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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ASTRAZENECA AB, ASTRAZENECA LP, KBI-E INC., and POZEN, INC., Plaintiffs, v. DR. REDDY'S LABORATORIES INC. and DR. REDDY'S LABORATORIES LTD., Defendants.	Civil Action No. **COMPLAINT FOR PATENT INFRINGEMENT AND CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.**

Plaintiffs AstraZeneca AB, AstraZeneca LP, KBI-E 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:

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") Nos. 202461 and 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 AstraZeneca AB ("AZ AB") is a corporation operating and existing under the laws of Sweden, with its principal place of business at S-151 85 Södertälje, Sweden.

3. Plaintiff AstraZeneca LP ("AZ LP") is a limited partnership operating and existing under the laws of the State of Delaware, with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19803.

4. Plaintiff KBI-E Inc. ("KBI-E") is a corporation operating and existing under the laws of the State of Delaware, with its principal place of business in Wilmington, Delaware.

5. 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.

6. 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).

7. 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.

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

BACKGROUND

The NDA

9. AZ LP 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.

10. VIMOVO® is a prescription drug 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®.

The Patent-In-Suit

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 A.

12. Pozen owns the '285 patent by assignment from the inventor John R. Plachetka. AZ AB is Pozen's exclusive licensee under the '285 patent. The '285 patent will expire on May 31, 2022.

13. The '285 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, or sale of the Vimovo® drug product.

14. Accordingly, pursuant to 21 U.S.C. § 355(c)(2), Pozen and the AstraZeneca Plaintiffs are submitting patent information for the '285 patent to the FDA in connection with its NDA No. 022511 for Vimovo® drug product. The FDA is expected to publish the same in the Orange Book.

ANDA No. 202461

15. On information and belief, Defendants filed ANDA No. 202461 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 No. 202461 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.

16. By letters dated March 11, 2011 (the "ANDA Notice Letter dated March 11, 2011") and September 19, 2011 (the "ANDA Notice Letter dated September 19, 2011"), Defendants notified Plaintiffs that Defendants had filed ANDA No. 202461 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.

ANDA No. 204206

17. 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 ("ANDA No. 204206 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.

18. By letter dated November 20, 2012 (the "ANDA Notice Letter dated November 20, 2012"), 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

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

20. 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.

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

22. 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.

23. 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.

24. 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.

25. 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.

26. On information and belief and as stated in the ANDA Notice Letters, the FDA received ANDA Nos. 202461 and 204206 from Dr. Reddy's Ltd. and Dr. Reddy's Inc.

27. In its ANDA Notice Letters dated March 11, 2011, and November 20, 2012, Defendants 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 ANDA Notice Letter is Lee Banks, Dr. Reddy's Laboratories Inc., 200 Somerset Corporate Blvd., Floor

7, Bridgewater, New Jersey 08807. In its ANDA Notice Letter dated September 19, 2011, Defendants 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 ANDA Notice Letter is Alan H. Pollack, Esq., Budd Larner, P.C., 150 John F. Kennedy Parkway, Short Hills, NJ 07078

28. By naming Lee Banks, Dr. Reddy's Laboratories Inc., 200 Somerset Corporate Blvd., Floor 7, Bridgewater, New Jersey 08807 and Alan H. Pollack, Esq., Budd Larner, P.C., 150 John F. Kennedy Parkway, Short Hills, NJ 07078 as their agents in their ANDA Notice Letters, Defendants have consented to jurisdiction in the State of New Jersey for this action.

29. 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 Laboratories Inc., 200 Somerset Corporate Blvd., Floor 7, Bridgewater, New Jersey 08807 and Alan H. Pollack, Esq., Budd Larner, P.C., 150 John F. Kennedy Parkway, Short Hills, NJ 07078 as its agents 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.

30. 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.*, Civil Action No. 3:11-cv-02317-JAP-DEA (D.N.J.); *AstraZeneca AB et al. v. Dr. Reddy's Laboratories, Inc. et al.*, Civil Action No. 3:13-cv-00091-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.).

31. 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 (Jul. 11, 2008).

32. 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.).

33. 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.

34. 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: ANDA NO. 202461 INFRINGEMENT OF THE '285 PATENT UNDER 35 U.S.C. § 271(e)(2)(A)

35. Plaintiffs incorporate by reference paragraphs 1-34 of this Complaint as if fully set forth herein.

36. By their ANDA Notice Letter dated March 11, 2011, 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."

37. On information and belief, at the time the ANDA Notice Letter dated March 11, 2011, was served, Defendants were aware of the statutory provisions and regulations referred to in paragraph 36, above.

38. The ANDA Notice Letter dated March 11, 2011, evidences Defendants' intent to market its ANDA No. 202461 Product before the expiration of U.S. Patent No. 6,875,872 (the "'872 patent"). The '872 patent expires on November 27, 2014.

39. Defendants' ANDA No. 202461 received tentative approval on August 12, 2013, and final approval on September 27, 2013.

40. Defendants have infringed one or more claims of the '285 patent under 35 U.S.C. § 271(e)(2), by filing their ANDA No. 202461 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.

41. On information and belief, the ANDA No. 202461 Product contains the pharmaceutical 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 No. 202461 Product is so made or so adapted. Upon information and belief, Defendants are aware that the ANDA No. 202461 Product will be used in contravention of Plaintiffs' rights under the '285 patent.

42. On information and belief, the commercial manufacture, use, sale, offer for sale, or importation into the United States of Dr. Reddy's ANDA No. 202461 Product, will constitute infringement of the '285 patent.

43. Because Defendants' ANDA No. 202461 has received final approval, Defendants can now market their ANDA No. 202461 Product. Unless enjoined, Plaintiffs believe Defendants will market their ANDA No. 202461 Product before the expiration of the '285 patent.

44. A definite and concrete, real and substantial, justiciable controversy exists between Plaintiffs and Defendants concerning Defendants' ANDA No. 202461 Product's infringement of the '285 patent.

45. 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: ANDA NO. 204206 INFRINGEMENT OF THE '285 PATENT UNDER 35 U.S.C. § 271(e)(2)(A)

46. Plaintiffs incorporate by reference paragraphs 1-34 of this Complaint as if fully set forth herein.

47. On information and belief, the making, using, selling, and/or offering for sale in the United States of Defendants' pharmaceutical compositions in unit dosage form comprising esomeprazole and naproxen described in Defendants' ANDA No. 204206 infringes the '285 patent.

48. Defendants have infringed the '285 patent under 35 U.S.C. § 271 (e)(2) 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.

49. On information and belief, the ANDA No. 204206 Product contains the pharmaceutical 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 No. 204206 Product is so made or so adapted. Upon information and belief, Defendants are aware

that the ANDA No. 204206 Product, if approved, will be used in contravention of Plaintiffs' rights under the '285 patent.

50. 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.

51. 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).

52. On information and belief, the manufacture, use, and sale of the ANDA No. 204206 Product, if approved by the FDA, will infringe the '285 patent claims.

53. 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 patent-in-suit are valid and enforceable;

B. A judgment that the ANDA No. 202461 Product infringes one or more claims of the patent-in-suit under 35 U.S.C. § 271(e)(2)(A);

C. A judgment that the ANDA No. 204206 Product infringes one or more claims of the patent-in-suit under 35 U.S.C. § 271(e)(2)(A);

D. A judgment providing that, pursuant to 35 U.S.C. § 271(e)(4)(A), FDA approval of Defendants' ANDA No. 202461 shall be withdrawn and the effective date of any FDA approval of Defendants' ANDA No. 202461 shall be no earlier than the later of the expiration date of the patent-in-suit or any later exclusivity to which Plaintiffs are or become entitled;

E. 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 patent-in-suit or any later exclusivity to which Plaintiffs are or become entitled;

F. 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. 202461 no earlier than the later of the expiration date of the patent-in-suit or any later exclusivity to which Plaintiffs are or become entitled;

G. 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 patent-in-suit 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: October 23, 2013

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:

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. LUPIN LTD., et al., C.A. No. 3:11-cv-04275-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. MYLAN PHARMACEUTICALS et al., C.A. No. 3:13-cv-04022-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: October 23, 2013

Respectfully Submitted,

By: *s/ John E. Flaherty*

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