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

HORIZON PHARMA, INC. and POZEN INC., Plaintiffs, v. LUPIN LTD, and LUPIN PHARMACEUTICALS INC., Defendants.	Civil Action No. 3:11-cv-04275-JAP-DEA (consolidated for discovery purposes with Civ. A. Nos. 3:11-cv-02317-JAP-DEA and 3:13-cv-00091-JAP-DEA and 3:11-cv-03038-JAP-DEA and 3:13-cv-04022-JAP-DEA) **THIRD AMENDED COMPLAINT FOR PATENT INFRINGEMENT (Amendment By Consent)**

Plaintiffs Horizon Pharma, Inc. and Pozen Inc. (collectively, "Plaintiffs"), by their attorneys, for their Third Amended Complaint against Defendants Lupin Ltd. and Lupin Pharmaceuticals Inc., (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. 202654 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 Lupin Ltd. ("Lupin Ltd.") is a corporation operating and existing under the laws of India, with its principal place of business at B/4 Laxmi Towers, Bandra Kurla Complex, Bandra (E), Mumbai 400 051, India, and its registered office at 159 CST Road, Kalina, Santacruz (E), Mumbai 400 098, India.

5. On information and belief, Defendant Lupin Pharmaceuticals Inc. ("Lupin Inc.") is a corporation operating and existing under the laws of the Commonwealth of Virginia, with its principal place of business at 111 South Calvert Street 21st Floor, Baltimore, MD 21202.

6. On information and belief, Lupin Inc. is a wholly-owned subsidiary of Lupin 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 a 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, Lupin Ltd. filed ANDA No. 202654 with the FDA under 21 U.S.C. § 355(j) to obtain FDA approval for Lupin Ltd. and Lupin Inc. to commercially manufacture, use, import, offer for sale, and sell in the United States naproxen and esomeprazole magnesium delayed release tablets containing 375 mg (naproxen)/20 mg (esomeprazole magnesium) or 500 mg naproxen (naproxen)/20 mg (esomeprazole magnesium) ("Lupin'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 June 10, 2011 (the "2011 ANDA Notice Letter"), Lupin Ltd. notified Plaintiffs that it had filed ANDA No. 202654 seeking approval to market Lupin's Naproxen and Esomeprazole Magnesium Delayed-Release Tablets and was providing information to Plaintiffs pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95 with respect to the '907 patent.

15. By letter dated March 12, 2014 (the "2014 ANDA Notice Letter"), Lupin Ltd. notified Plaintiffs that it had filed ANDA No. 202654 seeking approval to market Lupin's Naproxen and Esomeprazole Magnesium Delayed-Release Tablets and was providing information to Plaintiffs pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95 with respect to the '285 patent.

JURISDICTION AND VENUE

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

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, Lupin 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, Lupin Inc., with the assistance and/or at the direction of Lupin 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 Lupin's Naproxen and Esomeprazole Magnesium Delayed-Release Tablets and to seek approval from the FDA to sell Lupin's Naproxen and Esomeprazole Magnesium Delayed-Release Tablets throughout the United States, including within this judicial district.

21. On information and belief, both Lupin Ltd. and Lupin Inc. have been and are engaging in activities directed toward infringement of the '907 patent and the '285 patent (collectively "the patents-in-suit") by, *inter alia*, preparing and/or submitting ANDA No. 202654 seeking FDA approval to market Lupin's Naproxen and Esomeprazole Magnesium Delayed-Release Tablets. As stated in the 2011 ANDA Notice Letter and the 2014 ANDA Notice Letter, Defendants intend to market Lupin's Naproxen and Esomeprazole Magnesium Delayed-Release Tablets before expiration of the patents-in-suit. On information and belief and as stated in the

2011 ANDA Notice Letter and the 2014 ANDA Notice Letter, the FDA received ANDA No. 202654 from Lupin Ltd.

22. In its 2011 ANDA Notice Letter and 2014 ANDA Notice Letter, Lupin Ltd. stated that the name and address of its agent in the United States authorized to accept service of process for Defendants for purposes of an infringement action based upon its 2011 ANDA Notice Letter and 2014 ANDA Notice Letter is Robert F. Green of Leydig, Voit and Mayer Ltd., 180 North Stetson, Suite 4900, Chicago, IL 60601.

23. Upon information and belief, Lupin Ltd. is subject to personal jurisdiction in New Jersey because, among other things, Lupin Ltd., itself and through its wholly-owned subsidiary Lupin Inc., has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court in New Jersey. Upon information and belief, Lupin Ltd., itself and through its wholly-owned subsidiary Lupin Inc., manufactures, markets, and/or sells generic drugs throughout the United States and within the State of New Jersey, and therefore transacts business within the State of New Jersey related to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within the State of New Jersey. Lupin Ltd. is subject to personal jurisdiction in New Jersey on the basis of its inducement of and/or contribution to Lupin Inc.'s acts of infringement in New Jersey. In addition, Lupin Ltd. is subject to personal jurisdiction in New Jersey because, on information and belief, it controls and dominates Lupin Inc., and therefore the activities of Lupin Inc. in this jurisdiction are attributed to Lupin Ltd.

24. On information and belief, this Court has personal jurisdiction over Lupin Inc. because Lupin Inc. has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court in New Jersey. Upon

information and belief, Lupin Inc. manufactures, markets, and/or sells generic drugs throughout the United States and within the State of New Jersey and therefore transacts business within the State of New Jersey related to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within the State of New Jersey.

25. On information and belief, Lupin Inc. is registered to do business in New Jersey (business identification number 0100953673) and has appointed National Registered Agents, Inc., located at 100 Canal Pointe Blvd., Suite 212, Princeton, NJ 08540, as its registered agent for the receipt of service of process.

26. On information and belief, both Lupin Ltd. and Lupin Inc. have previously been sued in this district and have not challenged personal jurisdiction. *See, e.g., AstraZeneca AB et al. v. Lupin Ltd. and Lupin Pharm. Inc*., Civ. Action No. 3:09-cv-05404-JAP-TJB (D.N.J.); *Abbott Labs and Laboratories Fournier S.A. v. Lupin Ltd. and Lupin Pharm. Inc., Civ. Action* No. 2:09-cv-01007-GEB-MCA (D.N.J.); *Abbott Labs and Laboratories Fournier S.A. v. Lupin Ltd. and Lupin Pharm. Inc.*, Civ. Action No. 2:10-cv-01578-DMC-JAD (D.N.J.); *Tibotec Inc. and Tibotec Pharm. v. Lupin Ltd., et al.*, Civ. Action No. 2:10-cv-05954-WHW-MAS (D.N.J.); *Novartis Corp. et al. v. Lupin Ltd. and Lupin Pharm. Inc*., Civ. Action No. 2:06-cv-05954-GEB-ES (D.N.J.); and *Elan Int'l. Ltd. and Fournier Laboratories Ireland Ltd*., Civ. Action No. 2:09-cv-01008-GEB-MCA (D.N.J.).

27. On information and belief, Lupin Ltd. and Lupin Inc. have availed themselves of the jurisdiction of this court by initiating litigation in this district. *See, e.g., Lupin Ltd. and Lupin Pharm. Inc. v. Merck, Sharp & Dohme Corp*., Civ. Action No. 3:10-CV-683-JAP-TJB (D.N.J.).

28. 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. 202654, this Court has personal jurisdiction over Defendants. These activities satisfy due process and confer personal jurisdiction over Defendants consistent with New Jersey law.

29. 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))

30. Plaintiffs incorporate by reference paragraphs 1–29 of this Complaint as if fully set forth herein.

31. By their 2011 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."

32. On information and belief, at the time the 2011 ANDA Notice Letter was served, Defendants were aware of the statutory provisions and regulations referred to in paragraph 31, above.

33. Defendants' 2011 ANDA Notice Letter, which is required by statute and regulation to provide a full and detailed explanation regarding non-infringement (see paragraph 89 above), does not allege and does not address non-infringement of claims 1, 5, 9–17, 22–24, 28–29, 32–35, 37, 41–42, 45–48, and 50–55 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, and 50–55 of the '907 patent in the 2011 ANDA Notice Letter, Defendants admit that Lupin's Naproxen and Esomeprazole Magnesium Delayed-Release Tablets meet all limitations in claims 1, 5, 9–17, 22–24, 28–29, 32–35, 37, 41–42, 45–48, and 50–55 of the '907 patent.

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 Lupin'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, Lupin'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, Lupin'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 non-steroidal anti-inflammatory drugs (NSAIDS) by inhibiting gastric acid secretion. On information and belief, Defendants are aware that Lupin's Naproxen and Esomeprazole Magnesium Delayed-Release Tablets are so made or so adapted. On information and belief, Defendants are aware that Lupin'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 1–29 of this Complaint as if fully set forth herein.

40. By their 2014 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 '285 patent. This statutory section requires, *inter alia*, certification by the ANDA applicant that the subject patent, here the '285 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."

41. On information and belief, at the time the 2014 ANDA Notice Letter was served, Defendants were aware of the statutory provisions and regulations referred to in paragraph 40, above.

42. Defendants' 2014 ANDA Notice Letter, which is required by statute and regulation to provide a full and detailed explanation regarding non-infringement (see paragraph 98 above), does not allege and does 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 the 2014 ANDA Notice Letter, Defendants admit that Lupin's Naproxen and Esomeprazole Magnesium Delayed-Release Tablets meet all limitations in claims 1–4 of the '285 patent.

43. Defendants have infringed one or more claims of the '285 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 '285 patent.

44. On information and belief, the commercial manufacture, use, sale, offer for sale, or importation into the United States of Lupin's Naproxen and Esomeprazole Magnesium Delayed-Release Tablets, if approved by the FDA, will constitute direct infringement of claims 1–4 of the '285 patent.

45. On information and belief, Lupin'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 non-steroidal anti-inflammatory drugs (NSAIDS) by inhibiting gastric acid secretion. On information and belief, Defendants are aware that Lupin's Naproxen and Esomeprazole Magnesium Delayed-Release Tablets are so made or so adapted. On information and belief, Defendants are aware that Lupin's Naproxen and Esomeprazole Magnesium Delayed-Release Tablets, if approved, will be used in contravention of Plaintiffs' rights under the '285 patent.

46. 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. 202654 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. 202654 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. 202654 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: December 3, 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 Third Amended Complaint for Patent Infringement and supporting documents were caused to be served on December 3, 2014, by electronic mail and/or the ECF system upon all counsel of record.

Dated: December 3, 2014

By: *s/ John E. Flaherty*

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