taro Pharmaceuticals USA, Inc. and Taro Pharmaceutical Industries, Ltd. (collectively, “Defendants” or “Taro”), 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 Defendants’ 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. 9,101,591 (“the ’591 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 Taro Pharmaceuticals USA, Inc. (“Taro USA”) is a corporation organized and existing under the laws of the State of New York, having a principal place of business at 3 Skyline Drive, Hawthorne, New York, 10532.

6. On information and belief, Taro USA 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.

7. On information and belief, Defendant Taro Pharmaceutical Industries, Ltd. (“Taro Industries”) is an Israeli corporation having a principal place of business at 14 Hakitor Street, Haifa Bay, 2624761, Israel.

8. Shares of Taro Industries are listed on the New York Stock Exchange under the symbol TARO.

9. On information and belief, Taro Industries 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, including, at least, Taro USA.

10. On information and belief, Taro USA is a subsidiary of Taro Industries.

11. On information and belief, Taro USA is registered with the State of New Jersey as a wholesale distributor under Registration Number 5003062.

12. On information and belief, Taro USA acts at the direction of, under the control of, and for the benefit of Taro Industries and is controlled and/or dominated by Taro Industries.

13. In a letter dated January 30, 2015 (“the January 30<sup>th</sup> Letter”), which purports to provide notice under 21 U.S.C. § 355(j)(2)(B)(ii), Taro USA and Taro Industries are referred to therein as a single entity, being referenced therein as “collectively, Taro.”

14. On information and belief, the January 30<sup>th</sup> Letter states that ANDA No. 208098 was “submitted by Taro.”

15. On information and belief, Defendants participated and collaborated in the research and development, and the preparation and filing, of ANDA No. 208098 (“the

Taro ANDA”) for diclofenac sodium topical solution 2% w/w (“the Taro Product”), continue to participate and collaborate in seeking FDA approval of that application, and intend to participate and collaborate in the commercial manufacture, marketing, offer for sale and sale of the Taro Product throughout the United States, including in the State of New Jersey, in the event the FDA approves Taro’s ANDA.

16. On information and belief, Taro USA has availed itself of the rights, benefits and privileges of this Court by filing at least two complaints for patent infringement in the District of New Jersey: *Taro Pharmaceuticals North America, Inc. et al. v. Suven Life Sciences, Ltd.*, Civil Action No. 3:11-cv-02452 and *Taro Pharmaceuticals North America, Inc. et al. v. Synerx Pharma, LLC*, Civil Action No. 2:09-cv-03569.

17. On information and belief, Taro USA and Taro Industries have admitted to, consented to or have not contested, the jurisdiction of this Court in at least one prior District of New Jersey action: *Novartis Pharmaceuticals Corporation et al. v. Taro Pharmaceuticals USA, Inc. et al.*, Civil Action No. 2:06-cv-04178 (Taro USA admitting that personal jurisdiction and venue were proper in this judicial district, and Taro Industries consenting to same).

18. On information and belief, Taro USA and Taro Industries have availed themselves of the rights, benefits and privileges of this Court by asserting counterclaims in at least three prior District of New Jersey actions: *Pfizer, Inc. v. Taro Pharmaceuticals Industries, Ltd. et al.*, Civil Action No. 2:03-cv-05425, *Novartis Pharmaceuticals Corporation et al. v. Taro Pharmaceuticals USA, Inc. et al.*, Civil Action No. 2:06-cv-04178 and *Schering Corp. v. Taro Pharmaceuticals USA, Inc.*, Civil Action No. 2:01-cv-03531.

### **JURISDICTION AND VENUE**

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

20. This Court has personal jurisdiction over Defendants by virtue of, *inter alia*, their presence in New Jersey, having conducted business in New Jersey, having availed themselves of the rights and benefits of New Jersey law such that they should reasonably anticipate being haled into court in this judicial district, previously submitting to personal jurisdiction in this Court, availing themselves of the jurisdiction of this Court (*e.g.*, by the assertion of claims and 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 Taro products, within this judicial district, and through their intent to market and sell the Taro Product, if approved, to residents of this judicial district.

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

### **THE PATENT-IN-SUIT**

22. On August 11, 2015, the U.S. Patent and Trademark Office (“USPTO”) duly and legally issued the ’591 patent entitled “Diclofenac Topical Formulation.”

23. HZNP Limited currently is the sole assignee and owner of all right, title and interest in and to the ’591 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 ’591 patent is attached hereto as Exhibit A.

### **PENNSAID® 2%**

24. 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®.

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

26. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '591 patent was submitted to FDA for listing on August 11, 2015, and is listed, in the FDA publication entitled Approved Drug Products and Therapeutic Equivalence Evaluations ("the Orange Book") for the PENNSAID® 2% NDA.

27. The '591 patent covers PENNSAID® 2%.

### **TARO'S ANDA**

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

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

30. HZNP Limited received from Taro a letter, dated January 30, 2015 ("the January 30<sup>th</sup> Letter"), stating that Taro had included a certification in the Taro 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 Taro Product (the "Paragraph IV Certification").

31. The January 30<sup>th</sup> Letter states that the Taro 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. 9,101,591**

32. Plaintiffs re-allege and incorporate by reference the allegations of paragraphs 1-31 of this Complaint.

33. The '591 patent issued on August 11, 2015, and will expire no earlier than October 17, 2027.

34. Defendants have previously filed certifications in the Taro ANDA pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), seeking approval to market the Taro Product prior to the expiration of, *inter alia*, the '613 patent, which expires on October 17, 2027. Because the '591 patent also expires no earlier than October 17, 2027, Defendants seek approval of the Taro ANDA, and to market the Taro Product, prior to the expiration of the '591 patent.

35. By submitting and seeking approval of the Taro ANDA, and also seeking approval to engage in the commercial manufacture, use, offer to sell, sale or importation of the Taro Product, prior to date on which the '591 patent expires, Defendants have infringed the '591 patent pursuant to 35 U.S.C. § 271(e)(2)(A).

36. Defendants' commercial manufacture, use, offer to sell, or sale of the Taro Product within the United States, or importation of the Taro Product into the United States, during the term of the '591 patent, also would infringe the '591 patent under 35 U.S.C. § 271(a), (b) and/or (c).

37. Upon approval of the Taro ANDA, and commercialization of the Taro Product, Defendants will actively induce and/or contribute to infringement of the '591 patent.

38. Upon information and belief, Defendants had actual and constructive notice of the '591 patent as of its issue date, and Defendants' infringement of the '591 patent is willful.

39. 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 Taro's ANDA

be a date that is not earlier than the expiration of the '591 patent, or any later expiration of any exclusivity or extension of the '591 patent to which Plaintiffs or the patent may become entitled.

40. Plaintiffs will be substantially and irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to the infringement of the '591 patent.

41. Plaintiffs have no adequate remedy at law.

42. 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. 9,101,591**

43. Plaintiffs re-allege and incorporate by reference the allegations of paragraphs 1-42 of this Complaint.

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

45. 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.

46. Defendants' commercial manufacture, use, offer to sell, or sale of the Taro Product within the United States, or importation of the Taro Product into the United States, during the term of the '591 patent, would infringe the '591 patent.

47. Defendants seek approval of the Taro ANDA, and to market the Taro Product, prior to the expiration of the '591 patent.



48. Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, offer to sell, sell and/or import the Taro Product prior to the expiration of the '591 patent.

49. Plaintiffs are entitled to a declaratory judgment that the commercial manufacture, use, offer for sale, sale and/or importation of the Taro Product prior to the expiration of the '591 patent by Defendants would constitute direct infringement, contributory infringement, and/or active inducement of infringement of the '591 patent.

50. Plaintiffs will be substantially and irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to the infringement of the '591 patent.

51. Plaintiffs have no adequate remedy at law.

52. 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. 9,101,591;

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 Taro Product within the United States, or import the Taro Product into the United States, prior to the expiration date of the '591 patent, it will constitute an act of infringement of the '591 patent;

C. If Defendants commercially manufacture, use, offer to sell, or sell the Taro Product within the United States, or import the Taro Product into the United States, prior

to the expiration of the '591 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 Taro ANDA shall be a date not earlier than the expiration date of the '591 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: August 11, 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:

- *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 No. 1:15-cv-5025 is consolidated for all purposes with this action);
- *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. 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. 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.);
- *Horizon Pharma Ireland Limited, et al. v. Amneal Pharms. LLC*, Civil Action No. 15-cv-03367-NLH-AMD (D.N.J.);
- *Horizon Pharma Ireland Limited, et al. v. Amneal Pharms. LLC*, Civil Action No. 15-cv-05024-NLH-AMD (D.N.J.).

Date: August 11, 2015

s/ John E. Flaherty  
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