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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.

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

Defendants.

Civil Action No. 3:13-cv-03038-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 Watson Laboratories, Inc. – Florida and Actavis 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 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”); and 7,745,466 (“the ’466 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 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. 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 Actavis Pharma, Inc. (“Actavis Pharma”), formerly known as 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, Actavis 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, 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 Actavis 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, Actavis Pharma, formerly known as Watson Pharma, is another 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 Actavis Pharma. Upon information and belief, Watson Laboratories and Actavis 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 Actavis 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 the ’504 patent, the ’085 patent, the ’872 patent, the ’070 patent, the ’466 patent, and United States Patent Nos. 6,926,907 (the “’907 patent”) and 8,557,285 (the “’285 patent) (collectively, the “patents-in-suit”) by, *inter alia*, submitting to the FDA ANDA No. 204470 (“Defendants’ ANDA”). Defendants’ ANDA seeks the FDA’s approval to

manufacture, use, or sell commercially their proposed product called “Naproxen/Esomeprazole Magnesium Delayed Release Tablets, 500mg/20 mg” (hereinafter referred to as the “ANDA Product”), 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.

20. In a letter dated March 29, 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, ’085, ’872, ’070, ’907, and ’466 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. 204470 and service of the 2013 Notice Letter indicates a refusal to change their current course of action.

24. 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.

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

26. 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 Actavis 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.

27. 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).

28. 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 Actavis Pharma and Actavis.

FIRST CLAIM FOR RELIEF: '504 PATENT

29. Plaintiffs reallege paragraphs 1–28, above, as if set forth specifically herein.

30. 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.

31. 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.

32. 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.

33. 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.

34. 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.

35. 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.

36. 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.

37. 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.

38. 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.

39. 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.

40. 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.

41. 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 and use of the same meets all limitations of the '504 patent claims.

42. 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.

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

SECOND CLAIM FOR RELIEF: '085 PATENT

44. Plaintiffs reallege paragraphs 1–28, above, as if set forth specifically herein.

45. 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.

46. 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.

47. 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.

48. 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.

49. 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.

50. 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.

51. 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.

52. 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.

53. 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.

54. 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.

55. 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.

56. 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 patent are valid.

57. 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.

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

THIRD CLAIM FOR RELIEF: '872 PATENT

59. Plaintiffs reallege paragraphs 1–28, above, as if set forth specifically herein.

60. 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.

61. 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.

62. 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.

63. 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.

64. 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.

65. 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.

66. 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.

67. 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.

68. 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.

69. 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.

70. 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.

71. 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 '872 patent claims.

72. 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.

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

FOURTH CLAIM FOR RELIEF: '070 PATENT

74. Plaintiffs reallege paragraphs 1–28, above, as if set forth specifically herein.

75. 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.

76. 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.

77. 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.

78. 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.

79. 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.

80. 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.

81. 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.

82. 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.

83. 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.

84. 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.

85. 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.

86. 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 patent are valid.

87. 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.

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

FIFTH CLAIM FOR RELIEF: '466 PATENT

89. Plaintiffs reallege paragraphs 1–28, above, as if set forth specifically herein.

90. 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.

91. AstraZeneca AB has been and still is the owner of the '466 patent. KIB-E is AstraZeneca AB's exclusive licensee under the '466 patent. The '466 patent will expire on October 13, 2018.

92. 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.

93. 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 '466 patent.

94. 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 '466 patent.

95. 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 '466 patent.

96. 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.

97. 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.

98. 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.

99. 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 '466 patent.

100. Upon information and belief, the ANDA Product contains 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 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 '466 patent.

101. 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.

102. The 2013 Notice Letter does not allege and does not address invalidity of any claim of the '466 patent. By not addressing invalidity of any claim of the '466 patent in their 2013 Notice Letter, Defendants admit that the claims of the '466 patent are valid.

103. Upon information and belief, the manufacture, use, and sale of the ANDA Product infringes the '466 patent claims.

SIXTH CLAIM FOR RELIEF: '907 PATENT

104. Plaintiffs reallege paragraphs 1–28, above, as if set forth specifically herein.

105. 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, Inc., 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.

106. Pozen Inc. has been and still is the owner of the '907 patent. The '907 patent will expire on February 28, 2023.

107. Horizon is Pozen Inc.'s exclusive licensee under the '907 patent.

108. 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.

109. 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 claims 2, 3, 4, 6, 7, 8, 18, 19, 20, 21, 25, 26, 27, 30, 31, 36, 38, 39, 40, 43, 44, and 49 of the '907 patent.

110. 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 '907 patent.

111. 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 '907 patent.

112. 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.

113. 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.

114. 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 '907 patent.

115. 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 '907 patent.

116. Upon information and belief, the ANDA Product contains 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 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 '907 patent.

117. 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, 22, 23, 24, 28, 29, 32, 33, 34, 35, 37, 41, 42, 45, 46, 47, 48, 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, 22, 23, 24, 28, 29, 32, 33, 34, 35, 37, 41, 42, 45, 46,

47, 48, 50, 51, 52, 53, 54, and 55 of the '907 patent in their 2013 Notice Letter, Defendants admit that the ANDA Product meets all limitations of those claims.

118. 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.

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

SEVENTH CLAIM FOR RELIEF: '285 PATENT

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

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

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

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

124. 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.

125. Accordingly, pursuant to 21 U.S.C. § 355(c)(2), Plaintiffs submitted patent information for the '285 patent to the FDA in connection with NDA No. 022511 for VIMOVO® drug product. The FDA published the same in the Orange Book.

126. Defendants have infringed the '285 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 '285 patent.

127. Upon information and belief, the ANDA Product contains a component of the composition patented in the '285 patent, constitutes a material part of the inventions of the '285 patent, is especially made or especially adapted for use in an infringement of the '285 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 '285 patent.

128. On information and belief, Watson Laboratories has previously filed patent certifications in association with its ANDA No. 204470 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, Watson Laboratories is currently pursuing FDA final approval of its ANDA No. 204470 prior to the expiration date of the '285 patent.

129. Pursuant to 21 U.S.C. § 355(j)(2)(A)(vii), Watson Laboratories should file a patent certification in its pending ANDA No. 204470 with respect to the '285 patent, and Watson Laboratories must make a Paragraph IV Certification with respect to the '285 patent if Watson Laboratories continues to seek FDA final approval of its ANDA No. 204470 prior to May 31, 2022. On information and belief, Watson Laboratories' above-described activities are continuing and constitute an act of infringement of the '285 Patent under 35 U.S.C. § 271(e)(2).

130. Upon information and belief, the manufacture, use, and sale of the ANDA Product infringes the '285 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. 204470, 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, 500mg/20mg" be a date not earlier than the later of February 28, 2023, 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, '085, '872, 070, '466, '907, and '285 patents have been infringed by Defendants and remain valid and enforceable;
- (c) A judgment that Defendants' defenses and claims for relief with respect to the '504, '085, '872, 070, '466, and '907 patents 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, '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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