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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. LUPIN LTD. and LUPIN PHARMACEUTICALS INC., *Defendants.*	Civil Action No. 1:15-cv-05027 Hon. Noel L. Hillman, U.S.D.J. Hon. Ann Marie Donio, U.S.M.J. **AMENDED COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiffs Horizon Pharma Ireland Limited, HZNP Limited and Horizon Pharma USA, Inc. (collectively, "Plaintiffs"), by their undersigned attorneys, bring this action

against Defendants Lupin Limited and Lupin Pharmaceuticals, Inc. (collectively, "Defendants" or "Lupin"), 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. 9,066,913 ("the '913 patent") and United States Patent No. 9,101,591 ("the '591 patent") which cover 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 Lupin Limited ("Lupin Ltd.") is a corporation operating and existing under the laws of India, having a principal place of business at B/4 Laxmi Towers, Bandra Kurla Complex, Bandra (E), Mumbai 400 051, India, and its registered office at 159 CST Road, Kalina, Santacrux (E), Mumbai 400 098, India.

6. On information and belief, Lupin Ltd. 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 Lupin Pharmaceuticals Inc. ("LPI") is a corporation operating and existing under the laws of the Commonwealth of Virginia, with its principal place of business at 111 South Calvert Street 21st Floor, Baltimore, MD 21202.

8. On information and belief, LPI is in the business of, *inter alia*, 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.

9. On information and belief, LPI is a wholly-owned subsidiary of Lupin Ltd.

10. On information and belief, LPI is registered with the State of New Jersey as a wholesale distributor under Registration Number 5004060.

11. On information and belief, LPI is registered with the State of New Jersey, Division of Revenue and Enterprise Services, as Entity No. 0100953673.

12. On information and belief, LPI acts at the direction of, under the control of, and for the benefit of Lupin Ltd. and is controlled and/or dominated by Lupin Ltd.

13. On information and belief, Lupin Ltd. and LPI have at least one officer and/or director in common.

14. On information and belief, Defendants participated and collaborated in the research and development, and the preparation and filing, of ANDA No. 208021 ("the Lupin ANDA") for diclofenac sodium topical solution 2% w/w ("the Lupin 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 Lupin Product throughout the United States, including in the State of New Jersey, in the event the FDA approves Lupin's ANDA.

15. On information and belief, LPI is the US agent for Lupin Ltd. in connection with the filing of the Lupin ANDA with FDA and subsequent FDA communications relating thereto.

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

17. On information and belief, Lupin Ltd. and LPI have availed themselves of the rights, benefits and privileges of this Court by filing at least one complaint for patent infringement in the District of New Jersey: *Lupin Ltd. et al. v. Merck, Sharp & Dohm Corp*., Civil Action No. 3:10-cv-00683.

18. On information and belief, Lupin Ltd. and LPI have admitted to, consented to or have not contested the jurisdiction of this Court in at least five prior District of New Jersey actions: *Senju Pharmaceutical Co., Ltd. et al. v. Lupin Ltd. et al.*, Civil Action No. 1:15-cv-00335, *Senju Pharmaceutical Co., Ltd. et al. v. Lupin Ltd. et al.*, Civil Action No. 1:14-cv-05144, *Janssen Products, L.P. et al. v. Lupin Ltd. et al.*, Civil Action No. 2:14-cv-01370, *Takeda Pharmaceutical Co. Ltd. et al. v. Lupin Ltd. et al.*, Civil Action No. 3:12-cv-07333, and *Astrazeneca Pharmaceuticals LP et al. v. Lupin Ltd. et al.*, Civil Action No. 3:12-cv-06888.

19. On information and belief, Lupin Ltd. and LPI have availed themselves of the rights, benefits and privileges of this Court by asserting counterclaims in at least five prior District of New Jersey actions: *Senju Pharmaceutical Co., Ltd. et al. v. Lupin Ltd. et al.*, Civil Action No. 1:15-cv-00335, *Senju Pharmaceutical Co., Ltd. et al. v. Lupin Ltd. et al.*, Civil Action No. 1:14-cv-05144, *Janssen Products, L.P. et al. v. Lupin Ltd. et al.*, Civil Action No. 2:14-cv-01370, *Takeda Pharmaceutical Co. Ltd. et al. v. Lupin Ltd.*

et al., Civil Action No. 3:12-cv-07333, and *Astrazeneca Pharmaceuticals LP et al. v. Lupin Ltd. et al.*, Civil Action No. 3:12-cv-06888.

JURISDICTION AND VENUE

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

21. 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 Lupin products, within this judicial district, and through their intent to market and sell the Lupin Product, if approved, to residents of this judicial district.

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

THE PATENTS-IN-SUIT

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

24. 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.

25. On August 11, 2015, the USPTO duly and legally issued the '591 patent entitled "Diclofenac Topical Formulation."

26. 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 B.

PENNSAID® 2%

27. 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®.

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

29. 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.

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

31. 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 Orange Book for the PENNSAID® 2% NDA.

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

LUPIN'S ANDA

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

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

35. HZNP Limited received from Lupin Ltd. a letter, dated March 17, 2015 ("the March 17th Letter"), stating that Lupin Ltd. had included a certification in the Lupin 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 Lupin Product (the "Paragraph IV Certification").

36. The Lupin 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

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

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

39. Defendants have previously filed a Paragraph IV Certifications in the Lupin ANDA seeking approval to market the Lupin 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 Lupin ANDA, and to market the Lupin Product, prior to the expiration of the '913 patent.

40. By submitting and seeking approval of the Lupin ANDA, and also seeking approval to engage in the commercial manufacture, use, offer to sell, sale or importation of the Lupin 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).

41. Defendants' commercial manufacture, use, offer to sell, or sale of the Lupin Product within the United States, or importation of the Lupin 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).

42. Upon approval of the Lupin ANDA, and commercialization of the Lupin Product, Defendants will actively induce and/or contribute to infringement of the '913 patent.

43. 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.

44. 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 Lupin'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.

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 '913 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.

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

48. Plaintiffs re-allege and incorporate by reference the allegations of paragraphs 1-47 of this Amended Complaint.

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

50. 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.

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

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

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

54. Plaintiffs are entitled to a declaratory judgment that the commercial manufacture, use, offer for sale, sale and/or importation of the Lupin 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.

55. 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.

56. Plaintiffs have no adequate remedy at law.

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

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

58. Plaintiffs re-allege and incorporate by reference the allegations of paragraphs 1-57 of this Amended Complaint.

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

60. Defendants have previously filed a Paragraph IV Certifications in the Lupin ANDA seeking approval to market the Lupin 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 Lupin ANDA, and to market the Lupin Product, prior to the expiration of the '591 patent.

61. By submitting and seeking approval of the Lupin ANDA, and also seeking approval to engage in the commercial manufacture, use, offer to sell, sale or importation of the Lupin 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).

62. Defendants' commercial manufacture, use, offer to sell, or sale of the Lupin Product within the United States, or importation of the Lupin 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).

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

64. 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.

65. 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 Lupin'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.

66. 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.

67. Plaintiffs have no adequate remedy at law.

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

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

69. Plaintiffs re-allege and incorporate by reference the allegations of paragraphs 1-68 of this Amended Complaint.

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

71. 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.

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

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

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

75. Plaintiffs are entitled to a declaratory judgment that the commercial manufacture, use, offer for sale, sale and/or importation of the Lupin 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.

76. 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.

77. Plaintiffs have no adequate remedy at law.

78. 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 judgment declaring that Defendants have infringed and will infringe one or more claims of U.S. Patent No. 9,101,591;

C. 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 Lupin Product within the United States, or import the Lupin 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;

D. 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 Lupin Product within the United States, or import the Lupin 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;

E. If Defendants commercially manufacture, use, offer to sell, or sell the Lupin Product within the United States, or import the Lupin 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;

F. If Defendants commercially manufacture, use, offer to sell, or sell the Lupin Product within the United States, or import the Lupin 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;

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

H. That an order be issued under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of the Lupin ANDA shall be a date not earlier than the expiration date of the '591 patent, inclusive of any extensions;

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

J. Costs and expenses in this action; and

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

Date: August 11, 2015

s/ John E. Flaherty
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Of Counsel for Plaintiffs Horizon Pharma Ireland Limited, HZNP Limited and Horizon Pharma USA, Inc.

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., et al.*, 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. 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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Of Counsel for Plaintiffs Horizon Pharma Ireland Limited, HZNP Limited and Horizon Pharma USA, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on August 11, 2015, I caused the foregoing **AMENDED COMPLAINT FOR PATENT INFRINGEMENT** to be served by ECF and electronic mail upon counsel of record.

s/ John E. Flaherty
John E. Flaherty