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

HORIZON PHARMA, INC., HORIZON PHARMA USA, INC., and POZEN INC.,

Plaintiffs,

v.

DR. REDDY'S LABORATORIES INC. and DR. REDDY'S LABORATORIES LTD.,

Defendants.

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Horizon Pharma, Inc., Horizon Pharma USA, Inc., and Pozen Inc. (collectively, "Plaintiffs"), by their attorneys, for their Complaint against Dr. Reddy's Laboratories Inc. and Dr. Reddy's Laboratories Ltd. (collectively, "Defendants"), allege as follows:

THE PARTIES

1. Plaintiffs Horizon Pharma, Inc. and Horizon Pharma USA, Inc. (collectively, "Horizon") are corporations operating and existing under the laws of the State of Delaware, with their principal place of business at 150 South Saunders Road, Lake Forest, Illinois 60045.

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 1122 Oberlin Road, Raleigh, NC 27605-1137.

3. On information and belief, Defendant Dr. Reddy's Laboratories Inc. ("Dr. Reddy's Inc.") is a corporation operating and existing under the laws of the State of New Jersey, with its principal place of business at 107 College Road East, Princeton, NJ 08540.

4. On information and belief, Defendant Dr. Reddy's Laboratories Ltd. ("Dr. Reddy's Ltd.") is a corporation operating and existing under the laws of India, with its principal place of business at 8-2-337, Road No. 3, Banjara Hills, Hyderabad, Telangana, India 500 034.

5. On information and belief, Dr. Reddy's Inc. is a wholly-owned subsidiary of Dr. Reddy's Ltd.

BACKGROUND

The NDA

6. Horizon Pharma, Inc. 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.

7. 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 Patent-in-Suit

8. United States Patent No. 9,393,208 ("the '208 patent"), entitled "Method for Delivering a Pharmaceutical Composition to Patient in Need Thereof," was duly and legally issued by the United States Patent and Trademark Office on July 19, 2016. A true and correct copy of the '208 patent is attached as Exhibit A.

9. Horizon Pharma USA, Inc. and Pozen own the rights to the '208 patent. Horizon Pharma USA, Inc. is the exclusive licensee of Pozen's rights to the '208 patent. The '208 patent will expire on September 3, 2029.

10. The '208 patent is listed in the FDA Orange Book in connection with NDA No. 022511 for VIMOVO® Delayed-Release Tablets.

The ANDAs

11. On information and belief, Defendants filed ANDA No. 202461 ("ANDA I") 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 containing 375 mg or 500 mg of naproxen and 20.71 mg esomeprazole magnesium ("ANDA I Product"), which are generic versions of Plaintiffs' VIMOVO® Delayed-Release Tablets in 375 mg (naproxen)/20 mg (esomeprazole magnesium) and 500 mg (naproxen)/20 mg (esomeprazole magnesium) strengths, respectively.

12. On information and belief, ANDA I received tentative approval on August 12, 2013 and final approval on September 27, 2013.

13. On information and belief, Defendants filed ANDA No. 204206 ("ANDA II") 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 containing 375 mg or 500 mg of naproxen and 20.71 mg esomeprazole magnesium ("ANDA II Product"), which are generic versions of Plaintiffs' VIMOVO® Delayed-Release Tablets in 375 mg (naproxen)/20 mg (esomeprazole magnesium) and 500 mg (naproxen)/20 mg (esomeprazole magnesium) strengths, respectively.

14. Plaintiffs have sought access to confidential information from Defendants to evaluate Defendants' infringement of the '208 patent. To date, Defendants have not responded to Plaintiffs' requests. Accordingly, resort to the civil court process, with the protections and procedures of the discovery process, is necessary to ensure access to Defendants' confidential information about the ANDA I Product and the ANDA II Product and how they are made. This information is needed to confirm Plaintiffs' belief that the ANDA I Product and the ANDA II Product infringe the '208 patent.

JURISDICTION AND VENUE

15. 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).

16. On information and belief, Defendants have been and are engaging in activities directed toward infringement of the '208 patent by, *inter alia*, submitting to the FDA ANDA Nos. 202461 and 204206, receiving final approval to market ANDA I Product, and continuing to seek approval for ANDA II Product.

17. There is an actual controversy between Defendants and Plaintiffs as to whether Defendants infringe the '208 patent.

18. On information and belief, Dr. Reddy's Inc. is a corporation organized and existing under the laws of the State of New Jersey. By virtue of its incorporation in New Jersey, this Court has personal jurisdiction over Dr. Reddy's Inc.

19. On information and belief, Defendants are in the business of developing, formulating, manufacturing, marketing, offering to sell, selling, and commercializing pharmaceutical products.

20. On information and belief, Dr. Reddy's Ltd., either directly or through one or more of its wholly-owned subsidiaries and/or agents, develops, manufactures, distributes, markets, offers to sell, and sells generic drug products for sale and use throughout the United States, including within this judicial district.

21. On information and belief, Dr. Reddy's Inc., with the assistance and/or at the direction of Dr. Reddy's Ltd., develops, manufactures, distributes, markets, offers to sell, and sells generic drug products for sale and use throughout the United States, including within this judicial district.

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

23. On information and belief, both Dr. Reddy's Ltd. and Dr. Reddy's Inc. participated in the preparation and/or filing of ANDA Nos. 202461 and 204206.

24. On information and belief, the FDA received ANDA Nos. 202461 and 204206 from Dr. Reddy's Ltd. and Dr. Reddy's Inc.

25. On information and belief, by virtue of, *inter alia*, Dr. Reddy's Ltd.'s relationship with Dr. Reddy's Inc. in connection with the preparation and/or filing of ANDA Nos. 202461 and 204206; Dr. Reddy's Ltd.'s designation of Lee Banks, Dr. Reddy's Inc., 200 Somerset Corporate Blvd., Floor 7, Bridgewater, New Jersey 08807 as its agent for service of process; and the sales-related activities of Defendants in New Jersey, including but not limited to the substantial, continuous, and systematic distribution, marketing, and/or sales of pharmaceutical products to residents of New Jersey, this Court has personal jurisdiction over Dr. Reddy's Ltd.

26. On information and belief, Defendants have previously been sued in this district and have not challenged personal jurisdiction. See, e.g., *Wyeth LLC v. Dr. Reddy's Labs., Ltd. and Dr. Reddy's Labs., Inc.*, Civ. Action No. 3:10-cv-04551-FLW-DEA (D.N.J.); *Albany Molecular Research, Inc. v. Dr. Reddy's Labs., Ltd. and Dr. Reddy's Labs., Inc.*, Civ. Action No. 2:09-cv-04638-GEB-MCA (D.N.J.); *Sepracor, Inc. v. Teva Pharm. USA, Inc., et al.*, Civ. Action No. 2:09-cv-01 302-DMC-M F (D.N.J.); *Hoffman-La Roche Inc. v. Dr. Reddy's Labs., Ltd. and Dr. Reddy's Labs., Inc.*, Civ. Action No. 2:08-cv-04055-SRC-MAS (D.N.J.); *AstraZeneca AB et al. v. Dr. Reddy's Labs., Ltd. and Dr. Reddy's Labs., Inc.*, Civil Action No. 3:08-cv-00328-JA PTJB (D.N.J.); and *AstraZeneca AB et al. v. Dr. Reddy's Labs, Inc. and Dr. Reddy's Labs., Ltd.*, Civil Action Nos. 3:11 -cv-02317-JA P-DEA (D.N.J.) and 3:13-cv-00091 -JA P-DEA (D.N.J.).

27. On information and belief, both Defendants Dr. Reddy's Ltd. and Dr. Reddy's Inc. have admitted that each is subject to personal jurisdiction in this district. See, e.g., *AstraZeneca UK Ltd. and AstraZeneca Pharms. LP v. Dr. Reddy's Labs., Ltd. and Dr. Reddy's Labs., Inc.*, 3:08-cv-03237-MLC-TJB (D.N.J.), Answer to Complaint, 8 (July 11, 2008); *AstraZeneca AB et al. v. Dr. Reddy's Labs., Ltd. and Dr. Reddy's Labs., Inc.*, 3:11-cv-02317-JAP-DEA (D.N.J.), Answer to Second Amended Complaint, 29.

28. On information and belief, Defendants have availed themselves of the jurisdiction of this Court by initiating litigation in this district. See, e.g., *Dr. Reddy's Labs., Ltd. and Dr. Reddy's Labs., Inc. v. Eli Lilly & Co.*, Civ. Action No. 3:09-0192-GEB-LHG (D.N.J.); and *Dr. Reddy's Labs., Ltd. and Dr. Reddy's Labs., Inc. v. AstraZeneca AB et al.*, Civil Action No. 3:08-cv-02496-JAP-TJB (D.N.J.).

29. 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 Nos. 202461 and 204206, this Court has personal jurisdiction over Defendants. These activities satisfy due process and confer personal jurisdiction over Defendants consistent with New Jersey law.

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

COUNT I

(INFRINGEMENT OF THE '208 PATENT UNDER 35 U.S.C. § 271(e)(2))

31. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

32. The ’208 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, importation, offer for sale, or sale of the VIMOVO® product.

33. Accordingly, pursuant to 21 U.S.C. § 355(c)(2), Plaintiffs submitted patent information for the ’208 patent to the FDA in connection with NDA No. 022511 for the VIMOVO® product. On information and belief, this information is published in the FDA’s Orange Book.

34. 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 ’208 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.”

35. On information and belief, Defendants are aware of the statutory provisions and regulations referred to above and have maintained pursuit of their ANDA.

36. On information and belief, Defendants have previously filed patent certifications in association with their ANDA Nos. 202461 and 204206 seeking, *inter alia*, FDA final approval prior to February 28, 2023. The ’208 patent has an expiration date of September 3, 2029.

Therefore, on further information and belief, Defendants are currently pursuing FDA final approval of ANDA Nos. 202461 and 204206 before the '208 patent expires.

37. On information and belief, the making, using, selling, or offering for sale in the United States or the importation into the United States of Defendants' ANDA I Product and ANDA II Product infringes the '208 patent.

38. Defendants have infringed, either literally or under the doctrine of equivalents, the '208 patent under 35 U.S.C. § 271(e)(2) by filing ANDA Nos. 202461 and 204206 and continuing to seek approval from the FDA to engage in the commercial manufacture, use, importation, offer for sale, or sale of a drug to be used as claimed in the '208 patent before the expiration of the '208 patent.

39. On information and belief, Defendants' ANDA I Product is a material for use in practicing the methods patented in the '208 patent, constitutes a material part of the inventions of the '208 patent, is especially made or especially adapted for use in an infringement of the '208 patent, and is not a staple article or commodity of commerce suitable for substantial noninfringing use. On information and belief, Defendants are aware that the ANDA I Product is so made or so adapted. On information and belief, Defendants are aware that the ANDA I Product will be used in contravention of Plaintiffs' rights under the '208 patent.

40. On information and belief, Defendants' ANDA II Product is a material for use in practicing the methods patented in the '208 patent, constitutes a material part of the inventions of the '208 patent, is especially made or especially adapted for use in an infringement of the '208 patent, and is not a staple article or commodity of commerce suitable for substantial noninfringing use. On information and belief, Defendants are aware that the ANDA II Product is so made or so adapted. On information and belief, Defendants are aware that the ANDA II Product, if approved, will be used in contravention of Plaintiffs' rights under the '208 patent.

41. On information and belief, Defendants' above-described activities are continuing and constitute an act of infringement of the '208 patent under 35 U.S.C. § 271(e)(2).

42. 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 '208 PATENT)

43. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

44. The '208 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, importation, offer for sale, or sale of the VIMOVO® product.

45. On information and belief, Defendants' ANDA I Product and ANDA II Product are materials for use in practicing the methods patented in the '208 patent, constitute a material part of the inventions of the '208 patent, are especially made or especially adapted for use in an infringement of the '208 patent, and are not staple articles or commodities of commerce suitable for substantial noninfringing use. On information and belief, Defendants are aware that the ANDA I Product and the ANDA II Product are so made or so adapted.

46. On information and belief, the making, using, selling, or offering for sale in the United States or the importation into the United States of Defendants' ANDA I Product or ANDA II Product before the expiration of the '208 patent constitutes infringement of the '208 patent under 35 U.S.C. §§ 271(a), (b) and/or (c).

47. On information and belief, Defendants have previously filed patent certifications in association with their ANDA Nos. 202461 and 204206 seeking, *inter alia*, FDA final approval to market the ANDA I Product and the ANDA II Product before February 28, 2023.

48. On information and belief, Defendants' intend to market the ANDA I Product and the ANDA II Product before the '208 patent expires on September 3, 2029.

49. On information and belief, Defendants received FDA final approval to market the ANDA I Product on September 27, 2013. On information and belief, Defendants are aware that the manufacture, use, offer for sale, or sale in the United States or the importation into the United States of Defendants' ANDA I Product before the expiration of the '208 patent will infringe the '208 patent under 35 U.S.C. §§ 271(a), (b) and/or (c).

50. On information and belief, Defendants continue to seek FDA final approval for ANDA Product II. On information and belief, Defendants are aware that the manufacture, use, offer for sale, or sale in the United States or the importation into the United States of Defendants' ANDA II Product, if approved, will infringe the '208 patent 35 U.S.C. §§ 271(a), (b) and/or (c).

51. On information and belief, Defendants have made, and will continue to make, substantial preparation to manufacture, use, offer for sale, or sell in the United States or import into the United States their ANDA I Product and ANDA II Product before the '208 patent expires.

52. On information and belief, Defendants intend to engage in the commercial manufacture, use, offer for sale, or sale in the United States or importation into the United States of Defendants' ANDA I Product before the '208 patent expires. On information and belief, Defendants may launch their ANDA I Product at any time.

53. On information and belief, Defendants intend to engage in the commercial manufacture, use, offer for sale, or sale in the United States or importation into the United States

of Defendants' ANDA II Product after receiving FDA final approval of ANDA No. 204206 and before the '208 patent expires.

54. There is a definite and concrete, real and substantial, justiciable case or controversy between Plaintiffs and Defendants concerning infringement of the '208 patent by their ANDA Products such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by the Court.

55. 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.

56. 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 the ANDA I Product or the ANDA Product II will infringe one or more claims of the '208 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that the submission of Defendants' ANDAs infringes one or more claims of the '208 patent under 35 U.S.C. § 271 (e)(2)(A);

B. A judgment providing that, pursuant to 35 U.S.C. § 271 (e)(4)(A), the effective date of any FDA approval of Defendants' ANDAs shall be no earlier than the expiration date of the '208 patent or any later exclusivity to which Plaintiffs are or become entitled;

C. 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' ANDAs no earlier than the expiration date of the '208 patent or any later exclusivity to which Plaintiffs are or become entitled;

D. A declaration that Defendants have infringed the '208 patent;

E. 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' ANDAs would infringe the '208 patent;

F. 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' ANDAs no earlier than the expiration date of the '208 patent or any later exclusivity to which Plaintiffs are or become entitled;

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

H. Costs and expenses in this action; and

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

Dated: December 6, 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.);

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

HORIZON PHARMA, INC. et al. v. ACTAVIS LABORATORIES FL., INC.,et al., C.A. No. 3:16-cv-00426-MLC-DEA (D.N.J.);

HORIZON PHARMA, INC. et al. v. ACTAVIS LABORATORIES FL., INC., et al., C.A. No. 3:16-cv-04916-MLC-DEA (D.N.J.);

HORIZON PHARMA, INC. et al. v. DR. REDDY'S LABS. INC. et al, C.A. No. 3:16-cv-04918-MLC-DEA (D.N.J.);

HORIZON PHARMA, INC. et al. v. LUPIN LTD., et al., C.A. No. 3:16-cv-04920-MLC-DEA (D.N.J.); and

HORIZON PHARMA, INC. et al. v. MYLAN PHARMACEUTICALS et al., C.A. No. 3:16-cv-04921-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. The Dr. Reddy's, Lupin, Actavis, and Mylan Pharmaceuticals cases have been consolidated for discovery purposes and have been assigned to Magistrate Judge Arpert.

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: December 6, 2016

Respectfully submitted,

By: *s/ John E. Flaherty*

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