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

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

Plaintiffs,

v.

ANDRX LABS, LLC, ANDRX CORPORATION, and ACTAVIS, INC.,

Defendants.

Civil Action No. _____

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

Plaintiffs AstraZeneca AB, Aktiebolaget Hässle, AstraZeneca LP, and Zeneca Inc. (collectively, "Plaintiffs"), by their attorneys, for their Complaint against Andrx Labs, LLC ("Andrx Labs"), Andrx Corporation ("Andrx Corp."), and Actavis, Inc. ("Actavis"), 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. 207197 filed by or for the benefit of Andrx Labs, Andrx Corp, and Actavis (collectively, "Defendants" or "Andrx") with the United States Food and Drug Administration ("FDA") for approval to market generic versions of Plaintiffs' NEXIUM 24HR® 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 Södertälje, Sweden.

3. Plaintiff Aktiebolaget 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 ("NDA") from the FDA for an esomeprazole magnesium formulation that it sells under the name NEXIUM 24HR®.

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.

6. On information and belief, Defendant Andrx Labs is a company organized and existing under the laws of Delaware with its principal place of business at 4955 Orange Drive, Davie FL 33314.

7. On information and belief, Defendant Andrx Corp. is a company organized and existing under the laws of Delaware with its principal place of business at 4955 Orange Drive, Davie FL 33314.

8. On information and belief, Defendant Actavis is a company organized and existing under the laws of Nevada with its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054, in October 2012.

9. On information and belief, Andrx Labs is a wholly-owned subsidiary of Andrx Corp.

10. On information and belief, Andrx Corp. is a wholly-owned subsidiary of Actavis.

11. On information and belief, Actavis, either directly or through one or more of its wholly owned subsidiaries and/or agents, including Andrx Labs and Andrx Corp., 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.

12. On information and belief, Andrx Labs and Andrx Corp., with the assistance and/or at the direction of Actavis, develop, manufacture, distribute, market, offer to sell, and sell generic drug products for sale and use throughout the United States, including within this judicial district.

## BACKGROUND

### The NDA

13. AZ LP is the holder of 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

14. 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.

15. 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.

16. 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.

17. 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**

18. On information and belief, Andrx Labs filed ANDA No. 207197 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 ("the ANDA Product"), which are generic versions of Plaintiffs' NEXIUM 24HR® Esomeprazole Magnesium Delayed-Release Capsules, in a 20 mg dosage form.

19. By letter dated November 12, 2014 (the "ANDA Notice Letter"), Andrx Labs notified Plaintiffs that Andrx Labs had filed ANDA No. 207197 seeking approval to market the ANDA Product and that Andrx Labs was providing information to Plaintiffs pursuant to 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95.

**JURISDICTION AND VENUE**

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

21. On information and belief, Defendant Actavis is a company organized and existing under the laws of Nevada with its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054, in October 2012.

22. On information and belief, Andrx Labs, 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 the judicial district.

23. On information and belief, Actavis, with the assistance and/or at the direction of Andrx Labs and Andrx Corp., develops, manufactures, distributes, markets, offers to sell, and sells generic drug products for sale and use throughout the United States, including within the judicial district.

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

25. On information an belief, Defendants acted in concert to develop the ANDA Product and to seek approval from the FDA to sell the ANDA Product throughout the United States, including within this judicial district.

26. On information and belief and as stated in the ANDA Notice Letter, Andrx Labs prepared and filed ANDA No. 207197.

27. On information and belief and as stated in the ANDA Notice Letter, the FDA received ANDA No. 207197 from Andrx Labs.

28. On information and belief by virtue of, inter alia, Andrx Lab's relationship with Andrx Corp. and Actavis in connection with the preparation and/or filing of ANDA No. 207197 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 general personal jurisdiction over Defendants.

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. 207197, this Court has specific 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 1: INFRINGEMENT OF THE '085 PATENT**

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

32. On information and belief, Defendants submitted ANDA No. 207197 to the FDA under 21 U.S.C. § 355(j) in order to obtain approval to market the ANDA Product in the United States before the expiration of the '085 patent.

33. 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 the ANDA Product.

34. Under 35 U.S.C. § 271(e)(2)(A), the submission by Defendants to the FDA of ANDA No. 207197 to obtain approval for the commercial manufacture, use, sale, offer for sale, or importation into the United States of the ANDA Product 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.

35. On information and belief, the ANDA Product, 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.

36. 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.

37. 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**

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

39. On information and belief, Defendants submitted ANDA No. 207197 to the FDA under 21 U.S.C. § 355(j) in order to obtain approval to market the ANDA Product in the United States before the expiration of the '070 patent.

40. 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 the ANDA Product.

41. Under 35 U.S.C. § 271(e)(2)(A), the submission by Defendants to the FDA of ANDA No. 207197 to obtain approval for the commercial manufacture, use, sale, offer for sale, or importation into the United States of the ANDA Product 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.

42. On information and belief, the ANDA Product, 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.

43. 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.

44. 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. 207197 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. 207197 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. 207197 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: December 24, 2014

Respectfully submitted,

*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 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-JAP-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- JAP-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-JAP-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-JAP-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-JAP-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-JAP-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-JAP-TJB (District of New Jersey)

Date: December 24, 2014

By: *s/ John E. Flaherty*

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