John E. Flaherty
Jonathan M.H. Short
Carissa L. Rodrigue
McCARTER & ENGLISH, LLP
Four Gateway Center
100 Mulberry Street
Newark, New Jersey 07102
(973) 622-4444

Counsel for Plaintiffs AstraZeneca AB, AstraZeneca LP, and Pozen Inc.

Mary W. Bourke
Kristen Healey Cramer
Dana K. Severance
CONNOLLY BOVE LODGE & HUTZ LLP
1007 N. Orange Street
P.O. Box 2207
Wilmington, DE 19899
(302) 658-9141

William E. McShane
R. James Balls
CONNOLLY BOVE LODGE & HUTZ LLP
1875 Eye Street, NW
Suite 1100
Washington, DC 20006
(202) 572-0335

Of Counsel for Plaintiffs AstraZeneca AB, AstraZeneca LP, and Pozen Inc.

Stephen M. Hash
VINSON & ELKINS LLP
2801 Via Fortuna
Suite 100
Austin, TX 78746-7568
(512) 542-8504

Of Counsel for Plaintiff Pozen Inc.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ASTRAZENECA AB, ASTRAZENECA LP, and POZEN INC.,	CIVIL ACTION NO.
Plaintiffs,	**COMPLAINT FOR PATENT INFRINGEMENT**
v.	
DR. REDDY'S LABORATORIES INC. and DR. REDDY'S LABORATORIES LTD.,	
Defendants.	

Plaintiffs AstraZeneca AB, AstraZeneca LP, 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 a Abbreviated New Drug Application ("ANDA") No. 022511 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 the 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 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.

5. 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).

6. 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.

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

BACKGROUND

The NDA

8. 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.

9. 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

10. 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.

11. Pozen owns the '907 patent by assignment from the inventor. AZ AB is Pozen's exclusive licensee under the '907 patent.

The ANDA

12. 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, importation, offer for sale, and sale in the United States of naproxen and esomeprazole magnesium delayed release tablets containing 375 mg or 500 mg naproxen and 20.71 mg amorphous 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.

13. By letter dated March 11, 2011 (the "ANDA Notice Letter"), 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.

JURISDICTION AND VENUE

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

15. 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.

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

17. 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.

18. 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.

19. 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.

20. On information and belief, both Dr. Reddy's Ltd. and Dr. Reddy's Inc. participated in the preparation and/or filing of ANDA No. 202461.

21. On information and belief and as stated in the ANDA Notice Letter, the FDA received ANDA No. 202461 from Dr. Reddy's Ltd. and Dr. Reddy's Inc.

22. In its ANDA Notice Letter, 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 Inc., 200

Somerset Corporate Blvd., Floor 7, Bridgewater, New Jersey 08807.

23. By naming Lee Banks, Dr. Reddy's 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.

24. 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. 202461; 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.

25. 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-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.).

26. 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).

27. 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.).

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. 202461, 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. On information and belief, Defendants submitted ANDA No. 202461 to the FDA under 21 U.S.C. § 355(j) in order to obtain approval to market the Dr. Reddy's Naproxen and Esomeprazole Magnesium Delayed Release Tablets in the United States before the expiration of the '907 patent.

32. By its ANDA Notice Letter, Defendants informed Plaintiffs that they had submitted to the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), a certification alleging that

the '907 patent is invalid, unenforceable, or will not be infringed by the commercial manufacture, use, sale, offer for sale, or importation into the United States of the Dr. Reddy's Naproxen and Esomeprazole Magnesium Delayed Release Tablets.

33. Under 35 U.S.C. § 271(e)(2)(A), the submission by Defendants to the FDA of ANDA No. 202461 to obtain approval for the commercial manufacture, use, sale, offer for sale, or importation into the United States of the Dr. Reddy's Naproxen and Esomeprazole Magnesium Delayed Release Tablets before the expiration of the '907 patent constitutes infringement of one or more claims of the '907 patent, either literally or under the doctrine of equivalents.

34. 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.

35. On information and belief, the Dr. Reddy's Naproxen and Esomeprazole Magnesium Delayed Release Tablets, if approved by the FDA, 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 and encouragement, and will be uses that Defendants know or should know will occur. 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.

36. 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 '907 patent are valid and enforceable;

B. A judgment that the submission of ANDA No. 202461 by Defendants infringes one or more claims of the '907 patent 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. 202461 shall be no earlier than the expiration date of the '907 patent and any additional periods of exclusivity;

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. 202461 prior to the expiration of the '907 patent and any additional periods of exclusivity;

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: April 21, 2011

By: S/John E. Flaherty

John E. Flaherty
Jonathan M.H. Short
Carissa L. Rodrigue
McCARTER & ENGLISH, LLP
Four Gateway Center
100 Mulberry Street
Newark, New Jersey 07102
(973) 622-4444

Counsel for Plaintiffs AstraZeneca AB, AstraZeneca LP, and Pozen Inc.

Mary W. Bourke
Kristen Healey Cramer
Dana K. Severance
CONNOLLY BOVE LODGE & HUTZ LLP
1007 N. Orange Street
P.O. Box 2207
Wilmington, DE 19899
(302) 658-9141

William E. McShane
R. James Balls
CONNOLLY BOVE LODGE & HUTZ LLP
1875 Eye Street, NW
Suite 1100
Washington, DC 20006
(202) 572-0335

Of Counsel for Plaintiffs AstraZeneca AB, AstraZeneca LP, and Pozen Inc.

Stephen M. Hash
VINSON & ELKINS LLP
2801 Via Fortuna
Suite 100
Austin, TX 78746-7568
(512) 542-8504

Of Counsel for Plaintiff Pozen 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 related to the subject matter of the following actions:

- *ASTRAZENECA AB, et al. v. RANBAXY PHARMACEUTICALS, INC., et al.*, Civil Action No. 3:05-cv-05553-JAP-TJB (D.N.J.).
- *ASTRAZENECA AB, et al. v. DR. REDDY'S LABORATORIES, LTD., et al*., Civil Action No. 3:08-cv-00328-JAP-TJB (D.N.J.).
- *ASTRAZENECA AB, et al. v. TEVA PARENTERAL MEDICINES, INC., et al*., Civil Action No. 3:08-cv-02014-JAP-TJB (D.N.J.).
- *IVAX PHARMACEUTICALS, INC. v. ASTRAZENECA AB, et al*., Civil Action No. 3:08-cv-02165-JAP-TJB (D.N.J.).
- *DR. REDDY'S LABORATORIES, LTD., et al. v. ASTRAZENECA AB, et al*., Civil Action No. 3:08-cv-02496-JAP-TJB (D.N.J.).
- *ASTRAZENECA AB, et al. v. IVAX CORPORATION, et al*., Civil Action No. 3:08-cv-04993-JAP-TJB (D.N.J.).
- *ASTRAZENECA AB, et al. v. SANDOZ, INC.*, Civil Action No. 3:09-cv-00199-JAP-TJB (D.N.J.).
- *ASTRAZENECA AB, et al. v. LUPIN LTD., et al.,* Civil Action No. 3:09-cv-05404-JAP-TJB (D.N.J.).
- *ASTRAZENECA AB, et al. v. SUN PHARMA GLOBAL FZE, et al*., Civil Action No. 3:10-cv-01017-JAP -TJB (D.N.J.).
- *ASTRAZENECA AB, et al. v. HANMI USA, INC., et al*., Civil Action No. 3:11-cv-00760-JAP -TJB (D.N.J.).

The foregoing cases involve Nexium®, a product marketed by AstraZeneca that contains an esomeprazole magnesium formulation. VIMOVO®, the product at issue in the immediate case, also contains an esomeprazole magnesium formulation. The Nexium® cases have been assigned to Hon. Joel A. Pisano, U.S.D.J. The DRL defendants in this case are parties to certain of the Nexium® cases. AstraZeneca respectfully requests that this case likewise be assigned to Judge Pisano due to his familiarity with the subject matter.

Dated: April 21, 2011

By: S/John E. Flaherty

John E. Flaherty
Jonathan M.H. Short
Carissa L. Rodrigue
McCARTER & ENGLISH, LLP
Four Gateway Center
100 Mulberry Street
Newark, New Jersey 07102
(973) 622-4444

Counsel for Plaintiffs AstraZeneca AB, AstraZeneca LP, and Pozen Inc.

Mary W. Bourke
Kristen Healey Cramer
Dana K. Severance
CONNOLLY BOVE LODGE & HUTZ LLP
1007 N. Orange Street
P.O. Box 2207
Wilmington, DE 19899
(302) 658-9141

William E. McShane
R. James Balls
CONNOLLY BOVE LODGE & HUTZ LLP
1875 Eye Street, NW
Suite 1100
Washington, DC 20006
(202) 572-0335

Of Counsel for Plaintiffs AstraZeneca AB, AstraZeneca LP, and Pozen Inc.

Stephen M. Hash
VINSON & ELKINS LLP
2801 Via Fortuna
Suite 100
Austin, TX 78746-7568
(512) 542-8504

Of Counsel for Plaintiff Pozen Inc.