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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. TARO PHARMACEUTICALS USA, INC. and TARO PHARMACEUTICAL INDUSTRIES, LTD., *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 Taro Pharmaceuticals USA, Inc. and Taro Pharmaceutical Industries, Ltd. (collectively, "Defendants" or "Taro"), 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 Taro Pharmaceuticals USA, Inc. ("Taro USA") is a corporation organized and existing under the laws of the State of New York, having a principal place of business at 3 Skyline Drive, Hawthorne, New York, 10532.

6. On information and belief, Taro USA 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 Taro Pharmaceutical Industries, Ltd. ("Taro Industries") is an Israeli corporation having a principal place of business at 14 Hakitor Street, Haifa Bay, 2624761, Israel.

8. Shares of Taro Industries are listed on the New York Stock Exchange under the symbol TARO.

9. On information and belief, Taro Industries 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, including, at least, Taro USA.

10. On information and belief, Taro USA is a subsidiary of Taro Industries.

11. On information and belief, Taro USA is registered with the State of New Jersey as a wholesale distributor under Registration Number 5003062.

12. On information and belief, Taro USA acts at the direction of, under the control of, and for the benefit of Taro Industries and is controlled and/or dominated by Taro Industries.

13. In a letter dated January 30, 2015 ("the January 30th Letter"), which purports to provide notice under 21 U.S.C. § 355(j)(2)(B)(ii), Taro USA and Taro Industries are referred to therein as a single entity, being referenced therein as "collectively, Taro."

14. On information and belief, the January 30th Letter states that ANDA No. 208098 was "submitted by Taro."

15. On information and belief, Defendants participated and collaborated in the research and development, and the preparation and filing, of ANDA No. 208098 ("the Taro ANDA") for diclofenac sodium topical solution 2% w/w ("the Taro 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 Taro Product throughout the United States, including in the State of New Jersey, in the event the FDA approves Taro's ANDA.

16. On information and belief, Taro USA has availed itself of the rights, benefits and privileges of this Court by filing at least two complaints for patent infringement in the District of New Jersey: *Taro Pharmaceuticals North America, Inc. et al. v. Suven Life Sciences, Ltd.*, Civil Action No. 3:11-cv-02452 and *Taro Pharmaceuticals North America, Inc. et al. v. Synerx Pharma, LLC,* Civil Action No. 2:09-cv-03569.

17. On information and belief, Taro USA and Taro Industries have admitted to, consented to or have not contested, the jurisdiction of this Court in at least one prior District of New Jersey action: *Novartis Pharmaceuticals Corporation et al. v. Taro Pharmaceuticals USA., Inc. et al.*, Civil Action No. 2:06-cv-04178 (Taro USA admitting that personal jurisdiction and venue were proper in this judicial district, and Taro Industries consenting to same).

18. On information and belief, Taro USA and Taro Industries have availed themselves of the rights, benefits and privileges of this Court by asserting counterclaims in at least three prior District of New Jersey actions: *Pfizer, Inc. v. Taro Pharmaceuticals Industries, Ltd. et al.*, Civil Action No. 2:03-cv-05425, *Novartis Pharmaceuticals Corporation et al. v. Taro Pharmaceuticals USA, Inc. et al.*, Civil Action No. 2:06-cv-04178 and *Schering Corp. v. Taro Pharmaceuticals USA, Inc.*, Civil Action No. 2:01-cv-03531.

JURISDICTION AND VENUE

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

20. 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 Taro products, within this judicial district, and through their intent to market and sell the Taro Product, if approved, to residents of this judicial district.

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

THE PATENTS-IN-SUIT

22. 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.

23. 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.

24. 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.

25. 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.

26. 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.

27. 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%

28. 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®.

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

30. 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.

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

TARO'S ANDA

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

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

34. HZNP Limited received from Taro a letter, dated January 30, 2015 ("the January 30th Letter"), stating that Taro had included a certification in the Taro 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 Taro Product (the "Paragraph IV Certification").

35. The January 30th Letter states that the Taro 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

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

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

38. Defendants' commercial manufacture, use, offer to sell, or sale of the Taro Product within the United States, or importation of the Taro 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 Taro ANDA, and the commercial marketing thereof, Defendants will actively induce and/or contribute to infringement of the '078 patent.

40. This action is being filed within 45 days of receipt by Plaintiffs of the January 30th Letter which purportedly advised Plaintiffs of Taro's Paragraph IV Certification filed relative to the '078 patent.

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

42. 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 Taro'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.

43. 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.

44. Plaintiffs have no adequate remedy at law.

45. 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

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

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

48. Defendants' commercial manufacture, use, offer to sell, or sale of the Taro Product within the United States, or importation of the Taro 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).

49. Upon approval of the Taro ANDA, and the commercial marketing of the Taro Product, Defendants will actively induce and/or contribute to infringement of the '838 patent.

50. This action is being filed within 45 days of receipt by Plaintiffs of the January 30th Letter which purportedly advised Plaintiffs of Taro's Paragraph IV Certification filed relative to the '838 patent.

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

52. 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 Taro'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.

53. 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.

54. Plaintiffs have no adequate remedy at law.

55. 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

56. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-55 of this Complaint.

57. Defendants have infringed the '450 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Taro ANDA which seeks approval from the FDA to

engage in the commercial manufacture, use, offer to sell, sale or importation of the Taro Product prior to the expiration of the '450 patent.

58. Defendants' commercial manufacture, use, offer to sell, or sale of the Taro Product within the United States, or importation of the Taro 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).

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

60. This action is being filed within 45 days of receipt by Plaintiffs of the January 30th Letter which purportedly advised Plaintiffs of Taro's Paragraph IV Certification filed relative to the '450 patent.

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

62. 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 Taro'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.

63. 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.

64. Plaintiffs have no adequate remedy at law.

65. 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

66. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-65 of this Complaint.

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

68. Defendants' commercial manufacture, use, offer to sell, or sale of the Taro Product within the United States, or importation of the Taro 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).

69. This action is being filed within 45 days of receipt by Plaintiffs of the January 30th Letter which purportedly advised Plaintiffs of Taro's Paragraph IV Certification with respect to the '613 patent.

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

71. 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 Taro'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.

72. 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.

73. Plaintiffs have no adequate remedy at law.

74. 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

75. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-74 of this Complaint.

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

77. Defendants' commercial manufacture, use, offer to sell, or sale of the Taro Product within the United States, or importation of the Taro 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).

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

79. This action is being filed within 45 days of receipt by Plaintiffs of the January 30th Letter which purportedly advised Plaintiffs of Taro's Paragraph IV Certification filed relative to the '164 patent.

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

81. 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 Taro'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.

82. 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.

83. Plaintiffs have no adequate remedy at law.

84. 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

85. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-84 of this Complaint.

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

87. Defendants' commercial manufacture, use, offer to sell, or sale of the Taro Product within the United States, or importation of the Taro 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).

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

89. This action is being filed within 45 days of receipt by Plaintiffs of the January 30th Letter which purportedly advised Plaintiffs of Taro's Paragraph IV Certification filed relative to the '809 patent.

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

91. 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 Taro'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.

92. 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.

93. Plaintiffs have no adequate remedy at law.

94. 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 Taro Product within the United States, or importing the Taro 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 Taro Product within the United States, or importing the Taro 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 Taro Product within the United States, or importing the Taro 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 Taro Product within the United States, or importing the Taro 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 Taro Product within the United States, or importing the Taro 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 Taro Product within the United States, or importing the Taro 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 Taro Product within the United States, or import the Taro 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 Taro Product within the United States, or import the Taro 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 Taro Product within the United States, or import the Taro 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 Taro Product within the United States, or import the Taro 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 Taro Product within the United States, or import the Taro 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 Taro Product within the United States, or import the Taro 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 Taro 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: March 13, 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. 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.).

Date: March 13, 2015

s/ John E. Flaherty
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