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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.

MACLEODS PHARMACEUTICALS LTD.
and MACLEODS 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, and Zeneca Inc. (collectively, “Plaintiffs”), by their attorneys, for their Complaint against Macleods Pharmaceuticals Ltd. (“Macleods”) and Macleods Pharma USA, Inc. (“Macleods USA”), 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. 208511 filed by or for the benefit of Macleods and Macleods USA (collectively, “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 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 which it sells under the name NEXIUM[®].

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; 7,411,070; and 8,466,175.

6. Upon information and belief, Macleods is an Indian company having its principal place of business at Atlanta Arcade, Marol Church Road, Andheri (East), Mumbai, India 400059. Upon information and belief, Macleods is in the business of developing, manufacturing, marketing, and selling generic drugs.

7. Upon information and belief, Macleods USA is a wholly-owned subsidiary of Macleods.

8. Upon information and belief, Macleods USA is a corporation organized under the laws of the State of Delaware, with its principal place of business at 666 Plainsboro Road, Building 200, Suite 230, Plainsboro, New Jersey 08536. Upon information and belief, Macleods USA 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 Macleods.

9. Upon information and belief, Defendants collaborate to manufacture, import, market, distribute, and sell generic pharmaceutical products in the State of New Jersey and throughout the United States.

10. Upon information and belief, following any FDA approval of ANDA No. 208511, Macleods itself and through its U.S. agent, Macleods USA, will make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 208511 throughout the United States, and/or import such generic drug products into the United States.

BACKGROUND

The NDA

11. AZ LP is the holder of New Drug Application (“NDA”) No. 21153 for NEXIUM[®] Esomeprazole Magnesium Delayed-Release Capsules, 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 trihydrate is the active ingredient in NEXIUM[®].

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.

16. 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 C.

17. 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

18. On information and belief, Macleods filed ANDA No. 208511 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 pellets, 20 mg and 40 mg (“Macleods’s Esomeprazole Magnesium Delayed-Release Pellets”), which are generic versions of Plaintiffs’ NEXIUM[®] Esomeprazole Magnesium Delayed-Release Capsules, in 20 mg and 40 mg dosage forms.

19. By letter dated February 8, 2016 (the “ANDA Notice Letter”), Macleods notified Plaintiffs that Macleods had filed ANDA No. 208511 seeking approval to market Macleods’s

Esomeprazole Magnesium Delayed-Release Pellets and that Macleods was providing information to Plaintiffs pursuant to 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95.

Macleods's ANDA Notice Letter failed to provide "the name and address of an agent in the United States authorized to accept service of process" for applicants that, like Macleods, do not reside or have a place of business in the United States. *See* 21 C.F.R. § 314.95(c)(7).

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. Upon information and belief, Macleods is an Indian company having its principal place of business at Atlanta Arcade, Marol Church Road, Andheri (East), Mumbai, India 400059. Upon information and belief, Macleods is in the business of developing, manufacturing, marketing, and selling generic drugs.

22. On information and belief, Macleods, 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. Upon information and belief, Macleods purposefully has conducted and continues to conduct business, directly or indirectly, in this judicial district, and this judicial district is a likely destination of Macleods's generic products. Upon information and belief, Macleods is a "truly global pharmaceutical company" that has grown at an average rate of 22% over the last five years. *See* <http://www.macleodspharma.com/default.asp>. Upon information and belief, "Macleods has received FDA approval on 9 Abbreviated New Drug Applications and has

another 60 filed and awaiting approval.” *See*

<http://www.macleodspharma.com/UnitedStates.asp>.

24. On information and belief, Macleods USA is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 666 Plainsboro Road, Building 200, Suite 230, Plainsboro, New Jersey 08536. Macleods has designated Macleods Pharma USA, Inc., located in New Jersey, to accept service of process for this matter.

25. On information and belief, Macleods USA 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 Macleods.

26. On information and belief, Defendants acted in concert to develop Macleods’s Eesomeprazole Magnesium Delayed-Release Pellets and to seek approval from the FDA to sell Macleods’s Eesomeprazole Magnesium Delayed-Release Pellets throughout the United States, including within this judicial district.

27. On information and belief, and as stated in the ANDA Notice Letter, Macleods prepared and filed ANDA No. 208511.

28. On information and belief, and as stated in the ANDA Notice Letter, the FDA received ANDA No. 208511 from Macleods.

29. On information and belief, by virtue of, *inter alia*, Macleods’s preparation and/or filing of ANDA No. 208511 and sales-related activities 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 Macleods. *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.")

30. On information and belief, Macleods has previously been sued in this district and has not challenged personal jurisdiction. *See, e.g., AstraZeneca Pharmaceuticals LP et al. v. Macleods Pharmaceuticals, Ltd. et al.*, Civ. Action No. 2:15-cv-01513-CCC-MF (D.N.J.); *Otsuka Pharmaceutical Co., Ltd. v. Macleods Pharmaceuticals, Ltd. et al.*, Civ. Action No. 1:15-cv-5109-JBS-KMW (D.N.J.).

31. On information and belief, Macleods has availed itself of the jurisdiction of this court by asserting counterclaims in this district. *See, e.g., Otsuka Pharmaceutical Co., Ltd. v. Macleods Pharmaceuticals, Ltd. et al.*, Civ. Action No. 1:15-cv-5109-JBS-KMW (D.N.J.).

32. 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

33. Plaintiffs incorporate by reference paragraphs 1-32 of this Complaint as if fully set forth herein.

34. On information and belief, Defendants submitted ANDA No. 208511 to the FDA under 21 U.S.C. § 355(j) in order to obtain approval to market their Esomeprazole Magnesium Delayed-Release Pellets in the United States before the expiration of the '085 patent.

35. 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 Macleods's Esomeprazole Magnesium Delayed-Release Pellets.

36. Under 35 U.S.C. § 271(e)(2)(A), the submission by Defendants to the FDA of ANDA No. 208511 to obtain approval for the commercial manufacture, use, sale, offer for sale, or importation into the United States of Macleods's Esomeprazole Magnesium Delayed-Release Pellets 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.

37. On information and belief, Macleods's Esomeprazole Magnesium Delayed-Release Pellets, 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.

38. 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.

39. 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

40. Plaintiffs incorporate by reference paragraphs 1-39 of this Complaint as if fully set forth herein.

41. On information and belief, Defendants submitted ANDA No. 208511 to the FDA under 21 U.S.C. § 355(j) in order to obtain approval to market Macleods's Esomeprazole Magnesium Delayed-Release Pellets in the United States before the expiration of the '070 patent.

42. 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 Macleods's Esomeprazole Magnesium Delayed-Release Pellets.

43. Under 35 U.S.C. § 271(e)(2)(A), the submission by Defendants to the FDA of ANDA No. 208511 to obtain approval for the commercial manufacture, use, sale, offer for sale, or importation into the United States of Macleods's Esomeprazole Magnesium Delayed-Release Pellets 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.

44. On information and belief, Macleods's Esomeprazole Magnesium Delayed-Release Pellets, 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.

45. 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.

46. 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 '175 PATENT

47. Plaintiffs incorporate by reference paragraphs 1-46 of this Complaint as if fully set forth herein.

48. On information and belief, Defendants submitted ANDA No. 208511 to the FDA under 21 U.S.C. § 355(j) in order to obtain approval to market Macleods's Esomeprazole Magnesium Delayed-Release Pellets in the United States before the expiration of the '175 patent.

49. 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 Macleods's Esomeprazole Magnesium Delayed-Release Pellets.

50. Under 35 U.S.C. § 271(e)(2)(A), the submission by Defendants to the FDA of ANDA No. 208511 to obtain approval for the commercial manufacture, use, sale, offer for sale, or importation into the United States of Macleods's Esomeprazole Magnesium Delayed-Release

Pellets 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.

51. On information and belief, Macleods's Esomeprazole Magnesium Delayed-Release Pellets, 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.

52. 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 '175 patent's claims without any explanation or identifying any legal basis or supporting facts. Because Defendants allege that the '175 patent is invalid or unenforceable without any explanation or identifying any legal basis or supporting facts, Defendants effectively admit that the '175 patent is both valid and enforceable.

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.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that the claims of the '085, '070, and '175 patents are valid and enforceable;

B. A judgment that the submission of ANDA No. 208511 by Defendants infringes one or more claims of each of the '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 Macleods's ANDA No. 208511 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 Defendants, from making, using, selling, offering to sell, or importing theesomeprazole magnesium product described in Defendants' ANDA No. 208511 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: March 24, 2016

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-MLC-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- MLC-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-MLC-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-MLC-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-MLC-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-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. 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)

Date: March 24, 2016

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