IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, KBI INC. and KBI-E INC., Plaintiffs v. MYLAN LABORATORIES LIMITED, MYLAN LABORATORIES, INC., MYLAN, INC., MATRIX LABORATORIES LIMITED and MATRIX LABORATORIES, INC. Defendants.	C.A. No. _____

COMPLAINT FOR PATENT INFRINGEMENT

AstraZeneca AB, Aktiebolaget Hässle, AstraZeneca LP, KBI Inc. and KBI-E Inc. (collectively, "Plaintiffs"), for their complaint against Mylan Laboratories Limited, Mylan Laboratories, Inc., Mylan, Inc., Matrix Laboratories Limited and Matrix Laboratories, 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 KBI Inc. ("KBI") is a Delaware corporation having its principal place of business at Whitehouse Station, New Jersey.

5. 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 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 and Matrix Limited are corporations 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 and Matrix Limited are 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, Defendant Mylan Laboratories, Inc. ("Mylan Labs Inc.") was formerly known as Matrix Laboratories, Inc. ("Matrix Labs Inc."). Upon information and belief, Defendants Mylan Labs Inc. and Matrix Labs Inc. are corporations organized and existing under the laws of the State of Delaware, having their principal place of business at 76 South Orange Avenue, Suite 301, South Orange, New Jersey 07079-1923. Upon information and belief, Mylan Limited is the immediate parent of Mylan Labs Inc. Upon

information and belief, Mylan Labs Inc. and Matrix Labs Inc. are 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, Mylan, Inc., Mylan Limited and Mylan Labs Inc. act in concert for the purposes of seeking FDA approval, marketing, distributing, and selling generic pharmaceutical products, including in the State of Delaware.

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 Matrix Labs Inc. and has renamed them as Mylan Laboratories Limited and Mylan Laboratories, Inc., respectively.

JURISDICTION AND VENUE

10. 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.

11. On information and belief, Defendants 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") (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, prior to the expiration of the patents-in-suit.

12. In a letter dated January 24, 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 patents-in-suit.

13. Defendants' submission of ANDA No. 78-936 and service of the January 24, 2012 Notice Letter indicates a refusal to change their current course of action. Matrix Limited and its U.S. agent Matrix Labs Inc. (collectively "Matrix") notified AstraZeneca, Merck & Co., KBI-E, Inc. and KBI, Inc. ("AstraZeneca and Merck") of ANDA 78-936 in a letter dated July 24, 2007 ("Matrix Notice Letter"). The Matrix Notice Letter did not provide a certification to the '504, '872 and '192 patents.

14. There has been and is now an actual controversy between Defendants and Plaintiffs as to whether Defendants infringe the '504, '192 and '872 patents.

15. 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 Delaware such that they should reasonably anticipate being haled into court here; on information and belief, Matrix Labs Inc. and Mylan Labs Inc. are corporations organized and existing under the laws of Delaware; Defendants have had continuous and systematic contacts with this judicial district, including, on information and belief, selling pharmaceutical products in Delaware and deriving substantial revenues from those sales; and

Mylan, Inc., Matrix Limited and Matrix Labs Inc. have regularly submitted to the jurisdiction of this Court in various patent infringement actions. Thus, Defendants are subject to general jurisdiction in Delaware.

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

FIRST CLAIM FOR RELIEF: '504 PATENT

17. Plaintiffs reallege paragraphs 1-16, above, as if set forth specifically here.

18. 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.

19. 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.

20. The January 24, 2012 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.

21. In the January 24, 2012 Notice Letter, Defendants notified Plaintiffs that as part of their ANDA they 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."

22. On information and belief, at the time the January 24, 2012 Notice Letter was served, Defendants were aware of the statutory provisions and regulations referred to in paragraph 21, above.

23. The January 24, 2012 Notice Letter, which is required by statute and regulation to provide a full and detailed explanation regarding non-infringement (see paragraph 21, above), does not allege non-infringement of all claims of the '504 patent.

24. The January 24, 2012 Notice Letter, which is required by statute and regulation to provide a full and detailed explanation regarding invalidity (see paragraph 21, above), alleges invalidity of all claims of the '504 patent.

25. The January 24, 2012 Notice Letter, which is required by statute and regulation to provide a full and detailed explanation regarding unenforceability (see paragraph 21, above), does not allege unenforceability of the ’504 patent.

26. Even where asserted, the January 24, 2012 Notice Letter does not provide the full and detailed statement of Defendants’ factual and legal basis to support their non-infringement, invalidity and/or unenforceability allegations as to the ’504 patent.

27. Accordingly, the January 24, 2012 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.

28. Defendants have infringed the ’504 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, or the use of which is claimed in the this patent, prior to the expiration of the ’504 patent.

29. On information and belief, the ANDA Products, 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 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.

30. On information and belief, the ANDA Products are a component of the formulation patented in the ’504 patent, are a material for use in practicing the method patented in the ’504 patent, constitute a material part of those inventions, are especially made or

especially adapted for use in an infringement of the ’504 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, if approved, will be used in contravention of Plaintiffs’ rights under the ’504 patent.

31. The January 24, 2012 Notice Letter does not allege and does not address non-infringement of all claims of the ’504 patent. By not addressing non-infringement of all claims of the ’504 patent in its January 24, 2012 Notice Letter, Defendants admit that the ANDA Products meet all limitations of those non-addressed ’504 patent claims.

32. On information and belief, the manufacture, use and sale of the ANDA Products infringe the ’504 patent claims.

SECOND CLAIM FOR RELIEF: ’192 PATENT

33. Plaintiffs reallege paragraphs 1-16 and 20, above, as if set forth specifically here.

34. 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.

35. 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.

36. In the January 24, 2012 Notice Letter, Defendants 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."

37. On information and belief, at the time the January 24, 2012 Notice Letter was served, Defendants were aware of the statutory provisions and regulations referred to in paragraph 36, above.

38. The January 24, 2012 Notice Letter, which is required by statute and regulation to provide a full and detailed explanation regarding non-infringement (see paragraph 36, above), does not allege non-infringement of all claims of the '192 patent.

39. The January 24, 2012 Notice Letter, which is required by statute and regulation to provide a full and detailed explanation regarding invalidity (see paragraph 36, above), alleges invalidity of all claims of the ’192 patent.

40. The January 24, 2012 Notice Letter, which is required by statute and regulation to provide a full and detailed explanation regarding unenforceability (see paragraph 36, above), does not allege enforceability of the ’192 patent.

41. Even where asserted, the January 24, 2012 Notice Letter does not provide the full and detailed statement of their factual and legal bases to support their non- infringement, invalidity and/or unenforceability allegations as to the ’192 patent.

42. Accordingly, the January 24, 2012 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.

43. Defendants have infringed the ’192 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 the use of which is claimed in this patent, prior to the expiration of the ’192 patent.

44. On information and belief, the ANDA Products, if approved, will be administered to human patients in a therapeutically effective amount to treat gastric acid related diseases by inhibiting gastric acid secretion.

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

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

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

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

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

50. 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.

51. 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.

52. 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 '192 patent.

53. On information and belief, the ANDA Products are a material for use in practicing the method patented in the '192 patent, constitute a material part of that invention, are especially made or especially adapted for use in an infringement of the '192 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, if approved, will be used in contravention of Plaintiffs' rights under the '192 patent.

54. The January 24, 2012 Notice Letter does not allege and does not address non-infringement of all the claims of the '192 patent. By not addressing non- infringement of all claims of the '192 patent in its January 24, 2012 Notice Letter, Defendants admit that the ANDA Products meet all limitations of those non-addressed '192 patent claims.

55. On information and belief, the manufacture, use and sale of the ANDA Products infringe the '192 patent claims.

THIRD CLAIM FOR RELIEF: '872 PATENT

56. Plaintiffs reallege paragraphs 1-16 and 20, above, as if set forth specifically here.

57. 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.

58. 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.

59. In the January 24, 2012 Notice Letter, Defendants notified Plaintiffs that as part of their ANDA they 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."

60. On information and belief, at the time the January 24, 2012 Notice Letter was served, Defendants were aware of the statutory provisions and regulations referred to in paragraph 59, above.

61. The January 24, 2012 Notice Letter, which is required by statute and regulation to provide a full and detailed explanation regarding non-infringement (see paragraph 59, above), does not allege non-infringement of all the claims of the '872 patent.

62. The January 24, 2012 Notice Letter, which is required by statute and regulation to provide a full and detailed explanation regarding invalidity (see paragraph 59, above), alleges invalidity of all claims of the '872 patent.

63. The January 24, 2012 Notice Letter, which is required by statute and regulation to provide a full and detailed explanation regarding unenforceability (see paragraph 59, above), does not allege enforceability of the '872 patent.

64. Even where asserted, the January 24, 2012 Notice Letter did not provide the full and detailed statement of Defendants' factual and legal bases to support their non-infringement, invalidity and/or unenforceability allegations as to the '872 patent.

65. Accordingly, the January 24, 2012 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.

66. Defendants have infringed the ’872 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 ’872 patent.

67. On information and belief, the ANDA Products, if approved, will be administered to human patients at Defendants’ active behest and with its 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 ’872 patent.

68. On information and belief, the ANDA Products contain as their active ingredient, a component of the compound patented in the ’872 patent, constitute a material part of those inventions, are especially made or especially adapted for use in an infringement of the ’872 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, if approved, will be used in contravention of Plaintiffs’ rights under the ’872 patent.

69. The January 24, 2012 Notice Letter does not allege and does not address non-infringement of all claims of the ’872 patent. By not addressing non-infringement of all claims of the ‘872 patent in its January 24, 2012 Notice Letter, Defendants admit that the ANDA Products meet all limitations of those non-addressed ‘872 patent claims.

70. On information and belief, the manufacture, use and sale of the ANDA Product infringes the ’872 patent claims.

WHEREFORE, Plaintiffs respectfully request the following relief:

(a) A Judgment declaring that the effective date of any approval of Defendants’ ANDA No. 78-936 under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) for drug product called “Esomeprazole Magnesium Capsules, 20 mg, and 40 mg” be a date which is not earlier than the later of August 3, 2015, the expiration date of the last to expire of the patents-in-suit that is infringed, and the expiration of any exclusivity relating to the patent to which Plaintiffs are or will become entitled;

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

(c) A judgment declaring that Defendants have 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 Defendants’ defenses and claims for relief are limited to those presented in the January 24, 2012 Notice Letter;

(e) A permanent injunction against any infringement by Defendants of the ’504, ’192 and ’872 patents;

(f) A judgment that Defendants’ infringement is willful;

(g) A judgment that Defendants’ conduct is exceptional;

(h) An award of attorney 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 just and proper.

MCCARTER & ENGLISH, LLP

Dated: March 12, 2012

/s/ Daniel M. Silver

Michael P. Kelly (DE ID # 2295)
Daniel M. Silver (DE ID # 4758)
Renaissance Centre
405 N. King Street, 8th Floor
Wilmington, DE 19801
(302) 984-6300
(302) 984-6399 (fax)
mkelly@mccarter.com
dsilver@mccarter.com

Attorneys for Plaintiffs

Of Counsel:
Henry J. Renk
Bruce C. Haas
Joshua I. Rothman
FITZPATRICK, CELLA, HARPER & SCINTO
1290 Avenue of the Americas
New York, New York 10104-3800
(212) 218-2100

Einar Stole
COVINGTON & BURLING LLP
1201 Pennsylvania Avenue, NW
Washington, DC 20004-2401
(202) 662-6000