

John E. Flaherty
Jonathan M.H. Short
McCARTER & ENGLISH, LLP
Four Gateway Center
100 Mulberry Street
Newark, New Jersey 07102
(973) 622-4444

Attorneys for Plaintiffs
AstraZeneca AB, Aktiebolaget Hässle,
AstraZeneca LP, KBI Inc. and KBI-E Inc

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

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

ASTRAZENECA AB, AKTIEBOLAGET
HÄSSLE, ASTRAZENECA LP, KBI INC.
and KBI-E INC.,

Plaintiffs,

v.

TORRENT PHARMACEUTICALS
LIMITED and TORRENT PHARMA INC.,

Defendants.

Civil Action No. _____

**COMPLAINT FOR PATENT
INFRINGEMENT
AND CERTIFICATION PURSUANT TO
LOCAL RULE 11.2**

COMPLAINT FOR PATENT INFRINGEMENT

AstraZeneca AB, Aktiebolaget Hässle, AstraZeneca LP, KBI Inc. and KBI-E Inc. (collectively, “Plaintiffs”), for their complaint against Torrent Pharmaceuticals Limited and Torrent Pharma 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 Torrent Pharmaceuticals Ltd. (“Torrent Ltd.”) is a corporation organized and existing under the laws of India, having its principal place of business at International Operations Division, 4th Floor, Torrent Tower, Off Ashram Road, Ahmedabad, Gujarat 380009 India. Upon information and belief, Torrent Ltd. is

in the business of, among other things, manufacturing, marketing and selling generic copies of branded pharmaceutical products throughout the United States of America.

7. Upon information and belief, Defendant Torrent Pharma Inc. (“Torrent Inc.”) is a corporation organized and existing under the laws of Michigan, having its principal place of business at 5380 Holiday Terrace, Suite 40, Kalamazoo, Michigan 49009. Upon information and belief, Torrent Inc. is in the business of, among other things, manufacturing, marketing and selling generic copies of branded pharmaceutical products throughout the United States.

8. Upon information and belief, Torrent Inc. is a wholly-owned subsidiary of Torrent Ltd. Torrent Ltd. and Torrent Inc. operate as a single, integrated business; both companies share a website, www.torrentpharma.com; Torrent Inc. is identified on the Torrent Ltd. website as a contact for “general inquiries” regarding US operations and the companies collaborate in the manufacture, marketing, and sale of pharmaceutical products, including generic drug products manufactured and sold throughout the United States pursuant to approved abbreviated new drug applications.

JURISDICTION AND VENUE

9. 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.

10. 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”) by, *inter alia*,

submitting an Abbreviated New Drug Application designated ANDA No. 203636 seeking approval from the U.S. Food and Drug Administration (“FDA”) to manufacture commercially its proposed 20 mg and 40 mg products called “Esomeprazole Magnesium Delayed-Release Capsules 20 mg and 40 mg” (hereinafter referred to as the “ANDA Products”) containing the active ingredient esomeprazole magnesium.

11. In Torrent Ltd.’s notice letter dated December 15, 2011 entitled:

Patent Certification Notice – Torrent Pharmaceuticals Limited ANDA No. 203636 for Esomeprazole Magnesium Delayed-release Capsules 20 mg and 40 mg; Notice of Certification of Non-infringement and/or Invalidity of U.S. Patent No. 5,690,960, U.S. Patent No. 5,714,504, U.S. Patent No. 5,877,192, U.S. Patent No. 5,900,424, U.S. Patent No. 6,147,103, U.S. Patent No. 6,166,213, U.S. Patent No. 6,191,148, U.S. Patent No. 6,369,085, U.S. Patent No. 6,428,810, U.S. Patent No. 6,875,872 & U.S. Patent No. 7,411,070; and Offer of Confidential Access to Application

(hereinafter referred to as the “December 15, 2011 Notice Letter”), Torrent Ltd. indicated that it intends to market its esomeprazole magnesium products before the expiration of the ’504, ’192 and ’872 patents.

12. Defendants’ submission of ANDA No. 203636 and service of the December 15, 2011 Notice Letter indicates a refusal to change their current course of action.

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

14. This Court has personal jurisdiction over Torrent Ltd. because Torrent Ltd. has purposely availed itself of the benefits and protections of the laws of New Jersey such that it should reasonably anticipate being haled into court here. In addition, Torrent Ltd. has 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. Thus, Torrent Ltd. is subject to general jurisdiction in New Jersey.

15. This Court has personal jurisdiction over Torrent Inc. because Torrent Inc. has purposely availed itself of the benefits and protections of the laws of New Jersey such that it should reasonably anticipate being haled into court here. In addition, Torrent Inc. has 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. Thus, Torrent Inc. is subject to general jurisdiction in New Jersey.

16. In the December 15, 2011 Notice Letter Torrent Ltd. lists Torrent Inc. as a U.S. Agent for Torrent Ltd. and authorizes it to “accept service of process on behalf of Torrent”.

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 December 15, 2011 Notice Letter notified Plaintiffs that Defendants submitted ANDA 203636 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 December 15, 2011 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 December 15, 2011 Notice Letter was served, Defendants were aware of the statutory provisions and regulations referred to in paragraph 21, above.

23. The December 15, 2011 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 December 15, 2011 Notice Letter, which is required by statute and regulation to provide a full and detailed explanation regarding invalidity (see paragraph 21, above), does not allege invalidity of all claims of the ’504 patent.

25. The December 15, 2011 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 December 15, 2011 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 December 15, 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.

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 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, 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 December 15, 2011 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 December 15, 2011 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 December 15, 2011 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 December 15, 2011 Notice Letter was served, Defendants were aware of the statutory provisions and regulations referred to in paragraph 36, above.

38. The December 15, 2011 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 December 15, 2011 Notice Letter, which is required by statute and regulation to provide a full and detailed explanation regarding invalidity (see paragraph 36, above), does not allege invalidity of all claims of the '192 patent.

40. The December 15, 2011 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 December 15, 2011 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 December 15, 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.

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 interindividual 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 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, 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 December 15, 2011 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 December 15, 2011 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 December 15, 2011 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 December 15, 2011 Notice Letter was served, Defendants were aware of the statutory provisions and regulations referred to in paragraph 59, above.

61. The December 15, 2011 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 December 15, 2011 Notice Letter, which is required by statute and regulation to provide a full and detailed explanation regarding invalidity (see paragraph 59, above), does not allege invalidity of all claims of the '872 patent.

63. The December 15, 2011 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 December 15, 2011 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 December 15, 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.

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 are especially made or especially adapted for treatment of humans. 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 December 15, 2011 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 '504 patent in its December 15, 2011 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. 203636 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" 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 be come 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 December 15, 2011 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.

Respectfully Submitted,

Dated: January 26, 2012

By: s/John E. Flaherty
John E. Flaherty
Jonathan M.H. Short
McCARTER & ENGLISH, LLP
Four Gateway Center
100 Mulberry Street
Newark, New Jersey 07102
(973) 622-4444

Attorneys for Plaintiffs
ASTRAZENECA AB,
AKTIEBOLAGET HÄSSLE,
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And KBI-E INC.

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Henry J. Renk
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FITZPATRICK, CELLA, HARPER
& SCINTO
1290 Avenue of the Americas
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(212) 218-2100

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

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 actions:

ASTRAZENECA AB; AKTIEBOLAGET HÄSSLE; ASTRAZENECA LP; KBI INC.; and KBI-E INC. v. HETERO DRUGS, LTD., UNIT III and HETERO USA INC., 3:11-cv-04468-JAP-TJB (District of New Jersey).

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).

LUPIN LTD. and LUPIN PHARMACEUTICALS, INC. v. MERCK SHARP & DOHME CORP., 3:10-cv-00683-JAP-TJB (District of New Jersey).

Dated: January 26, 2012

By: s/John E. Flaherty
John E. Flaherty
Jonathan M.H. Short
McCARTER & ENGLISH, LLP
Four Gateway Center
100 Mulberry Street
Newark, New Jersey 07102
(973) 622-4444

Attorneys for Plaintiffs
ASTRAZENECA AB,
AKTIEBOLAGET HÄSSLE,
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and KBI-E INC.

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FITZPATRICK, CELLA, HARPER
& SCINTO

1290 Avenue of the Americas
New York, New York 10104-3800
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Einar Stole
COVINGTON & BURLING LLP
1201 Pennsylvania Avenue, NW
Washington, DC 20004-2401
(202) 662-6000