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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., ACTAVIS, INC. and ALLERGAN PLC, *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 Actavis Laboratories UT, Inc., Actavis, Inc., and Allergan plc (collectively, "Defendants"), 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 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 Actavis Laboratories UT, Inc. ("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, Actavis, Inc. is a corporation organized and existing under the laws of the State of Nevada, having a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey, 07054.

9. On information and belief, Actavis, Inc. 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, Actavis UT.

10. On information and belief, until on or about June 15, 2015, Actavis plc was the name of the parent company of Actavis, Inc. and Actavis UT.

11. On information and belief, Actavis plc acquired Allergan, Inc. on or about March 17, 2015.

12. Upon information and belief, Actavis plc changed its name to Allergan plc on or about June 15, 2015.

13. On information and belief, Defendant Allergan plc is a public limited company existing under the laws of Ireland, having a principal place of business at 1 Grand Canal Square, Docklands, Dublin 2, Ireland.

14. On information and belief, Allergan plc has its U.S. Administrative Headquarters, and a principal place of business, at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey, 07054

15. On information and belief, Allergan plc conducts its principal US operations at the New Jersey location of Actavis, Inc., namely Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey, 07054.

16. On information and belief, Allergan plc 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, Actavis UT and Actavis, Inc.

17. On information and belief, R&D activities of Allergan plc occur in, *inter alia*, Elizabeth, New Jersey.

18. On information and belief, Allergan plc manufactures finished products in Elizabeth, New Jersey.

19. On information and belief, Allergan plc owns, directly or indirectly via its subsidiaries (e.g., Actavis, Inc. and Actavis UT), property in New Jersey, including facilities used for manufacturing, R&D, and/or administrative functions.

20. On information and belief, Actavis, Inc. is a wholly-owned subsidiary of Allergan plc.

21. On information and belief, Actavis, Inc. acts at the direction of, under the control of, and for the benefit of Allergan plc and is controlled and/or dominated by Allergan plc.

22. On information and belief, Allergan plc and Actavis, Inc. have at least one officer and/or director in common.

23. On information and belief, Actavis, Inc. is registered as a manufacturer and wholesale drug distributor in the State of New Jersey under Registration Number 5003854.

24. On information and belief, Actavis, Inc. is registered with the State of New Jersey, Division of Revenue and Enterprise Services, as Entity No. 0101005391 (Morristown, NJ).

25. On information and belief, Actavis UT is a wholly-owned subsidiary of Actavis, Inc.

26. On information and belief, Actavis UT acts at the direction of, under the control of, and for the benefit of Actavis, Inc. and is controlled and/or dominated by Actavis, Inc.

27. On information and belief, Actavis UT and Actavis, Inc. have at least one officer and/or director in common.

28. On information and belief, Actavis UT is within the control of Actavis, Inc. and Allergan plc for purposes of responding to discovery in this action.

29. On information and belief, Actavis, Inc. organizes its operations by divisions—including at least Generics, Brands, and Distribution.

30. On information and belief, Actavis, Inc.'s Generics division is involved in the development, manufacture, marketing, sale, and distribution of generic pharmaceuticals.

31. On information and belief, the Generics Division prepares Abbreviated New Drug Applications ("ANDAs") which are submitted to the FDA, relying on contributions from other agents and/or subsidiaries, including, at least, Actavis UT.

32. On information and belief, each Defendant acts as an agent of the other, is a member and/or part of, and/or works in concert with each other as integrated parts of the Generics Division.

33. On information and belief, the Generic Division's products are developed and manufactured by, at least, Actavis UT, and the Generic Division's products are marketed, sold, and distributed throughout the United States, including in New Jersey, by at least Actavis UT.

34. On information and belief, each Defendant shares with the others at least some common employees, officers, and directors.

35. On information and belief, Defendants 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"), 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 Actavis UT Product throughout the United States, including in the State of New Jersey, in the event the FDA approves Actavis UT's ANDA.

36. 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.*, 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.

37. On information and belief, Actavis, Inc. has not contested, or has otherwise submitted to, the jurisdiction of this Court in at least nine prior District of New Jersey actions: *Astrazeneca AB et al. v. Watson Labs., Inc. – Florida, et al.*, Civil Action No. 13-3038; *Auxilium Pharms., Inc. et al. v. Watson Labs., Inc. et al.*, Civil Action No.

12-3084;[1] *Depomed, Inc. v. Actavis Elizabeth LLC et al.*, Civil Action No. 12-1358; *Noven Pharms. v. Watson Labs., Inc. et al.*, Civil Action No. 11-5997;[2] *Shire LLC, et al. v. Amneal Pharms. LLC et al.*, Civil Action No. 11-3781; *King Pharms. Inc. et al. v. Actavis, Inc. et al.*, Civil Action No. 09-6585; *Shire LLC v. Actavis South Atlantic, LLC et al.*, Civil Action No. 09-479; *King Pharms. Inc. et al. v. Actavis, Inc. et al.*, Civil Action No. 07-5041; *Sanofi-Aventis U.S. LLC et al. v. Actavis Totowa LLC et al.*, Civil Action No. 07-3142).

38. On information and belief, Actavis, Inc. has availed itself of the rights, benefits, and privileges of this Court by asserting counterclaims in at least one prior District of New Jersey action: *Auxilium Pharms., Inc. et al. v. Watson Labs., Inc. et al.*, Civil Action No. 12-3084.

JURISDICTION AND VENUE

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

40. 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 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.

[1] Watson Pharmaceuticals, Inc. submitted to the jurisdiction of this Court on July 6, 2012. Watson Pharmaceuticals, Inc. thereafter changed its name to Actavis, Inc.
[2] Watson Pharmaceuticals, Inc. submitted to the jurisdiction of this Court on November 4, 2011. Watson Pharmaceuticals, Inc. thereafter changed its name to Actavis, Inc.

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

THE PATENT-IN-SUIT

42. On August 11, 2015, the U.S. Patent and Trademark Office ("USPTO") duly and legally issued the '591 patent entitled "Diclofenac Topical Formulation."

43. HZNP Limited 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%

44. 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.

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

46. 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.

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

ACTAVIS UT'S ANDA

48. 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.

49. 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%.

50. HZNP Limited received from Actavis UT a letter, dated November 12, 2014 (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*, 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 Actavis UT Product (the "Paragraph IV Certification").

51. 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 '613 patent.

COUNT I FOR INFRINGEMENT OF U.S. PATENT NO. 9,101,591

52. Plaintiffs re-allege and incorporate by reference the allegations of paragraphs 1-51 of this Complaint.

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

54. Defendants have previously filed certifications in the Actavis UT ANDA pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), seeking approval to market the Actavis UT 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 Actavis UT ANDA, and to market the Actavis UT Product, prior to the expiration of the '591 patent.

55. 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 ’591 patent expires, Defendants have infringed the ’591 patent pursuant to 35 U.S.C. § 271(e)(2)(A).

56. Defendants’ 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 ’591 patent, also would infringe the ’591 patent under 35 U.S.C. § 271(a), (b) and/or (c).

57. Upon approval of the Actavis UT ANDA, and commercialization of the Actavis UT Product, Defendants will actively induce and/or contribute to infringement of the ’591 patent.

58. 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.

59. 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 ’591 patent, or any later expiration of any exclusivity or extension of the ’591 patent to which Plaintiffs or the patent may become entitled.

60. 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.

61. Plaintiffs have no adequate remedy at law.

62. 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

63. Plaintiffs re-allege and incorporate by reference the allegations of paragraphs 1-62 of this Complaint.

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

65. 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.

66. Defendants' 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 '591 patent, would infringe the '591 patent.

67. Defendants seek approval of the Actavis UT ANDA, and to market the Actavis UT Product, prior to the expiration of the '591 patent.

68. Defendants have 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 '591 patent.

69. 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 '591 patent by Defendants would constitute direct infringement, contributory infringement, and/or active inducement of infringement of the '591 patent.

70. 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.

71. Plaintiffs have no adequate remedy at law.

72. 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 Actavis UT Product within the United States, or import the Actavis UT 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 Actavis UT Product within the United States, or import the Actavis UT 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 Actavis UT 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

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