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Of Counsel for Plaintiff Horizon Therapeutics, Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

HORIZON THERAPEUTICS, INC.,

Plaintiff,

v.

LUPIN LTD. and LUPIN PHARMACEUTICALS, INC.,

Defendants.

Civil Action No. 1:15-CV-07624-RBK-JS

AMENDED COMPLAINT

Plaintiff Horizon Therapeutics, Inc., by its undersigned attorneys, brings 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 of the 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 Plaintiff's pharmaceutical product RAVICTI® (glycerol phenylbutyrate) ("RAVICTI®") prior to the expiration of United States Patent No. 9,095,559 ("the '559 patent").

THE PARTIES

2. Plaintiff Horizon Therapeutics, 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 Road, Lake Forest, IL 60045.

3. 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.

4. 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.

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

6. 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.

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

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

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

10. 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.

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

12. On information and belief, Defendants participated and collaborated in the research and development, and the preparation and filing, of ANDA No. 207694 ("the Lupin ANDA") for glycerol phenylbutyrate oral liquid ("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.

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

14. 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.

15. 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 & Dohme Corp*., Civil Action No. 3:10-cv-00683.

16. 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.

17. 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

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

19. 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.

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

THE PATENT-IN-SUIT

21. On August 4, 2015, the USPTO duly and legally issued the ’559 patent entitled “Methods of Therapeutic Monitoring of Nitrogen Scavenging Drugs.” At the time of its issue, the ’559 patent was assigned to Horizon Therapeutics, Inc. Horizon Therapeutics, Inc. currently is the sole assignee and owner of all right, title and interest in and to the ’559 patent, which claims methods related to the treatment of urea cycle disorder patients with glyceryl tri-[4-phenylbutyrate] based on measurement of fasting blood ammonia blood levels. A true and correct copy of the ’559 patent is attached hereto as Exhibit A.

RAVICTI®

22. Horizon Therapeutics, Inc. is the owner of FDA-approved New Drug Application No. 203284 (“the RAVICTI® NDA”) for glycerol phenylbutyrate oral liquid 1.1gm/ml, which is sold by Horizon Pharma USA, Inc. in the US under the tradename RAVICTI®.

23. RAVICTI® is currently approved by the FDA for use as a nitrogen- binding agent for chronic management of adult and pediatric patients ≥ 2 years of age with urea cycle disorders that cannot be managed by dietary protein restriction and/or amino acid supplementation alone.

24. Pursuant to 21 U.S.C. § 355, and attendant FDA regulations, the '559 patent is listed in the FDA publication entitled Approved Drug Products and Therapeutic Equivalence Evaluations ("the Orange Book") for the RAVICTI® NDA.

25. The '559 patent qualifies for listing in the Orange Book in connection with NDA No. 203284 because the '559 patent claims an approved use of RAVICTI®.

LUPIN'S ANDA

26. On information and belief, Lupin submitted the Lupin ANDA to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market glycerol phenylbutyrate oral liquid. On information and belief, the Lupin ANDA seeks approval to market the Lupin Product for use as a nitrogen-binding agent for chronic management of adult and pediatric patients ≥ 2 years of age with urea cycle disorders that cannot be managed by dietary protein restriction and/or amino acid supplementation alone.

27. On information and belief, the conditions of use for which Lupin seeks approval of the Lupin Product in the Lupin ANDA are the same as those set forth in the FDA-approved labeling for RAVICTI®.

28. On information and belief, the Lupin ANDA refers to and relies upon the RAVICTI® NDA and contains data that, according to Lupin, demonstrate the bioequivalence of the Lupin Product and RAVICTI®.

29. Horizon Therapeutics, Inc. received from Lupin Ltd. a letter, dated November 6, 2015 ("the November 6th Letter"), stating that Lupin Ltd. included a certification in the Lupin

ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the '559 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").

30. The Lupin ANDA seeks approval to engage in the commercial manufacture, use or sale of glycerol phenylbutyrate oral liquid before the expiration of the '559 patent.

COUNT I FOR INFRINGEMENT OF U.S. PATENT NO. 9,095,559

31. Plaintiff realleges and incorporates by reference the allegations of paragraphs 1-30 of this Complaint.

32. Defendants have infringed the '559 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Lupin ANDA which seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale or importation of the Lupin Product prior to the expiration of the '559 patent.

33. Defendants' use, offer to sell, or sale of the Lupin Product within the United States, during the term of the '559 patent also would infringe the '559 patent under 35 U.S.C. § 271(a), (b) and/or (c).

34. On information and belief, the conditions of use for the Lupin Product for which Lupin seeks approval in the Lupin ANDA fall within one or more of the claims of the '559 patent. If approved, use of the Lupin Product in accordance with the proposed labeling submitted in the Lupin ANDA would infringe one or more of the claims of the '559 patent.

35. Upon approval of the Lupin ANDA, and the commercial marketing thereof, Defendants will actively induce and/or contribute to infringement of the '559 patent.

36. Upon information and belief, Defendants had actual and constructive notice of the '559 patent prior to filing Lupin's ANDA, and Defendants' infringement of the '559 patent has

been, and continues to be, willful.

37. Plaintiff is 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 '559 patent, or any later expiration of any exclusivity or extension of the '559 patent to which Plaintiff or the patent may become entitled.

38. Plaintiff will be substantially and irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to the infringement of the '559 patent.

39. Plaintiff has no adequate remedy at law.

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for a judgment in their favor and against Defendants, and respectfully requests the following relief:

A. A judgment declaring that Defendants have infringed one or more claims of U.S. Patent No. 9,095,559;

B. A judgment pursuant to 35 U.S.C. § 271(e)(4) preliminarily and permanently enjoining 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, from using, offering to sell, or selling the Lupin Product within the United States, prior to the expiration date of the '559 patent;

C. If Defendants use, offer to sell, or sell the Lupin Product within the United States, prior to the expiration of the '559 patent, including any extensions, a judgment awarding Plaintiff

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 Lupin ANDA shall be a date not earlier than the expiration date of the '559 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;

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

Respectfully submitted,

Date: April 6, 2016

s/ John E. Flaherty
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Of Counsel for Plaintiff Horizon Therapeutics, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on April 6, 2016, I caused the foregoing AMENDED COMPLAINT to be served by ECF and electronic mail upon counsel of record.

s/ John E. Flaherty
John E. Flaherty