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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. ACTAVIS LABORATORIES UT, 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 Defendant Actavis Laboratories UT, Inc. ("Defendant" or "Actavis UT"), and hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising 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. 9,539,335 ("the '335 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 150 S. Saunders Rd, Lake Forest, Illinois.

5. On information and belief, Defendant Actavis UT is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 577 Chipeta Way, Salt Lake City, Utah.

6. On information and belief, Actavis UT was formerly known as Watson Laboratories, Inc. This change of name was effective in or about January 2015.

7. On information and belief, Actavis UT 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.

8. On information and belief, Defendant participated and collaborated in the research and development, and the preparation and filing, of Actavis UT's ANDA No. 207238 ("the Actavis UT ANDA") for diclofenac sodium topical solution 2% w/w ("the

Actavis UT Product"), continues to participate and collaborate in seeking FDA approval of that application, and intends to participate and collaborate in the commercial manufacture, marketing, offer for sale and sale of the Actavis UT Product throughout the United States, including in the State of New Jersey, in the event the FDA approves Actavis UT's ANDA.

9. On information and belief, Actavis UT (under its former name, Watson Laboratories, Inc.) has not contested, or has otherwise submitted to, the jurisdiction of this Court in at least 14 prior District of New Jersey actions: *Horizon Pharma Ireland Ltd. et al. v. Actavis Labs. UT, Inc.*, Civil Action No. 14-cv-7992 (NLH)(AMD); *Supernus Pharms., Inc. v. Actavis, Inc. et al.*, Civil Action No. 14-6102; *Supernus Pharms., Inc. v. Actavis, Inc. et al.*, Civil Action No. 14-1981; *Supernus Pharms., Inc. v. Actavis, Inc. et al.*, Civil Action No. 13-4740; *Auxilium Pharms., Inc. et al. v. Watson Labs., Inc., et al.*, Civil Action No. 12-3084; *Warner Chilcott Co. v. Watson Labs., Inc.*, Civil Action No. 12-2928; *Janssen Pharms., Inc, et al. v. Watson Labs., Inc., et al.*, Civil Action No. 08-5103; *Duramed Pharms. v. Watson Pharma, Inc, et al.*, Civil Action No. 07-5941; *Hoffman La-Roche Inc, et al. v. Cobalt Pharms. Inc., et al.*, Civil Action No. 07-4539; *Sanofi-Aventis et al. v. Watson Pharms., Inc., et al.*, Civil Action No. 07-443; *Warner Chilcott Co. v. Watson Pharms., Inc., et al.*, Civil Action No. 07-4697; *Novartis Corp. et al. v. Watson Labs., Inc., et al.*, Civil Action No. 06-1130; *Schering Corp. v. Zydus Pharms., USA, Inc., et al.*, Civil Action No. 06-4715; *Warner Chilcott Co. v. Watson Pharms., Inc., et al.*, Civil Action No. 06-3491.

JURISDICTION AND VENUE

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

11. This Court has personal jurisdiction over Defendant by virtue of, *inter alia*, their presence 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 Actavis UT products, within this judicial district, and through their intent to market and sell the Actavis UT Product, if approved, to residents of this judicial district.

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

THE PATENT-IN-SUIT

13. On January 10, 2017, the U.S. Patent and Trademark Office ("USPTO") duly and legally issued the '335 patent entitled "Diclofenac Topical Formulation."

14. HZNP Limited is the sole assignee and owner of all right, title and interest in and to the '335 patent, which discloses and claims, *inter alia*, a process for making a topical formulation 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 '335 patent is attached hereto as Exhibit A.

PENNSAID® 2%

15. 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 in the US under the trade name PENNSAID®, and which is sold by Horizon Pharma USA, Inc.

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

17. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '335 patent is currently listed in the FDA publication entitled Approved Drug Products and Therapeutic Equivalence Evaluations ("the Orange Book") for the PENNSAID® 2% NDA.

18. The ’335 patent covers PENNSAID® 2% and FDA-approved uses.

ACTAVIS UT’S ANDA

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

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

21. HZNP Limited received from Actavis UT a letter, dated May 3, 2017 (the “Actavis UT Notification”), stating that Actavis UT had included a certification in the Actavis UT ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that, *inter alia*, the ’335 patent is invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of the Actavis UT Product (the “Paragraph IV Certification”).

22. The Actavis UT Notification states that the Actavis UT ANDA seeks approval to engage in the commercial manufacture, use or sale of diclofenac sodium topical solution 2% before the expiration of the ’335 patent.

COUNT I FOR INFRINGEMENT OF U.S. PATENT NO. 9,539,335

23. Plaintiffs re-allege and incorporate by reference the allegations of paragraphs 1-22 of this Complaint.

24. The ’335 patent issued on January 10, 2017, and will expire no earlier than October 17, 2027.

25. By submitting and seeking approval of the Actavis UT ANDA, and also seeking approval to engage in the commercial manufacture, use, offer to sell, sale or

importation of the Actavis UT Product, prior to date on which the '335 patent expires, Defendant has infringed the '335 patent pursuant to 35 U.S.C. § 271(e)(2)(A).

26. Defendant's commercial manufacture, use, offer to sell, or sale of the Actavis UT Product within the United States, or importation of the Actavis UT Product into the United States, during the term of the '335 patent, also would infringe the '335 patent under 35 U.S.C. § 271(a), (b) and/or (c).

27. Upon approval of the Actavis UT ANDA, and commercialization of the Actavis UT Product, Defendant will actively induce and/or contribute to infringement of the '335 patent.

28. Upon information and belief, Defendant had actual and constructive notice of the '335 patent as of its issue date, and Defendant's infringement of the '335 patent is willful.

29. 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 Actavis UT's ANDA be a date that is not earlier than the expiration of the '335 patent, or any later expiration of any exclusivity or extension of the '335 patent to which Plaintiffs or the patent may become entitled.

30. Plaintiffs will be substantially and irreparably harmed if Defendant is not enjoined from infringing or actively inducing or contributing to the infringement of the '335 patent.

31. Plaintiffs have no adequate remedy at law.

32. 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. 9,539,335

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

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

35. 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.

36. Defendant's commercial manufacture, use, offer to sell, or sale of the Actavis UT Product within the United States, or importation of the Actavis UT Product into the United States, during the term of the '335 patent, would infringe the '335 patent.

37. Defendant seeks approval of the Actavis UT ANDA, and to market the Actavis UT Product, prior to the expiration of the '335 patent.

38. Defendant has made, and will continue to make, substantial preparation in the United States to manufacture, offer to sell, sell and/or import the Actavis UT Product prior to the expiration of the '335 patent.

39. Plaintiffs are entitled to a declaratory judgment that the commercial manufacture, use, offer for sale, sale and/or importation of the Actavis UT Product prior to the expiration of the '335 patent by Defendant would constitute direct infringement, contributory infringement, and/or active inducement of infringement of the '335 patent.

40. Plaintiffs will be substantially and irreparably harmed if Defendant is not enjoined from infringing or actively inducing or contributing to the infringement of the '335 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.

PRAYER FOR RELIEF

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

A. A judgment declaring that Defendant has infringed and will infringe one or more claims of U.S. Patent No. 9,539,335;

B. A declaration pursuant to 28 U.S.C. § 2201 that if Defendant, its 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, manufactures, uses, offers to sell, or sells the Actavis UT Product within the United States, or imports the Actavis UT Product into the United States, prior to the expiration date of the '335 patent, it will constitute an act of infringement of the '335 patent;

C. If Defendant commercially manufactures, uses, offers to sell, or sells the Actavis UT Product within the United States, or imports the Actavis UT Product into the United States, prior to the expiration of the '335 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 Actavis UT ANDA shall be a date not earlier than the expiration date of the '335 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: May 11, 2017

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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. Actavis Laboratories UT, Inc.*, Civil Action No. 14-cv-07992-NLH-AMD (D.N.J.) (Civil Action Nos. 1:15-cv-5025, -6131, and -6989, are consolidated for all purposes with this action)
- *Horizon Pharma Ireland Limited, et al. v. Actavis Laboratories UT, Inc.*, Civil Action No. 1:15-cv-07742-NLH-AMD (D.N.J.)
- *Horizon Pharma Ireland Limited, et al. v. Actavis Laboratories UT, Inc.*, Civil Action No. 1:16-cv-00645-NLH-AMD (D.N.J.)
- *Horizon Pharma Ireland Limited, et al. v. Actavis Laboratories UT, Inc.*, Civil Action No. 1:16-cv-05051-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.) (The schedules for Civil Action Nos. 1:15-cv-5027, -6935, -7745, 1:16-cv-00732 and -5054 are coordinated with this action)

May 11, 2017

s/ John E. Flaherty

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