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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, and ZENECA INC.,

Plaintiffs and Counterclaim-Defendants

v.

MYLAN LABORATORIES LIMITED, and MYLAN INC.,

Defendants and Counterclaim-Plaintiffs.

Civil Action No. 3:12-cv-01378(MLC)(TJB)

SECOND AMENDED COMPLAINT FOR PATENT INFRINGEMENT AND DEMAND FOR JURY TRIAL

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AstraZeneca AB, Aktiebolaget Hässle, AstraZeneca LP, and Zeneca Inc. (collectively, "Plaintiffs"), for their Second Amended Complaint against Mylan Laboratories Limited and Mylan Inc. (collectively, "Defendants"), hereby allege as follows:

THE PARTIES

1. 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.

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

3. 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®.

4. 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 the patents-in-suit.

5. Zeneca has granted AstraZeneca LP, the distributor of NEXIUM®, exclusive rights under the patents-in-suit.

6. Upon information and belief, Defendant Mylan Laboratories Limited ("Mylan Limited") was formerly known as Matrix Laboratories Limited ("Matrix Limited"). Upon information and belief, Defendants Mylan Limited is a corporation organized and existing under the laws of India, having their principal place of business at Plot No. 564/A/22, Road No. 92,

Jubilee Hills 500034, Hyderabad, India. Upon information and belief, Mylan Limited is in the business of, among other things, manufacturing, marketing and selling generic copies of branded pharmaceutical products throughout the United States, including within this district.

7. Upon information and belief, Matrix Laboratories, Inc. ("Matrix New Jersey") existed as a corporation organized and existing under the laws of Delaware at least in 2006 through 2007 with its principal place of business at 76 South Orange Avenue, Suite 301, South Orange, New Jersey 07079-1923. Upon information and belief Matrix New Jersey was in the business of, among other things, manufacturing, marketing and selling generic copies of branded pharmaceutical products throughout the United States, including within this district. Upon information and belief, at least in 2006 through 2007, Matrix Limited was the immediate parent of Matrix New Jersey.

8. Upon information and belief, Defendant Mylan, Inc. is a corporation organized and existing under the laws of Pennsylvania, having its principal place of business at 1500 Corporate Drive, Canonsburg, PA 15317. Upon information and belief, Mylan, Inc. is in the business of, among other things, manufacturing, marketing and selling generic copies of branded pharmaceutical products throughout the United States, including within this district.

9. Upon information and belief, Mylan, Inc. acquired Matrix Limited, and its subsidiary Matrix New Jersey on or around October 2011. Upon information and belief, Mylan, Inc. renamed Matrix Limited as Mylan Limited and Matrix New Jersey as Mylan Laboratories, Inc.

10. Upon information and belief, Mylan Limited is the parent company of Mylan Laboratories, Inc.

11. Upon information and belief, Mylan, Inc. is the parent company of Mylan Limited.

12. Upon information and belief, Mylan Limited is a wholly owned subsidiary of Mylan, N.V.

13. Upon information and belief, Mylan, Inc. is a wholly owned subsidiary of Mylan, N.V.

14. Upon information and belief Mylan Laboratories, Inc., Matrix Laboratories, Inc., and Matrix Laboratories Limited are within the control of defendant Mylan Inc. for purposes of responding to discovery in this action.

JURISDICTION AND VENUE

15. 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.

16. On information and belief, Defendants have been and are engaging in activities directed toward infringement of United States Patent Nos. 6,369,085 (the "'085 patent") and 7,411,070 (the "'070 patent") (collectively, the "patents-in-suit") by, inter alia, submitting to the FDA an Abbreviated New Drug Application ("ANDA") No. 78-936 ("Defendants' ANDA") seeking approval to manufacture commercially its proposed 20 mg and 40 mg products called "Esomeprazole Magnesium Capsules, 20 mg, and 40 mg" (hereinafter referred to as the "ANDA Products"), containing the active ingredient esomeprazole magnesium, by submitting to the FDA Drug Master Files ("DMFs"), including DMF #23120, and by

manufacturing, importing, using, offering to sell, and selling the ANDA Products prior to the expiration of the patents-in-suit.

17. In a letter dated July 24, 2007 ("2007 Notice Letter") from Matrix New Jersey's agent Keeto Sabharwal, Esq., then of the law firm of Blank Rome LLP, Matrix New Jersey notified Plaintiffs of the filing of Defendants' ANDA and that the ANDA included a certification, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification"), to the '085 patent.

18. In a letter dated August 22, 2008 ("2008 Notice Letter") from Matrix Limited and Matrix New Jersey's agent, the law firm of Blank Rome LLP, Matrix New Jersey notified Plaintiffs of an Amendment to Defendants' ANDA which included a certification, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification"), to the '070 patent.

19. In a letter dated January 24, 2012 ("2012 Notice Letter") from Mylan Limited's agent, the law firm of Perkins Coie, Mylan Limited notified Plaintiffs of the filing of Defendants' ANDA and that the ANDA included a certification, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification"), with respect to the '504, '192 and '872 patents.

20. On February 4, 2015, Defendants received from the FDA tentative approval of ANDA 78-936 for Esomeprazole Magnesium Delayed-release Capsules USP, 20 mg and 40 mg.

21. On July 10, 2015, Defendants requested from the FDA permission to import its ANDA Products into the United States prior to receiving final ANDA approval.

22. On July 24, 2015, Mylan received permission from the FDA to import its ANDA Products.

23. On August 3, 2015, Defendants received final approval of ANDA 78-936 from the FDA. Pursuant to this approval, Mylan launched its generic esomeprazole magnesium 20 mg and 40 mg capsules that same day.

24. Defendants' submission of ANDA No. 78-936 and service of the 2007, 2008 and 2012 Notice Letters, along with their at-risk launch, indicates a refusal to change their current course of action.

25. There has been and is now an actual controversy between Defendants and Plaintiffs as to whether Defendants infringe the '085 and '070 patents.

26. This Court has personal jurisdiction over Defendants because, *inter alia*, Defendants, on information and belief, have purposely availed themselves of the benefits and protections of the laws of New Jersey such that they should reasonably anticipate being haled into court here; Defendants have had continuous and systematic contacts with this judicial district, including, on information and belief, selling pharmaceutical products in New Jersey and deriving substantial revenues from those sales; on information and belief Mylan, Inc. and Mylan Limited are licensed to do business within New Jersey. Thus, Defendants are subject to general jurisdiction in New Jersey.

27. Upon information and belief, the acts of Mylan Limited complained of herein were done at the direction of, with the authorization of, and with the cooperation, participation and assistance of Matrix New Jersey, Mylan Laboratories, Inc., and Mylan Inc.

FIRST CLAIM FOR RELIEF: '085 PATENT

28. Plaintiffs reallege paragraphs 1–27, above, as if set forth specifically here.

29. The '085 patent (copy attached as Exhibit "A"), entitled "Form of S-Omeprazole," was issued on April 9, 2002 to AstraZeneca AB, upon assignment from the

inventors Hanna Cotton, Anders Kronström, Anders Mattson and Eva Möller. The '085 claims, inter alia, esomeprazole magnesium salts.

30. Plaintiff AstraZeneca AB has been and still is the owner of the '085 patent. Zeneca has exclusive rights in the United States to market and sell products covered by 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.

31. The 2007 Notice Letter notified Plaintiffs that Defendants submitted ANDA 78-936 to the FDA under 21 U.S.C. § 355(j), seeking the FDA's approval to manufacture, use, offer to sell and sell the ANDA Products as generic versions of the NEXIUM® product. On August 3, 2015, Defendants received FDA Approval for and launched the ANDA Products.

32. Defendants have infringed the '085 patent under 35 U.S.C. § 271(e)(2) by filing their 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 '085 patent.

33. Defendants have infringed and continue to infringe, contributorily infringe and/or induce infringement of one or more claims of the '085 patent, pursuant to 35 U.S.C. §§ 271(a), (b), (c) and/or (g), either directly or indirectly, literally or under the doctrine of equivalents, by manufacturing, using, offering for sale and selling in the United States and by importing in to the United States, without authority, the ANDA Product.

34. On information and belief, the ANDA Products have been and will be administered to human patients in a therapeutically effective amount to treat gastric acid related conditions. On information and belief, this administration has occurred and will occur at Defendants' active behest and with their intent, knowledge and encouragement. On information

and belief, Defendants actively encourage, aid and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '085 patent.

35. The ANDA Products contain as their active ingredient, a component of the compound patented in the '085 patent, constitute a material part of those inventions, are especially made or especially adapted for use in an infringement of the '085 patent, and are not a staple article or commodity of commerce suitable for substantial noninfringing use. On information and belief, Defendants are aware that the ANDA Products are so made or so adapted. On information and belief, Defendants are aware that the ANDA Products will be used in contravention of Plaintiffs' rights under the '085 patent.

36. On information and belief, the ANDA Products are made using a process that is covered by the '085 patent.

37. On information and belief, the manufacture, use, offer for sale, sale, or importation of the ANDA Product infringes the '085 patent claims.

38. Defendants' infringement of the '085 patent has been willful, as Defendants have been aware of the '085 patent since at least July 24, 2007, when Defendants referenced the '085 patent in their 2007 Notice Letter. Defendants knew or should have known of the objectively high risk that their manufacture, use, offer for sale, sale, or importation of the ANDA Products infringed the '085 patent.

39. Plaintiffs have been damaged as a result of Defendants' infringement of the '085 patent. Plaintiffs are entitled to recover from Defendants the damages sustained by Plaintiffs as a result of Defendants' infringing in an amount subject to proof at trial, including lost profits and an amount not less than a reasonable royalty.

40. The infringement by Defendants of the ’085 patent will continue to cause Plaintiffs irreparable injury and damage for which there is no adequate remedy at law unless and until Defendants are enjoined from infringing the patent.

SECOND CLAIM FOR RELIEF: ’070 PATENT

41. Plaintiffs reallege paragraphs 1–27, above, as if set forth specifically here.

42. The ’070 patent (copy attached as Exhibit “B”), entitled “Form of S-Omeprazole,” was issued on August 12, 2008 to AstraZeneca AB, upon assignment from the inventors Hanna Cotton, Anders Kronström, Anders Mattson and Eva Möller. The ’070 patent claims, inter alia, esomeprazole magnesium salts of esomeprazole trihydrate and processes for preparing the claimed salts.

43. Plaintiff AstraZeneca AB has been and still is the owner of the ’070 patent. Zeneca has exclusive rights in the United States to market and sell products covered by 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.

44. The 2008 Notice Letter notified Plaintiffs that Defendants submitted ANDA 78-936 to the FDA under 21 U.S.C. § 355(j), seeking the FDA’s approval to manufacture, use, offer to sell and sell the ANDA Products as generic versions of the NEXIUM® product. On August 3, 2015, Defendants received FDA Approval for and launched the ANDA Products.

45. Defendants have infringed the ’070 patent under 35 U.S.C. § 271 (e)(2) by filing their 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 ’070 patent.

46. Defendants have infringed and continue to infringe, contributorily infringe and/or induce infringement of one or more claims of the ’070 patent, pursuant to 35 U.S.C. §§ 271(a), (b), (c) and/or (g), either directly or indirectly, literally or under the doctrine of equivalents, by

manufacturing, using, offering for sale and selling in the United States and by importing in to the United States, without authority, the ANDA Products.

47. On information and belief, the ANDA Products have been and will be administered to human patients at Defendants' active behest and with its intent, knowledge and encouragement. On information and belief, Defendants actively encourage, aid, and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '070 patent.

48. The ANDA Products contain as their active ingredient, a component of the compound patented in the '070 patent, constitute a material part of those inventions, are especially made or especially adapted for use in an infringement of the '070 patent, and are not a staple article or commodity of commerce suitable for substantial noninfringing use. On information and belief, Defendants are aware that the ANDA Products are so made or so adapted. On information and belief, Defendants are aware that the ANDA Products will be used in contravention of Plaintiffs' rights under the '070 patent.

49. On information and belief, the ANDA Products are made using a process that is covered by the '070 patent.

50. On information and belief, the manufacture, use, offer for sale, sale, or importation of the ANDA Product infringes the '070 patent claims.

51. Defendants' infringement of the '070 patent has been willful, as Defendants have been aware of the '070 patent since at least August 22, 2008, when Defendants referenced the '070 patent in their 2008 Notice Letter. Defendants knew or should have known of the objectively high risk that their manufacture, use, offer for sale, sale, or importation of the ANDA Products infringed the '070 patent.

52. Plaintiffs have been damaged as a result of Defendants' infringement of the '070 patent. Plaintiffs are entitled to recover from Defendants the damages sustained by Plaintiffs as a result of Defendants' infringing in an amount subject to proof at trial, including lost profits and an amount not less than a reasonable royalty.

53. The infringement by Defendants of the '070 patent will continue to cause Plaintiffs irreparable injury and damage for which there is no adequate remedy at law unless and until Defendants are enjoined from infringing the patent.

JURY DEMAND

54. Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiffs demand a trial by jury.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

(a) A judgment declaring that the '085 and '070 patents remain valid, remain enforceable and have been infringed by Defendants;

(b) A permanent injunction against any infringement by Defendants of the '085 and '070 patents;

(c) A judgment awarding Plaintiffs all damages adequate to compensate for Defendants' infringement, and in no event less than a reasonable royalty for Defendants' acts of infringement, including all pre-judgment and post-judgment interest at the maximum rate permitted by law;

(d) An accounting of infringing importation, sales, or offers for sale not presented at or occurring after trial and an award by the court of additional damages for any such infringing acts;

(e) A judgment that Defendants' infringement is willful;

(f) A judgment that Defendants' conduct is exceptional;

(g) An award of attorney fees in this action under 35 U.S.C. § 285;

(h) Costs and expenses in this action; and

(i) Such other relief as this Court may deem just and proper.

Dated: September 14, 2015

Respectfully submitted,

By: *s/John E. Flaherty*

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