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**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.

Document Filed Electronically

**COMPLAINT FOR  
PATENT INFRINGEMENT**

**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 Nos. 8,404,215 ("the '215 patent"), 8,642,012 ("the '012 patent"), and 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 520 Lake Cook Road, Suite 520, Deerfield, Illinois.

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, Santacruz (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 existing under the laws of the Commonwealth of Virginia, with its principal place of business at 111 South Calvert Street 21<sup>st</sup> 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, 1338(a), 2201 and 2202.

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 PATENTS-IN-SUIT**

21. On March 26, 2013, the U.S. Patent and Trademark Office (“USPTO”) duly and legally issued the ’215 patent entitled “Methods of Therapeutic Monitoring of Nitrogen Scavenging Drugs.” At the time of its issue, the ’215 patent was assigned to Hyperion Therapeutics Inc., which later changed its name to Horizon Therapeutics, Inc. Horizon Therapeutics, Inc. currently is the sole assignee and owner of all right, title and interest in and to the ’215 patent, which discloses and claims, *inter alia*, a method for adjusting the dosage of a nitrogen scavenging drug in a subject who has previously been administered an initial dosage of the nitrogen scavenging drug. A true and correct copy of the ’215 patent is attached hereto as Exhibit A.

22. On February 4, 2014, the USPTO duly and legally issued the ’012 patent entitled “Methods of Treatment Using Ammonia-Scavenging Drugs.” At the time of its issue, the ’012 patent was assigned to Hyperion Therapeutics Inc., which later changed its name to Horizon Therapeutics, Inc. Horizon Therapeutics, Inc. currently is the sole assignee and owner of all right, title and interest in and to the ’012 patent, which discloses and claims, *inter alia*, a method of treating a patient having urea cycle disorder. A true and correct copy of the ’012 patent is attached hereto as Exhibit B.

23. 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

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