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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, KBI INC. and KBI-E INC., Plaintiffs, v. HETERO DRUGS, LTD., UNIT III and HETERO USA INC. Defendants.	Civil Action No. _____ COMPLAINT FOR PATENT INFRINGEMENT AND CERTIFICATION PURSUANT TO LOCAL RULE 11.2

JURISDICTION AND VENUE

1. This is an action for patent infringement arising under the Patent and Food and Drug laws of the United States, Titles 35 and 21, United States Code. Jurisdiction and venue

are based on 28 U.S.C. §§ 1331, 1338(a), 1391(b), 1391(c), 1400(b), 2201, 2202 and 35 U.S.C. § 271.

2. On information and belief, Hetero Drugs, Ltd., Unit III and Hetero USA Inc. (collectively "Hetero") have been and are engaging in activities directed toward infringement of United States Patent Nos. 5,714,504 (the "'504 patent"); 5,877,192 (the "'192 patent") and 6,875,872 (the "'872 patent") by, *inter alia*, submitting an Abbreviated New Drug Application designated ANDA No. 202-784 and by submitting Drug Master Files (DMF) seeking FDA's approval to manufacture commercially its proposed 20 mg and 40 mg product called "Esomeprazole Magnesium Delayed-Release Capsules, 20 mg and 40 mg" (hereinafter referred to as "Hetero's ANDA Product") containing the active ingredient esomeprazole magnesium.

3. In Hetero's notice letter entitled "Notification Pursuant to Section 505(j)(2)(B) of the Federal Food, Drug, and Cosmetic Act for U.S. Patent Nos. 5,690,960; 5,714,504; 5,877,192; 5,900,424; 6,147,103; 6,166,213; 6,191,148; 6,369,085; 6,428,810; 6,875,872 and 7,411,070" (hereinafter referred to as the "June 17, 2011 Notice Letter"), Hetero indicated that it intends to market its esomeprazole magnesium products before the expiration of the '504, '192 and '872 patents.

4. Hetero's submission of ANDA No. 202-784 and service of its June 17, 2011 Notice Letter indicates a refusal to change its current course of action.

5. There has been and is now an actual controversy between Hetero and Plaintiffs as to whether Hetero infringes the '504, '192 and '872 patents.

THE PARTIES

6. Plaintiff AstraZeneca AB is a company organized and existing under the laws of Sweden, having its principal place of business at Södertälje, Sweden. AstraZeneca AB was a corporate name change from Astra Aktiebolaget.

7. Plaintiff Aktiebolaget Hässle ("Hässle") is a company organized and existing under the laws of Sweden, having its principal place of business at Mölndal, Sweden.

8. Plaintiff AstraZeneca LP is a limited partnership organized under the laws of Delaware having its principal place of business at Wilmington, Delaware. AstraZeneca LP holds an approved New Drug Application from the United States Food and Drug Administration ("FDA") for an esomeprazole magnesium formulation which it sells under the name NEXIUM®.

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

10. Plaintiff KBI-E Inc. ("KBI-E") is a Delaware corporation, having its principal place of business at Wilmington, Delaware. KBI and KBI-E have exclusive rights in the United States to patents-in-suit.

11. On information and belief, Hetero Drugs Ltd., Unit III ("Hetero Drugs") is an Indian corporation having a principal place of business at 7-2-A-2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderbad—500 018, A.P. India.

12. On information and belief, Hetero USA Inc. ("Hetero USA") is a Delaware corporation having a principle place of business at 1035 Centennial Ave., Piscataway, New Jersey 08854. On information and belief, Hetero USA is a wholly owned subsidiary of Hetero Drugs.

13. On information and belief, Hetero Drugs is in the business of, among other things, manufacturing, marketing and selling generic versions of branded pharmaceutical products for the U.S. market through various operating subsidiaries, including Hetero USA and Camber.

14. On information and belief, this Court has personal jurisdiction over Hetero because Hetero has been doing business in New Jersey, has continuous and systematic contacts with New Jersey, and has engaged in activities together related to the subject matter of this action.

FIRST CLAIM FOR RELIEF: '504 PATENT

15. AstraZeneca AB, Hässle, AstraZeneca LP, KBI and KBI-E (collectively, "Plaintiffs") reallege paragraphs 1-14, above, as if set forth specifically here.

16. The '504 patent (copy attached as Exhibit "A"), entitled "Compositions," was issued 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 AstraZeneca AB. The '504 patent claims, *inter alia*, pharmaceutical formulations comprising alkaline salts of esomeprazole (including esomeprazole magnesium) and methods of using esomeprazole magnesium.

17. Plaintiff AstraZeneca 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.

18. Hetero's June 17, 2011 Notice Letter notified Plaintiffs that it had submitted an Abbreviated New Drug Application ("ANDA") to the FDA under 21 U.S.C.

§ 355(j), seeking the FDA's approval to manufacture, use, offer to sell and sell Hetero's ANDA Product as a generic version of the NEXIUM® product.

19. In the June 17, 2011 Notice Letter, Hetero notified Plaintiffs that as part of its ANDA it had filed a certification of the type described in 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV") with respect to the '504 patent. This statutory section requires, *inter alia*, certification by the ANDA applicant that the subject patent, here the '504 patent, "is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted . . . ." The statute (21 U.S.C. § 355(j)(2)(B)(iv)) also requires a Paragraph IV notice to "include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)) specify, *inter alia*, that a Paragraph IV notification must include "[a] detailed statement of the factual and legal basis of applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement is to include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation."

20. On information and belief, at the time Hetero's June 17, 2011 Notice Letter was served, Hetero was aware of the statutory provisions and regulations referred to in paragraph 19, above.

21. Hetero's June 17, 2011 Notice Letter, which is required by statute and regulation to provide a full and detailed explanation of the grounds supporting any allegation of non-infringement (see paragraph 19, above), does not allege non-infringement of all claims of the '504 patent.

22. Hetero's June 17, 2011 Notice Letter, which is required by statute and regulation to provide a full and detailed explanation of the grounds supporting any allegation of unenforceability (see paragraph 19, above), does not address unenforceability of or inequitable conduct relating to the '504 patent.

23. Even where asserted, Hetero's June 17, 2011 Notice Letter did not provide the full and detailed statement of its factual and legal basis to support its non-infringement, invalidity and/or unenforceability allegations as to the '504 patent.

24. Accordingly, Hetero's June 17, 2011 Notice Letter fails to comply with the law, as specified in 21 U.S.C. § 355(j), and FDA rules and regulations, as specified in 21 C.F.R. § 314.95.

25. Hetero has infringed the '504 patent under 35 U.S.C. § 271(e)(2) by filing its ANDA seeking approval from the FDA to engage in the commercial manufacture, use or sale of a drug claimed in this patent, or the use of which is claimed in the this patent, prior to the expiration of the '504 patent.

26. On information and belief, Hetero's ANDA Product, if approved, will be 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 Hetero's active behest and with its intent, knowledge and encouragement. On information and belief, Hetero will actively encourage, aid and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '504 patent.

27. On information and belief, Hetero's ANDA Product are especially made or especially adapted to inhibit gastric acid secretion and for use in the treatment of

gastrointestinal inflammatory disease via the administration of a therapeutically effective amount of a pharmaceutical formulation containing the claimed esomeprazole magnesium and a pharmaceutically acceptable carrier. On information and belief, Hetero is aware that its Hetero's ANDA Product are so made or so adapted. On information and belief, Hetero is aware that its Hetero's ANDA Product, if approved, will be used in contravention of Plaintiffs' rights under the '504 patent.

28. Hetero's June 17, 2011 Notice Letter does not allege and does not address non-infringement of the claims of the '504 patent. By not addressing non-infringement of claims of the '504 patent in its June 17, 2011 Notice Letter, Hetero admits that Hetero's ANDA Product meets all limitations of claims of the '504 patent.

29. On information and belief, the manufacture, use and sale of Hetero's ANDA Product infringe the '504 patent claims.

SECOND CLAIM FOR RELIEF: '192 PATENT

30. Plaintiffs reallege paragraphs 1-14 and 18, above, as if set forth specifically here.

31. The '192 patent, (copy attached as Exhibit "B"), entitled "Method For The Treatment Of Gastric Acid-Related Diseases And Production Of Medication Using (-) Enantiomer Of Omeprazole," was issued on March 2,1999 to Astra Aktiebolag, upon assignment from the inventors Per Lindberg and Lars Weidolf. The patent was subsequently assigned to AstraZeneca AB. The '192 patent claims, *inter alia*, methods for treatment of gastric acid related diseases by administering a therapeutically effective amount of esomeprazole and pharmaceutically acceptable salts thereof and methods for producing a medicament for such treatment.

32. Plaintiff AstraZeneca AB has been and still is the owner of the '192 patent. The '192 patent will expire on May 27,2014 and pediatric exclusivity relating to the '192 patent expires on November 27, 2014.

33. In the June 17, 2011 Notice Letter, Hetero notified Plaintiffs that as part of its ANDA it had filed a certification of the type described in 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV") with respect to the '192 patent. This statutory section requires, *inter alia*, certification by the ANDA applicant that the subject patent, here the '192 patent, "is invalid or will not be infringed by the manufacture, use, offer to sale or sale of the new drug for which the application is submitted .... " The statute (21 U.S.C. § 355(j)(2)(B)(iv)) also requires a Paragraph IV notice to "include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)) specify, *inter alia*, that a Paragraph IV notification must include "[a] detailed statement of the factual and legal basis of applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement is to include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds of supporting the allegation."

34. On information and belief, at the time Hetero's June 17, 2011 Notice Letter was served, Hetero was aware of the statutory provisions and regulations referred to in paragraph 33, above.

35. Hetero's June 17, 2011 Notice Letter, which is required by statute and regulation to provide a full and detailed explanation of the grounds supporting any allegation of

non-infringement (see paragraph 33, above), does not allege non-infringement of all claims of the '192 patent.

36. Hetero's June 17, 2011 Notice Letter, which is required by statute and regulation to provide a full and detailed explanation of the grounds supporting any allegation of unenforceability (see paragraph 33, above), does not address unenforceability of or inequitable conduct relating to the '192 patent.

37. Even where asserted, Hetero's June 17, 2011 Notice Letter did not provide the full and detailed statement of its factual and legal bases to support its non-infringement, invalidity and/or unenforceability allegations as to the patent '192.

38. Accordingly, Hetero's June 17, 2011 Notice Letter fails to comply with the law, as specified in 21 U.S.C. § 355(j), and FDA rules and regulations, as specified in 21 C.F.R. § 314.95.

39. Hetero has infringed the '192 patent under 35 U.S.C. § 271(e)(2) by filing its ANDA seeking approval from the FDA to engage in the commercial manufacture, use or sale of a drug the use of which is claimed in this patent, prior to the expiration of the '192 patent.

40. On information and belief, Hetero's ANDA Product, if approved, will be administered to human patients in a therapeutically effective amount to treat gastric acid related diseases by inhibiting gastric acid secretion.

41. On information and belief such administration will effect decreased inter individual variation in plasma levels (AUC) during such treatment.

42. On information and belief such treatment will effect increased average plasma levels(AUC) per dosage unit.

43. On information and belief such treatment will effect a pronounced increase in gastrin levels in slow metabolisers during such treatment.

44. On information and belief such treatment will effect decreased CYP1A induction in slow metabolisers during such treatment.

45. On information and belief such treatment will elicit an improved antisecretory effect during such treatment.

46. On information and belief such treatment will elicit an improved clinical effect comprising accelerated rate of healing and accelerated rate of symptom relief during such treatment.

47. On information and belief the amount to be administered will be between about 20 mg and about 40 mg total daily dose during such treatment.

48. On information and belief, this administration will occur at Hetero's active behest and with its intent, knowledge and encouragement.

49. On information and belief, Hetero will actively encourage, aid and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '192 patent.

50. On information and belief, Hetero's ANDA Product are especially made or especially adapted to inhibit gastric acid secretion and for use in the treatment of gastrointestinal inflammatory disease via the administration of a therapeutically effective amount of a pharmaceutical formulation containing the magnesium salt of esomeprazole. On information and belief, Hetero is aware that its Hetero's ANDA Product are so made or so adapted.

51. On information and belief, Hetero is aware that its ANDA Product, if approved, will be used in contravention of Plaintiffs' rights under the '192 patent.

52. Hetero's June 17, 2011 Notice Letter does not allege and does not address non-infringement of the claims of the '192 patent. By not addressing non-infringement of claims of the '192 patent in its June 17, 2011 Notice Letter, Hetero admits that Hetero's ANDA Product meets all limitations of claims of the '192 patent.

53. On information and belief, the manufacture, use and sale of Hetero's ANDA Product infringe the '192 patent claims.

THIRD CLAIM FOR RELIEF: '872 PATENT

54. Plaintiffs reallege paragraphs 1-14 and 18, above, as if set forth specifically here.

55. The '872 patent, (copy attached as Exhibit "C"), entitled "Compounds," was issued on April 5, 2005 to AstraZeneca AB, upon assignment from the inventors Per Lennart Lindberg and Sverker Von Unge. The '872 patent claims, *inter alia*, esomeprazole magnesium salts.

56. Plaintiff AstraZeneca AB has been and still is the owner of the '872 patent. The '872 patent will expire on May 27, 2014 and pediatric exclusivity relating to the '872 patent expires on November 27,2014.

57. In the June 17, 2011 Notice Letter, Hetero notified Plaintiffs that as part of its ANDA it had filed a certification of the type described in 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV") with respect to the '872 patent. This statutory section requires, *inter alia*, certification by the ANDA applicant that the subject patent, here the '872 patent, "is invalid or will not be infringed by the manufacture, use, offer to sale or sale of the new drug for which the application is submitted .... " The statute (21 U.S.C. § 355(j)(2)(B)(iv)) also requires a Paragraph IV notice to "include a detailed statement of the factual and legal basis of the applicant's opinion

that the patent is not valid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)) specify, *inter alia*, that a Paragraph IV notification must include "[a] detailed statement of the factual and legal basis of applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement is to include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds of supporting the allegation."

58. On information and belief, at the time Hetero's June 17, 2011 Notice Letter was served, Hetero was aware of the statutory provisions and regulations referred to in paragraph 57, above.

59. Hetero's June 17, 2011 Notice Letter, which is required by statute and regulation to provide a full and detailed explanation of the grounds supporting any allegation of non-infringement (see paragraph 57, above), does not allege non-infringement of all the claims of the '872 patent.

60. Hetero's June 17, 2011 Notice Letter, which is required by statute and regulation to provide a full and detailed explanation of the grounds supporting any allegation of unenforceability (see paragraph 57, above), does not address unenforceability of or inequitable conduct relating to the '872 patent.

61. Even where asserted, Hetero's June 17, 2011 Notice Letter did not provide the full and detailed statement of its factual and legal bases to support its non-infringement, invalidity and/or unenforceability allegations as to the patent '872.

62. Accordingly, Hetero's June 17, 2011 Notice Letter fails to comply with the law, as specified in 21 U.S.C. § 355(j), and FDA rules and regulations, as specified in 21 C.F.R. § 314.95.

63. Hetero has infringed the '872 patent under 35 U.S.C. § 271 (e)(2) by filing its ANDA seeking approval from the FDA to engage in the commercial manufacture, use or sale of a drug claimed in this patent, prior to the expiration of the '872 patent.

64. On information and belief, Hetero's ANDA Product, if approved, will be administered to human patients at Hetero's active behest and with its intent, knowledge and encouragement. On information and belief, Hetero will actively encourage, aid and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '872 patent.

65. On information and belief, Hetero's ANDA Product are especially made or especially adapted for treatment of humans. On information and belief, Hetero is aware that its Hetero's ANDA Product are so made or so adapted. On information and belief, Hetero is aware that its Hetero's ANDA Product, if approved, will be used in contravention of Plaintiffs' rights under the '872 patent.

66. Hetero's June 17, 2011 Notice Letter does not allege and does not address non-infringement of the claims of the '872 patent. By not addressing non-infringement of claims of the '872 patent in its June 17, 2011 Notice Letter, Hetero admits that Hetero's ANDA Product meets all limitations of claims of the '872 patent.

67. On information and belief, the manufacture, use and sale of Hetero's ANDA Product infringe the '872 patent claims.

WHEREFORE, Plaintiffs respectfully request the following relief:

(a) A Judgment declaring that the effective date of any approval of Hetero's ANDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) for drug product called "Esomeprazole Magnesium Delayed-Release Capsules, 20 mg and 40 mg" must be later than August 3, 2015, the expiration date of the last patent-in-suit that is infringed, including pediatric exclusivity relating to the patent;

(b) A judgment declaring that the '504, '192, '872 patents remain valid, remain enforceable and have been infringed by defendant Hetero;

(c) A judgment declaring that Hetero has not complied with the requirements of 35 U.S.C. § 271(e)(2), 21 U.S.C. § 355(j)(2)(A)(vii)(IV), 21 U.S.C. § 355(j)(2)(B)(iv), 21 C.F.R. § 314.94 and 21 U.S.C. § 314.95;

(d) A judgment that Hetero's defenses and claims for relief are limited to those presented in Hetero's December 29, 2010 Letter;

(e) A permanent injunction against any infringement by Hetero of the '504, '192, '872 patents;

(f) A judgment that Hetero's infringement is willful;

(g) A judgment that Hetero's conduct is exceptional;

(h) Attorneys' fees in this action under 35 U.S.C. § 285;

(i) Costs and expenses in this action; and

(j) Such other relief as this Court may deem proper.

Respectfully Submitted,

Dated: August 2, 2011

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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 the subject of the following pending actions:

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., 3:11-CV-00760-JAP-TJB (District of New Jersey).

ASTRAZENECA AB; AKTIEBOLAGET HÄSSLE; ASTRAZENECA LP; KBI INC.; and KBI-E INC. v. LUPIN LTD. and LUPIN PHARMACEUTICALS, INC., 3:09-cv-05404-JAP-TJB (District of New Jersey).

ASTRAZENECA AB; AKTIEBOLAGET HÄSSLE; ASTRAZENECA LP; KBI INC.; and KBI-E INC. v. SUN PHARMA GLOBAL FZE, SUN PHARMACEUTICAL INDUSTRIES, INC., and SUN PHARMACEUTICAL INDUSTRIES, LTD., 3:10-cv-01017-JAP-TJB (District of New Jersey).

Dated: August 2, 2011

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