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Of Counsel for Plaintiffs

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

ASTRAZENECA AB, AKTIEBOLAGET HASSLE, ASTRAZENECA LP, KBI INC., and KBI-E INC.,

Plaintiffs,

v.

AUROBINDO PHARMA LIMITED and AUROBINDO PHARMA USA 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, KBI Inc., and KBI-E Inc. (collectively, "Plaintiffs"), by their attorneys, for their Complaint against Aurobindo Pharma Limited and Aurobindo Pharma USA Inc. (collectively, "Defendants" or "Aurobindo"), 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. 205606 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® 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 Hassle ("Hassle") is a corporation organized and existing under the laws of Sweden, having its principal place of business at Molndal, 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 which it sells under the name NEXIUM®.

5. Plaintiff KBI Inc. ("KBI") is a Delaware corporation having its principal place of business at Whitehouse Station, New Jersey.

6. Plaintiff KBI-E Inc. ("KBI-E") is a Delaware corporation having its principal place of business at Wilmington, Delaware. KBI-E has exclusive rights in the United States to market and sell products covered by United States Patent Nos. 5,714,504, 6,369,085,7,411,070, and 8,466,175.

7. On information and belief, Defendant Aurobindo Pharma Limited ("Aurobindo Ltd.") is a private limited liability company incorporated and existing under the laws of India with its principal place of business at Andhra Pradesh, India and offices at 6 Wheeling Road, Dayton, New Jersey 08810.

8. On information and belief, Defendant Aurobindo Pharma USA Inc. ("Aurobindo USA") is a corporation operating and existing under the laws of the State of Delaware with its principal place of business at 2400 Route 130 North, Dayton, New Jersey 08810.

9. On information and belief, Defendant Aurobindo USA is a wholly-owned subsidiary of Aurobindo Ltd.

BACKGROUND

The NDA

10. AZ LP is the holder of New Drug Application ("NDA") No. 21153 for NEXIUM® Esomeprazole Magnesium Delayed-Release Tablets, in 20 mg and 40 mg dosage forms. NEXIUM® is a prescription drug approved for use to relieve the symptoms of acid reflux disease and treat erosive esophagitis. Esomeprazole magnesium is the active ingredient in NEXIUM®.

The Patents-in-Suit

11. United States Patent No. 5,714,504 ("the '504 patent"), entitled "Compositions," was duly and legally issued by the United States Patent and Trademark Office ("USPTO") on February 3, 1998 to Astra Aktiebolag upon assignment from the inventors Per Lennart Lindberg and Sverker Von Unge. The patent was subsequently assigned to AZ AB. The claims of the '504 patent are directed, *inter alia*, to pharmaceutical formulations comprising alkaline salts of esomeprazole (including esomeprazole magnesium) and methods of using esomeprazole magnesium. A true and correct copy of the '504 patent is attached as Exhibit A.

12. Plaintiff AZ AB has been and is still the owner of the '504 patent. The '504 patent will expire on February 3, 2015, and pediatric exclusivity relating to the '504 patent expires on August 3, 2015.

13. United States Patent No. 6,369,085 ("the '085 patent"), entitled "Form of S-Omeprazole," was duly and legally issued by the USPTO on April 9, 2002 to AZ AB, upon assignment from the inventors Hanna Cotton, Anders Kronstrom, Anders Mattson, and Eva Moller. 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 B.

14. 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.

15. 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 C.

16. 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.

17. United States Patent No. 8,466, 175 ("the '175 patent"), entitled "Form of S-omeprazole," was duly and legally issued by the USPTO on June 18, 2013 to AZ AB upon assignment from inventors Hanna Cotton, Anders Kronstrom, Anders Mattson, and Eva Moller. The claims of the '175 patent are directed to, *inter alia*, methods of treating Heliobacter infections comprising administration of magnesium salts of esomeprazole trihydrate. A true and correct copy of the '175 patent is attached as Exhibit D.

18. Plaintiff AZ AB has been and still is the owner of the '175 patent. The '175 patent will expire on May 25, 2018, and pediatric exclusivity relating to the '175 patent expires on November 25, 2018.

The ANDA

19. On information and belief, Aurobindo Ltd. filed ANDA No. 205606 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 tablets, 20 mg and 40 mg ("Aurobindo's Esomeprazole Magnesium Delayed-Release Tablets"), which are generic versions of Plaintiffs' NEXIUM® Esomeprazole Magnesium Delayed-Release Tablets, in 20 mg and 40 mg dosage forms.

20. By letter dated October 18, 2013, and received October 21, 2013, (the "ANDA Notice Letter"), Aurobindo Ltd. notified Plaintiffs that Aurobindo Ltd. had filed ANDA No. 205606 seeking approval to market Aurobindo's Esomeprazole Magnesium Delayed-Release Tablets and that Aurobindo Ltd. was providing information to Plaintiffs pursuant to 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95.

21. On information and belief, Aurobindo Ltd. sells its products in New Jersey and throughout the United States through Aurobindo USA.

JURISDICTION AND VENUE

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

23. On information and belief, Aurobindo Ltd. is a private limited liability company incorporated and existing under the laws of India with its principal place of business at Andhra Pradesh, India and offices at 6 Wheeling Road, Dayton, New Jersey 08810.

24. On information and belief, Aurobindo 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.

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

26. On information and belief, Aurobindo USA, with the assistance and/or at the direction of Aurobindo 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.

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

28. On information and belief and as stated in the ANDA Notice Letter, Aurobindo Ltd. prepared and filed ANDA No. 205606.

29. On information and belief and as stated in the ANDA Notice Letter, the FDA received ANDA No. 205606 from Aurobindo Ltd.

30. Aurobindo USA has designated Gangadhara Rao Gorla, 6 Wheeling Road, Dayton, New Jersey 08810 as its agent authorized to accept service of process.

31. By naming Gangadhara Rao Gorla, 6 Wheeling Road, Dayton, New Jersey 08810 as its agent, Aurobindo USA has consented to jurisdiction in the State of New Jersey for this action.

32. On information and belief by virtue of, *inter alia*, Aurobindo Ltd.'s relationship with Aurobindo USA in connection with the preparation and/or filing of ANDA No. 205606, 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 Aurobindo Ltd.

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 No. 205606, 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 1: INFRINGEMENT OF THE '504 PATENT

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

36. On information and belief, Defendants submitted ANDA No. 205606 to the FDA under 21 U.S.C. § 355(j) in order to obtain approval to market Aurobindo's Esomeprazole Magnesium Delayed-Release Tablets in the United States before the expiration of the '504 patent.

37. 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 '504 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 Aurobindo's Esomeprazole Magnesium Delayed-Release Tablets.

38. Under 35 U.S.C. § 271(e)(2)(A), the submission by Defendants to the FDA of ANDA No. 205606 to obtain approval for the commercial manufacture, use, sale, offer for sale, or importation into the United States of Aurobindo's Esomeprazole Magnesium Delayed-Release Tablets before the expiration of the '504 patent constitutes infringement of one or more claims of the '504 patent, either literally or under the doctrine of equivalents.

39. On information and belief, Aurobindo's Esomeprazole Magnesium Delayed-Release Tablets, 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 '504 patent.

40. The ANDA Notice Letter, which is required by statute and regulation to provide a full and detailed explanation regarding all defenses, does not allege non-infringement of any claims of the '504 patent. By not alleging non-infringement, Defendants admit that Aurobindo's Esomeprazole Magnesium Delayed-Release Tablets meet each limitation of each claim of the '504 patent.

41. 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 '085 PATENT

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

43. On information and belief, Defendants submitted ANDA No. 205606 to the FDA under 21 U.S.C. § 355(j) in order to obtain approval to market Aurobindo's Esomeprazole Magnesium Delayed-Release Tablets in the United States before the expiration of the '085 patent.

44. 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 Aurobindo's Esomeprazole Magnesium Delayed-Release Tablets.

45. Under 35 U.S.C. § 271(e)(2)(A), the submission by Defendants to the FDA of ANDA No. 205606 to obtain approval for the commercial manufacture, use, sale, offer for sale, or importation into the United States of Aurobindo's Esomeprazole Magnesium Delayed-Release Tablets 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.

46. On information and belief, Aurobindo's Esomeprazole Magnesium Delayed-Release Tablets, 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.

47. 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 3: INFRINGEMENT OF THE '070 PATENT

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

49. On information and belief, Defendants submitted ANDA No. 205606 to the FDA under 21 U.S.C. § 355(j) in order to obtain approval to market Aurobindo's Esomeprazole

Magnesium Delayed-Release Tablets in the United States before the expiration of the '070 patent.

50. 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 Aurobindo's Esomeprazole Magnesium Delayed-Release Tablets.

51. Under 35 U.S.C. § 271(e)(2)(A), the submission by Defendants to the FDA of ANDA No. 205606 to obtain approval for the commercial manufacture, use, sale, offer for sale, or importation into the United States of Aurobindo's Esomeprazole Magnesium Delayed-Release Tablets 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.

52. On information and belief, Aurobindo's Esomeprazole Magnesium Delayed-Release Tablets, 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.

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.

COUNT 4: INFRINGEMENT OF THE '175 PATENT

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

55. On information and belief, Defendants submitted ANDA No. 205606 to the FDA under 21 U.S.C. § 355(j) in order to obtain approval to market Aurobindo's Esomeprazole Magnesium Delayed-Release Tablets in the United States before the expiration of the '175 patent.

56. 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 '175 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 Aurobindo's Esomeprazole Magnesium Delayed-Release Tablets.

57. Under 35 U.S.C. § 271(e)(2)(A), the submission by Defendants to the FDA of ANDA No. 205606 to obtain approval for the commercial manufacture, use, sale, offer for sale, or importation into the United States of Aurobindo's Esomeprazole Magnesium Delayed-Release Tablets before the expiration of the '175 patent constitutes infringement of one or more claims of the '175 patent, either literally or under the doctrine of equivalents.

58. On information and belief, Aurobindo's Esomeprazole Magnesium Delayed-Release Tablets, 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, including Heliobacter infection. 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 '175 patent.

59. 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 '504, '085, '070, and '175 patents are valid and enforceable;

B. A judgment that the submission of ANDA No. 205606 by Defendants infringes one or more claims of each of the '504, '085, '070, and '175 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. 205606 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. 205606 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 3, 2013.

Respectfully submitted,

s/ John E. Flaherty

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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-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).

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: December 3, 2013

By: *s/ John E. Flaherty*

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