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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. HETERO USA INC., HETERO LABS LIMITED UNIT-III, and HETERO LABS LIMITED, 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 Hetero USA Inc., Hetero Labs Limited Unit-III, and Hetero Labs Limited (collectively, "Defendants" or "Hetero"), 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. 208939 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 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 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 (collectively, the "Patents-in-suit").

6. Upon information and belief, Hetero USA Inc. is a corporation organized and existing under the laws of Delaware, having its principal place of business at 1035 Centennial Ave, Piscataway, New Jersey 08854. Upon information and belief, Hetero USA Inc. is in the

business of marketing, distributing, and selling, in the State of New Jersey and throughout the United States, pharmaceutical drugs, including generic pharmaceutical drugs manufactured by Hetero.

7. Upon information and belief, Hetero Labs Limited Unit-III is a corporation organized and existing under the laws of India, having its principal place of business at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad – 500 018, A.P. India.

8. Upon information and belief, Hetero Labs Limited is a corporation organized and existing under the laws of India, having its principal place of business at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad – 500 018, A.P. India.

9. Upon information and belief, Hetero USA Inc. is a wholly-owned subsidiary of Hetero Labs Limited.

10. Upon information and belief, Hetero Labs Limited Unit-III is a division of Hetero Labs Limited.

BACKGROUND

The NDA

11. 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

12. 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.

13. 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.

14. 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.

15. 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

16. On information and belief, Hetero USA Inc. filed ANDA No. 208939 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 Eq. Base ("Hetero'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.

17. By letter dated March 17, 2016 (the "ANDA Notice Letter"), Defendants notified Plaintiffs that Hetero USA Inc., on behalf of Hetero Labs Limited Unit-III and Hetero Labs Limited, had filed ANDA No. 208939 seeking approval to market Hetero's Esomeprazole Magnesium Delayed-Release Capsules and that Hetero 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

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, this Court has jurisdiction over Hetero because Hetero USA Inc. has its principal place of business in New Jersey and is the agent of Hetero Labs Limited Unit-III and Hetero Labs Limited. Upon information and belief, Hetero USA Inc. is acting as the agent of Hetero Labs Limited Unit-III and Hetero Labs Limited with respect to ANDA No. 208939.

20. In the alternative, this Court has jurisdiction over Hetero Labs Limited Unit-III because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met.

21. In the alternative, this Court has jurisdiction over Hetero Labs Limited because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met.

22. This Court also has jurisdiction over Hetero Labs Limited Unit-III because, *inter alia*, this action arises from actions of Hetero Labs Limited Unit-III directed toward New Jersey, and because Hetero Labs Limited Unit-III has purposefully availed itself of the rights and benefits of New Jersey law by engaging in systematic and continuous contacts with New Jersey. Upon information and belief, Hetero Labs Limited Unit-III regularly and continuously transacts business within the State of New Jersey, including by selling pharmaceutical products in New

Jersey, either on its own or through its agent Hetero USA Inc. Upon information and belief, Hetero USA Inc.'s principal place of business is located in Piscataway, New Jersey. Upon information and belief, Hetero Labs Limited Unit-III derives substantial revenue from the sale of those products in New Jersey and has availed itself of the privilege of conducting business within the State of New Jersey.

23. This Court also has jurisdiction over Hetero Labs Limited because, *inter alia*, this action arises from actions of Hetero Labs Limited directed toward New Jersey, and because Hetero Labs Limited has purposefully availed itself of the rights and benefits of New Jersey law by engaging in systematic and continuous contacts with New Jersey. Upon information and belief, Hetero Labs Limited regularly and continuously transacts business within the State of New Jersey, including by selling pharmaceutical products in New Jersey, either on its own or through its subsidiary and agent Hetero USA Inc. Upon information and belief, Hetero USA Inc.'s principal place of business is located in Piscataway, New Jersey. Upon information and belief, Hetero Labs Limited derives substantial revenue from the sale of those products in New Jersey and has availed itself of the privilege of conducting business within the State of New Jersey.

24. This Court also has jurisdiction over Hetero USA Inc. because, *inter alia*, upon information and belief, Hetero USA Inc.'s principal place of business is located in Piscataway, New Jersey. Upon information and belief, Hetero USA Inc., directly or indirectly, manufactures, imports, markets, and sells generic drugs throughout the United States and in this judicial district.

25. On information and belief, Hetero has previously been sued in this district and has not challenged personal jurisdiction. *See, e.g., Takeda GmbH et al. v. Hetero USA Inc. et al.*,

Civ. Action No. 3:16-cv-1280-FLW-DEA (D.N.J.); *BTG Int'l Ltd. v. Actavis Labs. Fl, Inc. et al.*, Civ. Action No. 2:15-cv-5909-KM-JBC (D.N.J.); *Takeda GmbH et al. v. Hetero USA Inc. et al.*, Civ. Action No. 3:15-cv-3385-FLW-DEA (D.N.J.); *Otsuka Pharmaceutical Co., Ltd. v. Hetero Drugs Limited et al.*, Civ. Action No. 1:15-cv-0161-JBS-KMW (D.N.J.).

26. On information and belief, Hetero has availed itself of the jurisdiction of this court by asserting counterclaims in this district. *See, e.g., Takeda GmbH et al. v. Hetero USA Inc. et al.*, Civ. Action No. 3:16-cv-1280-FLW-DEA (D.N.J.); *Otsuka Pharmaceutical Co., Ltd. v. Hetero Drugs Limited et al.*, Civ. Action No. 1:15-cv-0161-JBS-KMW (D.N.J.).

27. On information and belief, Hetero USA Inc. has availed itself of the jurisdiction of this court by initiating litigation in this district. *See, e.g., Symed Labs Limited et al. v. Amneal Pharmaceuticals LLC*, Civ. Action No. 2:15-cv-8307-MCA-MAH (D.N.J.).

28. 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. 208939, this Court has personal jurisdiction over Defendants. These activities satisfy due process and confer personal jurisdiction over Defendants consistent with New Jersey law. *See, e.g., Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, No. 15-1456, slip op. at 14 (Fed. Cir. Mar. 18, 2016) (holding that minimum-contacts requirement for specific personal jurisdiction is established where Defendant's "ANDA filings and its distribution channels establish that [the Defendant] plans to market its proposed drugs in [the State where the complaint was filed] and the lawsuit is about patent constraints on such in-State marketing.").

29. Venue is proper in this District pursuant to the provisions of Title 28, United States Code, Sections 1391(b)-(d), and 1400(b).

COUNT 1: INFRINGEMENT OF THE '085 PATENT

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

31. On information and belief, Defendants submitted ANDA No. 208939 to the FDA under 21 U.S.C. § 355(j) in order to obtain approval to market Hetero's Esomeprazole Magnesium Delayed-Release Capsules in the United States before the expiration of the '085 patent.

32. 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 Hetero's Esomeprazole Magnesium Delayed-Release Capsules.

33. Under 35 U.S.C. § 271(e)(2)(A), the submission by Defendants to the FDA of ANDA No. 208939 to obtain approval for the commercial manufacture, use, sale, offer for sale, or importation into the United States of Hetero'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.

34. On information and belief, Hetero's Esomeprazole Magnesium Delayed-Release Capsules, if approved by the FDA, 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 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.

35. The ANDA Notice Letter, which is required by statute and regulation to provide a full and detailed explanation regarding all defenses, provides only a bare allegation of invalidity and unenforceability of the '085 patent's claims without any explanation or identifying any legal basis or supporting facts. Because Defendants allege that the '085 patent is invalid or unenforceable without any explanation or identifying any legal basis or supporting facts, Defendants effectively admit that the '085 patent is both valid and enforceable.

36. 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

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

38. On information and belief, Defendants submitted ANDA No. 208939 to the FDA under 21 U.S.C. § 355(j) in order to obtain approval to market Hetero's Esomeprazole Magnesium Delayed-Release Capsules in the United States before the expiration of the '070 patent.

39. 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 Hetero's Esomeprazole Magnesium Delayed-Release Capsules.

40. Under 35 U.S.C. § 271(e)(2)(A), the submission by Defendants to the FDA of ANDA No. 208939 to obtain approval for the commercial manufacture, use, sale, offer for sale, or importation into the United States of Hetero'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.

41. On information and belief, Hetero's Esomeprazole Magnesium Delayed-Release Capsules, if approved by the FDA, 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 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.

42. The ANDA Notice Letter, which is required by statute and regulation to provide a full and detailed explanation regarding all defenses, provides only a bare allegation of invalidity and unenforceability of the '070 patent's claims without any explanation or identifying any legal basis or supporting facts. Because Defendants allege that the '070 patent is invalid or unenforceable without any explanation or identifying any legal basis or supporting facts, Defendants effectively admit that the '070 patent is both valid and enforceable.

43. 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. 208939 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. 208939 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. 208939 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: April 29, 2016

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, and ZENECA 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, and ZENECA 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, and ZENECA 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, and ZENECA 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, and ZENECA INC. v. KREMERS URBAN PHARMACEUTICALS*, C.A. No. 3:13-cv-7299-MLC-TJB (District of New Jersey)

- *ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, and ZENECA 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-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)

- *ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, and ZENECA INC. v. LUPIN LTD. and LUPIN PHARMACEUTICALS INC.*, C.A. No. 3:15-cv-06092-MLC-TJB (District of New Jersey)

- *ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, and ZENECA INC. v. ALKEM LABORATORIES LTD., and ASCEND LABORATORIES, LLC.*, C.A. No. 3:15-cv-06609-MLC-TJB (District of New Jersey)

- *ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, and ZENECA INC. v. ZYDUS PHARMACEUTICALS (USA) INC., and CADILA HEALTHCARE LTD. (dba ZYDUS CADILA)*, C.A. No. 3:15-cv-07415-MLC-TJB (District of New Jersey)

- *ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, and ZENECA INC. v. DR. REDDY'S LABORATORIES, LTD. and DR. REDDY'S LABORATORIES, INC.*, C.A. No. 3:15-cv-08267-MLC-TJB (District of New Jersey)

- *ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, and ZENECA INC. v. MACLEODS PHARMACEUTICALS LTD. and MACLEODS PHARMA USA, INC.*, C.A. No. 3:16-cv-01682-MLC-TJB (District of New Jersey)

Dated: April 29, 2016

Respectfully submitted,

s/ John E. Flaherty

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