John E. Flaherty
Ravin R. Patel
McCARTER & ENGLISH LLP
Four Gateway Center
100 Mulberry St.
Newark, NJ 07102
(973) 622-4444

Attorneys for Plaintiff Horizon Therapeutics, Inc.

Dennis A. Bennett
GLOBAL PATENT GROUP, LLC
1005 North Warson Road, Suite 404
St. Louis, Missouri 63132
(314) 812-8020

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. 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, 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 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.

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

Therapeutics, Inc. currently is the sole assignee and owner of all right, title and interest in and to the '559 patent, which discloses and claims, *inter alia*, methods for evaluating daily ammonia exposure based on a single fasting ammonia blood level measurement. A true and correct copy of the '559 patent is attached hereto as Exhibit C.

RAVICTI®

24. 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®.

25. 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.

26. Pursuant to 21 U.S.C. § 355, and attendant FDA regulations, the '215, '012, and '559 patents are listed in the FDA publication entitled Approved Drug Products and Therapeutic Equivalence Evaluations ("the Orange Book") for the RAVICTI® NDA.

27. The '215, '012, and '559 patents qualify for listing in the Orange Book in connection with NDA No. 203284 because each patent claims an approved use of RAVICTI®.

LUPIN'S ANDA

28. 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.

29. 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®.

30. 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®.

31. Horizon Therapeutics, Inc. received from Lupin Ltd. a letter, dated September 4, 2015 ("the September 4th 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 '215 and '012 patents are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of the Lupin Product (the "Paragraph IV Certification").

32. The Lupin ANDA seeks approval to engage in the commercial manufacture, use or sale of glycerol phenylbutyrate oral liquid before the expiration of the '215 and '012 patents.

COUNT I FOR INFRINGEMENT OF U.S. PATENT NO. 8,404,215

33. Plaintiff realleges and incorporates by reference the allegations of paragraphs 1-32 of this Complaint.

34. Defendants have infringed the '215 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 '215 patent.

35. Defendants' use, offer to sell, or sale of the Lupin Product within the United States, during the term of the '215 patent also would infringe the '215 patent under 35 U.S.C. § 271(a), (b) and/or (c).

36. 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 '215 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 '215 patent.

37. Upon approval of the Lupin ANDA, and the commercial marketing thereof, Defendants will actively induce and/or contribute to infringement of the '215 patent.

38. This action is being filed within 45 days of receipt by Plaintiff of the September 4th Letter which purportedly advised Plaintiff of Lupin's Paragraph IV Certification filed relative to the '215 patent.

39. Upon information and belief, Defendants had actual and constructive notice of the '215 patent prior to filing Lupin's ANDA, and Defendants' infringement of the '215 patent has been, and continues to be, willful.

40. 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 '215 patent, or any later expiration of any exclusivity or extension of the '215 patent to which Plaintiff or the patent may become entitled.

41. Plaintiff will be substantially and irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to the infringement of the '215 patent.

42. Plaintiff has no adequate remedy at law.

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

COUNT II FOR INFRINGEMENT OF U.S. PATENT NO. 8,642,012

44. Plaintiff realleges and incorporates by reference the allegations of paragraphs 1-43 of this Complaint.

45. Defendants have infringed the '012 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 '012 patent.

46. Defendants' use, offer to sell, or sale of the Lupin Product within the United States, during the term of the '012 patent also would infringe the '012 patent under 35 U.S.C. § 271(a), (b) and/or (c).

47. Upon 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 '012 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 '012 patent.

48. Upon approval of the Lupin ANDA, and the commercial marketing of the Lupin Product, Defendants will actively induce and/or contribute to infringement of the '012 patent.

49. This action is being filed within 45 days of receipt by Plaintiff of the September 4th Letter which purportedly advised Plaintiff of Lupin's Paragraph IV Certification filed relative to the '012 patent.

50. Upon information and belief, Defendants had actual and constructive notice of the '012 patent prior to filing Lupin's ANDA, and Defendants' infringement of the '012 patent has been, and continues to be, willful.

51. 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 '012 patent, or any later expiration of any exclusivity or extension of the '012 patent to which Plaintiff or the patent may become entitled.

52. Plaintiff will be substantially and irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to the infringement of the '012 patent.

53. Plaintiff has no adequate remedy at law.

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

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

55. Plaintiff realleges and incorporates by reference the allegations of paragraphs 1-54 of this Complaint.

56. The '559 patent issued on August 4, 2015, and will expire on March 9, 2032.

57. Defendants have filed a Paragraph IV Certification in the Lupin ANDA seeking approval to market the Lupin Product prior to the expiration of, *inter alia*, the '215 patent, which expires on March 9, 2032. Because the '559 patent also expires on March 9, 2032, Defendants seek approval of the Lupin ANDA, and to market the Lupin Product, prior to the expiration of the '559 patent.

58. 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 the date on which the '559 patent expires, Defendants have infringed the '559 patent pursuant to 35 U.S.C. § 271(e)(2)(A).

59. 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).

60. Upon 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.

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

62. Upon information and belief, Defendants had actual and constructive notice of the '559 patent as of its issue date, and Defendants' infringement of the '559 patent is willful.

63. 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.

64. 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.

65. Plaintiff has no adequate remedy at law.

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

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

67. Plaintiff realleges and incorporates by reference the allegations of paragraphs 1-66 of this Complaint.

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

69. There currently exists an actual case or controversy such that the Court may entertain Plaintiff's 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.

70. Defendants' use, offer to sell, or sale of the Lupin Product within the United States, during the term of the '559 patent, would infringe the '559 patent

71. Defendants seek approval of the Lupin ANDA, and to market the Lupin Product, prior to the expiration of the '559 patent.

72. 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 '559 patent.

73. Plaintiff is entitled to a declaratory judgment that the use, offer for sale, and/or sale of the Lupin Product prior to the expiration of the '559 patent by Defendants would constitute direct infringement, contributory infringement, and/or active inducement of infringement of the '559 patent.

74. 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.

75. Plaintiff has no adequate remedy at law.

76. 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. 8,404,215;

B. A judgment declaring that Defendants have infringed one or more claims of U.S. Patent No. 8,642,012;

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

D. 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 '215 patent;

E. 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 '012 patent;

F. 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;

G. 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, use, offer to sell, or sell the Lupin Product within the United States, prior to the expiration date of the '559 patent, it will constitute an act of infringement of the '559 patent;

H. If Defendants use, offer to sell, or sell the Lupin Product within the United States, prior to the expiration of the '215 patent, including any extensions, a judgment awarding Plaintiff monetary relief together with interest;

I. If Defendants use, offer to sell, or sell the Lupin Product within the United States, prior to the expiration of the '012 patent, including any extensions, a judgment awarding Plaintiff monetary relief together with interest;

J. 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;

K. 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 '215, '012, and/or '559 patents, inclusive of any extensions;

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

M. Costs and expenses in this action; and

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

Date: October 19, 2015

s/John E. Flaherty
John E. Flaherty
Ravin R. Patel
McCARTER & ENGLISH LLP
Four Gateway Center
100 Mulberry St.
Newark, NJ 07102
(973) 622-4444

Attorneys for Plaintiff Horizon Therapeutics, Inc.

Dennis A. Bennett
GLOBAL PATENT GROUP, LLC
1005 North Warson Road, Suite 404
St. Louis, Missouri 63132
(314) 812-8020

Of Counsel for Plaintiff Horizon Therapeutics, Inc.

CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Plaintiff Horizon Therapeutics, Inc., by its undersigned attorneys, hereby certify pursuant to Local Civil Rule 11.2 that the matter in controversy, to the extent that it is directed to allegations of infringement of the '215 patent and the '012 patent, is the subject of the following pending action, which involves a different defendant and a different ANDA and does not involve the '559 patent:

- *Hyperion Therapeutics, Inc. v. Par Pharmaceutical, Inc.*,
  Civil Action No. 14-cv-00384-JRG-RSP (E.D. Tex.);
  (Horizon Therapeutics, Inc. was formerly known as Hyperion Therapeutics, Inc.)

Date: October 19, 2015

s/ John E. Flaherty
John E. Flaherty
Ravin R. Patel
McCARTER & ENGLISH LLP
Four Gateway Center
100 Mulberry St.
Newark, NJ 07102
(973) 622-4444

Attorneys for Plaintiff Horizon Therapeutics, Inc.

Dennis A. Bennett
GLOBAL PATENT GROUP, LLC
1005 North Warson Road, Suite 404
St. Louis, Missouri 63132
(314) 812-8020

Of Counsel for Plaintiff Horizon Therapeutics, Inc.