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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., and ACTAVIS PHARMA, INC.

Defendants.

Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

COMPLAINT FOR PATENT INFRINGEMENT

Horizon Pharma, Inc., and Pozen Inc. (collectively, "Plaintiffs") for their Complaint against Actavis Laboratories FL, Inc. and Actavis Pharma, Inc. (collectively, "Defendants"), hereby 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. Horizon holds approved New Drug Application No. 022511 from the United States Food and Drug Administration ("FDA") for a delayed-release naproxen/esomeprazole magnesium formulation that it sells under the name VIMOVO®.

2. Plaintiff 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, ("Watson Laboratories") 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. Upon information and belief, Defendant Actavis Pharma, Inc. ("Actavis Pharma"), formerly known as Watson Pharma, Inc. ("Watson Pharma"), is a corporation organized and existing under the laws of Delaware, having its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054. Upon information and belief, Actavis Pharma is in the business of, *inter alia*, selling and distributing generic copies of branded pharmaceutical products in New Jersey and throughout the United States, including some that are manufactured by Watson Laboratories and/or for which Watson Laboratories is the named applicant of the approved ANDAs.

5. Upon information and belief, Actavis Pharma and Actavis Laboratories (collectively, "Actavis") are each wholly-owned subsidiaries of Actavis, Inc. Actavis, Inc. was formerly known as Watson Pharmaceuticals, Inc. ("Watson Pharmaceuticals") until on or around January 24, 2013. Actavis is a corporation organized and existing under the laws of Nevada, having its principal place of business at Morris Corporate Center III, 400 Interpace Parkway,

Parsippany, New Jersey 07054. Actavis, Inc. was dismissed as a party to this case on August 5, 2013. *See* D.N. 15.

6. Upon 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.

7. Upon information and belief, Actavis Laboratories and Actavis Pharma are parties to one or more contractual agreements regarding the distribution of generic pharmaceutical products.

8. Upon information and belief, each Defendant shares with the other at least some common employees, officers, and directors.

JURISDICTION AND VENUE

9. This is an action for patent infringement arising under the Patent and Food and Drug laws of the United States, Titles 35 and 21, United States Code. Jurisdiction and venue are based on 28 U.S.C. §§ 1331, 1338(a), 1391(b), 1391(c), 1400(b), 2201, 2202, and 35 U.S.C. § 271.

10. Upon information and belief, Defendants have been and are engaging in activities directed toward infringement of United States Patent Nos. 6,926,907 (the "'907 patent") and 8,557,285 (the "'285 patent) (collectively, the "patents-in-suit") by, *inter alia*, submitting to the FDA ANDA No. 204470 ("Defendants'

Original ANDA"). The '907 and '285 patents are attached hereto as Exhibits A and B, respectively. Defendants' Original ANDA seeks the FDA's approval to manufacture, use, or sell commercially their proposed product called "Naproxen/Esomeprazole Magnesium Delayed Release Tablets, 500mg/20 mg" (hereinafter referred to as the "Original ANDA Product"), containing the active ingredients naproxen and esomeprazole magnesium, prior to the expiration of the patents-in-suit, as a generic version of the VIMOVO® product.

11. Upon information and belief, Defendants have been and are engaging in activities directed toward infringement of the patents-in-suit by, *inter alia*, submitting to the FDA an amendment to ANDA No. 204470 ("Defendants' ANDA Amendment"). Defendants' ANDA Amendment seeks the FDA's approval to manufacture, use, or sell commercially their proposed product called "Naproxen/Esomeprazole Magnesium Delayed Release Tablets, 375mg/20 mg" (hereinafter referred to as the "Amended ANDA Product"), containing the active ingredients naproxen and esomeprazole magnesium, prior to the expiration of the patents-in-suit, as a generic version of the VIMOVO® product.

12. In a letter dated March 29, 2013 ("March 2013 Notice Letter") from Ms. Janet Vaughn, Watson Laboratories' Director of Regulatory Affairs, Watson Laboratories notified Plaintiffs of the filing of Defendants' Original ANDA and that the Original ANDA included a certification, pursuant to 21 U.S.C.

§ 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification"), with respect to, *inter alia*, the '907 patent.

13. In a letter dated November 5, 2013 ("November 2013 Notice Letter") from Ms. Janet Vaughn, Watson Laboratories' Director of Regulatory Affairs, Watson Laboratories provided Plaintiffs with a Paragraph IV Certification with respect to the '285 patent.

14. In a letter dated October 9, 2015 ("October 2015 Notice Letter") from Ms. Janet Vaughn, Actavis Laboratories FL Inc.'s Director of Regulatory Affairs, Actavis notified Plaintiffs of the filing of Defendants' ANDA Amendment and that the ANDA Amendment included a Paragraph IV Certification with respect to, *inter alia*, the '907 and '285 patents.

15. Paragraph IV of 21 U.S.C. § 355(j)(2)(B) requires certification by the ANDA applicant that the subject patent "is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted . . ." 21 U.S.C. § 355(j)(2)(B)(iv) 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 invalid 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 the 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 of supporting the allegation."

16. Upon information and belief, at the time the March 2013 Notice Letter was served, Defendants were aware of the statutory provisions and regulations referred to in paragraph 15, above.

17. Defendants' submission of ANDA No. 204470 and the ANDA Amendment and service of the March 2013, November 2013, and October 2015 Notice Letters indicate a refusal to change their current course of action.

18. Defendants' Paragraph IV Certifications to Plaintiffs state Defendants' intention to seek approval to market a generic copy of VIMOVO® product prior to expiration of the '907 and '285 patents. The last of these patents to expire is the '907 patent, which expires on February 28, 2023.

19. There is now an actual controversy between Defendants and Plaintiffs as to whether Defendants' Original ANDA Product and Amended ANDA Product (collectively, "ANDA Products") infringe the '907 and '285 patents.

20. This Court has personal jurisdiction over Defendants because, *inter alia*, Defendants, upon 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, upon 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, upon information and belief, are licensed to do business within New Jersey. Thus, Defendants are subject to general jurisdiction in New Jersey.

21. Upon information and belief, Actavis Laboratories has previously purposefully availed itself of the benefits and protections of the U.S. District Court for the District of New Jersey including by, *inter alia*, filing a complaint in *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. 3:12-01358-JAP-TJB (D.I. 47).

22. Upon information and belief, the acts of Watson Laboratories complained of herein were done at the direction of, with the authorization of, and with the cooperation, participation, and assistance of Actavis.

FIRST CLAIM FOR RELIEF: '907 PATENT

23. Plaintiffs reallege paragraphs 1–22, above, as if set forth specifically herein.

24. The '907 patent, entitled "Pharmaceutical Compositions for the Coordinated Delivery of NSAIDs" was issued on August 9, 2005, to Pozen, Inc., upon assignment from the inventor John R. Plachetka. The '907 patent claims, *inter alia*, pharmaceutical compositions that provide for the coordinated release of an acid inhibitor and an NSAID and a method for treating pain or inflammation comprising administration of such compositions.

25. Pozen Inc. has been and still is the owner of the '907 patent. The '907 patent will expire on February 28, 2023.

26. Horizon is Pozen Inc.'s exclusive licensee under the '907 patent.

27. In the March 2013 Notice Letter and October 2015 Notice Letter, Defendants notified Plaintiffs that, as part of their ANDA, they had filed a Paragraph IV certification with respect to the '907 patent.

28. The March 2013 Notice Letter and October 2015 Notice Letter, which are required by statute and regulation to provide a full and detailed explanation regarding non-infringement (see paragraph 15, above), allege non-infringement of claims 2, 3, 4, 6, 7, 8, 18, 19, 20, 21, 25, 26, 27, 30, 31, 36, 38, 39, 40, 43, 44, and 49 of the '907 patent.

29. The March 2013 Notice Letter and October 2015 Notice Letter, which are required by statute and regulation to provide a full and detailed explanation

regarding invalidity (see paragraph 15, above) allege invalidity of all claims of the ’907 patent.

30. The March 2013 Notice Letter and October 2015 Notice Letter, which are required by statute and regulation to provide a full and detailed explanation regarding unenforceability (see paragraph 15, above), do not allege unenforceability of the ’907 patent.

31. Even where asserted, the March 2013 Notice Letter and October 2015 Notice Letter do not provide the full and detailed statement of Defendants’ factual and legal basis to support their non-infringement and/or invalidity allegations as to the ’907 patent.

32. Accordingly, the March 2013 Notice Letter and October 2015 Notice Letter fail to comply with federal statute, as specified in 21 U.S.C. § 355(j), and FDA rules and regulations, as specified in 21 C.F.R. § 314.95.

33. Defendants have infringed the ’907 patent under 35 U.S.C. § 271(e)(2) by filing their ANDA, seeking approval from the FDA to engage in the commercial manufacture, use, or sale of a drug claimed in this patent, prior to the expiration of the ’907 patent.

34. Upon information and belief, the ANDA Products, if approved, will be administered to human patients at Defendants’ active behest and with their intent, knowledge, and encouragement. Upon information and belief, Defendants

will actively encourage, aid, and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '907 patent.

35. Upon information and belief, the ANDA Products contain a component of the composition patented in the '907 patent, is a material for use in practicing the methods patented in the '907 patent, constitutes a material part of those inventions, is especially made or especially adapted for use in an infringement of the '907 patent, and is not a staple article or commodity of commerce suitable for substantial noninfringing use. Upon information and belief, Defendants are aware that the ANDA Products are so made or so adapted. Upon information and belief, Defendants are aware that the ANDA Products, if approved, will be used in contravention of Plaintiffs' rights under the '907 patent.

36. The March 2013 Notice Letter and October 2015 Notice Letter do not allege and do not address non-infringement of claims 1, 5, 9-17, 22-24, 28, 29, 32-35, 37, 41, 42, 45-48, 50-54, and 55 of the '907 patent. By not addressing non-infringement of claims 1, 5, 9-17, 22-24, 28, 29, 32-35, 37, 41, 42, 45-48, 50-54, and 55 of the '907 patent in their March 2013 Notice Letter and October 2015 Notice Letter, Defendants admit that the ANDA Product meets all limitations of those claims.

37. The March 2013 Notice Letter and October 2015 Notice Letter do not allege and does not address unenforceability of the '907 patent. By not addressing

unenforceability of the ’907 patent in their March Notice Letter, Defendants admit that the ’907 patent is enforceable.

38. Upon information and belief, the manufacture, use, and sale of the ANDA Products infringe the ’907 patent claims.

SECOND CLAIM FOR RELIEF: ’285 PATENT

39. Plaintiffs reallege paragraphs 1-38, above, as if set forth specifically herein.

40. The ’285 patent, entitled “Pharmaceutical Compositions for the Coordinated Delivery of NSAIDs” was issued on October 15, 2013, to Pozen, Inc. upon assignment from the inventor John R. Plachetka. The ’285 patent claims, *inter alia*, pharmaceutical compositions that comprise esomeprazole and naproxen.

41. Pozen, Inc. has been and still is the owner of the ‘285 patent. The ’285 patent will expire on May 31, 2022.

42. Horizon is Pozen Inc.’s exclusive licensee under the ’285 patent.

43. In the November 2013 Notice Letter and October 2015 Notice Letter, Defendants notified Plaintiffs that, as part of their ANDA, they had filed a Paragraph IV certification with respect to the ’285 patent.

44. The November 2013 Notice Letter and October 2015 Notice Letter, which are required by statute and regulation to provide a full and detailed

explanation regarding non-infringement (see paragraph 15, above), do not allege non-infringement of any claims of the ‘285 patent.

45. The November 2013 Notice Letter and October 2015 Notice Letter, which are required by statute and regulation to provide a full and detailed explanation regarding invalidity (see paragraph 15, above) allege invalidity of all claims of the ’285 patent.

46. The November 2013 Notice Letter and October 2015 Notice Letter, which are required by statute and regulation to provide a full and detailed explanation regarding unenforceability (see paragraph 15, above), do not allege unenforceability of the ’285 patent.

47. Even where asserted, the November 2013 Notice Letter and October 2015 Notice Letter do not provide the full and detailed statement of Defendants’ factual and legal basis to support their invalidity allegations as to the ’285 patent.

48. Accordingly, the November 2013 Notice Letter and October 2015 Notice Letter fail to comply with federal statute, as specified in 21 U.S.C. § 355(j), and FDA rules and regulations, as specified in 21 C.F.R. § 314.95

49. Defendants have infringed the ’285 patent under 35 U.S.C. § 271(e)(2) by filing their ANDA, seeking approval from the FDA to engage in the commercial manufacture, use, or sale of a drug claimed in this patent, prior to the expiration of the ’285 patent.

50. Upon information and belief, the ANDA Products contain a component of the composition patented in the ’285 patent, constitutes a material part of the inventions of the ’285 patent, is especially made or especially adapted for use in an infringement of the ’285 patent, and is not a staple article or commodity of commerce suitable for substantial noninfringing use. Upon information and belief, Defendants are aware that the ANDA Products are so made or so adapted. Upon information and belief, Defendants are aware that the ANDA Products, if approved, will be used in contravention of Plaintiffs’ rights under the ‘285 patent.

51. The November 2013 Notice Letter and October 2015 Notice Letter do not allege and do not address non-infringement of claims 1-4 of the ’285 patent. By not addressing non-infringement of claims 1-4 of the ’285 patent in their November 2013 Notice Letter and October 2015 Notice Letter, Defendants admit that the ANDA Product meets all limitations of those claims.

52. The November 2013 Notice Letter and October 2015 Notice Letter do not allege and does not address unenforceability of the ’285 patent. By not addressing unenforceability of the ’907 patent in their March Notice Letter, Defendants admit that the ’285 patent is enforceable.

53. Upon information and belief, the manufacture, use, and sale of the ANDA Products infringe the ’285 patent claims.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

(a) A judgment declaring that the effective date of any approval of Defendants' ANDA No. 204470, filed under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), for drug products called "Naproxen/Esomeprazole Magnesium Delayed Release Tablets, 500mg/20mg" and "Naproxen/Esomeprazole Magnesium Delayed Release Tablets, 375mg/20mg"be a date not earlier than the later of February 28, 2023, the expiration date of the last to expire of the patents-in-suit that is infringed, and the expiration of any exclusivity relating to such patent to which Plaintiffs are or will become entitled;

(b) A judgment declaring that the '907, and '285 patents have been infringed by Defendants and remain valid and enforceable;

(c) A permanent injunction against any infringement by Defendants, their officers, agents, attorneys, employees, successors, and assigns, and those acting in privity or concert with them, of the '907 and '285 patents;

(d) A judgment that Defendants' infringement is willful;

(e) A judgment that Defendants' conduct is exceptional;

(f) An award of attorney fees in this action under 35 U.S.C. § 285;

(g) Costs and expenses in this action; and

(h) Such other relief as this Court may deem just and proper.

Dated: November 24, 2015

Respectfully submitted,

By: *s/ John E. Flaherty*

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Of Counsel for Plaintiff Horizon Pharma, Inc.

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.); and

HORIZON PHARMA, INC. et al v. MYLAN PHARMACEUTICALS INC., et al, C.A. No. 3:15-cv-03327-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. Case Nos. 3:11-cv-02317-MLC-DEA, 3:13-cv-00091-MLC-DEA, 3:11-cv-04275-MLC-DEA, 3:13-cv-03038-MLC-DEA, and 3:13-cv-04022-MLC-DEA have been consolidated for discovery purposes and have been assigned to Magistrate Judge Arpert. The remaining cases have been assigned to Magistrate Judge Arpert, but have not yet been consolidated for discovery purposes.

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: November 24, 2015

Respectfully submitted,

By: *s/ John E. Flaherty*

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