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

ASTRAZENECA AB, ASTRAZENECA LP, KBI-E INC., HORIZON PHARMA, INC., and POZEN INC., Plaintiffs, v. MYLAN PHARMACEUTICALS INC., MYLAN LABORATORIES LIMITED, and MYLAN, INC., Defendants.	Civil Action No. 3:13-cv-04022-JAP-DEA **FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT**

FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT

AstraZeneca AB, AstraZeneca LP, KBI-E Inc., Horizon Pharma, Inc., and Pozen Inc. (collectively, "Plaintiffs") for their First Amended Complaint against Mylan Pharmaceuticals Inc., 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 AstraZeneca LP is a limited partnership organized under the laws of Delaware, having its principal place of business at Wilmington, Delaware.

3. Plaintiff KBI-E Inc. ("KBI-E") is a Delaware corporation having its principal place of business at Wilmington, Delaware.

4. KBI-E has exclusive rights in the United States to market and sell products covered by United States Patent Nos. 5,714,504 (the "'504 patent"); 6,369,085 (the "'085 patent"); 6,875,872 (the "'872 patent"); 7,411,070 (the "'070 patent"); 7,745,466 ("the '466 patent"), and 5,948,789 (the "'789 patent").

5. Plaintiff Horizon Pharma, Inc. ("Horizon") is a corporation operating and existing under the laws of the State of Delaware, with its principal place of business at 520 Lake Cook Road, Suite 520, Deerfield, Illinois 60015. Horizon holds approved New Drug Application No. 022511 from the United States Food and Drug Administration ("FDA") for a delayed-release naproxen / esomeprazole magnesium formulation that it sells under the name VIMOVO®.

6. Plaintiff Pozen Inc. ("Pozen") is a corporation operating and existing under the laws of the State of Delaware, with its principal place of business at 1414 Raleigh Road, Chapel Hill, North Carolina 27517.

7. Pozen owns United States Patent Nos. 6,926,907 (the "'907 patent") and 8,557,285 (the "'285 patent") by assignment from the inventor. Horizon is Pozen's exclusive licensee under the '907 and '285 patents.

8. Upon information and belief, Defendant Mylan Pharmaceuticals Inc. is a corporation organized and existing under the laws of West Virginia, having its principal place of business at 781 Chestnut Ridge Rd, Morgantown, West Virginia 26505. Upon information and belief, Mylan Pharmaceuticals, 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, Defendant Mylan Laboratories Limited ("Mylan Limited") was formerly known as Matrix Laboratories Limited ("Matrix Limited"). Upon information and belief, Defendant 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, Hyderabad 500034 Andhra Pradesh, 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.

10. 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, *inter alia*, manufacturing, marketing, and selling generic copies of branded pharmaceutical products in New Jersey and throughout the United States.

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

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

13. Upon information and belief, Mylan Pharmaceuticals, Inc., and Mylan Limited are within the control of Defendant Mylan Inc. for purposes of responding to discovery in this action.

JURISDICTION AND VENUE

14. 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.

15. Upon information and belief, Defendants have been and are engaging in activities directed toward infringement of the ’504 patent, ’085 patent, the ’872 patent, the ’070 patent, the ’789 patent, the ’466 patent, the ’907 patent, and the ’285 patent (collectively, the “patents-in-suit”) by, *inter alia*, submitting to the FDA ANDA No. 204920 (“Defendants’ ANDA”) and by submitting Drug Master Files (DMF), including DMF #23120. Defendants’ ANDA seeks the FDA’s approval to manufacture, use, or sell commercially their proposed naproxen/esomeprazole magnesium delayed-release tablets, 375 mg/20 mg and 500 mg/20 mg (hereinafter referred to as the “ANDA Products”), containing the active ingredients naproxen and

esomeprazole magnesium, prior to the expiration of the patents-in-suit, as a generic version of the VIMOVO® product.

16. In a letter dated May 16, 2013 ("2013 Notice Letter") from Mylan Pharmaceutical's agent, the law firm of Perkins Coie, Mylan Pharmaceuticals Inc., 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 U.S. Patent No. 5,900,424, as well as the '504, '085, '872, '070, '907, and '466 patents.

17. Upon information and belief, Mylan Limited is the holder of DMF No. 23120, which is incorporated by reference in ANDA No. 204920.

18. 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 . . . ." 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 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."

19. 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 18, above.

20. Defendants' submission of ANDA No. 204920 and service of the 2013 Notice Letter indicates a refusal to change their current course of action.

21. Defendants' Paragraph IV Notice to Plaintiffs states Defendants' intention to seek approval to market a generic copy of VIMOVO® product prior to expiration of the '504, '085, '872, '907, '070, and '466 patents. The last of these patents to expire is the '907 patent, which expires on February 28, 2023. The first of these patents to expire is the '872 patent, which expires on November 27, 2014.

22. There is now an actual controversy between Defendants and Plaintiffs as to whether Defendants infringe the '504, '085, '872, '907, '070, '466, '789, and '285 patents.

23. 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, selling pharmaceutical products in New Jersey and deriving substantial revenues from those sales; and 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.

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

FIRST CLAIM FOR RELIEF: '504 PATENT

25. Plaintiffs reallege paragraphs 1–24, above, as if set forth specifically herein.

26. The ’504 patent (a copy of which is 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.

27. Plaintiff AstraZeneca AB has been and is still the owner of the ’504 patent. KBI-E is AstraZeneca AB’s exclusive licensee under 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.

28. 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.

29. The 2013 Notice Letter, which is required by statute and regulation to provide a full and detailed explanation regarding non-infringement (*see* paragraph 18, above), alleges that Mylan does not infringe any claim of the ’504 patent.

30. The 2013 Notice Letter, which is required by statute and regulation to provide a full and detailed explanation regarding invalidity (*see* paragraph 18, above), alleges invalidity of all claims of the ’504 patent.

31. The 2013 Notice Letter, which is required by statute and regulation to provide a full and detailed explanation regarding unenforceability (*see* paragraph 18, above), does not allege unenforceability of the ’504 patent.

32. 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.

33. 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.

34. 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.

35. Upon 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 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.

36. Upon information and belief, the ANDA Products are 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 Products are so made or so adapted. Upon information and belief, Defendants are aware that the ANDA Products, if approved, will be used in contravention of Plaintiffs' rights under the '504 patent.

37. 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 patent is enforceable.

38. Upon information and belief, the manufacture, use, and sale of the ANDA Products infringes the ’504 patent claims.

SECOND CLAIM FOR RELIEF: ’085 PATENT

39. Plaintiffs reallege paragraphs 1–24, above, as if set forth specifically herein.

40. The ’085 patent (a copy of which is attached as Exhibit B), 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 patent claims, *inter alia*, esomeprazole magnesium salts and methods of preparing and using the claimed salts.

41. Plaintiff AstraZeneca AB has been and still is the owner of the ’085 patent. KBI-E is AstraZeneca AB’s exclusive licensee under the ’504 patent. The ’085 patent will expire on May 25, 2018, and pediatric exclusivity relating to the ’085 patent expires on November 25, 2018.

42. 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.

43. The 2013 Notice Letter, which is required by statute and regulation to provide a full and detailed explanation regarding non-infringement (*see* paragraph 18, above), alleges non-infringement of all the claims of the ’085 patent.

44. The 2013 Notice Letter, which is required by statute and regulation to provide a full and detailed explanation regarding invalidity (*see* paragraph 18, above), alleges invalidity of the claims of the '085 patent.

45. The 2013 Notice Letter, which is required by statute and regulation to provide a full and detailed explanation regarding unenforceability (*see* paragraph 18, above), does not allege unenforceability of the '085 patent.

46. 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 '085 patent.

47. 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.

48. 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.

49. Upon information and belief, the ANDA Products, 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.

50. Upon information and belief, the ANDA Products are 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 Products are so made or so adapted. Upon information and belief, Defendants are aware that the ANDA Products, if approved, will be used in contravention of Plaintiffs’ rights under the ’085 patent.

51. 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 patent is enforceable.

52. Upon information and belief, the manufacture, use, and sale of the ANDA Products infringes the ’085 patent claims.

THIRD CLAIM FOR RELIEF: ’872 PATENT

53. Plaintiffs reallege paragraphs 1–24, above, as if set forth specifically herein.

54. The ’872 patent (a copy of which is 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.

55. Plaintiff AstraZeneca AB has been and still is the owner of the ’872 patent. KBI-E is AstraZeneca AB’s exclusive licensee under the ’504 patent. The ’872 patent will expire on May 27, 2014, and pediatric exclusivity relating to the ’872 patent expires on November 27, 2014.

56. 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.

57. The 2013 Notice Letter, which is required by statute and regulation to provide a full and detailed explanation regarding non-infringement (*see* paragraph 18, above), does not allege non-infringement of all the claims of the '872 patent.

58. The 2013 Notice Letter, which is required by statute and regulation to provide a full and detailed explanation regarding invalidity (*see* paragraph 18, above), alleges invalidity of all claims of the '872 patent.

59. The 2013 Notice Letter, which is required by statute and regulation to provide a full and detailed explanation regarding unenforceability (*see* paragraph 18, above), does not allege unenforceability of the '872 patent.

60. 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 '872 patent.

61. 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.

62. 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.

63. Upon information and belief, the ANDA Products, 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.

64. Upon information and belief, the ANDA Products contain a component of the compounds 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. Upon information and belief, Defendants are aware that the ANDA Products are so made or so adapted. Upon information and belief, Defendants are aware that the ANDA Products, if approved, will be used in contravention of Plaintiffs' rights under the '872 patent.

65. The 2013 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 their 2013 Notice Letter, Defendants admit that the ANDA Products meet all limitations of those non-addressed '872 patent claims.

66. 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 patent is enforceable.

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

FOURTH CLAIM FOR RELIEF: '070 PATENT

68. Plaintiffs reallege paragraphs 1–24, above, as if set forth specifically herein.

69. The '070 patent (a copy of which is attached as Exhibit D), 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.

70. Plaintiff AstraZeneca AB has been and still is the owner of the '070 patent. KBI-E is AstraZeneca AB's exclusive licensee under the '504 patent. The '070 patent will expire on May 25, 2018, and pediatric exclusivity relating to the '070 patent expires on November 25, 2018.

71. 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.

72. The 2013 Notice Letter, which is required by statute and regulation to provide a full and detailed explanation regarding non-infringement (*see* paragraph 18, above), alleges non-infringement of all the claims of the '070 patent.

73. The 2013 Notice Letter, which is required by statute and regulation to provide a full and detailed explanation regarding invalidity (*see* paragraph 18 above), alleges invalidity of the claims of the '070 patent.

74. The 2013 Notice Letter, which is required by statute and regulation to provide a full and detailed explanation regarding unenforceability (*see* paragraph 18, above), does not allege unenforceability of the '070 patent.

75. 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 '070 patent.

76. 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.

77. 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.

78. Upon 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. 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.

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

80. 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.

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

FIFTH CLAIM FOR RELIEF: '466 PATENT

82. Plaintiffs reallege paragraphs 1–24, above, as if set forth specifically herein.

83. The ’466 patent (a copy of which is attached as Exhibit E), entitled “Form of S-Omeprazole” was issued on June 29, 2010, to AstraZeneca AB upon assignment from the inventors Hanna Cotton, Anders Kronstrom, Anders Mattson, and Eva Moller. The ’466 patent claims, *inter alia*, pharmaceutical compositions comprising a first and second active ingredient and a pharmaceutically acceptable carrier, wherein the first active ingredient is a magnesium salt of S-omeprazole trihydrate, and methods for treating gastric acid related conditions comprising administration of the aforementioned compositions.

84. AstraZeneca AB has been and still is the owner of the ’466 patent. KBI-E is AstraZeneca AB’s exclusive licensee under the ’466 patent. The ‘466 patent will expire on October 13, 2018.

85. 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 ’466 patent.

86. The 2013 Notice Letter, which is required by statute and regulation to provide a full and detailed explanation regarding non-infringement (*see* paragraph 18, above), alleges non-infringement of all the claims of the ’466 patent.

87. The 2013 Notice Letter, which is required by statute and regulation to provide a full and detailed explanation regarding invalidity (*see* paragraph 18, above), does not allege invalidity of all of the claims of the ’466 patent.

88. The 2013 Notice Letter, which is required by statute and regulation to provide a full and detailed explanation regarding unenforceability (*see* paragraph 18, above), does not allege unenforceability of the ’466 patent.

89. 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 '466 patent.

90. 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.

91. Defendants have infringed the '466 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 '466 patent.

92. Upon information and belief, the ANDA Products, 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 '466 patent.

93. Upon information and belief, the ANDA Products contain a component of the composition patented in the '466 patent, is a material for use in practicing the methods patented in the '466 patent, constitutes a material part of those inventions, is especially made or especially adapted for use in an infringement of the '466 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 Products are so made or so adapted. Upon information and belief, Defendants are aware that the ANDA Products, if approved, will be used in contravention of Plaintiffs' rights under the '466 patent.

94. The 2013 Notice Letter does not allege and does not address unenforceability of the ’466 patent. By not addressing unenforceability of the ’466 patent in their 2013 Notice Letter, Defendants admit that the ’466 patent is enforceable.

95. The 2013 Notice Letter does not allege and does not address invalidity of all of the claims of the ’466 patent. By not addressing invalidity of all of the claims of the ’466 patent in their 2013 Notice Letter, Defendants admit that the unaddressed claims of the ’466 patent are valid.

96. Upon information and belief, the manufacture, use, and sale of the ANDA Products infringes the ’466 patent claims.

SIXTH CLAIM FOR RELIEF: ’907 PATENT

97. Plaintiffs reallege paragraphs 1–24, above, as if set forth specifically herein.

98. The ’907 patent (a copy of which is attached as Exhibit F), entitled “Pharmaceutical Compositions for the Coordinated Delivery of NSAIDs” was issued on August 9, 2005, to Pozen upon assignment from the inventor John R. Plachetka. The ’907 patent claims, *inter alia*, pharmaceutical compositions that provide for the coordinated release of an acid inhibitor and an NSAID and a method for treating pain or inflammation comprising administration of such compositions.

99. Pozen has been and still is the owner of the ’907 patent. The ‘907 patent will expire on February 28, 2023.

100. Horizon is Pozen’s exclusive licensee under the ’907 patent.

101. 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 ’907 patent.

102. The 2013 Notice Letter, which is required by statute and regulation to provide a full and detailed explanation regarding non-infringement (*see* paragraph 18, above), alleges non-infringement of claims 2, 3, 4, 6, 7, 8, 18, 21, 25, 26, 27, 30, 31, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, and 49 of the ’907 patent.

103. The 2013 Notice Letter, which is required by statute and regulation to provide a full and detailed explanation regarding invalidity (*see* paragraph 18, above) alleges invalidity of 1, 5, 9, 10, 11, 12, 13, 14, 15, 16, 17, 19, 20, 22, 23, 24, 28, 29, 32, 33, 34, 35, 50, 51, 52, 53, 54, and 55 of the ’907 patent.

104. The 2013 Notice Letter, which is required by statute and regulation to provide a full and detailed explanation regarding unenforceability (*see* paragraph 18, above), does not allege unenforceability of the ’907 patent.

105. 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 ’907 patent.

106. 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.

107. Defendants have infringed the ’907 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 ’907patent.

108. Upon information and belief, the ANDA Products, 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 '907 patent.

109. Upon information and belief, the ANDA Products contain a component of the composition patented in the '907 patent, is a material for use in practicing the methods patented in the '907 patent, constitutes a material part of those inventions, is especially made or especially adapted for use in an infringement of the '907 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 Products are so made or so adapted. Upon information and belief, Defendants are aware that the ANDA Products, if approved, will be used in contravention of Plaintiffs' rights under the '907 patent.

110. The 2013 Notice Letter does not allege and does not address non-infringement of claims 1, 5, 9, 10, 11, 12, 13, 14, 15, 16, 17, 19, 20, 22, 23, 24, 28, 29, 32, 33, 34, 35, 50, 51, 52, 53, 54, and 55 of the '907 patent. By not addressing non-infringement of claims 1, 5, 9, 10, 11, 12, 13, 14, 15, 16, 17, 19, 20, 22, 23, 24, 28, 29, 32, 33, 34, 35, 50, 51, 52, 53, 54, and 55 of the '907 patent in their 2013 Notice Letter, Defendants admit that the ANDA Products meet all limitations of those claims.

111. The 2013 Notice Letter does not allege and does not address invalidity of claims 2, 3, 4, 6, 7, 8, 18, 21, 25, 26, 27, 30, 31, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, and 49 of the '907 patent. By not addressing invalidity of claims 2, 3, 4, 6, 7, 8, 18, 21, 25, 26, 27, 30, 31, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, and 49 of the '907 patent in their 2013 Notice Letter, Defendants admit that those claims are valid.

112. The 2013 Notice Letter does not allege and does not address unenforceability of the '907 patent. By not addressing unenforceability of the '907 patent in their 2013 Notice Letter, Defendants admit that the '907 patent is enforceable.

113. Upon information and belief, the manufacture, use, and sale of the ANDA Products infringes the '907 patent claims.

SEVENTH CLAIM FOR RELIEF: '789 PATENT

114. Plaintiffs reallege paragraphs 1–24, above, as if set forth specifically here.

115. The '789 Patent (a copy of which is attached as Exhibit G), entitled "Process For Synthesis Of Substituted Sulphoxides," was issued on September 7, 1999 to Astra Aktiebolag, upon assignment from the inventors Magnus Erik Larsson, Urban Jan Stenhede, Henrik Sörensen, Sverker Per Oskar von Unge and Hanna Kristina Cotton. The patent was subsequently assigned to AstraZeneca AB. The '789 patent claims, inter alia, processes for the synthesis of sulfoxide compounds.

116. Plaintiff AstraZeneca AB has been and still is the owner of the '789 patent. KBI-E is AstraZeneca AB's exclusive licensee under the '504 patent. The '789 patent will expire on July 3, 2015.

117. The Defendants submitted to FDA an Abbreviated New Drug Application, No. 204920, seeking FDA's approval to manufacture, use and sell Defendants' proposed naproxen/esomeprazole magnesium delayed release tablets, 375 mg/20 mg and 500 mg/20 mg as a generic version of the VIMOVO® Delayed-Release Capsules.

118. Upon information and belief, Defendants' proposed naproxen/esomeprazole magnesium delayed release tablets, 375 mg/20 mg and 500 mg/20 mg contain esomeprazole magnesium that was produced by a method patented in the '789 patent.

119. Upon information and belief, the naproxen/esomeprazole magnesium delayed release tablets, 375 mg/20 mg and 500 mg/20 mg (or its active ingredient, esomeprazole magnesium) will not be materially changed by subsequent processes and will not become a trivial or nonessential component of another product.

120. Upon information and belief, Defendants' importation of naproxen/esomeprazole magnesium delayed release tablets, (or its active ingredient, esomeprazole magnesium), if approved, will infringe the claims of the '789 patent, under 35 U.S.C. § 271 (g).

121. Upon information and belief, Defendants' offers to sell, sales, or uses of naproxen/esomeprazole magnesium delayed release tablets, (or its active ingredient, esomeprazole magnesium), if approved, and which are made by a process patented in the '789 patent, will infringe the claims of the '789 patent, under 35 U.S.C. § 271 (g).

EIGHTH CLAIM FOR RELIEF: '285 PATENT

122. Plaintiffs reallege paragraphs 1–24, above, as if set forth specifically here.

123. The '285 patent (a copy of which is attached as Exhibit H), entitled "Pharmaceutical Compositions for the Coordinated Delivery of NSAIDs," was issued on October 15, 2013, to Pozen upon assignment from the inventor John R. Plachetka. The '285 patent claims, *inter alia*, pharmaceutical compositions in unit dosage form comprising esomeprazole and naproxen.

124. Pozen has been and still is the owner of the '285 patent. The '285 patent will expire on May 31, 2022.

125. Horizon is Pozen's exclusive licensee under the '285 patent.

126. The ’285 patent is a patent with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the VIMOVO® drug product.

127. Accordingly, pursuant to 21 U.S.C. § 355(c)(2), Plaintiffs submitted patent information for the ’285 patent to the FDA in connection with its NDA No. 022511 for VIMOVO® drug product, which is now published in the Orange Book.

128. Upon information and belief, the making, using, selling, and/or offering for sale in the United States of Defendants’ pharmaceutical compositions in unit dosage form comprising esomeprazole and naproxen described in Defendants’ ANDA infringes the ’285 patent.

129. Defendants have infringed the ’285 patent under 35 U.S.C. § 271 (e)(2) by filing their ANDA and continuing to seek 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 ’285 patent.

130. Upon information and belief, the ANDA Products contain the pharmaceutical composition patented in the ’285 patent, constitute a material part of the inventions of the ’285 patent, are especially made or especially adapted for use in an infringement of the ’285 patent, and are not staple articles or commodities of commerce suitable for substantial noninfringing use. Upon information and belief, Defendants are aware that the ANDA Products are so made or so adapted. Upon information and belief, Defendants are aware that the ANDA Products, if approved, will be used in contravention of Plaintiffs’ rights under the ’285 patent.

131. Upon information and belief, Defendants have previously filed patent certifications in association with their ANDA No. 204920 seeking, *inter alia*, FDA final approval prior to November 27, 2014. The ’285 patent has an expiration date of May 31, 2022.

Therefore, on further information and belief, Defendants are currently pursuing FDA final approval of their ANDA No. 204920 prior to the expiration date of the '285 patent.

132. Pursuant to 21 U.S.C. § 355(j)(2)(A)(vii), Defendants should file a patent certification in their pending ANDA No. 204920 with respect to the '285 patent, and Defendants must make a Paragraph IV Certification with respect to the '285 patent if Defendants continue to seek FDA final approval of their ANDA No. 204920 prior to May 31, 2022. On information and belief, Defendants' above-described activities are continuing and constitute an act of infringement of the '285 Patent under 35 U.S.C. § 271(e)(2).

133. Upon information and belief, the manufacture, use, and sale of the ANDA Products infringes the '285 patent claims.

134. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

(a) A judgment declaring that the effective date of any approval of Defendants' ANDA No. 204920, filed under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), for a drug product called "naproxen/esomeprazole magnesium delayed release tablets, 375 mg/20 mg" or "naproxen/esomeprazole magnesium delayed release tablets, 500 mg/20 mg" be a date not earlier than the later of 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, '085, '872, 070, '466, '789, '907, and '285 patents have been infringed by Defendants and remain valid and enforceable;

(c) A judgment that Defendants' defenses and claims for relief are limited to those presented in the 2013 Notice Letter;

(d) 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, '085, '872, 070, '466, '789, '907, and '285 patents;

(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: April 10, 2014

Respectfully Submitted,

By: *s/ John E. Flaherty*

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that true copies of the foregoing First Amended Complaint for Patent Infringement and supporting documents were caused to be served on April 10, 2014, by electronic mail and/or the ECF system upon all counsel of record.

Dated: April 10, 2014

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