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

HORIZON PHARMA, INC. and POZEN INC., Plaintiffs, v. DR. REDDY'S LABORATORIES INC. and DR. REDDY'S LABORATORIES LTD., Defendants.	Civil Action No. 3:13-cv-00091-JAP-DEA (consolidated for discovery purposes with Civ. A. Nos. 3:11-cv-02317-JAP-DEA and 3:11-cv-04275-JAP-DEA and 3:11-cv-06348-JAP-DEA)

FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT

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

NATURE OF THE ACTION

1. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100 *et seq.*, and in particular under 35 U.S.C. § 271(e). This action relates to Abbreviated New Drug Application ("ANDA") No. 204206 filed by or for the benefit of Defendants with the United States Food and Drug Administration ("FDA") for approval to market generic versions of Plaintiffs' VIMOVO® pharmaceutical products that are sold in the United States.

THE PARTIES

2. 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.

3. 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.

4. 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 200 Somerset Corporate Boulevard, Bridgewater, New Jersey 08807 (Somerset County).

5. 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, 500 034, India.

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

BACKGROUND

The NDA

7. 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.

8. 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

9. 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 a method of treating a patient for pain or inflammation comprising administration of the aforementioned compositions (claims 22–52). A true and correct copy of the '907 patent is attached as Exhibit A.

10. 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.

11. 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. A true and correct copy of the '285 patent is attached as Exhibit B.

12. 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.

The ANDA

13. On information and belief, Defendants filed ANDA No. 204206 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 ("Dr. Reddy's Naproxen and Esomeprazole Magnesium Delayed-Release Tablets"), 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. By letter dated November 20, 2012 (the "ANDA Notice Letter"), Defendants notified Plaintiffs that Defendants had filed ANDA No. 204206 seeking approval to market Dr. Reddy's Naproxen and Esomeprazole Magnesium Delayed-Release Tablets and that Defendants were providing information to Plaintiffs pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95.

JURISDICTION AND VENUE

15. Subject matter jurisdiction over this action is proper pursuant to the provisions of Title 28, United States Code, Sections 1331 and 1338(a).

16. 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.

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

18. 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.

19. 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.

20. On information and belief, Defendants acted in concert to develop Dr. Reddy's Naproxen and Esomeprazole Magnesium Delayed-Release Tablets and to seek approval from the FDA to sell Dr. Reddy's Naproxen and Esomeprazole Magnesium Delayed-Release Tablets throughout the United States, including within this judicial district.

21. On information and belief, both Dr. Reddy's Ltd. and Dr. Reddy's Inc. participated in the preparation and/or filing of ANDA No. 204206.

22. On information and belief and as stated in the ANDA Notice Letter, the FDA received ANDA No. 204206 from Dr. Reddy's Ltd. and Dr. Reddy's Inc.

23. In their ANDA Notice Letter, Defendants stated that the name and address of their agent in the United States authorized to accept service of process for Defendants for purposes of an infringement action based upon their ANDA Notice Letter is Lee Banks, Dr. Reddy's Laboratories Inc., 200 Somerset Corporate Blvd., Floor 7, Bridgewater, New Jersey 08807.

24. By naming Lee Banks, Dr. Reddy's Laboratories Inc., 200 Somerset Corporate Blvd., Floor 7, Bridgewater, New Jersey 08807 as their agent, Defendants have consented to jurisdiction in the State of New Jersey for this action.

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 No. 204206; Dr. Reddy's Ltd.'s designation of Lee Banks, Dr. Reddy's Laboratories 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.*, *AstraZeneca AB et al. v. Dr. Reddy's Laboratories, Inc. et al.*, Civ. Action No. 3:11-cv-02317-JAP-DEA (D.N.J); *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-01302-DMC-MF (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.); and *AstraZeneca AB et al. v. Dr. Reddy's Labs., Ltd. and Dr. Reddy's Labs., Inc.*, Civil Action No. 3:08-cv-00328-JAP-TJB (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).

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 No. 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 pursuant to the provisions of Title 28, United States Code, Sections 1391(c) and (d), and 1400(b).

COUNT I
(INFRINGEMENT OF THE '907 PATENT UNDER 35 U.S.C. § 271(e)(2)(A))

31. Plaintiffs incorporate by reference paragraphs 1–30 of this Complaint as if fully set forth herein.

32. By their ANDA Notice Letter, Defendants informed Plaintiffs that as part of their ANDA they had filed a certification of the type described in 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV") with respect to the '907 patent. This statutory section requires, *inter alia*, certification by the ANDA applicant that the subject patent, here the '907 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."

33. On information and belief, at the time the ANDA Notice Letter, Defendants were aware of the statutory provisions and regulations referred to in paragraph 32, above.

34. Defendants have infringed one or more claims of the '907 patent under 35 U.S.C. § 271(e)(2), either literally or under the doctrine of equivalents, 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.

35. On information and belief, the commercial manufacture, use, sale, offer for sale, or importation into the United States of Dr. Reddy's Naproxen and Esomeprazole Magnesium

Delayed-Release Tablets, if approved by the FDA, will constitute direct infringement of claims 1, 5, 9–17, and 53–55 of the '907 patent.

36. On information and belief, Dr. Reddy's Naproxen and Esomeprazole Magnesium Delayed-Release Tablets, if approved, will be prescribed and administered to human patients 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 NSAIDs, which uses will constitute direct infringement of claims 22, 23, 35, 48, and 50–52 of the '907 patent. On information and belief, these uses will occur with Defendants' specific intent, knowledge, and encouragement. On information and belief, Defendants will actively induce, encourage, aid, and abet this prescription and administration, with knowledge and specific intent that these uses will be in contravention of Plaintiffs' rights under the '907 patent.

37. On information and belief, Dr. Reddy's Naproxen and Esomeprazole Magnesium Delayed-Release Tablets are especially made or especially adapted 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 NSAIDs by inhibiting gastric acid secretion. On information and belief, Defendants are aware that Dr. Reddy's Naproxen and Esomeprazole Magnesium Delayed-Release Tablets are so made or so adapted. On information and belief, Defendants are aware that Dr. Reddy's Naproxen and Esomeprazole Magnesium Delayed-Release Tablets, if approved, will be used in contravention of Plaintiffs' rights under the '907 patent.

38. 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
(INFRINGEMENT OF THE '285 PATENT UNDER 35 U.S.C. § 271(e)(2)(A))

39. Plaintiffs incorporate by reference paragraphs 1–30 of this Complaint as if fully set forth herein.

40. On information and belief, the making, using, selling, and/or offering for sale in the United States of Dr. Reddy's Naproxen and Esomeprazole Magnesium Delayed-Release Tablets described in Defendants' ANDA No. 204206 infringes the '285 patent.

41. Defendants have infringed the '285 patent under 35 U.S.C. § 271(e)(2), either literally or under the doctrine of equivalents, by filing their ANDA and continuing to seek 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.

42. On information and belief, Dr. Reddy's Naproxen and Esomeprazole Magnesium Delayed-Release Tablets contain the pharmaceutical composition patented in the '285 patent, constitute a material part of the inventions of the '285 patent, are especially made or especially adapted for use in an infringement of the '285 patent, and are not staple articles or commodities of commerce suitable for substantial noninfringing use. Upon information and belief, Defendants are aware that Dr. Reddy's Naproxen and Esomeprazole Magnesium Delayed-Release Tablets are so made or so adapted. Upon information and belief, Defendants are aware that Dr. Reddy's Naproxen and Esomeprazole Magnesium Delayed-Release Tablets, if approved, will be used in contravention of Plaintiffs' rights under the '285 patent.

43. On information and belief, Defendants have previously filed patent certifications in association with their ANDA No. 204206 seeking, *inter alia*, FDA final approval prior to November 27, 2014. The '285 patent has an expiration date of May 31, 2022. Therefore, on further information and belief, Defendants are currently pursuing FDA final approval of their ANDA No. 204206 prior to the expiration date of the '285 patent.

44. Pursuant to 21 U.S.C. § 355(j)(2)(A)(vii), Defendants should file a patent certification in their pending ANDA No. 204206 with respect to the '285 patent, and Defendants must make a Paragraph IV Certification with respect to the '285 patent if Defendants continue to seek FDA final approval of their ANDA No. 204206 prior to May 31, 2022. On information and belief, Defendants' above-described activities are continuing and constitute an act of infringement of the '285 patent under 35 U.S.C. § 271(e)(2).

45. On information and belief, the commercial manufacture, use, sale, offer for sale, or importation into the United States of Dr. Reddy's Naproxen and Esomeprazole Magnesium Delayed-Release Tablets, if approved by the FDA, will infringe the '285 patent claims.

50. 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.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that the claims of the patents-in-suit are valid and enforceable;

B. A judgment that the submission of ANDA No. 204206 by Defendants infringes one or more claims of the patents-in-suit 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. 204206 shall be no earlier than the later of the expiration date of the last to expire of the patents-in-suit 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. 204206 no earlier than the later of the expiration date of the last to expire of the patents-in-suit or any later exclusivity to which Plaintiffs are or become entitled;

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

F. Costs and expenses in this action; and

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

Dated: February 25, 2014

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:

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

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

ASTRAZENECA AB et al. v. DR. REDDY'S LABS. INC. et al, C.A. No. 3:13-cv-06157-JAP-DEA (D.N.J.);

ASTRAZENECA AB et al. v. LUPIN LTD., et al., C.A. No. 3:11-cv-04275-JAP-DEA (D.N.J.);

ASTRAZENECA AB et al. v. LUPIN LTD., et al., C.A. No. 3:13-cv-06315-JAP-DEA (D.N.J.);

ASTRAZENECA AB et al. v. ANCHEN PHARMS., INC., C.A. No. 3:11-cv-06348-JAP-DEA (D.N.J.);

ASTRAZENECA AB et al. v. WATSON LABORATORIES, INC.- FLORIDA, et al., C. A. No. 3:13-cv-03038-JAP-DEA (D.N.J.);

ASTRAZENECA AB et al. v. WATSON LABORATORIES, INC.- FLORIDA, et al., C. A. No. 3:13-cv-06318-JAP-DEA (D.N.J.);

ASTRAZENECA AB et al. v. MYLAN PHARMACEUTICALS et al., C.A. No. 3:13-cv-04022-JAP-DEA (D.N.J.)

ASTRAZENECA AB et al. v. MYLAN PHARMACEUTICALS et al., C.A. No. 3:13-cv-06316-JAP-DEA (D.N.J.)

ASTRAZENECA AB, et al. v. MYLAN LABORATORIES LTD. et al., C.A. No. 3:12-cv-01378-JAP-TJB (D.N.J.);

ASTRAZENECA AB et al. v. WATSON LABORATORIES, INC. - FLORIDA et al., C.A. No. 3:13-cv-01669-JAP-TJB (D.N.J.); and

ASTRAZENECA AB et al. v. WOCKHARDT LIMITED et al., C.A. No. 3:13-cv-04854-JAP-TJB (D.N.J.).

The foregoing cases involve products that contain an esomeprazole magnesium formulation. The matter in controversy involves the same esomeprazole magnesium formulations. All of these cases have been assigned to Hon. Joel A. Pisano, U.S.D.J. The DRL, Lupin, and Anchen 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 Pisano'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 Pisano and Magistrate Judge Arpert.

Dated: February 25, 2014

Respectfully submitted,

By: *s/ John E. Flaherty*

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Of Counsel for Plaintiff Horizon Pharma, Inc.

CERTIFICATE OF SERVICE

The undersigned hereby certifies that true copies of the foregoing First Amended Complaint for Patent Infringement, Certification Pursuant to L. Civ. R. 11.2, and supporting documents were caused to be served on February 25, 2014, by electronic mail and/or the ECF system upon all counsel of record.

Dated: February 25, 2014

By: *s/ John E. Flaherty*

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