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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.

ACTAVIS LABORATORIES FL, INC., and ACTAVIS PHARMA, 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 Actavis Laboratories FL, Inc. ("Actavis Florida"), and Actavis Pharma, Inc. ("Actavis Pharma"), 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. 206364 filed by or for the benefit of Actavis Florida and Actavis Pharma (collectively, "Defendants" or "Actavis") 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 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®.

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. Upon information and belief, Actavis Florida is a corporation organized and existing under the laws of Florida, having its principal place of business at 4955 Orange Drive, Davie, Florida 33314. Upon information and belief, Actavis Florida 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, Actavis Florida is a wholly-owned subsidiary of Andrx Corporation (a Delaware corporation, having its principal place of business at 4955 Orange Drive, Davie, Florida 33314), which is a wholly-owned subsidiary of Actavis, Inc. (a Nevada corporation, having its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054).

8. On information and belief, Actavis Pharma is a corporation organized and existing under the laws of Delaware, having its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054. Upon information and belief, Actavis Pharma is in the business of, inter alia, selling and distributing generic copies of branded pharmaceutical products in New Jersey and throughout the United States, including some that are manufactured by Actavis Florida and/or for which Actavis Florida is the named applicant of the approved ANDAs.

9. On information and belief, Actavis Pharma is a wholly owned subsidiary of Actavis, Inc.

BACKGROUND

The NDA

10. 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

11. 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.

12. 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.

13. 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.

14. 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

15. On information and belief, Actavis Florida filed ANDA No. 206364 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 ("Actavis's Esomeprazole Magnesium Delayed-Release Capsules"), which are generic versions of Plaintiffs' NEXIUM 24HR® Esomeprazole Magnesium Delayed-Release Capsules, in a 20 mg dosage form.

16. By letter dated October 7, 2014 (the "ANDA Notice Letter"), Actavis Florida notified Plaintiffs that Actavis Florida had filed ANDA No. 206364 seeking approval to market Actavis's Esomeprazole Magnesium Delayed-Release Capsules and that Actavis Florida was providing information to Plaintiffs pursuant to 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95.

17. On information and belief, Actavis Florida sells products manufactured by Actavis Pharma in New Jersey and throughout the United States.

JURISDICTION AND VENUE

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

19. On information and belief, Defendant Actavis Pharma is a corporation organized and existing under the laws of Delaware, having its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

20. On information and belief, Actavis Florida, 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.

21. On information and belief, Actavis Pharma, with the assistance and/or at the direction of Actavis Florida, 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.

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

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

24. On information and belief and as stated in the ANDA Notice Letter, Actavis Florida prepared and filed ANDA No. 206364.

25. On information and belief and as stated in the ANDA Notice Letter, the FDA received ANDA No. 206364 from Actavis Florida.

26. On information and belief by virtue of, inter alia, Actavis Florida's relationship with Actavis Pharma in connection with the preparation and/or filing of ANDA No. 206364 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 Actavis Florida.

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. 206364, 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. 206364 to the FDA under 21 U.S.C. § 355(j) in order to obtain approval to market Actavis'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 Actavis'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. 206364 to obtain approval for the commercial manufacture, use, sale, offer for sale,

or importation into the United States of Actavis'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, Actavis'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. 206364 to the FDA under 21 U.S.C. § 355(j) in order to obtain approval to market Actavis'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 Actavis'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. 206364 to obtain approval for the commercial manufacture, use, sale, offer for sale, or importation into the United States of Actavis'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, Actavis'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. 206364 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. 206364 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. 206364 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: November 20, 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. HANMI USA, INC., HANMI PHARMACEUTICAL CO., LTD., HANMI FINE CHEMICAL CO., LTD, and HANMI HOLDINGS CO., LTD.*, C.A. No. 3:11-cv-00760-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).

The foregoing cases involve NEXIUM®, a product marketed by AstraZeneca that contains an esomeprazole magnesium formulation. The NEXIUM® cases have been assigned to Hon. Joel A. Pisano, U.S.D.J. Plaintiffs respectfully request that this case likewise be assigned to Judge Pisano due to his familiarity with the subject matter.

Date: November 20, 2014

By: *s/ John E. Flaherty*

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