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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. IGI LABORATORIES, INC., *Defendant.*	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 IGI Laboratories, Inc. ("Defendant" or "IGI"), 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 Defendant's 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 IGI is a corporation organized under the laws of the state of Delaware, having its principal place of business at 105 Lincoln Avenue, Buena, New Jersey 08310.

6. On information and belief, IGI 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 and through the actions of its agents and subsidiaries.

7. On information and belief, IGI is registered with the State of New Jersey, Division of Revenue and Enterprise Services, as Entity No. 0100187002.

8. On information and belief, IGI has offices, laboratory and manufacturing facilities located at 105 Lincoln Avenue, Buena, New Jersey 08310.

9. On information and belief, IGI currently markets within the US, and in this judicial district, generic topical pharmaceutical products.

10. On information and belief, IGI submitted to the FDA ANDA No. 208248 ("the IGI ANDA") for diclofenac sodium topical solution 2% w/w ("the IGI Product"), continues to seek FDA approval of that application, and intends to participate in the commercial manufacture, marketing, offer for sale and sale of the IGI Product throughout the United States, including in the State of New Jersey, in the event the FDA approves IGI's ANDA.

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

JURISDICTION AND VENUE

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

13. This Court has personal jurisdiction over IGI by virtue of, *inter alia*, the fact that its principal place of business is in New Jersey, having conducted business in New Jersey, having availed itself of the rights and benefits of New Jersey law such that it should reasonably anticipate being haled into court in this judicial district, 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 IGI products, within this judicial district, and through its intent to market and sell the IGI Product, if approved, to residents of this judicial district.

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

THE PATENTS-IN-SUIT

15. 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.

16. 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.

17. 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.

18. 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.

19. 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.

20. 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%

21. 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®.

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

23. 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.

24. The '078, '838, '450, '613, '164 and '809 patents cover PENNSAID® 2%.

IGI'S ANDA

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

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

27. The IGI 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.

28. On information and belief, IGI forwarded, via certified mail/registered mail, a letter dated March 24, 2015, to the following sole addressee: "Timothy Patrick Walbert, Director, HZNP Limited, Riverside One, Sir John Rogerson's Quay, Dublin 2, Ireland" ("the March 24th Letter"). The March 24th Letter stated that IGI included a certification in the IGI 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 IGI Product (the "Paragraph IV Certification").

29. 21 U.S.C. § 355(j)(2)(B)(ii) requires that an "applicant that makes a certification described in subparagraph (A)(vii)(IV) [*i.e.*, a Paragraph IV Certification] shall give notice as required under this subparagraph . . . ." 21 U.S.C. § 355(j)(2)(B)(iii) states that an "applicant required to give notice shall give notice to—(I) each owner of the patent that is the subject of the certification (or a representative of the owner designated to receive such notice); and (II) the holder of the approved application [NDA] under subsection (b) of this section for the drug that is claimed by the patent or a use of which is claimed by the patent (or a representative of the holder designated to receive such a notice."

30. 21 U.S.C. § 355(j)(5)(B)(iii) states that if " the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii) [*i.e.*, the Paragraph IV Certification], the [FDA] approval shall be made effective immediately unless, before the expiration of 45 days after the date on which the notice described in paragraph (2)(B) is received, an action is brought for infringement of the patent that is the subject of the certification . . . . * * * If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice . . . or such shorter or longer period as the court may order . . . ."

31. The assignment records of the U.S. Patent and Trademark Office relative to the '078, '838, '450, '613, '164 and '809 patents identify the address of HZNP Limited as 21 Laffan St., Hamilton, Pembroke, Bermuda HM09.

32. IGI to date has not forwarded a letter to HZNP Limited at its corporate address (*i.e.,* 21 Laffan St., Hamilton, Pembroke, Bermuda HM09) advising HZNP Limited that IGI included a Paragraph IV Certification in the IGI ANDA relative to the

'078, '838, '450, '613, '164 and '809 patents. IGI therefore failed to give proper notice to HZNP Limited, the sole owner of the patents, as required by 21 U.S.C. § 355(j)(2)(B).

33. IGI to date has not forwarded a letter to Horizon Pharma Ireland Limited advising Horizon Pharma Ireland Limited that IGI included a Paragraph IV Certification in the IGI ANDA relative to the '078, '838, '450, '613, '164 and '809 patents. IGI therefore failed to give proper notice to Horizon Pharma Ireland Limited, the sole owner of the PENNSAID® 2% NDA, as required by 21 U.S.C. § 355(j)(2)(B).

34. The March 24th Letter failed to, and as such IGI has yet to, provide proper notice of its Paragraph IV Certification as required by 21 U.S.C. § 355(j)(2)(B).

35. As this action for infringement of the patents that were the subject of the IGI Paragraph IV Certification was brought before the expiration of 45 days after the date on which notice of the Paragraph IV Certification was received by (i) the owner of the patents (*i.e.,* HZNP Limited) and (ii) the owner of the NDA (*i.e.,* Horizon Pharma Ireland Limited), the 45-day period has not expired, as that period cannot commence until the patent owner and the NDA owner have received notice in accordance with 21 U.S.C. § 355(j)(2)(B). Accordingly, the IGI ANDA is subject to a 30-month stay against final FDA approval under 21 U.S.C. § 355(j)(5)(B)(iii).

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

36. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-35 of this Complaint.

37. Defendant has infringed the '078 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the IGI ANDA which seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale or importation of the IGI Product prior to the expiration of the '078 patent.

38. Defendant's commercial manufacture, use, offer to sell, or sale of the IGI Product within the United States, or importation of the IGI 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).

39. Upon approval of the IGI ANDA, and the commercial marketing thereof, Defendant will actively induce and/or contribute to infringement of the '078 patent.

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

41. 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 IGI'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.

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

43. Plaintiffs have no adequate remedy at law.

44. 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

45. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-44 of this Complaint.

46. Defendant has infringed the '838 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the IGI ANDA which seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale or importation of the IGI Product prior to the expiration of the '838 patent.

47. Defendant's commercial manufacture, use, offer to sell, or sale of the IGI Product within the United States, or importation of the IGI 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).

48. Upon approval of the IGI ANDA, and the commercial marketing of the IGI Product, Defendant will actively induce and/or contribute to infringement of the '838 patent.

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

50. 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 IGI'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.

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

52. Plaintiffs have no adequate remedy at law.

53. 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

54. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-53 of this Complaint.

55. Defendant has infringed the '450 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the IGI ANDA which seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale or importation of the IGI Product prior to the expiration of the '450 patent.

56. Defendant's commercial manufacture, use, offer to sell, or sale of the IGI Product within the United States, or importation of the IGI 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).

57. Upon approval of the IGI ANDA, and commercialization of the IGI Product, Defendant will actively induce and/or contribute to infringement of the '450 patent.

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

59. 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 IGI'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.

60. Plaintiffs will be substantially and irreparably harmed if Defendant is not enjoined from infringing or actively inducing or contributing to the infringement of the '450 patent.

61. Plaintiffs have no adequate remedy at law.

62. 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

63. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-62 of this Complaint.

64. Defendant has infringed the '613 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the IGI ANDA, which seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale or importation of the IGI Product prior to the expiration of the '613 patent.

65. Defendant's commercial manufacture, use, offer to sell, or sale of the IGI Product within the United States, or importation of the IGI 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).

66. Upon information and belief, Defendant had actual and constructive notice of the '613 patent prior to filing IGI's ANDA, and Defendant's infringement of the '613 patent has been, and continues to be, willful.

67. 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 IGI'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.

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

69. Plaintiffs have no adequate remedy at law.

70. 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

71. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-70 of this Complaint.

72. Defendant has infringed the '164 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the IGI ANDA, which seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale or importation of the IGI Product prior to the expiration of the '164 patent.

73. Defendant's commercial manufacture, use, offer to sell, or sale of the IGI Product within the United States, or importation of the IGI 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).

74. Upon approval of the IGI ANDA, and commercialization of the IGI Product, Defendant will actively induce and/or contribute to infringement of the '164 patent.

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

76. 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 IGI'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.

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

78. Plaintiffs have no adequate remedy at law.

79. 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

80. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-79 of this Complaint.

81. Defendant has infringed the '809 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the IGI ANDA, which seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale or importation of the IGI Product prior to the expiration of the '809 patent.

82. Defendant's commercial manufacture, use, offer to sell, or sale of the IGI Product within the United States, or importation of the IGI 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).

83. Upon approval of the IGI ANDA, and commercialization of the IGI Product, Defendant will actively induce and/or contribute to infringement of the '809 patent.

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

85. 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 IGI'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.

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

87. Plaintiffs have no adequate remedy at law.

88. 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 Defendant, and respectfully request the following relief:

A. A judgment declaring that Defendant has infringed one or more claims of U.S. Patent No. 8,217,078;

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

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

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

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

F. A judgment declaring that Defendant has 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 Defendant, its 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 IGI Product within the United States, or importing the IGI 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 Defendant, its 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 IGI Product within the United States, or importing the IGI 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 Defendant, its 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 IGI Product within the United States, or importing the IGI 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 Defendant, its 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 IGI Product within the United States, or importing the IGI 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 Defendant, its 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 IGI Product within the United States, or importing the IGI 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 Defendant, its 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 IGI Product within the United States, or importing the IGI Product into the United States, prior to the expiration date of the '809 patent;

M. If Defendant commercially manufactures, uses, offers to sell, or sells the IGI Product within the United States, or imports the IGI 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 Defendant commercially manufactures, uses, offers to sell, or sells the IGI Product within the United States, or imports the IGI 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 Defendant commercially manufactures, uses, offers to sell, or sells the IGI Product within the United States, or imports the IGI 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 Defendant commercially manufactures, uses, offers to sell, or sells the IGI Product within the United States, or imports the IGI 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 Defendant commercially manufactures, uses, offers to sell, or sells the IGI Product within the United States, or imports the IGI 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 Defendant commercially manufactures, uses, offers to sell, or sells the IGI Product within the United States, or imports the IGI 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 IGI 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: May 21, 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. Watson Laboratories, Inc., et al.*, Civil Action No. 14-cv-07992-NLH-AMD (D.N.J.);
- *Horizon Pharma Ireland Limited, et al. v. Taro Pharmaceuticals USA, Inc. et al.*, Civil Action No. 15-cv-02046-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.); and
- *Horizon Pharma Ireland Limited, et al. v. Amneal Pharmaceuticals LLC*, Civil Action No. 15-cv-03367-NLH-AMD (D.N.J.).

Date: May 21, 2015

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