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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

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

Plaintiffs

v.

WATSON LABORATORIES, INC. – FLORIDA, WATSON PHARMA, INC., and ACTAVIS, INC.,

Defendants.

Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT AND CERTIFICATION PURSUANT TO LOCAL CIVIL 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 Watson Laboratories, Inc. – Florida, Watson Pharma, Inc., and Actavis, 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 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 approved New Drug Application No. 021153 from the United States Food and Drug Administration ("FDA") for a delayed-release esomeprazole magnesium formulation that 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.

6. KBI and KBI-E have exclusive rights in the United States to the patents-in-suit.

7. Upon information and belief, Defendant Watson Laboratories, Inc. – Florida ("Watson Laboratories") was formerly known as Andrx Pharmaceuticals, Inc. ("Andrx

Pharmaceuticals"). Upon information and belief, Watson Laboratories is a corporation organized and existing under the laws of Florida, having its principal place of business at 4955 Orange Drive, Davie, Florida 33314. Upon information and belief, Watson Laboratories is in the business of, *inter alia*, developing, manufacturing, and obtaining regulatory approval of generic copies of branded pharmaceutical products throughout the United States, including within this district.

8. Upon information and belief, Defendant Watson Pharma, Inc. ("Watson Pharma") is a corporation organized and existing under the laws of Delaware, having its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054. Upon information and belief, Watson Pharma is in the business of, *inter alia*, selling and distributing generic copies of branded pharmaceutical products in New Jersey and throughout the United States, including some that are manufactured by Watson Laboratories and/or for which Watson Laboratories is the named applicant of the approved ANDAs.

9. Upon information and belief, Defendant Actavis, Inc. ("Actavis") was formerly known as Watson Pharmaceuticals, Inc. ("Watson Pharmaceuticals") until on or around January 24, 2013. Actavis is a corporation organized and existing under the laws of Nevada, having its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054. Upon information and belief, Actavis is in the business of, *inter alia*, developing, manufacturing, obtaining regulatory approval, marketing, selling, and distributing generic copies of branded pharmaceutical products throughout the United States, including within this district, through its own actions and through the actions of its agents and subsidiaries, including at least Watson Laboratories and Watson Pharma.

10. Upon information and belief, Watson Pharmaceuticals acquired Andrx Pharmaceuticals on or around November 3, 2006. Upon information and belief, Watson Pharmaceuticals renamed Andrx Pharmaceuticals as Watson Laboratories.

11. Upon information and belief, Watson Laboratories is a wholly-owned subsidiary of Andrx Corporation, a Delaware corporation, having its principal place of business at 4955 Orange Drive, Davie, Florida 33314, that is a wholly-owned subsidiary of Actavis.

12. Upon information and belief, Watson Pharma is a wholly-owned subsidiary of Actavis.

13. Upon information and belief, Actavis organizes its operations by divisions— including at least Generics, Brands, and Distribution—and, before the name change, Watson Pharmaceuticals reported its financial results in its Securities and Exchange Commission ("SEC") filings by reference to these divisions. Upon information and belief, Watson Pharmaceuticals consolidated its financial results with subsidiaries in its SEC filings at least since 2007 and did not file separate financial reports to the SEC for each subsidiary.

14. Upon information and belief, Actavis' Generics Division is involved in the development, manufacture, marketing, sale, and distribution of generic pharmaceuticals. Upon information and belief, each Defendant acts as an agent of the other and/or works in concert with each other as integrated parts of the Generics Division. Upon information and belief, the Generics Division develops and submits Abbreviated New Drug Applications ("ANDAs") to the FDA, relying on contributions from at least Defendants.

15. Upon information and belief, the head of the Generics Division is an employee of Actavis, the Generic Division's ANDAs are submitted by at least Watson

Laboratories, the Generics Division's products are developed and manufactured by at least Watson Laboratories, and the Generics Division's products are marketed, sold, and distributed throughout the United States, including in New Jersey, by at least Watson Pharma. Upon information and belief, Watson Laboratories and Watson Pharma are parties to one or more contractual agreements regarding the distribution of generic pharmaceutical products.

16. Upon information and belief, each Defendant shares with the others at least some common employees, officers, and directors.

17. Upon information and belief, Watson Laboratories and Watson Pharma are within the control of Actavis for purposes of responding to discovery in this action.

JURISDICTION AND VENUE

18. 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.

19. Upon 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"); 6,369,085 (the "'085 patent"); 6,875,872 (the "'872 patent"); and 7,411,070 (the "'070 patent") (collectively, the "patents-in-suit") by, *inter alia*, submitting to the FDA ANDA No. 204358 ("Defendants' ANDA"). Defendants' ANDA seeks the FDA's approval to manufacture, use, or sell commercially their proposed product called "Esomeprazole Magnesium Delayed Release Capsules, 40 mg" (hereinafter referred to as the "ANDA Product"), containing the active ingredient esomeprazole magnesium, prior to the expiration of the patents-in-suit, as a generic version of the NEXIUM® product.

20. In a letter dated February 4, 2013 ("2013 Notice Letter") from Ms. Janet Vaughn, Watson Laboratories' Director of Regulatory Affairs, Watson Laboratories 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"), with respect to the '504, '192, '085, '872, and '070 patents.

21. Paragraph IV requires certification by the ANDA applicant that the subject patent "is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted ...." 21 U.S.C. § 355(j)(2)(B)(iv) requires a Paragraph IV notice to "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid 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 the 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."

22. Upon information and belief, at the time the 2013 Notice Letter was served, Defendants were aware of the statutory provisions and regulations referred to in paragraph 21, above.

23. Defendants' submission of ANDA No. 204358 and service of the 2013 Notice Letter indicates a refusal to change their current course of action.

24. There is now an actual controversy between Defendants and Plaintiffs as to whether Defendants infringe the '504, '192, '085, '872, and '070 patents.

25. This Court has personal jurisdiction over Defendants because, *inter alia*, Defendants, upon 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, upon information and belief, maintaining executive offices in New Jersey and deriving substantial revenues from the sale of pharmaceutical products in New Jersey; and at least Watson Pharma and Actavis, upon information and belief, are licensed to do business within New Jersey. Thus, Defendants are subject to general jurisdiction in New Jersey.

26. Upon information and belief, Watson Laboratories has previously purposefully availed itself of the benefits and protections of the U.S. District Court for the District of New Jersey including by, *inter alia*, filing a complaint in *Shionogi Inc. et al. v. Nostrum Labs., Inc. et al.*, C.A. No. 1:12-cv-04402-RBK-JS (D.I. 1), and asserting counterclaims in this Court in *Depomed, Inc. v. Actavis Elizabeth LLC et al.*, C.A. No. 3:12-01358-JAP-TJB (D.I. 47).

27. Upon information and belief, the acts of Watson Laboratories complained of herein were done at the direction of, with the authorization of, and with the cooperation, participation, and assistance of Watson Pharma and Actavis.

FIRST CLAIM FOR RELIEF: ’504 PATENT

28. Plaintiffs reallege paragraphs 1-27, above, as if set forth specifically herein.

29. 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 the claimed salts.

30. Plaintiff 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.

31. In the 2013 Notice Letter, Defendants notified Plaintiffs that, as part of their ANDA, they had filed a Paragraph IV certification with respect to the '504 patent.

32. The 2013 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 any claim of the '504 patent.

33. The 2013 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.

34. The 2013 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.

35. Even where asserted, the 2013 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.

36. Accordingly, the 2013 Notice Letter fails to comply with federal statute, as specified in 21 U.S.C. § 355(j), and FDA rules and regulations, as specified in 21 C.F.R. § 314.95.

37. 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.

38. Upon information and belief, the ANDA Product, 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 diseases. Upon information and belief, this administration will occur at Defendants’ active behest and with their intent, knowledge, and encouragement. Upon 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.

39. Upon information and belief, the ANDA Product is a component of the formulations patented in the ’504 patent, is a material for use in practicing the methods patented in the ’504 patent, constitutes a material part of those inventions, is especially made or especially adapted for use in an infringement of the ’504 patent, and is not a staple article or commodity of commerce suitable for substantial noninfringing use. Upon information and belief, Defendants are aware that the ANDA Product is so made or so adapted. Upon information and belief, Defendants are aware that the ANDA Product, if approved, will be used in contravention of Plaintiffs’ rights under the ’504 patent.

40. The 2013 Notice Letter does not allege and does not address non-infringement of any claim of the ’504 patent. By not addressing non-infringement of any claim of the ’504 patent in their 2013 Notice Letter, Defendants admit that the ANDA Product meets all limitations of the non-addressed ’504 patent claims.

41. The 2013 Notice Letter does not allege and does not address unenforceability of the '504 patent. By not addressing unenforceability of the '504 patent in their 2013 Notice Letter, Defendants admit that the '504 is enforceable.

42. Upon information and belief, the manufacture, use, and sale of the ANDA Product infringes the '504 patent claims.

SECOND CLAIM FOR RELIEF: '192 PATENT

43. Plaintiffs reallege paragraphs 1-27, above, as if set forth specifically herein.

44. 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 or pharmaceutically acceptable salts thereof and methods for producing a medicament for such treatment.

45. 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.

46. In the 2013 Notice Letter, Defendants notified Plaintiffs that, as part of their ANDA, they had filed a Paragraph IV certification with respect to the '192 patent.

47. The 2013 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 any claim of the '192 patent.

48. The 2013 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 '192 patent.

49. The 2013 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 '192 patent.

50. Even where asserted, the 2013 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.

51. Accordingly, the 2013 Notice Letter fails to comply with federal statute, as specified in 21 U.S.C. § 355(j), and FDA rules and regulations, as specified in 21 C.F.R. § 314.95.

52. 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.

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

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

55. Upon information and belief, such treatment will effect increased average plasma levels (AUC) per dosage unit.

56. Upon information and belief, such treatment will effect a less pronounced increase in gastrin levels in slow metabolizers during such treatment.

57. Upon information and belief, such treatment will effect decreased CYP1A induction in slow metabolizers during such treatment.

58. Upon information and belief, such treatment will elicit an improved antisecretory effect during such treatment.

59. Upon 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.

60. Upon information and belief, the amount to be administered will be between about 20 mg and about 40 mg total daily dose during such treatment.

61. Upon information and belief, this administration will occur at Defendants' active behest and with their intent, knowledge, and encouragement. Upon 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.

62. Upon information and belief, the ANDA Product is a material for use in practicing the methods patented in the '192 patent, constitutes a material part of those inventions, is especially made or especially adapted for use in an infringement of the '192 patent, and is not a staple article or commodity of commerce suitable for substantial noninfringing use.

Upon information and belief, Defendants are aware that the ANDA Product is so made or so adapted. Upon information and belief, Defendants are aware that the ANDA Product, if approved, will be used in contravention of Plaintiffs' rights under the '192 patent.

63. The 2013 Notice Letter does not allege and does not address non-infringement of any claim of the '192 patent. By not addressing non-infringement of any claim of the '192 patent in their 2013 Notice Letter, Defendants admit that the ANDA Product meets all limitations of the non-addressed '192 patent claims.

64. The 2013 Notice Letter does not allege and does not address unenforceability of the '192 patent. By not addressing unenforceability of the '192 patent in their 2013 Notice Letter, Defendants admit that the '192 is enforceable.

65. Upon information and belief, the manufacture, use, and sale of the ANDA Product infringes the '192 patent claims.

THIRD CLAIM FOR RELIEF: '085 PATENT

66. Plaintiffs reallege paragraphs 1-27, above, as if set forth specifically herein.

67. The '085 patent (copy attached as Exhibit C), 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 and methods of preparing and using the claimed salts.

68. Plaintiff AstraZeneca 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.

69. In the 2013 Notice Letter, Defendants notified Plaintiffs that, as part of their ANDA, they had filed a Paragraph IV certification with respect to the '085 patent.

70. The 2013 Notice Letter, which is required by statute and regulation to provide a full and detailed explanation regarding non-infringement (*see* paragraph 21, above), alleges non-infringement of all the claims of the '085 patent.

71. The 2013 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 any claim of the '085 patent.

72. The 2013 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 '085 patent.

73. Even where asserted, the 2013 Notice Letter does not provide the full and detailed statement of Defendants' factual and legal bases to support their non-infringement allegations as to the '085 patent.

74. Accordingly, the 2013 Notice Letter fails to comply with federal statute, as specified in 21 U.S.C. § 355(j), and FDA rules and regulations, as specified in 21 C.F.R. § 314.95.

75. 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.

76. Upon information and belief, the ANDA Product, if approved, will be administered to human patients in a therapeutically effective amount to treat gastric acid

related conditions. Upon information and belief, this administration will occur at Defendants' active behest and with their intent, knowledge, and encouragement. Upon 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.

77. Upon information and belief, the ANDA Product is a component of the compounds patented in the '085 patent, is a material for use in practicing the methods patented in the '085 patent, constitutes a material part of those inventions, is especially made or especially adapted for use in an infringement of the '085 patent, and is not a staple article or commodity of commerce suitable for substantial noninfringing use. Upon information and belief, Defendants are aware that the ANDA Product is so made or so adapted. Upon information and belief, Defendants are aware that the ANDA Product, if approved, will be used in contravention of Plaintiffs' rights under the '085 patent.

78. The 2013 Notice Letter does not allege and does not address invalidity of any claim of the '085 patent. By not addressing invalidity of any claim of the '085 patent in their 2013 Notice Letter, Defendants admit that the claims of the '085 are valid.

79. The 2013 Notice Letter does not allege and does not address unenforceability of the '085 patent. By not addressing unenforceability of the '085 patent in their 2013 Notice Letter, Defendants admit that the '085 is enforceable.

80. Upon information and belief, the manufacture, use, and sale of the ANDA Product infringes the '085 patent claims.

FOURTH CLAIM FOR RELIEF: '872 PATENT

81. Plaintiffs reallege paragraphs 1-27, above, as if set forth specifically herein.

82. The ’872 patent (copy attached as Exhibit D), 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.

83. 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.

84. In the 2013 Notice Letter, Defendants notified Plaintiffs that, as part of its ANDA, they had filed a Paragraph IV certification with respect to the ’872 patent.

85. The 2013 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 any claim of the ’872 patent.

86. The 2013 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 ’872 patent.

87. The 2013 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 ’872 patent.

88. Even where asserted, the 2013 Notice Letter does 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.

89. Accordingly, the 2013 Notice Letter fails to comply with federal statute, as specified in 21 U.S.C. § 355(j), and FDA rules and regulations, as specified in 21 C.F.R. § 314.95.

90. 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.

91. Upon information and belief, the ANDA Product, if approved, will be administered to human patients at Defendants’ active behest and with their intent, knowledge, and encouragement. Upon 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.

92. Upon information and belief, the ANDA Product contains a component of the compounds patented in the ’872 patent, constitutes a material part of those inventions, is especially made or especially adapted for use in an infringement of the ’872 patent, and is not a staple article or commodity of commerce suitable for substantial noninfringing use. Upon information and belief, Defendants are aware that the ANDA Product is so made or so adapted. Upon information and belief, Defendants are aware that the ANDA Product, if approved, will be used in contravention of Plaintiffs’ rights under the ’872 patent.

93. The 2013 Notice Letter does not allege and does not address non-infringement of any claim of the ’872 patent. By not addressing non-infringement of any claim of the ‘872 patent in their 2013 Notice Letter, Defendants admit that the ANDA Product meets all limitations of the non-addressed ‘872 patent claims.

94. The 2013 Notice Letter does not allege and does not address unenforceability of the '872 patent. By not addressing unenforceability of the '872 patent in their 2013 Notice Letter, Defendants admit that the '872 is enforceable.

95. Upon information and belief, the manufacture, use, and sale of the ANDA Product infringes the '872 patent claims.

FIFTH CLAIM FOR RELIEF: '070 PATENT

96. Plaintiffs reallege paragraphs 1-27, above, as if set forth specifically herein.

97. The '070 patent (copy attached as Exhibit E), 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 and processes for preparing the claimed salts.

98. Plaintiff AstraZeneca 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.

99. In the 2013 Notice Letter, Defendants notified Plaintiffs that, as part of their ANDA, they had filed a Paragraph IV certification with respect to the '070 patent.

100. The 2013 Notice Letter, which is required by statute and regulation to provide a full and detailed explanation regarding non-infringement (*see* paragraph 21, above), alleges non-infringement of all the claims of the '070 patent.

101. The 2013 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 any claim of the '070 patent.

102. The 2013 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 '070 patent.

103. Even where asserted, the 2013 Notice Letter does 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 '070 patent.

104. Accordingly, the 2013 Notice Letter fails to comply with federal statute, as specified in 21 U.S.C. § 355(j), and FDA rules and regulations, as specified in 21 C.F.R. § 314.95.

105. 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.

106. Upon information and belief, the ANDA Product, if approved, will be administered to human patients at Defendants' active behest and with their intent, knowledge, and encouragement. Upon 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.

107. Upon information and belief, the ANDA Product contains a component of the compound patented in the '070 patent, is a material for use in practicing the methods patented in the '070 patent, constitutes a material part of those inventions, is especially made or especially adapted for use in an infringement of the '070 patent, and is not a staple article or commodity of commerce suitable for substantial noninfringing use. Upon information

and belief, Defendants are aware that the ANDA Product is so made or so adapted. Upon information and belief, Defendants are aware that the ANDA Product, if approved, will be used in contravention of Plaintiffs' rights under the '070 patent.

108. The 2013 Notice Letter does not allege and does not address invalidity of any claim of the '070 patent. By not addressing invalidity of any claim of the '070 patent in their 2013 Notice Letter, Defendants admit that the claims of the '070 are valid.

109. The 2013 Notice Letter does not allege and does not address unenforceability of the '070 patent. By not addressing unenforceability of the '070 patent in their 2013 Notice Letter, Defendants admit that the '070 patent is enforceable.

110. Upon information and belief, the manufacture, use, and sale of the ANDA Product infringes the '070 patent claims.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

(a) A judgment declaring that the effective date of any approval of Defendants' ANDA No. 204358, filed under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), for a drug product called "Esomeprazole Magnesium Delayed Release Capsules, 40 mg" be a date not earlier than the later of November 25, 2018, the expiration date of the last to expire of the patents-in-suit that is infringed, and the expiration of any exclusivity relating to such patent to which Plaintiffs are or will become entitled;

(b) A judgment declaring that the '504, '192, '085, '872, and '070 patents have been infringed by Defendants, and remain valid and enforceable;

(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 2013 Notice Letter;

(e) A permanent injunction against any infringement by Defendants, their officers, agents, attorneys, employees, successors, and assigns, and those acting in privity or concert with them, of the '504, '192, '085, '872, and '070 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: March 19, 2013

By: *s/John E. Flaherty*

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CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Pursuant to Local Civil Rule 11.2, I hereby certify that the matter in controversy is the subject of the following actions:

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., C.A. No. 3:11-cv-00760-JAP-TJB (District of New Jersey); and

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-JAP-TJB (District of New Jersey).

Dated: March 19, 2013

By: *s/John E. Flaherty*

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