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

Attorneys for Plaintiffs Horizon Pharma Ireland Limited, HZNP Limited and Horizon Pharma USA, Inc.

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

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

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. 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 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 Nos. 8,217,078 ("the '078 patent"), 8,252,838 ("the '838 patent"), 8,546,450 ("the '450 patent"), 8,563,613 ("the '613 patent"), 8,618,164 ("the '164 patent") and 8,871,809 ("the '809 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 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. v et al. v. Lupin Ltd. et al.*, Civil Action No. 1:15-cv-00335, *Senju Pharmaceutical Co., Ltd. v 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. v et al. v. Lupin Ltd. et al.*, Civil Action No. 1:15-cv-00335, *Senju Pharmaceutical Co., Ltd. v 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 July 10, 2012, the U.S. Patent and Trademark Office ("USPTO") duly and legally issued the '078 patent entitled "Treatment of Pain with Topical Diclofenac." At the time of its issue, the '078 patent was assigned to Nuvo Research Inc., which later assigned the '078 patent to HZNP Limited. HZNP Limited currently is the sole assignee and owner of all right, title and interest in and to the '078 patent, which discloses and claims, *inter alia*, a method of applying topical agents to a knee of a patient with pain. A true and correct copy of the '078 patent is attached hereto as Exhibit A.

24. On August 28, 2012, the USPTO duly and legally issued the '838 patent entitled "Diclofenac Topical Formulation." At the time of its issue, the '838 patent was assigned to Nuvo Research Inc., which later assigned the '838 patent to HZNP Limited. HZNP Limited currently is the sole assignee and owner of all right, title and interest in and to the '838 patent, which discloses and claims, *inter alia*, a pharmaceutical formulation containing diclofenac sodium. A true and correct copy of the '838 patent is attached hereto as Exhibit B.

25. On October 1, 2013, the USPTO duly and legally issued the '450 patent entitled "Treatment of Pain with Topical Diclofenac Compounds." At the time of its issue, the '450 patent was assigned to Nuvo Research Inc., which later assigned the '450 patent to HZNP Limited. HZNP Limited currently is the sole assignee and owner of all right, title and interest in and to the '450 patent, which discloses and claims, *inter alia*, a method of treating a patient with combination therapy comprising administering a therapeutically effective amount of an oral NSAID and applying a topical diclofenac preparation to a knee. A true and correct copy of the '450 patent is attached hereto as Exhibit C.

26. On October 22, 2013, the USPTO duly and legally issued the '613 patent entitled "Diclofenac Topical Formulation." At the time of its issue, the '613 patent was assigned to Nuvo Research Inc., which later assigned the '613 patent to HZNP Limited. HZNP Limited currently is the sole assignee and owner of all right, title and interest in and to the '613 patent, which discloses and claims, *inter alia*, a pharmaceutical formulation containing diclofenac sodium. A true and correct copy of the '613 patent is attached hereto as Exhibit D.

27. On December 31, 2013, the USPTO duly and legally issued the '164 patent entitled "Treatment of Pain with Topical Diclofenac Compounds." At the time of its issue, the '164 patent was assigned to Nuvo Research Inc., which later assigned the '164 patent to HZNP Limited. HZNP Limited currently is the sole assignee and owner of all right, title and interest in and to the '164 patent, which discloses and claims, *inter alia*,

a method for applying topical agents to a knee of a patient with pain. A true and correct copy of the '164 patent is attached hereto as Exhibit E.

28. On October 28, 2014, the USPTO duly and legally issued the '809 patent entitled "Diclofenac Topical Formulation." At the time of its issue, the '809 patent was assigned to Nuvo Research Inc., which later assigned the '809 patent to HZNP Limited. HZNP Limited currently is the sole assignee and owner of all right, title and interest in and to the '809 patent, which discloses and claims, *inter alia*, a pharmaceutical formulation containing diclofenac sodium. A true and correct copy of the '809 patent is attached hereto as Exhibit F.

PENNSAID® 2%

29. 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®.

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

31. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '078, '838, '450, '613, '164 and '809 patents are listed in the FDA publication entitled Approved Drug Products and Therapeutic Equivalence Evaluations ("the Orange Book") for the PENNSAID® 2% NDA.

32. The '078, '838, '450, '613, '164 and '809 patents cover 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 the '078, '838, '450, '613, '164 and '809 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").

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 '078, '838, '450, '613, '164 and '809 patents.

COUNT I FOR INFRINGEMENT OF U.S. PATENT NO. 8,217,078

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

38. Defendants have infringed the '078 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 '078 patent.

39. 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 '078 patent also would infringe the '078 patent under 35 U.S.C. § 271(a), (b) and/or (c).

40. Upon approval of the Lupin ANDA, and the commercial marketing thereof, Defendants will actively induce and/or contribute to infringement of the '078 patent.

41. This action is being filed within 45 days of receipt by Plaintiffs of the March 17th Letter which purportedly advised Plaintiffs of Lupin's Paragraph IV Certification filed relative to the '078 patent.

42. Upon information and belief, Defendants had actual and constructive notice of the '078 patent prior to filing Lupin's ANDA, and Defendants' infringement of the '078 patent has been, and continues to be, willful.

43. 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 '078 patent, or any later expiration of any exclusivity or extension of the '078 patent to which Plaintiffs or the patent may become entitled.

44. Plaintiffs will be substantially and irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to the infringement of the '078 patent.

45. Plaintiffs have no adequate remedy at law.

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

COUNT II FOR INFRINGEMENT OF U.S. PATENT NO. 8,252,838

47. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-46 of this Complaint.

48. Defendants have infringed the '838 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 '838 patent.

49. 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 '838 patent also would infringe the '838 patent under 35 U.S.C. § 271(a), (b) and/or (c).

50. 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 '838 patent.

51. This action is being filed within 45 days of receipt by Plaintiffs of the March 17th Letter which purportedly advised Plaintiffs of Lupin's Paragraph IV Certification filed relative to the '838 patent.

52. Upon information and belief, Defendants had actual and constructive notice of the '838 patent prior to filing Lupin's ANDA, and Defendants' infringement of the '838 patent has been, and continues to be, willful.

53. 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 '838 patent, or any later expiration of any exclusivity or extension of the '838 patent to which Plaintiffs or the patent may become entitled.

54. Plaintiffs will be substantially and irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to the infringement of the '838 patent.

55. Plaintiffs have no adequate remedy at law.

56. 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. 8,546,450

57. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-56 of this Complaint.

58. Defendants have infringed the '450 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 '450 patent.

59. 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 '450 patent also would infringe the '450 patent under 35 U.S.C. § 271(a), (b) and/or (c).

60. Upon approval of the Lupin ANDA, and commercialization of the Lupin Product, Defendants will actively induce and/or contribute to infringement of the '450 patent.

61. This action is being filed within 45 days of receipt by Plaintiffs of the March 17th Letter which purportedly advised Plaintiffs of Lupin's Paragraph IV Certification filed relative to the '450 patent.

62. Upon information and belief, Defendants had actual and constructive notice of the '450 patent prior to filing Lupin's ANDA, and Defendants' infringement of the '450 patent has been, and continues to be, willful.

63. 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 '450 patent, or any later expiration of any exclusivity or extension of the '450 patent to which Plaintiffs or the patent may become entitled.

64. Plaintiffs will be substantially and irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to the infringement of the ’450 patent.

65. Plaintiffs have no adequate remedy at law.

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

COUNT IV FOR INFRINGEMENT OF U.S. PATENT NO. 8,563,613

67. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-66 of this Complaint.

68. Defendants have infringed the ’613 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 ’613 patent.

69. 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 ’613 patent, would further infringe the ’613 patent under 35 U.S.C. § 271(a), (b) and/or (c).

70. This action is being filed within 45 days of receipt by Plaintiffs of the March 17th Letter which purportedly advised Plaintiffs of Lupin’s Paragraph IV Certification with respect to the ’613 patent.

71. Upon information and belief, Defendants had actual and constructive notice of the ’613 patent prior to filing Lupin’s ANDA, and Defendants’ infringement of the ’613 patent has been, and continues to be, willful.

72. 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 '613 patent, or any later expiration of any exclusivity or extension of the '613 patent to which Plaintiffs or the patent may become entitled.

73. Plaintiffs will be substantially and irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to the infringement of the '613 patent.

74. Plaintiffs have no adequate remedy at law.

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

COUNT V FOR INFRINGEMENT OF U.S. PATENT NO. 8,618,164

76. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-75 of this Complaint.

77. Defendants have infringed the '164 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 '164 patent.

78. 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 '164 patent also would infringe the '164 patent under 35 U.S.C. § 271(a), (b) and/or (c).

79. Upon approval of the Lupin ANDA, and commercialization of the Lupin Product, Defendants will actively induce and/or contribute to infringement of the '164 patent.

80. This action is being filed within 45 days of receipt by Plaintiffs of the March 17th Letter which purportedly advised Plaintiffs of Lupin's Paragraph IV Certification filed relative to the '164 patent.

81. Upon information and belief, Defendants had actual and constructive notice of the '164 patent prior to filing Lupin's ANDA, and Defendants' infringement of the '164 patent has been, and continues to be, willful.

82. 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 '164 patent, or any later expiration of any exclusivity or extension of '164 patent to which Plaintiffs or the patent may become entitled.

83. Plaintiffs will be substantially and irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to the infringement of the '164 patent.

84. Plaintiffs have no adequate remedy at law.

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

COUNT VI FOR INFRINGEMENT OF U.S. PATENT NO. 8,871,809

86. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-85 of this Complaint.

87. Defendants have infringed the '809 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 '809 patent.

88. 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 '809 patent also would infringe the '809 patent under 35 U.S.C. § 271(a), (b) and/or (c).

89. Upon approval of the Lupin ANDA, and commercialization of the Lupin Product, Defendants will actively induce and/or contribute to infringement of the '809 patent.

90. This action is being filed within 45 days of receipt by Plaintiffs of the March 17th Letter which purportedly advised Plaintiffs of Lupin's Paragraph IV Certification filed relative to the '809 patent.

91. Upon information and belief, Defendants had actual and constructive notice of the '809 patent prior to filing Lupin's ANDA, and Defendants' infringement of the '809 patent has been, and continues to be, willful.

92. 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 '809 patent, or any later expiration of any exclusivity or extension of the '809 patent to which Plaintiffs or the patent may become entitled.

93. Plaintiffs will be substantially and irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to the infringement of the '809 patent.

94. Plaintiffs have no adequate remedy at law.

95. 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 one or more claims of U.S. Patent No. 8,217,078;

B. A judgment declaring that Defendants have infringed one or more claims of U.S. Patent No. 8,252,838;

C. A judgment declaring that Defendants have infringed one or more claims of U.S. Patent No. 8,546,450;

D. A judgment declaring that Defendants have infringed one or more claims of U.S. Patent No. 8,563,613;

E. A judgment declaring that Defendants have infringed one or more claims of U.S. Patent No. 8,618,164;

F. A judgment declaring that Defendants have infringed one or more claims of U.S. Patent No. 8,871,809;

G. 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 manufacturing, using, offering to sell, or selling the Lupin Product within the United States, or importing the Lupin Product into the United States, prior to the expiration date of the ’078 patent;

H. 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 manufacturing, using, offering to sell, or selling the Lupin Product within the United States, or importing the Lupin Product into the United States, prior to the expiration date of the ’838 patent;

I. 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 manufacturing, using, offering to sell, or selling the Lupin Product within the United States, or importing the Lupin Product into the United States, prior to the expiration date of the ’450 patent;

J. 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 manufacturing, using, offering to sell, or selling the Lupin Product within the United States, or importing the Lupin Product into the United States, prior to the expiration date of the ’613 patent;

K. 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 manufacturing, using, offering to sell, or selling the Lupin Product within the United States, or importing the Lupin Product into the United States, prior to the expiration date of the ’164 patent;

L. 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 manufacturing, using, offering to sell, or selling the Lupin Product within the United States, or importing the Lupin Product into the United States, prior to the expiration date of the ’809 patent;

M. 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 ’078 patent, including any extensions, a judgment awarding Plaintiffs monetary relief together with interest;

N. 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 '838 patent, including any extensions, a judgment awarding Plaintiffs monetary relief together with interest;

O. 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 '450 patent, including any extensions, a judgment awarding Plaintiffs monetary relief together with interest;

P. 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 '613 patent, including any extensions, a judgment awarding Plaintiffs monetary relief together with interest;

Q. 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 '164 patent, including any extensions, a judgment awarding Plaintiffs monetary relief together with interest;

R. 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 '809 patent, including any extensions, a judgment awarding Plaintiffs monetary relief together with interest;

S. 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 '078, '838, '450, '613, '164 and/or '809 patents, inclusive of any extensions;

T. Attorneys' fees in this action as an exceptional case pursuant to 35 U.S.C. § 285;

U. Costs and expenses in this action; and

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

Date: April 30, 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 Plaintiffs Horizon Pharma Ireland Limited, HZNP Limited and Horizon Pharma USA, Inc.

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

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. Watson Laboratories, Inc., et al.*, Civil Action No. 14-cv-07992-NLH-AMD (D.N.J.);
- *Horizon Pharma Ireland Limited, et al. v. Paddock Laboratories, LLC, et al.*, Civil Action No. 15-cv-00368-NLH-AMD (D.N.J.);
- *Horizon Pharma Ireland Limited, et al. v. Paddock Laboratories, LLC, et al.*, Civil Action No. 15-cv-00043-SLR (D. Del.);
- *Horizon Pharma Ireland Limited, et al. v. Taro Pharmaceuticals USA, Inc. et al.*, Civil Action No. 15-cv-02046-NLH-AMD (D.N.J.).

Date: April 30, 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 Plaintiffs Horizon Pharma Ireland Limited, HZNP Limited and Horizon Pharma USA, Inc.

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

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