IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

HORIZON MEDICINES LLC and NUVO PHARMACEUTICALS (IRELAND) DESIGNATED ACTIVITY COMPANY, Plaintiffs, v. AJANTA PHARMA LTD. and AJANTA PHARMA USA, INC., Defendants.	C.A. No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Horizon Medicines LLC and Nuvo Pharmaceuticals (Ireland) Designated Activity Company (collectively, "Plaintiffs"), by their attorneys, for their Complaint against Ajanta Pharma Ltd. and Ajanta Pharma USA, Inc. (collectively, "Defendants"), allege as follows:

THE PARTIES

1. Plaintiff Horizon Medicines LLC ("Horizon") is a corporation operating and existing under the laws of the State of Delaware, with their principal place of business at 150 South Saunders Road, Lake Forest, Illinois 60045.

2. Plaintiff Nuvo Pharmaceuticals (Ireland) Designated Activity Company ("Nuvo") is a corporation operating and existing under the laws of Ireland, with its principal place of business at 88 Harcourt Street, Dublin 2, DO2 DK18.

3. On information and belief, Defendant Ajanta Pharma Ltd. ("Ajanta Ltd.") is a corporation operating and existing under the laws of India, with its principal place of business at Ajanta House, Charkop, Kandivili West, Mumbai-400 067, Maharashtra, India.

4. On information and belief, Defendant Ajanta Pharma USA, Inc. ("Ajanta USA") is a corporation operating and existing under the laws of the State of New Jersey, with its principal place of business at One Grand Commons, 440 US Highway 22 East, Suite 150, Bridgewater, NJ 08807.

5. On information and belief, Ajanta Pharma USA, Inc. is a wholly-owned subsidiary of Ajanta Pharma Ltd.

BACKGROUND

The NDA

6. Horizon is the holder of New Drug Application ("NDA") No. 022511 for VIMOVO® (naproxen and esomeprazole magnesium) Delayed-Release Tablets, in 375 mg (naproxen)/20 mg (esomeprazole magnesium) and 500 mg (naproxen)/20 mg (esomeprazole magnesium) dosage forms.

7. VIMOVO® Delayed-Release Tablets are prescription drugs approved for use to relieve the signs and symptoms of osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis and to decrease the risk of stomach (gastric) ulcers in patients at risk of developing stomach ulcers from treatment with non-steroidal anti-inflammatory drugs (NSAIDs). Naproxen and esomeprazole magnesium are the active ingredients in VIMOVO® Delayed-Release Tablets.

The Patents-in-Suit

8. United States Patent No. 9,345,695 ("the '695 patent"), entitled "Pharmaceutical Compositions for the Coordinated Delivery of NSAIDs," was duly and legally issued by the United States Patent and Trademark Office on May 24, 2016. A true and correct copy of the '695 patent is attached as Exhibit A.

9. Nuvo owns the rights to the ’695 patent. Horizon is the exclusive licensee of Nuvo’s rights to the ’695 patent. The ’695 patent will expire on May 31, 2022.

10. The ’695 patent is listed in the FDA Orange Book in connection with NDA No. 022511 for VIMOVO® Delayed-Release Tablets.

11. United States Patent No. 8,852,636 (“the ’636 patent”), entitled “Pharmaceutical Compositions for the Coordinated Delivery of NSAIDs,” was duly and legally issued by the United States Patent and Trademark Office on October 7, 2014. A true and correct copy of the ’636 patent is attached as Exhibit B.

12. Nuvo owns the rights to the ’636 patent. Horizon is the exclusive licensee of Nuvo’s rights to the ’636 patent. The ’636 patent will expire on May 31, 2022.

13. The ’636 patent is listed in the FDA Orange Book in connection with NDA No. 022511 for VIMOVO® Delayed-Release Tablets.

14. United States Patent No. 8,858,996 (“the ’996 patent”), entitled “Pharmaceutical Compositions for the Coordinated Delivery of NSAIDs,” was duly and legally issued by the United States Patent and Trademark Office on October 14, 2014. A true and correct copy of the ’996 patent is attached as Exhibit C.

15. Nuvo owns the rights to the ’996 patent. Horizon is the exclusive licensee of Nuvo’s rights to the ’996 patent. The ’996 patent will expire on May 31, 2022.

16. The ’996 patent is listed in the FDA Orange Book in connection with NDA No. 022511 for VIMOVO® Delayed-Release Tablets.

17. United States Patent No. 9,161,920 (“the ’920 patent”), entitled “Pharmaceutical Compositions for the Coordinated Delivery of NSAIDs,” was duly and legally issued by the

United States Patent and Trademark Office on October 20, 2015. A true and correct copy of the '920 patent is attached as Exhibit D.

18. Nuvo owns the rights to the '920 patent. Horizon is the exclusive licensee of Nuvo's rights to the '920 patent. The '920 patent will expire on May 31, 2022.

19. The '920 patent is listed in the FDA Orange Book in connection with NDA No. 022511 for VIMOVO® Delayed-Release Tablets.

20. United States Patent No. 9,198,888 ("the '888 patent"), entitled "Pharmaceutical Compositions for the Coordinated Delivery of NSAIDs," was duly and legally issued by the United States Patent and Trademark Office on December 1, 2015. A true and correct copy of the '888 patent is attached as Exhibit E.

21. Nuvo owns the rights to the '888 patent. Horizon is the exclusive licensee of Nuvo's rights to the '888 patent. The '888 patent will expire on May 31, 2022.

22. The '888 patent is listed in the FDA Orange Book in connection with NDA No. 022511 for VIMOVO® Delayed-Release Tablets.

23. United States Patent No. 9,707,181 ("the '181 patent"), entitled "Pharmaceutical Compositions for the Coordinated Delivery of NSAIDs," was duly and legally issued by the United States Patent and Trademark Office on July 18, 2017. A true and correct copy of the '181 patent is attached as Exhibit F.

24. Nuvo owns the rights to the '181 patent. Horizon is the exclusive licensee of Nuvo's rights to the '181 patent. The '181 patent will expire on May 31, 2022.

25. The '181 patent is listed in the FDA Orange Book in connection with NDA No. 022511 for VIMOVO® Delayed-Release Tablets.

The ANDA

26. On information and belief, Defendants filed ANDA No. 213699 (the "ANDA") with the FDA under 21 U.S.C. § 355(j) to obtain FDA approval for the commercial manufacture, use, import, offer for sale, and sale in the United States of naproxen and esomeprazole magnesium delayed-release tablets containing 375 mg or 500 mg of naproxen and 20 mg esomeprazole magnesium ("ANDA Product"), which are generic versions of Plaintiffs' VIMOVO® Delayed-Release Tablets in 375 mg (naproxen)/20 mg (esomeprazole magnesium) and 500 mg (naproxen)/20 mg (esomeprazole magnesium) strengths, respectively.

JURISDICTION AND VENUE

27. This action arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, including 35 U.S.C. § 271, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

28. On information and belief, Defendants have been and are engaging in activities directed toward infringement of the '695, '636, '996, '920, '888 and '181 patents (collectively, the "patents-in-suit") by, *inter alia*, submitting to the FDA ANDA No. 213699 and continuing to seek approval for the ANDA.

29. There is an actual controversy between Defendants and Plaintiffs as to whether Defendants infringe the patents-in-suit.

30. On information and belief, Ajanta Ltd. and Ajanta USA collaborate to develop, manufacture, import, market, and distribute, and/or sell pharmaceutical products, including generic drug products that will be manufactured and sold pursuant to the ANDA, throughout the United States and the District of Delaware.

31. On information and belief, Ajanta Ltd. and Ajanta USA hold themselves out as a unitary entity for the purposes of manufacturing, marketing, selling and distributing generic products.

32. On information and belief, Ajanta Ltd. and Ajanta USA work in concert with each other with respect to the regulatory approval, manufacturing, marketing, sale, and distribution of generic pharmaceutical products in the District of Delaware and throughout the Unites States.

33. Ajanta Ltd. is subject to personal jurisdiction in this District due, among other things, to its substantial, systematic, purposeful, and continuous contacts in this District. On information and belief, Ajanta Ltd., directly or through its wholly-owned subsidiary Ajanta USA, manufactures, markets, imports, and sells generic drugs for distribution in the District of Delaware and throughout the United States. On information and belief, Ajanta Ltd. purposefully has conducted and continues to conduct business, directly or through its wholly-owned subsidiary Ajanta USA, in the District of Delaware, and this Judicial District is a destination for Ajanta Ltd.'s generic products.

34. Ajanta USA is subject to personal jurisdiction in this District due, among other things, to its substantial, systematic, purposeful, and continuous contact in this District. On information and belief, Ajanta USA, directly or through its affiliate Ajanta Ltd., manufactures, markets, imports, and sells generic drugs for distribution in the District of Delaware and throughout the United States. On information and belief, Ajanta USA purposefully has conducted and continues to conduct business, directly or through its affiliate Ajanta Ltd., in the District of Delaware, and this Judicial District is a destination for Ajanta USA's generic products.

35. Ajanta Ltd.'s website states "[w]e are gradually building a meaningful presence in the US market with select product portfolio, which include complex technology products to get the competitive advantage in the market place. We expect US market to be our key growth driver in the coming years." *See* http://www.ajantapharma.com/overview.html (accessed September 9, 2019.)

36. Ajanta Ltd.'s website further states "[o]ur products are already available on the shelf in US through our subsidiary, located in New Jersey, the hub of pharma industry in USA." *See* http://www.ajantapharma.com/generics.html (accessed September 9, 2019.)

37. According to its website, Ajanta USA is a wholly-owned subsidiary of Ajanta Ltd. The website further states "[s]ince making the strategic decision to enter the US market, our Research and Development (R&D) team began developing a product portfolio of [ANDA] filings with a mix of immediate-release, Extended-release, Delayed-release, Orally Disintegrating Tablets and Powders." *See* http://www.ajantapharmausa.com/overview.html (accessed September 9, 2019.)

38. On information and belief, Ajanta Ltd. and Ajanta USA acted in concert to develop the ANDA Product and to seek approval from the FDA to sell the ANDA Product throughout the United States, including within this Judicial District.

39. On information and belief, both Ajanta Ltd. and Ajanta USA participated in the preparation and/or filing of ANDA No. 213699.

40. On information and belief, the FDA received ANDA No. 213699 from Ajanta Ltd. and Ajanta USA.

41. On information and belief, Defendants have previously been sued in this district and have not challenged personal jurisdiction. *See, e.g., Amgen, Inc. v. Ajanta Pharma Ltd.*, Civ.

Action No. 1:16-cv-00899-GMS (D. Del.); *Pfizer Inc. v. Ajanta Pharma Ltd.*, Civ. Action No. 1:19-cv-517-LPS (D. Del.); *Allergan Sales, LLC v. Ajanta Pharma Ltd.*, Civ. Action No. 1:19-cv-01249-LPS (D. Del.).

42. On information and belief, both Defendants have admitted that each is subject to personal jurisdiction in this district. *See, e.g., Amgen, Inc v. Ajanta Pharma Ltd.*, Civ. Action No. 1:16-cv-00899-GMS (D. Del.), Answer to Complaint, ¶¶ 9& 10 (November 18, 2016); *Pfizer Inc. v. Ajanta Pharma Ltd.*, Civ. Action No. 1:19-cv-517-LPS (D. Del.), Answer to Complaint, ¶ 11 (May 13, 2019); *Allergan Sales, LLC v. Ajanta Pharma Ltd.*, Civ. Action No. 1:19-cv-01249-LPS (D. Del.) (consented to jurisdiction), Complaint, ¶ 8 (July 2, 2019).

43. On information and belief, by virtue of, *inter alia*, Defendants' continuous and systematic contacts with Delaware, including but not limited to the above-described contacts, and the actions on behalf of Defendants in connection with ANDA No. 213699, this Court has personal jurisdiction over Defendants. These activities satisfy due process and confer personal jurisdiction over Defendants consistent with Delaware law.

44. Venue is proper in this District under 28 U.S.C. § 1400(b).

COUNT I

INFRINGEMENT OF THE '695 PATENT UNDER 35 U.S.C. § 271(e)(2))

45. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

46. The '695 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, importation, offer for sale, or sale of the VIMOVO® product.

47. Accordingly, pursuant to 21 U.S.C. § 355(c)(2), Plaintiffs submitted patent information for the '695 patent to the FDA in connection with NDA No. 022511 for the VIMOVO® product. On information and belief, this information is published in the FDA's Orange Book.

48. 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV") requires, *inter alia*, certification by the ANDA applicant that the subject patent in the Orange Book, here the '695 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 not valid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)) specify, *inter alia*, that a Paragraph IV notification must include "[a] detailed statement of the factual and legal basis of applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement is to include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation."

49. On information and belief, Defendants are aware of the statutory provisions and regulations referred to above and have maintained pursuit of their ANDA.

50. On information and belief, Defendants have filed a patent certification in association with their ANDA No. 213699 seeking, *inter alia*, FDA final approval. On information and belief, Defendants are currently pursuing FDA final approval of ANDA No. 213699 before the '695 patent expires on May 31, 2022.

51. On information and belief, the making, using, selling, or offering for sale in the United States or the importation into the United States of Defendants' ANDA Product infringes the '695 patent.

52. Defendants have infringed, either literally or under the doctrine of equivalents, the '695 patent under 35 U.S.C. § 271(e)(2) by filing ANDA No. 213699 and continuing to seek approval from the FDA to engage in the commercial manufacture, use, importation, offer for sale, or sale of a drug to be used as claimed in the '695 patent before the expiration of the '695 patent.

53. On information and belief, Defendants' ANDA Product is a material for use in practicing the methods patented in the '695 patent, constitutes a material part of the inventions of the '695 patent, is especially made or especially adapted for use in an infringement of the '695 patent, and is not a staple article or commodity of commerce suitable for substantial noninfringing use. On information and belief, Defendants are aware that the ANDA Product is so made or so adapted. On information and belief, Defendants are aware that the ANDA Product will be used in contravention of Plaintiffs' rights under the '695 patent.

54. On information and belief, Defendants' above-described activities are continuing and constitute an act of infringement of the '695 patent under 35 U.S.C. § 271(e)(2).

55. 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.

COUNT II

(DECLARATORY JUDGMENT AS TO THE '695 PATENT)

56. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

57. The '695 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, importation, offer for sale, or sale of the VIMOVO® product.

58. On information and belief, Defendants' ANDA Product contain the pharmaceutical composition patented in the '695 patent, are materials for use in practicing the methods patented in the '695 patent, constitute a material part of the inventions of the '695 patent, are especially made or especially adapted for use in an infringement of the '695 patent, and are not staple articles or commodities of commerce suitable for substantial noninfringing use. On information and belief, Defendants are aware that the ANDA Product are so made or so adapted.

59. On information and belief, the making, using, selling, or offering for sale in the United States or the importation into the United States of Defendants' ANDA Product before the expiration of the '695 patent constitutes infringement of the '695 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

60. The ANDA Notice Letter show Defendants' intent to market the ANDA Product before the '695 patent expires on May 31, 2022.

61. On information and belief, Defendants continue to seek FDA final approval for Defendant's ANDA Product. On information and belief, Defendants are aware that the manufacture, use, sale, or offer for sale in the United States or the importation into the United

States of Defendants' ANDA Product, if approved, will infringe the '695 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

62. On information and belief, Defendants have made, and will continue to make, substantial preparation to manufacture, use, sell, or offer to sell in the United States or import into the United States their ANDA Product before the '695 patent expires.

63. On information and belief, Defendants intend to engage in the commercial manufacture, use, sale, or offer for sale in the United States or importation into the United States of Defendants' ANDA Product after receiving FDA final approval of ANDA No. 213699 and before the '695 patent expires.

64. Defendants maintain, on information and belief, and Plaintiffs deny that the '695 patent is invalid or unenforceable and that Defendants' ANDA Product do not or will not infringe the '695 patent. Accordingly, a definite and concrete, real and substantial, justiciable case or controversy exists between Plaintiffs and Defendants concerning infringement of the '695 patent by Defendants' ANDA Product.

65. 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.

66. Plaintiffs are entitled to a declaration that the making, using, sale, or offer for sale in the United States or the importation into the United States of ANDA Product will infringe one or more claims of the '695 patent.

COUNT III

(INFRINGEMENT OF THE '636 PATENT UNDER 35 U.S.C. § 271(e)(2))

67. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

68. The '636 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, importation, offer for sale, or sale of the VIMOVO® product.

69. Accordingly, pursuant to 21 U.S.C. § 355(c)(2), Plaintiffs submitted patent information for the '636 patent to the FDA in connection with NDA No. 022511 for the VIMOVO® product. On information and belief, this information is published in the FDA's Orange Book.

70. 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV") requires, *inter alia*, certification by the ANDA applicant that the subject patent in the Orange Book, here the '636 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 not valid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)) specify, *inter alia*, that a Paragraph IV notification must include "[a] detailed statement of the factual and legal basis of applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement is to include "(i) [f] or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation."

71. On information and belief, Defendants are aware of the statutory provisions and regulations referred to above and have maintained pursuit of their ANDA.

72. On information and belief, Defendants have filed a patent certification in association with their ANDA No. 213699 seeking, *inter alia*, FDA final approval. On information and belief, Defendants are currently pursuing FDA final approval of ANDA No. 213699 before the '636 patent expires on May 31, 2022.

73. On information and belief, the making, using, selling, or offering for sale in the United States or the importation into the United States of Defendants' ANDA Product infringes the '636 patent.

74. Defendants have infringed, either literally or under the doctrine of equivalents, the '636 patent under 35 U.S.C. § 271(e)(2) by filing ANDA No. 213699 and continuing to seek approval from the FDA to engage in the commercial manufacture, use, importation, offer for sale, or sale of a drug to be used as claimed in the '636 patent before the expiration of the '636 patent.

75. On information and belief, Defendants' ANDA Product is a material for use in practicing the methods patented in the '636 patent, constitutes a material part of the inventions of the '636 patent, is especially made or especially adapted for use in an infringement of the '636 patent, and is not a staple article or commodity of commerce suitable for substantial noninfringing use. On information and belief, Defendants are aware that the ANDA Product is so made or so adapted. On information and belief, Defendants are aware that the ANDA Product will be used in contravention of Plaintiffs' rights under the '636 patent.

76. On information and belief, Defendants' above-described activities are continuing and constitute an act of infringement of the '636 patent under 35 U.S.C. § 271(e)(2).

77. 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.

COUNT IV

(DECLARATORY JUDGMENT AS TO THE '636 PATENT)

78. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

79. The '636 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, importation, offer for sale, or sale of the VIMOVO® product.

80. On information and belief, Defendants' ANDA Product contain the pharmaceutical composition patented in the '636 patent, are materials for use in practicing the methods patented in the '636 patent, constitute a material part of the inventions of the '636 patent, are especially made or especially adapted for use in an infringement of the '636 patent, and are not staple articles or commodities of commerce suitable for substantial noninfringing use. On information and belief, Defendants are aware that the ANDA Product are so made or so adapted.

81. On information and belief, the making, using, selling, or offering for sale in the United States or the importation into the United States of Defendants' ANDA Product before the expiration of the '636 patent constitutes infringement of the '636 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

82. The ANDA Notice Letter show Defendants' intent to market the ANDA Product before the '636 patent expires on May 31, 2022.

83. On information and belief, Defendants continue to seek FDA final approval for Defendant's ANDA Product. On information and belief, Defendants are aware that the manufacture, use, sale, or offer for sale in the United States or the importation into the United States of Defendants' ANDA Product, if approved, will infringe the '636 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

84. On information and belief, Defendants have made, and will continue to make, substantial preparation to manufacture, use, sell, or offer to sell in the United States or import into the United States their ANDA Product before the '636 patent expires.

85. On information and belief, Defendants intend to engage in the commercial manufacture, use, sale, or offer for sale in the United States or importation into the United States of Defendants' ANDA Product after receiving FDA final approval of ANDA No. 213699 and before the '636 patent expires.

86. Defendants maintain, on information and belief, and Plaintiffs deny that the '636 patent is invalid or unenforceable and that Defendants' ANDA Product do not or will not infringe the '636 patent. Accordingly, a definite and concrete, real and substantial, justiciable case or controversy exists between Plaintiffs and Defendants concerning infringement of the '636 patent by Defendants' ANDA Product.

87. 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.

88. Plaintiffs are entitled to a declaration that the making, using, sale, or offer for sale in the United States or the importation into the United States of ANDA Product will infringe one or more claims of the '636 patent.

COUNT V

(INFRINGEMENT OF THE '996 PATENT UNDER 35 U.S.C. § 271(e)(2))

89. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

90. The '996 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, importation, offer for sale, or sale of the VIMOVO® product.

91. Accordingly, pursuant to 21 U.S.C. § 355(c)(2), Plaintiffs submitted patent information for the '996 patent to the FDA in connection with NDA No. 022511 for the VIMOVO® product. On information and belief, this information is published in the FDA's Orange Book.

92. 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV") requires, *inter alia*, certification by the ANDA applicant that the subject patent in the Orange Book, here the '996 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 not valid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)) specify, *inter alia*, that a Paragraph IV notification must include "[a] detailed statement of the factual and legal basis of applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement is to include "(i) [f] or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation."

93. On information and belief, Defendants are aware of the statutory provisions and regulations referred to above and have maintained pursuit of their ANDA.

94. On information and belief, Defendants have filed a patent certification in association with their ANDA No. 213699 seeking, *inter alia*, FDA final approval. On information and belief, Defendants are currently pursuing FDA final approval of ANDA No. 213699 before the '996 patent expires on May 31, 2022.

95. On information and belief, the making, using, selling, or offering for sale in the United States or the importation into the United States of Defendants' ANDA Product infringes the '996 patent.

96. Defendants have infringed, either literally or under the doctrine of equivalents, the '996 patent under 35 U.S.C. § 271(e)(2) by filing ANDA No. 213699 and continuing to seek approval from the FDA to engage in the commercial manufacture, use, importation, offer for sale, or sale of a drug to be used as claimed in the '996 patent before the expiration of the '996 patent.

97. On information and belief, Defendants' ANDA Product is a material for use in practicing the methods patented in the '996 patent, constitutes a material part of the inventions of the '996 patent, is especially made or especially adapted for use in an infringement of the '996 patent, and is not a staple article or commodity of commerce suitable for substantial noninfringing use. On information and belief, Defendants are aware that the ANDA Product is so made or so adapted. On information and belief, Defendants are aware that the ANDA Product will be used in contravention of Plaintiffs' rights under the '996 patent.

98. On information and belief, Defendants' above-described activities are continuing and constitute an act of infringement of the '996 patent under 35 U.S.C. § 271(e)(2).

99. 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.

COUNT VI

(DECLARATORY JUDGMENT AS TO THE '996 PATENT)

100. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

101. The '996 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, importation, offer for sale, or sale of the VIMOVO® product.

102. On information and belief, Defendants' ANDA Product contain the pharmaceutical composition patented in the '996 patent, are materials for use in practicing the methods patented in the '996 patent, constitute a material part of the inventions of the '996 patent, are especially made or especially adapted for use in an infringement of the '996 patent, and are not staple articles or commodities of commerce suitable for substantial noninfringing use. On information and belief, Defendants are aware that the ANDA Product are so made or so adapted.

103. On information and belief, the making, using, selling, or offering for sale in the United States or the importation into the United States of Defendants' ANDA Product before the expiration of the '996 patent constitutes infringement of the '996 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

104. The ANDA Notice Letter show Defendants' intent to market the ANDA Product before the '996 patent expires on May 31, 2022.

105. On information and belief, Defendants continue to seek FDA final approval for Defendant's ANDA Product. On information and belief, Defendants are aware that the manufacture, use, sale, or offer for sale in the United States or the importation into the United States of Defendants' ANDA Product, if approved, will infringe the '996 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

106. On information and belief, Defendants have made, and will continue to make, substantial preparation to manufacture, use, sell, or offer to sell in the United States or import into the United States their ANDA Product before the '996 patent expires.

107. On information and belief, Defendants intend to engage in the commercial manufacture, use, sale, or offer for sale in the United States or importation into the United States of Defendants' ANDA Product after receiving FDA final approval of ANDA No. 213699 and before the '996 patent expires.

108. Defendants maintain, on information and belief, and Plaintiffs deny that the '996 patent is invalid or unenforceable and that Defendants' ANDA Product do not or will not infringe the '996 patent. Accordingly, a definite and concrete, real and substantial, justiciable case or controversy exists between Plaintiffs and Defendants concerning infringement of the '996 patent by Defendants' ANDA Product.

109. 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.

110. Plaintiffs are entitled to a declaration that the making, using, sale, or offer for sale in the United States or the importation into the United States of ANDA Product will infringe one or more claims of the '996 patent.

COUNT VII

(INFRINGEMENT OF THE '920 PATENT UNDER 35 U.S.C. § 271(e)(2))

111. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

112. The '920 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, importation, offer for sale, or sale of the VIMOVO® product.

113. Accordingly, pursuant to 21 U.S.C. § 355(c)(2), Plaintiffs submitted patent information for the '920 patent to the FDA in connection with NDA No. 022511 for the VIMOVO® product. On information and belief, this information is published in the FDA's Orange Book.

114. 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV") requires, *inter alia*, certification by the ANDA applicant that the subject patent in the Orange Book, here the '920 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 not valid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)) specify, *inter alia*, that a Paragraph IV notification must include "[a] detailed statement of the factual and legal basis of applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement is to include "(i) [f] or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation."

115. On information and belief, Defendants are aware of the statutory provisions and regulations referred to above and have maintained pursuit of their ANDA.

116. On information and belief, Defendants have filed a patent certification in association with their ANDA No. 213699 seeking, *inter alia*, FDA final approval. On information and belief, Defendants are currently pursuing FDA final approval of ANDA No. 213699 before the '920 patent expires on May 31, 2022.

117. On information and belief, the making, using, selling, or offering for sale in the United States or the importation into the United States of Defendants' ANDA Product infringes the '920 patent.

118. Defendants have infringed, either literally or under the doctrine of equivalents, the '920 patent under 35 U.S.C. § 271(e)(2) by filing ANDA No. 213699 and continuing to seek approval from the FDA to engage in the commercial manufacture, use, importation, offer for sale, or sale of a drug to be used as claimed in the '920 patent before the expiration of the '920 patent.

119. On information and belief, Defendants' ANDA Product is a material for use in practicing the methods patented in the '920 patent, constitutes a material part of the inventions of the '920 patent, is especially made or especially adapted for use in an infringement of the '920 patent, and is not a staple article or commodity of commerce suitable for substantial noninfringing use. On information and belief, Defendants are aware that the ANDA Product is so made or so adapted. On information and belief, Defendants are aware that the ANDA Product will be used in contravention of Plaintiffs' rights under the '920 patent.

120. On information and belief, Defendants' above-described activities are continuing and constitute an act of infringement of the '920 patent under 35 U.S.C. § 271(e)(2).

121. 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.

COUNT VIII

(DECLARATORY JUDGMENT AS TO THE '920 PATENT)

122. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

123. The '920 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, importation, offer for sale, or sale of the VIMOVO® product.

124. On information and belief, Defendants' ANDA Product contain the pharmaceutical composition patented in the '920 patent, are materials for use in practicing the methods patented in the '920 patent, constitute a material part of the inventions of the '920 patent, are especially made or especially adapted for use in an infringement of the '920 patent, and are not staple articles or commodities of commerce suitable for substantial noninfringing use. On information and belief, Defendants are aware that the ANDA Product are so made or so adapted.

125. On information and belief, the making, using, selling, or offering for sale in the United States or the importation into the United States of Defendants' ANDA Product before the expiration of the '920 patent constitutes infringement of the '920 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

126. The ANDA Notice Letter show Defendants' intent to market the ANDA Product before the '920 patent expires on May 31, 2022.

127. On information and belief, Defendants continue to seek FDA final approval for Defendant's ANDA Product. On information and belief, Defendants are aware that the manufacture, use, sale, or offer for sale in the United States or the importation into the United States of Defendants' ANDA Product, if approved, will infringe the '920 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

128. On information and belief, Defendants have made, and will continue to make, substantial preparation to manufacture, use, sell, or offer to sell in the United States or import into the United States their ANDA Product before the '920 patent expires.

129. On information and belief, Defendants intend to engage in the commercial manufacture, use, sale, or offer for sale in the United States or importation into the United States of Defendants' ANDA Product after receiving FDA final approval of ANDA No. 213699 and before the '920 patent expires.

130. Defendants maintain, on information and belief, and Plaintiffs deny that the '920 patent is invalid or unenforceable and that Defendants' ANDA Product do not or will not infringe the '920 patent. Accordingly, a definite and concrete, real and substantial, justiciable case or controversy exists between Plaintiffs and Defendants concerning infringement of the '920 patent by Defendants' ANDA Product.

131. 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.

132. Plaintiffs are entitled to a declaration that the making, using, sale, or offer for sale in the United States or the importation into the United States of ANDA Product will infringe one or more claims of the '920 patent.

COUNT IX

(INFRINGEMENT OF THE '888 PATENT UNDER 35 U.S.C. § 271(e)(2))

133. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

134. The '888 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, importation, offer for sale, or sale of the VIMOVO® product.

135. Accordingly, pursuant to 21 U.S.C. § 355(c)(2), Plaintiffs submitted patent information for the '888 patent to the FDA in connection with NDA No. 022511 for the VIMOVO® product. On information and belief, this information is published in the FDA's Orange Book.

136. 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV") requires, *inter alia*, certification by the ANDA applicant that the subject patent in the Orange Book, here the '888 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 not valid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)) specify, *inter alia*, that a Paragraph IV notification must include "[a] detailed statement of the factual and legal basis of applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement is to include "(i) [f] or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation."

137. On information and belief, Defendants are aware of the statutory provisions and regulations referred to above and have maintained pursuit of their ANDA.

138. On information and belief, Defendants have filed a patent certification in association with their ANDA No. 213699 seeking, *inter alia*, FDA final approval. On information and belief, Defendants are currently pursuing FDA final approval of ANDA No. 213699 before the '888 patent expires on May 31, 2022.

139. On information and belief, the making, using, selling, or offering for sale in the United States or the importation into the United States of Defendants' ANDA Product infringes the '888 patent.

140. Defendants have infringed, either literally or under the doctrine of equivalents, the '888 patent under 35 U.S.C. § 271(e)(2) by filing ANDA No. 213699 and continuing to seek approval from the FDA to engage in the commercial manufacture, use, importation, offer for sale, or sale of a drug to be used as claimed in the '888 patent before the expiration of the '888 patent.

141. On information and belief, Defendants' ANDA Product is a material for use in practicing the methods patented in the '888 patent, constitutes a material part of the inventions of the '888 patent, is especially made or especially adapted for use in an infringement of the '888 patent, and is not a staple article or commodity of commerce suitable for substantial noninfringing use. On information and belief, Defendants are aware that the ANDA Product is so made or so adapted. On information and belief, Defendants are aware that the ANDA Product will be used in contravention of Plaintiffs' rights under the '888 patent.

142. On information and belief, Defendants' above-described activities are continuing and constitute an act of infringement of the '888 patent under 35 U.S.C. § 271(e)(2).

143. 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.

COUNT X

(DECLARATORY JUDGMENT AS TO THE '888 PATENT)

144. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

145. The '888 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, importation, offer for sale, or sale of the VIMOVO® product.

146. On information and belief, Defendants' ANDA Product contain the pharmaceutical composition patented in the '888 patent, are materials for use in practicing the methods patented in the '888 patent, constitute a material part of the inventions of the '888 patent, are especially made or especially adapted for use in an infringement of the '888 patent, and are not staple articles or commodities of commerce suitable for substantial noninfringing use. On information and belief, Defendants are aware that the ANDA Product are so made or so adapted.

147. On information and belief, the making, using, selling, or offering for sale in the United States or the importation into the United States of Defendants' ANDA Product before the expiration of the '888 patent constitutes infringement of the '888 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

148. The ANDA Notice Letter show Defendants' intent to market the ANDA Product before the '888 patent expires on May 31, 2022.

149. On information and belief, Defendants continue to seek FDA final approval for Defendant's ANDA Product. On information and belief, Defendants are aware that the manufacture, use, sale, or offer for sale in the United States or the importation into the United States of Defendants' ANDA Product, if approved, will infringe the '888 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

150. On information and belief, Defendants have made, and will continue to make, substantial preparation to manufacture, use, sell, or offer to sell in the United States or import into the United States their ANDA Product before the '888 patent expires.

151. On information and belief, Defendants intend to engage in the commercial manufacture, use, sale, or offer for sale in the United States or importation into the United States of Defendants' ANDA Product after receiving FDA final approval of ANDA No. 213699 and before the '888 patent expires.

152. Defendants maintain, on information and belief, and Plaintiffs deny that the '888 patent is invalid or unenforceable and that Defendants' ANDA Product do not or will not infringe the '888 patent. Accordingly, a definite and concrete, real and substantial, justiciable case or controversy exists between Plaintiffs and Defendants concerning infringement of the '888 patent by Defendants' ANDA Product.

153. 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.

154. Plaintiffs are entitled to a declaration that the making, using, sale, or offer for sale in the United States or the importation into the United States of ANDA Product will infringe one or more claims of the '888 patent.

COUNT XI

(INFRINGEMENT OF THE '181 PATENT UNDER 35 U.S.C. § 271(e)(2))

155. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

156. The '181 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, importation, offer for sale, or sale of the VIMOVO® product.

157. Accordingly, pursuant to 21 U.S.C. § 355(c)(2), Plaintiffs submitted patent information for the '181 patent to the FDA in connection with NDA No. 022511 for the VIMOVO® product. On information and belief, this information is published in the FDA's Orange Book.

158. 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV") requires, *inter alia*, certification by the ANDA applicant that the subject patent in the Orange Book, here the '181 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 not valid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)) specify, *inter alia*, that a Paragraph IV notification must include "[a] detailed statement of the factual and legal basis of applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement is to include "(i) [f] or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation."

159. On information and belief, Defendants are aware of the statutory provisions and regulations referred to above and have maintained pursuit of their ANDA.

160. On information and belief, Defendants have filed a patent certification in association with their ANDA No. 213699 seeking, *inter alia*, FDA final approval. On information and belief, Defendants are currently pursuing FDA final approval of ANDA No. 213699 before the '181 patent expires on May 31, 2022.

161. On information and belief, the making, using, selling, or offering for sale in the United States or the importation into the United States of Defendants' ANDA Product infringes the '181 patent.

162. Defendants have infringed, either literally or under the doctrine of equivalents, the '181 patent under 35 U.S.C. § 271(e)(2) by filing ANDA No. 213699 and continuing to seek approval from the FDA to engage in the commercial manufacture, use, importation, offer for sale, or sale of a drug to be used as claimed in the '181 patent before the expiration of the '181 patent.

163. On information and belief, Defendants' ANDA Product is a material for use in practicing the methods patented in the '181 patent, constitutes a material part of the inventions of the '181 patent, is especially made or especially adapted for use in an infringement of the '181 patent, and is not a staple article or commodity of commerce suitable for substantial noninfringing use. On information and belief, Defendants are aware that the ANDA Product is so made or so adapted. On information and belief, Defendants are aware that the ANDA Product will be used in contravention of Plaintiffs' rights under the '181 patent.

164. On information and belief, Defendants' above-described activities are continuing and constitute an act of infringement of the '181 patent under 35 U.S.C. § 271(e)(2).

165. 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.

COUNT XII

(DECLARATORY JUDGMENT AS TO THE '181 PATENT)

166. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

167. The '181 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, importation, offer for sale, or sale of the VIMOVO® product.

168. On information and belief, Defendants' ANDA Product contain the pharmaceutical composition patented in the '181 patent, are materials for use in practicing the methods patented in the '181 patent, constitute a material part of the inventions of the '181 patent, are especially made or especially adapted for use in an infringement of the '181 patent, and are not staple articles or commodities of commerce suitable for substantial noninfringing use. On information and belief, Defendants are aware that the ANDA Product are so made or so adapted.

169. On information and belief, the making, using, selling, or offering for sale in the United States or the importation into the United States of Defendants' ANDA Product before the expiration of the '181 patent constitutes infringement of the '181 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

170. The ANDA Notice Letter show Defendants' intent to market the ANDA Product before the '181 patent expires on May 31, 2022.

171. On information and belief, Defendants continue to seek FDA final approval for Defendant's ANDA Product. On information and belief, Defendants are aware that the manufacture, use, sale, or offer for sale in the United States or the importation into the United States of Defendants' ANDA Product, if approved, will infringe the '181 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

172. On information and belief, Defendants have made, and will continue to make, substantial preparation to manufacture, use, sell, or offer to sell in the United States or import into the United States their ANDA Product before the '181 patent expires.

173. On information and belief, Defendants intend to engage in the commercial manufacture, use, sale, or offer for sale in the United States or importation into the United States of Defendants' ANDA Product after receiving FDA final approval of ANDA No. 213699 and before the '181 patent expires.

174. Defendants maintain, on information and belief, and Plaintiffs deny that the '181 patent is invalid or unenforceable and that Defendants' ANDA Product do not or will not infringe the '181 patent. Accordingly, a definite and concrete, real and substantial, justiciable case or controversy exists between Plaintiffs and Defendants concerning infringement of the '181 patent by Defendants' ANDA Product.

175. 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.

176. Plaintiffs are entitled to a declaration that the making, using, sale, or offer for sale in the United States or the importation into the United States of ANDA Product will infringe one or more claims of the '181 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that the submission of Defendants' ANDA infringes one or more claims of the patents-in-suit under 35 U.S.C. § 271 (e)(2)(A);

B. A judgment providing that, pursuant to 35 U.S.C. § 271 (e)(4)(A), the effective date of any FDA approval of Defendants' ANDA shall be no earlier than the expiration date of the patents-in-suit or any later exclusivity to which Plaintiffs are or become entitled;

C. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) permanently enjoining Defendants, and all persons acting in concert with any of them, from making, using, selling, offering to sell, or importing the naproxen and esomeprazole magnesium product described in Defendants' ANDA no earlier than the expiration date of the patents-in-suit or any later exclusivity to which Plaintiffs are or become entitled;

D. A declaration that Defendants have infringed the patents-in-suit;

E. A declaration that the commercial use, sale, offer for sale, manufacture in the United States and/or importation into the United States by Defendants of the naproxen and esomeprazole magnesium product described in Defendants' ANDA would infringe the patents-in-suit;

F. An order preliminarily and permanently enjoining Defendants, and all persons acting in concert with any of them, from making, using, selling, offering to sell, or importing the naproxen and esomeprazole magnesium product described in Defendants' ANDA no earlier than the expiration date of the patents-in-suit or any later exclusivity to which Plaintiffs are or become entitled;

G. Attorneys' fees in this action pursuant to 35 U.S.C. § 285;

H. Costs and expenses in this action; and

I. Such further and other relief as this Court may deem just and proper.

Dated: September 27, 2019

BARNES & THORNBURG LLP

/s/ Chad S.C. Stover

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