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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

HORIZON PHARMA, INC. and POZEN INC.,

Plaintiffs,

v.

ACTAVIS LABORATORIES FL., INC., ACTAVIS PHARMA, INC., and ACTAVIS, INC.

Defendants.

Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Horizon Pharma, Inc. and Pozen Inc. (collectively, "Plaintiffs"), by their attorneys, for their Complaint against Actavis Laboratories FL, Inc., Actavis Pharma, Inc., and Actavis, Inc. (collectively, "Defendants"), allege as follows:

THE PARTIES

1. Plaintiff Horizon Pharma, Inc. ("Horizon") is a corporation operating and existing under the laws of the State of Delaware, with its principal place of business at 520 Lake Cook Road, Suite 520, Deerfield, Illinois 60015.

2. Plaintiff Pozen Inc. ("Pozen") is a corporation operating and existing under the laws of the State of Delaware, with its principal place of business at 1414 Raleigh Road, Chapel Hill, North Carolina 27517.

3. On information and belief, Defendant Actavis Laboratories FL, Inc. ("Actavis Laboratories") was formerly known as Watson Laboratories, Inc. – Florida, which was formerly known as Andrx Pharmaceuticals, Inc. ("Andrx Pharmaceuticals"). On information and belief, Actavis Laboratories is a corporation organized and existing under the laws of Florida, with its principal place of business at 4955 Orange Drive, Davie, Florida 33314. On information and belief, Actavis Laboratories is in the business of, *inter alia*, developing, manufacturing, marketing, and obtaining regulatory approval of generic copies of branded pharmaceutical products throughout the United States, including within this district.

4. On information and belief, Defendant Actavis Pharma, Inc. ("Actavis Pharma") was formerly known as Watson Pharma, Inc. ("Watson Pharma"). On information and belief, Defendant Actavis Pharma is a corporation organized and existing under the laws of Delaware, with its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054. On information and belief, Actavis Pharma is in the business of,

inter alia, selling and distributing generic copies of branded pharmaceutical products, including some that are manufactured by Actavis Laboratories and/or for which Actavis Laboratories is the named applicant of the approved ANDAs, throughout the United States, including within this district.

5. On information and belief, Defendant Actavis, Inc. ("Actavis") was formerly known as Watson Pharmaceuticals, Inc. ("Watson Pharmaceuticals") until on or about January 24, 2013. On information and belief, Actavis is a corporation organized and existing under the laws of Nevada, with its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054. On information and belief, Actavis 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 district, through its own actions and through the actions of its agents and subsidiaries, including at least Actavis Laboratories and Actavis Pharma.

6. On information and belief, Watson Pharmaceuticals acquired Andrx Pharmaceuticals on or about November 3, 2006. On information and belief, Watson Pharmaceuticals renamed Andrx Pharmaceuticals as Watson Laboratories. On information and belief, Watson Laboratories was renamed as Actavis Laboratories.

7. On information and belief, Actavis Laboratories is a wholly-owned subsidiary of Andrx Corporation, a Delaware corporation, with its principal place of business at 4955 Orange Drive, Davie, Florida 33314. On information and belief, Andrx Corporation is a wholly-owned subsidiary of Actavis.

8. On information and belief, Actavis Pharma, formerly known as Watson Pharma, is another wholly-owned subsidiary of Actavis.

9. On information and belief, Actavis organizes its operations by divisions—including at least Generics, Brands, and Distribution—and, before the name change, Watson Pharmaceuticals reported its financial results in its Securities and Exchange Commission ("SEC") filings by reference to these divisions. On information and belief, Watson Pharmaceuticals consolidated its financial results with subsidiaries in its SEC filings at least since 2007 and did not file separate financial reports to the SEC for each subsidiary.

10. On information and belief, Actavis' Generics Division is involved in the development, manufacture, marketing, sale, and distribution of generic pharmaceuticals. On information and belief, Defendants act as agents of each other and/or work in concert with each other as integrated parts of the Generics Division. On information and belief, the Generics Division develops and submits Abbreviated New Drug Applications ("ANDAs") to the FDA, relying on contributions from at least Defendants.

11. On information and belief, the head of the Generics Division is an employee of Actavis, the Generic Division's ANDAs are submitted by at least Actavis Laboratories, the Generic Division's products are developed and manufactured by at least Actavis Laboratories, and the Generic Division's products are marketed, sold, and distributed throughout the United States, including in this district, by at least Actavis Pharma. On information and belief, Actavis Laboratories and Actavis Pharma are parties to one or more contractual agreements regarding the distribution of generic pharmaceutical products.

12. On information and belief, Defendants share with each other at least some common employees, officers, and directors.

13. On information and belief, Actavis Laboratories and Actavis Pharma are within the control of Actavis for purposes of responding to discovery in this action.

BACKGROUND

The NDA

14. Horizon is the holder of New Drug Application ("NDA") No. 022511 for VIMOVO® (naproxen and esomeprazole magnesium) Delayed-Release Tablets, in 375 mg (naproxen)/20 mg (esomeprazole magnesium) and 500 mg (naproxen)/20 mg (esomeprazole magnesium) dosage forms.

15. VIMOVO® Delayed-Release Tablets are prescription drugs approved for use to relieve the signs and symptoms of osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis and to decrease the risk of stomach (gastric) ulcers in patients at risk of developing stomach ulcers from treatment with non-steroidal anti-inflammatory drugs (NSAIDs). Naproxen and esomeprazole magnesium are the active ingredients in VIMOVO® Delayed-Release Tablets.

The Patents-in-Suit

16. United States Patent No. 9,161,920 ("the '920 patent"), entitled "Pharmaceutical Compositions for the Coordinated Delivery of NSAIDs," was duly and legally issued by the United States Patent and Trademark Office on October 20, 2015. The claims of the '920 patent are directed to methods of reducing the incidence of NSAID-associated gastric ulcers by administering a pharmaceutical composition in unit dose form comprising naproxen and esomeprazole. A true and correct copy of the '920 patent is attached as Exhibit A.

17. Pozen owns the '920 patent by assignment. Horizon is Pozen's exclusive licensee under the '920 patent. The '920 patent will expire on May 31, 2022.

18. The '920 patent is listed in the FDA Orange Book in connection with NDA No. 022511 for VIMOVO® Delayed-Release Tablets.

19. United States Patent No. 9,198,888 ("the '888 patent"), entitled "Pharmaceutical Compositions for the Coordinated Delivery of NSAIDs," was duly and legally issued by the United States Patent and Trademark Office on December 1, 2015. The claims of the '888 patent are directed to a method of reducing the incidence of NSAID-associated gastric ulcers by administering a pharmaceutical composition in unit dosage form comprising naproxen and esomeprazole. A true and correct copy of the '888 patent is attached as Exhibit B.

20. Pozen owns the '888 patent by assignment. Horizon is Pozen's exclusive licensee under the '888 patent. The '888 patent will expire on May 31, 2022.

21. The '888 patent is listed in the FDA Orange Book in connection with NDA No. 022511 for VIMOVO® Delayed-Release Tablets.

Related Patents

22. United States Patent No. 6,926,907 ("the '907 patent"), entitled "Pharmaceutical Compositions for the Coordinated Delivery of NSAIDs," was duly and legally issued by the United States Patent and Trademark Office on August 9, 2005. The claims of the '907 patent are directed to pharmaceutical compositions that provide for the coordinated release of an acid inhibitor and an NSAID (claims 1–21, and 53–55) and methods of treating a patient for pain or inflammation comprising administration of the aforementioned compositions (claims 22–52).

23. Pozen owns the '907 patent by assignment. Horizon is Pozen's exclusive licensee under the '907 patent. The '907 patent will expire on February 28, 2023.

24. The '907 patent is listed in the FDA Orange Book in connection with NDA No. 022511 for VIMOVO® Delayed-Release Tablets.

25. United States Patent No. 8,557,285 ("the '285 patent"), entitled "Pharmaceutical Compositions for the Coordinated Delivery of NSAIDs," was duly and legally issued by the

United States Patent and Trademark Office on October 15, 2013. The claims of the '285 patent are directed to pharmaceutical compositions in unit dosage form comprising esomeprazole and naproxen.

26. Pozen owns the '285 patent by assignment. Horizon is Pozen's exclusive licensee under the '285 patent. The '285 patent will expire on May 31, 2022.

27. The '285 patent is listed in the FDA Orange Book in connection with NDA No. 022511 for VIMOVO® Delayed-Release Tablets.

28. United States Patent No. 8,852,636 ("the '636 patent"), entitled "Pharmaceutical Compositions for the Coordinated Delivery of NSAIDs" was duly and legally issued by the United States Patent and Trademark Office on October 7, 2014. The claims of the '636 patent are directed to pharmaceutical compositions in unit dosage form comprising esomeprazole and naproxen (claims 1–4, 7–10, 13–18) and methods of treating a patient for pain or inflammation comprising administration of the aforementioned compositions (claims 5–6, 11–12). A true and correct copy of the '636 patent is attached as Exhibit A.

29. Pozen owns the '636 patent by assignment. Horizon is Pozen's exclusive licensee under the '636 patent. The '636 patent will expire on May 31, 2022.

30. The '636 patent is listed in the FDA Orange Book in connection with NDA No. 022511 for VIMOVO® Delayed-Release Tablets.

31. United States Patent No. 8,858,996 ("the '996 patent"), entitled "Pharmaceutical Compositions for the Coordinated Delivery of NSAIDs," was duly and legally issued by the United States Patent and Trademark Office on October 14, 2014. The claims of the '996 patent are directed to pharmaceutical compositions in unit dosage form comprising esomeprazole and naproxen (claims 1–9, 12–15) and methods of treating a patient for pain or inflammation

comprising administration of the aforementioned compositions (claims 10–11, 16–19). A true and correct copy of the '996 patent is attached as Exhibit B.

32. Pozen owns the '996 patent by assignment. Horizon is Pozen's exclusive licensee under the '996 patent. The '996 patent will expire on May 31, 2022.

33. The '996 patent is listed in the FDA Orange Book in connection with NDA No. 022511 for VIMOVO® Delayed-Release Tablets.

34. United States Patent No. 8,865,190 ("the '190 patent"), entitled "Pharmaceutical Compositions for the Coordinated Delivery of NSAIDs," was duly and legally issued by the United States Patent and Trademark Office on October 21, 2014. The claims of the '190 patent are directed to a process for preparing pharmaceutical compositions in unit dosage form comprising esomeprazole and naproxen. A true and correct copy of the '190 patent is attached as Exhibit C.

35. Pozen owns the '190 patent by assignment. Horizon is Pozen's exclusive licensee under the '190 patent. The '190 patent will expire on May 31, 2022.

The ANDA

36. On information and belief, Defendants filed ANDA No. 204470 ("Defendants' ANDA") with the FDA under 21 U.S.C. § 355(j) to obtain FDA approval for the commercial manufacture, use, import, offer for sale, and sale in the United States of naproxen and esomeprazole magnesium delayed-release tablets, 500 mg (naproxen)/20 mg (esomeprazole magnesium) and 375 mg (naproxen)/20 mg (esomeprazole magnesium) ("Actavis' ANDA Product"), which are generic versions of Plaintiffs' VIMOVO® Delayed-Release Tablets in the 500 mg (naproxen)/20 mg (esomeprazole magnesium) and 375 mg (naproxen)/20 mg (esomeprazole magnesium) strength.

37. By letter dated March 29, 2013 (the "March 2013 ANDA Notice Letter"), Defendants notified AstraZeneca AB (Horizon's predecessor-in-interest as holder of NDA No. 022511 and as exclusive licensee for the '907 patent and the '285 patent) and Pozen that Defendants had filed ANDA No. 204470 seeking approval to market Actavis' ANDA Product and that Defendants were providing information pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95 regarding certain patents including the '907 patent.

38. By letter dated November 5, 2013 (the "November 2013 ANDA Notice Letter"), Defendants notified AstraZeneca AB and Pozen that Defendants had filed ANDA No. 204470 seeking approval to market Actavis' ANDA Product and that Defendants were providing information pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95 regarding the '285 patent.

39. By letter dated May 29, 2015 (the "May 2015 ANDA Notice Letter"), Defendants notified Horizon and Pozen that Defendants had filed ANDA No. 204470 seeking approval to market Actavis' ANDA Product and that Defendants were providing information pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95 regarding the '636 patent, the '996 patent, and U.S. Patent No.8,945,621 (the '621 patent).

40. By letter dated October 9, 2015 (the "October 2015 ANDA Notice Letter"), Defendants notified Horizon and Pozen that Defendants had filed an Amendment to ANDA No. 204470 seeking approval to market Actavis' ANDA Product in the dosage strength 375mg/20mg and that Defendants were providing information pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95 regarding, *inter alia*, the '907, '285, '636, '996, and '621 patents.

41. By letter dated December 10, 2015 (the "December 2015 ANDA Notice Letter"), Defendants notified Horizon and Pozen that Defendants had filed ANDA No. 204470 seeking

approval to market Actavis' ANDA Product and that Defendants were providing information pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95 regarding the '920 patent.

JURISDICTION AND VENUE

42. This action arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, including 35 U.S.C. § 271, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

43. On information and belief, Defendants have been and are engaging in activities directed toward infringement of the '920 and '888 patents (collectively, the "patents-in-suit") by, *inter alia*, submitting to the FDA ANDA No. 204470 and continuing to seek approval for Actavis' ANDA Product.

44. Defendants' March 2013 and October 2015 ANDA Notice Letter states Defendants' intention to seek FDA approval to market a generic version of the VIMOVO® product before the related '907 patent expires on February 28, 2023. Defendants' November 2013 and October 2015 ANDA Notice Letter states Defendants' intention to seek FDA approval to market a generic version of the VIMOVO® product before the related '285 patent expires on May 31, 2022.

45. There is now an actual controversy between Defendants and Plaintiffs as to whether Defendants' infringe or will infringe the '920 and '888 patents with Actavis' ANDA Product.

46. This Court has personal jurisdiction over Defendants because, *inter alia*, Defendants, on information and belief, have purposely availed themselves of the benefits and protections of the laws of New Jersey such that they should reasonably anticipate being haled into court here; Defendants have had continuous and systematic contacts with this judicial

district, including, on information and belief, maintaining executive offices in New Jersey and deriving substantial revenues from the sale of pharmaceutical products in New Jersey; and at least Actavis Pharma and Actavis, on information and belief, are licensed to do business within New Jersey. Thus, Defendants are subject to general jurisdiction in New Jersey.

47. On information and belief, Actavis Laboratories has previously purposefully availed itself of the benefits and protections of this district including, *inter alia*, by filing a complaint in the U.S. District Court for the District of New Jersey (*Shionogi Inc. et al. v. Nostrum Labs., Inc. et al.*, C.A. No. 1:12-cv-04402-RBK-JS (D.I. 1)) and asserting counterclaims in this Court (in *Depomed, Inc. v. Actavis Elizabeth LLC et al.*, C.A. No. 3:12-cv-01358-JAP-TJB (D.I. 47) and in *AstraZeneca AB et al. v. Actavis Laboratories FL Inc. et al.*, C.A. No. 3:13-cv-03038-JAP-DEA (D.I. 54)).

48. On information and belief, the acts of Actavis Laboratories complained of herein were done at the direction of, with the authorization of, and with the cooperation, participation, and assistance of Actavis Pharma and Actavis.

49. On information and belief, Defendants acted in concert to develop Actavis' ANDA Product and to seek approval from the FDA to sell Actavis' ANDA Product throughout the United States, including within this judicial district.

50. On information and belief, Actavis Laboratories, Actavis Pharma, and Actavis participated in the preparation and/or filing of ANDA No 204470.

51. On information and belief and as stated in the March ANDA Notice Letter and the November ANDA Notice Letter, the FDA received ANDA No. 204470 from Defendants.

52. On information and belief, by virtue of, *inter alia*, Defendants' continuous and systematic contacts with New Jersey, including but not limited to the above-described contacts,

and the actions on behalf of Defendants in connection with ANDA No. 204470, this Court has personal jurisdiction over Defendants. These activities satisfy due process and confer personal jurisdiction over Defendants consistent with New Jersey law.

53. Venue is proper in this District under 28 U.S.C. §§ 1391(b), 1391(c), and 1400(b).

COUNT I
(INFRINGEMENT OF THE '920 PATENT UNDER 35 U.S.C. § 271(e)(2))

54. Plaintiffs incorporate by reference paragraphs 1–53 of this Complaint as if fully set forth herein.

55. The '920 patent is a patent with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, sale, or importation of the VIMOVO® product.

56. Accordingly, pursuant to 21 U.S.C. § 355(c)(2), Plaintiffs timely submitted patent information for the '920 patent to the FDA in connection with NDA No. 022511 for the VIMOVO® product. This information has been published in the FDA's Orange Book.

57. 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV") requires, *inter alia*, certification by the ANDA applicant that the subject patent in the Orange Book, here the '920 patent, "is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted . . . ." The statute (21 U.S.C. § 355(j)(2)(B)(iv)) also requires a Paragraph IV notice to "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is not valid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)) specify, *inter alia*, that a Paragraph IV notification must include "[a] detailed statement of the factual and legal basis of applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement is to include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the

claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation."

58. On information and belief, Defendants were aware of the statutory provisions and regulations referred to in paragraph 57 above when they served the March ANDA Notice Letter regarding certain patents including the '907 patent and when they served the November ANDA Notice Letter regarding the '285 patent.

59. On information and belief, Defendants have previously filed patent certifications in association with their ANDA No. 204470 seeking, *inter alia*, FDA final approval prior to February 28, 2023. The '920 patent has an expiration date of May 31, 2022. Therefore, on further information and belief, Defendants are currently pursuing FDA final approval of ANDA No. 204470 before the '920 patent expires.

60. On information and belief, the making, using, selling, or offering for sale in the United States or the importation into the United States of Actavis' ANDA Product infringes the '920 patent.

61. Defendants have infringed, either literally or under the doctrine of equivalents, the '920 patent under 35 U.S.C. § 271(e)(2) by filing ANDA No. 204470 and continuing to seek approval from the FDA to engage in the commercial manufacture, use, sale, or importation of a drug to be used as claimed in the '920 patent before the expiration of the '920 patent.

62. On information and belief, Actavis' ANDA Product is a material for use in practicing the methods patented in the '920 patent, constitutes a material part of the inventions of the '920 patent, is especially made or especially adapted for use in an infringement of the '920 patent, and is not a staple article or commodity of commerce suitable for substantial noninfringing use. On information and belief, Defendants are aware that Actavis' ANDA

Product is so made or so adapted. On information and belief, Defendants are aware that Actavis' ANDA Product, if approved, will be used in contravention of Plaintiffs' rights under the '920 patent.

63. On information and belief, Defendants' above-described activities are continuing and constitute an act of infringement of the '920 patent under 35 U.S.C. § 271(e)(2).

64. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

COUNT II
(DECLARATORY JUDGMENT AS TO THE '920 PATENT)

65. Plaintiffs incorporate by reference paragraphs 1–64 of this Complaint as if fully set forth herein.

66. The '920 patent is a patent with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, sale, or importation of the VIMOVO® product.

67. On information and belief, Actavis' ANDA Product is a material for use in practicing the methods patented in the '920 patent, constitutes a material part of the inventions of the '920 patent, is especially made or especially adapted for use in an infringement of the '920 patent, and is not a staple article or commodity of commerce suitable for substantial noninfringing use. On information and belief, Defendants are aware that Actavis' ANDA Product is so made or so adapted.

68. On information and belief, the making, using, selling, or offering for sale in the United States or the importation into the United States of Actavis' ANDA Product before the

expiration of the '920 patent constitutes infringement of the '920 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

69. On information and belief, Defendants have previously filed patent certifications in association with their ANDA No. 204470 seeking, *inter alia*, FDA final approval to market Actavis' ANDA Product before February 28, 2023.

70. The March 2013 ANDA Notice Letter and the November 2013 ANDA Notice Letter show Defendants' intent to market Actavis' ANDA Product before the '920 patent expires on May 31, 2022.

71. On information and belief, Defendants continue to seek FDA final approval for Actavis' ANDA Product. On information and belief, Defendants are aware that the manufacture, use, sale, or offer for sale in the United States or the importation into the United States of Actavis' ANDA Product, if approved, will infringe the '920 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

72. On information and belief, Defendants have made, and will continue to make, substantial preparation to manufacture, use, sell, or offer to sell in the United States or import into the United States Actavis' ANDA Product before the '920 patent expires.

73. On information and belief, Defendants intend to engage in the commercial manufacture, use, sale, or offer for sale in the United States or importation into the United States of Actavis' ANDA Product after receiving FDA final approval of ANDA No. 204470 and before the '920 patent expires.

74. Defendants maintain, on information and belief, and Plaintiffs deny that the '920 patent is invalid or unenforceable and that Actavis' ANDA Product does not or will not infringe the '920 patent. Accordingly, a definite and concrete, real and substantial, justiciable case or

controversy exists between Plaintiffs and Defendants concerning infringement of the '920 patent by Actavis' ANDA Product.

75. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

76. Plaintiffs are entitled to a declaration that the making, using, sale, or offer for sale in the United States or the importation into the United States of Actavis' ANDA Product will infringe one or more claims of the '920 patent.

COUNT III
(INFRINGEMENT OF THE '888 PATENT UNDER 35 U.S.C. § 271(e)(2))

77. Plaintiffs incorporate by reference paragraphs 1–77 of this Complaint as if fully set forth herein.

78. The '888 patent is a patent with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, sale, or importation of the VIMOVO® product.

79. Accordingly, pursuant to 21 U.S.C. § 355(c)(2), Plaintiffs timely submitted patent information for the '888 patent to the FDA in connection with NDA No. 022511 for the VIMOVO® product. This information has been published in the FDA's Orange Book.

80. 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV") requires, *inter alia*, certification by the ANDA applicant that the subject patent in the Orange Book, here the '888 patent, "is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted . . . ." The statute (21 U.S.C. § 355(j)(2)(B)(iv)) also requires a Paragraph IV notice to "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is not valid or will not be infringed." The FDA Rules and

Regulations (21 C.F.R. § 314.95(c)) specify, *inter alia*, that a Paragraph IV notification must include "[a] detailed statement of the factual and legal basis of applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement is to include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation."

81. On information and belief, Defendants were aware of the statutory provisions and regulations referred to in paragraph 80 above when they served the March 2013 ANDA Notice Letter regarding certain patents including the '907 patent and when they served the November 2013 ANDA Notice Letter regarding the '285 patent.

82. On information and belief, Defendants have previously filed patent certifications in association with their ANDA No. 204470 seeking, *inter alia*, FDA final approval prior to February 28, 2023. The '888 patent has an expiration date of May 31, 2022. Therefore, on further information and belief, Defendants are currently pursuing FDA final approval of ANDA No. 204470 before the '888 patent expires.

83. Pursuant to 21 U.S.C. § 355(j)(2)(A)(vii), Defendants should file a patent certification in their pending ANDA No. 204470 with respect to the '888 patent and must make a Paragraph IV certification with respect to the '888 patent if Defendants continue to seek FDA final approval of their ANDA No. 204470 before the '888 patent expires.

84. On information and belief, the making, using, selling, or offering for sale in the United States or the importation into the United States of Actavis' ANDA Product infringes the '888 patent.

85. Defendants have infringed, either literally or under the doctrine of equivalents, the ’888 patent under 35 U.S.C. § 271(e)(2) by filing ANDA No. 204470 and continuing to seek approval from the FDA to engage in the commercial manufacture, use, sale, or importation of a drug to be used as claimed in the ’888 patent before the expiration of the ’888 patent.

86. On information and belief, Actavis’ ANDA Product is a material for use in practicing the methods patented in the ’888 patent, constitutes a material part of the inventions of the ’888 patent, is especially made or especially adapted for use in an infringement of the ’888 patent, and is not a staple article or commodity of commerce suitable for substantial noninfringing use. On information and belief, Defendants are aware that Actavis’ ANDA Product is so made or so adapted. On information and belief, Defendants are aware that Actavis’ ANDA Product, if approved, will be used in contravention of Plaintiffs’ rights under the ’888 patent.

87. On information and belief, Defendants’ above-described activities are continuing and constitute an act of infringement of the ’888 patent under 35 U.S.C. § 271(e)(2).

88. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

COUNT IV
(DECLARATORY JUDGMENT AS TO THE ’888 PATENT)

89. Plaintiffs incorporate by reference paragraphs 1–88 of this Complaint as if fully set forth herein.

90. The ’888 patent is a patent with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, sale, or importation of the VIMOVO® product.

91. On information and belief, Actavis' ANDA Product is a material for use in practicing the methods patented in the '888 patent, constitutes a material part of the inventions of the '888 patent, is especially made or especially adapted for use in an infringement of the '888 patent, and is not a staple article or commodity of commerce suitable for substantial noninfringing use. On information and belief, Defendants are aware that Actavis' ANDA Product is so made or so adapted.

92. On information and belief, the making, using, selling, or offering for sale in the United States or the importation into the United States of Actavis' ANDA Product before the expiration of the '888 patent constitutes infringement of the '888 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

93. On information and belief, Defendants have previously filed patent certifications in association with their ANDA No. 204470 seeking, *inter alia*, FDA final approval to market Actavis' ANDA Product before February 28, 2023.

94. The March ANDA Notice Letter and the November ANDA Notice Letter show Defendants' intent to market Actavis' ANDA Product before the '888 patent expires on May 31, 2022.

95. On information and belief, Defendants continue to seek FDA final approval for Actavis' ANDA Product. On information and belief, Defendants are aware that the manufacture, use, sale, or offer for sale in the United States or the importation into the United States of Actavis' ANDA Product, if approved, will infringe the '888 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

96. On information and belief, Defendants have made, and will continue to make, substantial preparation to manufacture, use, sell, or offer to sell in the United States or import into the United States Actavis' ANDA Product before the '888 patent expires.

97. On information and belief, Defendants intend to engage in the commercial manufacture, use, sale, or offer for sale in the United States or importation into the United States of Actavis' ANDA Product after receiving FDA final approval of ANDA No. 204470 and before the '888 patent expires.

98. Defendants maintain, on information and belief, and Plaintiffs deny that the '888 patent is invalid or unenforceable and that Actavis' ANDA Product does not or will not infringe the '888 patent. Accordingly, a definite and concrete, real and substantial, justiciable case or controversy exists between Plaintiffs and Defendants concerning infringement of the '888 patent by Actavis' ANDA Product.

99. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

100. Plaintiffs are entitled to a declaration that the making, using, sale, or offer for sale in the United States or the importation into the United States of Actavis' ANDA Product will infringe one or more claims of the '888 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that the claims of the '920 and '888 patents are valid and enforceable;

B. A judgment that the submission of ANDA No. 204470 by Defendants infringes one or more claims of the '920 and '888 patents under 35 U.S.C. § 271(e)(2)(A);

C. A judgment providing that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any FDA approval of Defendants' ANDA No. 204470 shall be no earlier than the expiration date of the '920 and '888 patents or any later exclusivity to which Plaintiffs are or become entitled;

D. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) permanently enjoining Defendants, and all persons acting in concert with any of them, from making, using, selling, offering to sell, or importing the naproxen and esomeprazole magnesium product described in Defendants' ANDA No. 204470 no earlier than the expiration date of the '920, and '888 patents or any later exclusivity to which Plaintiffs are or become entitled;

E. A declaration that Defendants have infringed the '920 and '888 patents;

F. A declaration that the commercial use, sale, offer for sale, manufacture in the United States and/or importation into the United States by Defendants of the naproxen and esomeprazole magnesium product described in Defendants' ANDA No. 204470 would infringe the '920 and '888 patents;

G. An order preliminarily and permanently enjoining Defendants, and all persons acting in concert with any of them, from making, using, selling, offering to sell, or importing the naproxen and esomeprazole magnesium product described in Defendants' ANDA No. 204470 no earlier than the expiration date of the '920 and '888 patents or any later exclusivity to which Plaintiffs are or become entitled;

H. Attorneys' fees in this action pursuant to 35 U.S.C. § 285;

I. Costs and expenses in this action; and

J. Such further and other relief as this Court may deem just and proper.

Dated: January 25, 2016 Respectfully submitted,

By: *s/ John E. Flaherty*

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CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Pursuant to Local Civil Rule 11.2, I hereby certify that the matter in controversy is the subject of the following actions:

HORIZON PHARMA, INC. et al. v. DR. REDDY'S LABS. INC., et al., C.A. No. 3:11-cv-02317-MLC-DEA (D.N.J.);

HORIZON PHARMA, INC. et al. v. DR. REDDY'S LABS. INC. et al, C.A. No. 3:13-cv-00091-MLC-DEA (D.N.J.);

HORIZON PHARMA, INC. et al. v. LUPIN LTD., et al., C.A. No. 3:11-cv-04275-MLC-DEA (D.N.J.);

HORIZON PHARMA, INC. et al. v. ACTAVIS LABORATORIES FL., INC., et al., C.A. No. 3:13-cv-03038-MLC-DEA (D.N.J.);

HORIZON PHARMA, INC. et al. v. MYLAN PHARMACEUTICALS et al., C.A. No. 3:13-cv-04022-MLC-DEA (D.N.J.);

HORIZON PHARMA, INC. et al v. ACTAVIS LABORATORIES FL., INC., et al, C.A. No. 3:15-cv-03322-MLC-DEA (D.N.J.);

HORIZON PHARMA, INC. et al v. DR. REDDY'S LABORATORIES INC., et al, C.A. No. 3:15-cv-03324-MLC-DEA (D.N.J.);

HORIZON PHARMA, INC. et al v. LUPIN LTD., et al, C.A. No. 3:15-cv-03326-MLC-DEA (D.N.J.);

HORIZON PHARMA, INC. et al v. MYLAN PHARMACEUTICALS INC., et al, C.A. No. 3:15-cv-03327-MLC-DEA (D.N.J.);

HORIZON PHARMA, INC. et al. v. ACTAVIS LABORATORIES FL., INC., et al., C.A. No. 3:15-cv-08523-MLC-DEA (D.N.J.); and

HORIZON PHARMA, INC. et al. v. ACTAVIS LABORATORIES FL., INC., et al., C.A. No. 3:15-cv-08524-MLC-DEA (D.N.J.).

The foregoing cases involve products that contain esomeprazole magnesium and naproxen. The matter in controversy involves the same esomeprazole magnesium and naproxen formulations. All of these cases have been assigned to Hon. Mary L. Cooper, U.S.D.J. and the Hon. Douglas E. Arpert, U.S.M.J.

Therefore, for the sake of judicial economy and with regard to Judge Cooper's and Judge Arpert's familiarity of the patents asserted in the matter in controversy, Plaintiffs believe these cases and the matter in controversy are all related. Accordingly, Plaintiffs respectfully request that the matter in controversy be assigned to Judge Cooper and Magistrate Judge Arpert.

Dated: January 25, 2016

Respectfully submitted,

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