

John E. Flaherty  
Ravin R. Patel  
McCARTER & ENGLISH LLP  
Four Gateway Center  
100 Mulberry Street  
Newark, New Jersey 07102  
(973) 622-4444

*Counsel for Plaintiffs AstraZeneca AB,  
Aktiebolaget Hassle, AstraZeneca LP,  
and Zeneca Inc.*

Einar Stole  
Edward H. Rippey  
COVINGTON & BURLING LLP  
One CityCenter, 850 Tenth St. NW  
Washington, DC 20001  
(202) 662-6000

*Of Counsel for Plaintiffs*

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

ASTRAZENECA AB, AKTIEBOLAGET  
HÄSSLE, ASTRAZENECA LP, and  
ZENECA INC.,

Plaintiffs,

v.

LUPIN LTD. and LUPIN  
PHARMACEUTICALS INC.,

Defendants.

Civil Action No. \_\_\_\_\_

**COMPLAINT FOR  
PATENT INFRINGEMENT  
AND CERTIFICATION PURSUANT TO  
LOCAL CIVIL RULE 11.2**

Plaintiffs AstraZeneca AB, Aktiebolaget Hassle, AstraZeneca LP, and Zeneca Inc.  
(collectively, "Plaintiffs"), by their attorneys, for their 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. 207432 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’ NEXIUM 24HR<sup>®</sup> 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 Aktiebolaget Hässle (“Hässle”) is a corporation organized and existing under the laws of Sweden, having its principal place of business at Mölndal, Sweden

4. 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. AZ LP holds an approved New Drug Application from the FDA for an esomeprazole magnesium formulation that it sells under the name NEXIUM 24HR<sup>®</sup>.

5. Plaintiff Zeneca Inc. (“Zeneca”) is a Delaware corporation having its principal place of business at Wilmington, Delaware. Zeneca has exclusive rights in the United States to market and sell products covered by United States Patent Nos. 6,369,085 and 7,411,070 (collectively, the “Patents-in-suit”).

6. Upon 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. Upon information and belief, Lupin Ltd. is in the business of, inter alia, developing, manufacturing, and obtaining regulatory approval of generic copies of branded pharmaceutical products throughout the United States, including within this district.

7. Upon 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. Upon information and belief, Lupin Inc. is in the business of, inter alia, selling and distributing generic copies of branded pharmaceutical products throughout the United States, including within this district.

8. On information and belief, Lupin Inc. is a wholly-owned subsidiary of Lupin Ltd.

## **BACKGROUND**

### **The NDA**

9. AZ LP is the holder of New Drug Application (“NDA”) No. 204655 for NEXIUM 24HR® Esomeprazole Magnesium Delayed-Release Capsules, 20 mg. NEXIUM 24HR® is an over the counter drug approved for the treatment of frequent heartburn (2 or more days a week). Esomeprazole magnesium trihydrate is the active ingredient in NEXIUM 24HR®.

### **The Patents-in-Suit**

10. United States Patent No. 6,369,085 (“the ’085 patent”), entitled “Form of S-Omeprazole,” was duly and legally issued by the United States Patent and Trademark Office (“the USPTO”) on April 9, 2002 to AZ AB, upon assignment from the inventors Hanna Cotton, Anders Kronstrom, Anders Mattson, and Eva Möller. The ’085 patent claims, inter alia, magnesium salts of esomeprazole trihydrate, pharmaceutical compositions comprising the

claimed salts, methods of treatment using the claimed salts, and processes for preparing the claimed salts. A true and correct copy of the '085 patent is attached as Exhibit A.

11. Plaintiff AZ AB has been and still is the owner of the '085 patent. The '085 patent will expire on May 25, 2018, and pediatric exclusivity relating to the '085 patent expires on November 25, 2018.

12. United States Patent No. 7,411,070 ("the '070 patent"), entitled "Form of S-omeprazole," was duly and legally issued by the USPTO on August 12, 2008 to AZ AB upon assignment from inventors Hanna Cotton, Anders Kronstrom, Anders Mattson, and Eva Moller. The claims of the '070 patent are directed to, inter alia, magnesium salts of esomeprazole trihydrate and processes for preparing the claimed salts. A true and correct copy of the '070 patent is attached as Exhibit B.

13. Plaintiff AZ AB has been and still is the owner of the '070 patent. The '070 patent will expire on May 25, 2018, and pediatric exclusivity relating to the '070 patent expires on November 25, 2018.

#### **The ANDA**

14. On information and belief, Lupin Ltd. filed ANDA No. 207432 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 esomeprazole magnesium delayed-release capsules, 20 mg ("Lupin's Esomeprazole Magnesium Delayed-Release Capsules"), which are generic versions of Plaintiffs' NEXIUM 24HR<sup>®</sup> Esomeprazole Magnesium Delayed-Release Capsules, in a 20 mg dosage form.

15. By letter dated June 26, 2015 (the "ANDA Notice Letter"), Lupin Ltd. notified Plaintiffs that Lupin Ltd. had filed ANDA No. 207432 seeking approval to market Lupin's

Esomeprazole Magnesium Delayed-Release Capsules and that Lupin Ltd. was providing information to Plaintiffs pursuant to 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95.

16. On information and belief, Lupin Inc. sells products manufactured by Lupin Ltd. in New Jersey and throughout the United States.

### **JURISDICTION AND VENUE**

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

18. Upon information and belief, 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.

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

20. On information and belief, both Lupin Ltd. and Lupin Inc. have been and are engaging in activities directed toward infringement of the "Patents-in-suit by, inter alia, preparing and/or submitting ANDA No. 207432 seeking FDA approval to market Lupin's Esomeprazole Magnesium Delayed Release Capsules. As stated in the ANDA Notice Letter, Defendants intend to market Lupin's Esomeprazole Magnesium Delayed Release Capsules before expiration of the Patents-in-suit. On information and belief and as stated in the ANDA Notice Letter, the FDA received ANDA No. 207432 from Lupin Ltd.

21. In its 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 ANDA Notice Letter is Clifford Katz, Kelley Drye & Warren LLP, 101 Park Avenue, New York, NY 10178.

22. 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.

23. 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.

24. 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.

25. 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. et al*, Civ. Action No. 3:11-cv-04275-JAP-DEA (D.N.J.); *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 Laboratoires 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 Laboratoires 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. v. Lupin Ltd. and Lupin Pharm. Inc.*, Civ. Action No. 2:09-cv-01008-GEB-MCA (D.N.J.).

26. 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.).

27. 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. 207432, this Court has

personal jurisdiction over Defendants. These activities satisfy due process and confer personal jurisdiction over Defendants consistent with New Jersey law.

28. 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 1: INFRINGEMENT OF THE '085 PATENT**

29. Plaintiffs incorporate by reference paragraphs 1-28 of this Complaint as if fully set forth herein.

30. On information and belief, Defendants submitted ANDA No. 207432 to the FDA under 21 U.S.C. § 355(j) in order to obtain approval to market Lupin's Esomeprazole Magnesium Delayed-Release Capsules in the United States before the expiration of the '085 patent.

31. By their 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 '085 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 Lupin's Esomeprazole Magnesium Delayed-Release Capsules.

32. Under 35 U.S.C. § 271(e)(2)(A), the submission by Defendants to the FDA of ANDA No. 207432 to obtain approval for the commercial manufacture, use, sale, offer for sale, or importation into the United States of Lupin's Esomeprazole Magnesium Delayed-Release Capsules before the expiration of the '085 patent constitutes infringement of one or more claims of the '085 patent, either literally or under the doctrine of equivalents.

33. On information and belief, Lupin's Esomeprazole Magnesium Delayed-Release Capsules, if approved by the FDA, will be prescribed and administered to human patients in a



therapeutically effective amount to inhibit gastric acid secretion and for the treatment of gastrointestinal inflammatory disease. On information and belief, this administration will occur at Defendants' active behest and with their intent, knowledge, and encouragement. On information and belief, Defendants will actively encourage, aid and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '085 patent.

34. The ANDA Notice Letter, which is required by statute and regulation to provide a full and detailed explanation regarding all defenses, does not allege invalidity or unenforceability of any claims of the '085 patent. By not alleging invalidity or unenforceability, Defendants effectively admit that the '085 patent is both valid and enforceable.

35. 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 2: INFRINGEMENT OF THE '070 PATENT**

36. Plaintiffs incorporate by reference paragraphs 1-28 of this Complaint as if fully set forth herein.

37. On information and belief, Defendants submitted ANDA No. 207432 to the FDA under 21 U.S.C. § 355(j) in order to obtain approval to market Lupin's Esomeprazole Magnesium Delayed-Release Capsules in the United States before the expiration of the '070 patent.

38. By their 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 '070 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 Lupin's Esomeprazole Magnesium Delayed-Release Capsules.

39. Under 35 U.S.C. § 271(e)(2)(A), the submission by Defendants to the FDA of ANDA No. 207432 to obtain approval for the commercial manufacture, use, sale, offer for sale, or importation into the United States of Lupin's Esomeprazole Magnesium Delayed-Release Capsules before the expiration of the '070 patent constitutes infringement of one or more claims of the '070 patent, either literally or under the doctrine of equivalents.

40. On information and belief, Lupin's Esomeprazole Magnesium Delayed-Release Capsules, if approved by the FDA, will be prescribed and administered to human patients in a therapeutically effective amount to inhibit gastric acid secretion and for the treatment of gastrointestinal inflammatory disease. On information and belief, this administration will occur at Defendants' active behest and with their intent, knowledge, and encouragement. On information and belief, Defendants will actively encourage, aid and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '070 patent.

41. The ANDA Notice Letter, which is required by statute and regulation to provide a full and detailed explanation regarding all defenses, does not allege invalidity or unenforceability of any claims of the '070 patent. By not alleging invalidity or unenforceability, Defendants effectively admit that the '070 patent is both valid and enforceable.

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.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs respectfully request the following relief:

- A. A judgment that the claims of the '085 and '070 patents are valid and enforceable;
- B. A judgment that the submission of ANDA No. 207432 by Defendants infringes one or more claims of each of the '085 and '070 patents under 35 U.S.C. § 271(e)(2);
- 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. 207432 shall be no earlier than the latest expiration date of the Patents-in-suit 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 esomeprazole magnesium product described in Defendants' ANDA No. 207432 prior to the latest expiration of the Patents-in-suit 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: August 7, 2015

Respectfully submitted,

s/ John E. Flaherty

John E. Flaherty  
Ravin R. Patel  
McCARTER & ENGLISH LLP  
Four Gateway Center  
100 Mulberry Street  
Newark, New Jersey 07102  
(973) 622-4444

*Counsel for Plaintiffs AstraZeneca  
AB, Aktiebolaget Hassle,  
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Einar Stole  
Edward H. Rippey  
COVINGTON & BURLING LLP  
One CityCenter, 850 Tenth St. NW

Washington, DC 20001  
(202) 662-6000  
*Of Counsel for Plaintiffs*

**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, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, KBI INC., and KBI-E INC. v. MYLAN LABORATORIES LTD. and MYLAN, INC.*, C.A. No. 3:12-cv- 01378-MLC-TJB (District of New Jersey)
- *ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, KBI INC., and KBI-E INC. v. WATSON LABORATORIES, INC. – FLORIDA*, C.A. No. 3:13-cv-01669- MLC-TJB (District of New Jersey)
- *ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, KBI INC., and KBI-E INC. v. WOCKHARDT LIMITED and WOCKHARDT USA LLC*, C.A. No. 3:13- cv-04854-MLC-TJB (District of New Jersey)
- *ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, KBI INC., and KBI-E INC. v. AUROBINDO PHARMA LIMITED and AUROBINDO PHARMA USA Inc.*, C.A. No. 3:13-cv-7298-MLC-TJB (District of New Jersey)
- *ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, KBI INC., and KBI-E INC. v. KREMERS URBAN PHARMACEUTICALS, KREMERS URBAN DEVELOPMENT CO., and KREMERS URBAN LLC*, C.A. No. 3:13-cv-7299-MLC-TJB (District of New Jersey)
- *ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, KBI INC., and KBI-E INC. v. ZYDUS PHARMACEUTICALS (USA) INC., and CADILA HEALTHCARE LTD. (dba ZYDUS CADILA)*, C.A. No. 3:14-cv-4782-MLC-TJB (District of New Jersey)
- *ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, and ZENECA INC. v. ACTAVIS LABORATORIES FL, INC., and ACTAVIS PHARMA, INC.*, C.A. No. 3:14-cv-7263-MLC-TJB (District of New Jersey)
- *ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, and ZENECA INC. v. ACTAVIS LABORATORIES FL, INC., and ACTAVIS PHARMA, INC.*, C.A. No. 3:14-cv-7870-MLC-TJB (District of New Jersey)
- *ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, and ZENECA INC. v. ANDRX LABS, LLC, ANDRX CORPORATION, and ACTAVIS, INC.*, C.A. No. 3:14-cv-8030-MLC-TJB (District of New Jersey)
- *ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, and ZENECA INC. v. PERRIGO COMPANY PLC, PERRIGO COMPANY, L. PERRIGO COMPANY, and PADDOCK LABORATORIES, LLC*, C.A. No. 3:15-cv-1057-MLC-TJB (District of New Jersey)

- *ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, and ZENECA INC. v. HEC PHARM CO., LTD., HEC PHARM GROUP, and HEC PHARM USA INC., C.A. No. 3:15-cv-06025-MLC-TJB (District of New Jersey)*

Dated: August 7, 2015

Respectfully submitted,

*s/ John E. Flaherty*

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John E. Flaherty  
Ravin R. Patel  
McCARTER & ENGLISH LLP  
Four Gateway Center  
100 Mulberry Street  
Newark, New Jersey 07102  
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