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

HORIZON PHARMA, INC. and POZEN INC.,

Plaintiffs,

v.

MYLAN PHARMACEUTICALS INC., MYLAN LABORATORIES LIMITED, and MYLAN, INC.,

Defendants.

Civil Action No. 3:15-cv-03327 (MLC) (DEA)

SECOND AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Horizon Pharma, Inc. and Pozen Inc. (collectively, "Plaintiffs"), by their attorneys, for their Complaint against Mylan Pharmaceuticals Inc., Mylan Laboratories Limited, and Mylan, Inc. (collectively, "Defendants"), allege as follows:

THE PARTIES

1. 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.

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

3. On information and belief, Defendant Mylan Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of West Virginia, with its principal place of business at 781 Chestnut Ridge Rd., Morgantown, West Virginia 26505. On information and belief, Mylan Pharmaceuticals Inc. is in the business of, *inter alia*, manufacturing, marketing, and selling generic copies of branded pharmaceutical products throughout the United States, including within this district.

4. On information and belief, Defendant Mylan Laboratories Limited ("Mylan Limited") was formerly known as Matrix Laboratories Limited ("Matrix Limited"). On information and belief, Defendant Mylan Limited is a corporation organized and existing under the laws of India, with its principal place of business at Plot No. 564/A/22, Road No. 92, Hyderabad 500034 Andhra Pradesh, India. On information and belief, Mylan Limited is in the

business of, *inter alia*, manufacturing, marketing, and selling generic copies of branded pharmaceutical products throughout the United States, including within this district.

5. On information and belief, Defendant Mylan, Inc. is a corporation organized and existing under the laws of Pennsylvania, with its principal place of business at 1000 Mylan Blvd., Canonsburg, Pennsylvania 15317. On information and belief, Mylan, Inc. is in the business of, *inter alia*, manufacturing, marketing, and selling generic copies of branded pharmaceutical products throughout the United States, including within this district.

6. On information and belief, Mylan, Inc. is the parent company of Mylan Pharmaceuticals Inc.

7. On information and belief, Mylan, Inc. is the parent company of Mylan Limited.

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

BACKGROUND

The NDA

9. 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.

10. 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

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. The claims of the '636 patent are directed to pharmaceutical compositions in unit dosage form comprising esomeprazole and naproxen (claims 1–4, 7–10, 13–18) and methods of treating a patient for pain or inflammation comprising administration of the aforementioned compositions (claims 5–6, 11–12). A true and correct copy of the '636 patent is attached as Exhibit A.

12. Pozen owns the '636 patent by assignment. Horizon is Pozen's exclusive licensee under 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. The claims of the '996 patent are directed to pharmaceutical compositions in unit dosage form comprising esomeprazole and naproxen (claims 1–9, 12–15) and methods of treating a patient for pain or inflammation comprising administration of the aforementioned compositions (claims 10–11, 16–19). A true and correct copy of the '996 patent is attached as Exhibit B.

15. Pozen owns the '996 patent by assignment. Horizon is Pozen's exclusive licensee under 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. 8,865,190 (“the ’190 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 21, 2014. The claims of the ’190 patent are directed to a process for preparing pharmaceutical compositions in unit dosage form comprising esomeprazole and naproxen. A true and correct copy of the ’190 patent is attached as Exhibit C.

18. Pozen owns the ’190 patent by assignment. Horizon is Pozen’s exclusive licensee under the ’190 patent. The ’190 patent will expire on May 31, 2022.

19. 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. The claims of the ’920 patent are directed to methods of reducing the incidence of NSAID-associated gastric ulcers by administering a pharmaceutical composition in unit dose form comprising naproxen and esomeprazole. A true and correct copy of the ’920 patent is attached as Exhibit D.

20. Pozen owns the ’920 patent by assignment. Horizon is Pozen’s exclusive licensee under the ’920 patent. The ’920 patent will expire on May 31, 2022.

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

22. 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. The claims of the ’888 patent

are directed to a method of reducing the incidence of NSAID-associated gastric ulcers by administering a pharmaceutical composition in unit dosage form comprising naproxen and esomeprazole. A true and correct copy of the '888 patent is attached as Exhibit E.

23. Pozen owns the '888 patent by assignment. Horizon is Pozen's exclusive licensee under the '888 patent. The '888 patent will expire on May 31, 2022.

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

Related Patents

25. United States Patent No. 6,926,907 ("the '907 patent"), entitled "Pharmaceutical Compositions for the Coordinated Delivery of NSAIDs," was duly and legally issued by the United States Patent and Trademark Office on August 9, 2005. The claims of the '907 patent are directed to pharmaceutical compositions that provide for the coordinated release of an acid inhibitor and an NSAID (claims 1–21, and 53–55) and methods of treating a patient for pain or inflammation comprising administration of the aforementioned compositions (claims 22–52).

26. Pozen owns the '907 patent by assignment. Horizon is Pozen's exclusive licensee under the '907 patent. The '907 patent will expire on February 28, 2023.

27. The '907 patent is listed in the FDA Orange Book in connection with NDA No. 022511 for VIMOVO® drug product.

28. United States Patent No. 8,557,285 ("the '285 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 15, 2013. The claims of the '285 patent are directed to pharmaceutical compositions in unit dosage form comprising esomeprazole and naproxen.

29. Pozen owns the ’285 patent by assignment. Horizon is Pozen’s exclusive licensee under the ’285 patent. The ’285 patent will expire on May 31, 2022.

30. The ’285 patent is listed in the FDA Orange Book in connection with NDA No. 022511 for VIMOVO® drug product.

The ANDA

31. On information and belief, Defendants filed ANDA No. 204920 (“Defendants’ 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 in 375 mg (naproxen)/20 mg (esomeprazole magnesium) and 500 mg (naproxen)/20 mg (esomeprazole magnesium) strengths (“Mylan’s 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.

32. By letter dated May 16, 2013 (the “May 2013 ANDA Notice Letter”), Defendants notified AstraZeneca AB (Horizon’s predecessor-in-interest as holder of NDA No. 022511 and as exclusive licensee for the ’907 patent and the ’285 patent) and Pozen that Defendants had filed ANDA No. 204920 seeking approval to market Mylan’s ANDA Product and that Defendants were providing information pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95 regarding certain patents including the ’907 patent.

33. On January 23, 2015, Plaintiffs requested that Defendants provide Paragraph IV certifications with respect to *inter alia* the ’285, ’636, and ’996 patents..

34. By three letters each dated February 9, 2015 (the “February 2015 ANDA Notice Letters”), Defendants notified Horizon and Pozen that Defendants had filed ANDA No. 204920

seeking approval to market Mylan's ANDA Product and that Defendants were providing information pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95 regarding the '285, '636, and '996 patents.

35. By a letter dated January 26, 2016 (the "January 2016 ANDA Notice Letter"), Defendants notified Horizon and Pozen that Defendants had filed ANDA No. 204920 seeking approval to market Mylan's ANDA Product and that Defendants were providing information pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95 regarding the '920 and '888 patents.

JURISDICTION AND VENUE

36. 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).

37. On information and belief, Defendants have been and are engaging in activities directed toward infringement of the '636, '996,'190, '920, and '888 patents (collectively, the "patents-in-suit") by, *inter alia*, submitting to the FDA ANDA No. 204920 and continuing to seek approval for Mylan's ANDA Product.

38. Defendants' ANDA May 2013 Notice Letter states Defendants' intention to seek FDA approval to market a generic version of the VIMOVO® product before the related '907 patent expires on February 28, 2023.

39. There is now an actual controversy between Defendants and Plaintiffs as to whether Defendants infringe the '636, '996,'190, '920, and '888 patents.

40. This Court has personal jurisdiction over Defendants because, *inter alia*, Defendants, on 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, on information and belief, selling pharmaceutical products in New Jersey and deriving substantial revenues from those sales; and, on information and belief, Mylan, Inc. and Mylan Limited are licensed to do business within New Jersey. Thus, Defendants are subject to general jurisdiction in New Jersey.

41. On information and belief, Defendants acted in concert to develop Mylan's ANDA Product and to seek approval from the FDA to sell Mylan's ANDA Product throughout the United States, including within this judicial district.

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

43. On information and belief, Mylan Pharmaceuticals Inc., Mylan Limited, and Mylan, Inc. participated in the preparation and/or filing of ANDA No 204920.

44. On information and belief and as stated in the May 2013 ANDA Notice Letter, the FDA received ANDA No. 204920 from Defendants.

45. On information and belief, by virtue of, *inter alia*, Defendants' continuous and systematic contacts with New Jersey, including but not limited to the above-described contacts, and the actions on behalf of Defendants in connection with ANDA No. 204920, this Court has personal jurisdiction over Defendants. These activities satisfy due process and confer personal jurisdiction over Defendants consistent with New Jersey law.

46. Venue is proper in this District under 28 U.S.C. §§ 1391(b), 1391(c), and 1400(b).

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

47. Plaintiffs incorporate by reference paragraphs 1–46 of this Complaint as if fully set forth herein.

48. 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, sale, or importation of the VIMOVO® product.

49. 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 will be published in the FDA's Orange Book.

50. 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."

51. On information and belief, Defendants were aware of the statutory provisions and regulations referred to in paragraph 50 above when they served the May 2013 ANDA Notice Letter regarding certain patents including the ’907 patent.

52. On information and belief, Defendants have previously filed patent certifications in association with their ANDA No. 204920 seeking, *inter alia*, FDA final approval prior to February 28, 2023. The ’636 patent has an expiration date of May 31, 2022. Therefore, on further information and belief, Defendants are currently pursuing FDA final approval of ANDA No. 204920 before the ’636 patent expires.

53. On information and belief, the making, using, selling, or offering for sale in the United States or the importation into the United States of Mylan’s ANDA Product infringes the ’636 patent.

54. 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. 204920 and continuing to seek approval from the FDA to engage in the commercial manufacture, use, sale, or importation of a drug claimed in the ’636 patent before the expiration of the ’636 patent.

55. On information and belief, Mylan’s ANDA Product contains the pharmaceutical composition patented in the ’636 patent, 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 Mylan’s ANDA Product is so made or so adapted. On information and belief, Defendants are aware that Mylan’s ANDA Product, if approved, will be used in contravention of Plaintiffs’ rights under the ’636 patent.

56. 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).

57. 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 '636 PATENT)

58. Plaintiffs incorporate by reference paragraphs 1–57 of this Complaint as if fully set forth herein.

59. 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, sale, or importation of the VIMOVO® product.

60. On information and belief, Mylan's ANDA Product contains the pharmaceutical composition patented in the '636 patent, 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 Mylan's ANDA Product is so made or so adapted.

61. On information and belief, the making, using, selling, or offering for sale in the United States or the importation into the United States of Mylan's 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).

62. On information and belief, Defendants have previously filed patent certifications in association with their ANDA No. 204920 seeking, *inter alia*, FDA final approval to market Mylan's ANDA Product before February 28, 2023.

63. The February 2015 ANDA Notice Letter shows Defendants' intent to market Mylan's ANDA Product before the '636 patent expires on May 31, 2022.

64. On information and belief, Defendants continue to seek FDA final approval for Mylan'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 Mylan's ANDA Product, if approved, will infringe the '636 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

65. 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 Mylan's ANDA Product before the '636 patent expires.

66. 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 Mylan's ANDA Product after receiving FDA final approval of ANDA No. 204920 and before the '636 patent expires.

67. Defendants maintain, on information and belief, and Plaintiffs deny that the '636 patent is invalid or unenforceable and that Mylan's ANDA Product does 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 Mylan's ANDA Product.

68. 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.

69. 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 Mylan's ANDA Product will infringe one or more claims of the '636 patent.

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

70. Plaintiffs incorporate by reference paragraphs 1–69 of this Complaint as if fully set forth herein.

71. 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, sale, or importation of the VIMOVO® product.

72. Accordingly, pursuant to 21 U.S.C. § 355(c)(2), Plaintiffs timely submitted patent information for the '996 patent to the FDA in connection with NDA No. 022511 for the VIMOVO® product. This information has been published in the FDA's Orange Book.

73. 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."

74. On information and belief, Defendants were aware of the statutory provisions and regulations referred to in paragraph 73 above when they served the May 2013 ANDA Notice Letter regarding certain patents including the '907 patent and when they served the February 2015 ANDA Notice Letter regarding the '285 patent.

75. On information and belief, Defendants have previously filed patent certifications in association with their ANDA No. 204920 seeking, *inter alia*, FDA final approval prior to February 28, 2023. The '996 patent has an expiration date of May 31, 2022. Therefore, on further information and belief, Defendants are currently pursuing FDA final approval of ANDA No. 204920 before the '996 patent expires.

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

77. 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. 204920 and continuing to seek approval from the FDA to engage in the commercial manufacture, use, sale, or importation of a drug claimed in the '996 patent before the expiration of the '996 patent.

78. On information and belief, Mylan's ANDA Product contains the pharmaceutical composition patented in the '996 patent, 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 Mylan’s ANDA Product is so made or so adapted. On information and belief, Defendants are aware that Mylan’s ANDA Product, if approved, will be used in contravention of Plaintiffs’ rights under the ’996 patent.

79. 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).

80. 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 ’996 PATENT)

81. Plaintiffs incorporate by reference paragraphs 1–80 of this Complaint as if fully set forth herein.

82. 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, sale, or importation of the VIMOVO® product.

83. On information and belief, Mylan’s ANDA Product contains the pharmaceutical composition patented in the ’996 patent, 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 Mylan’s ANDA Product is so made or so adapted.

84. On information and belief, the making, using, selling, or offering for sale in the United States or the importation into the United States of Mylan's 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).

85. On information and belief, Defendants have previously filed patent certifications in association with their ANDA No. 204920 seeking, *inter alia*, FDA final approval to market Mylan's ANDA Product before February 28, 2023.

86. The May 2013 ANDA Notice Letter and the February 2015 ANDA Notice Letter show Defendants' intent to market Mylan's ANDA Product before the '996 patent expires on May 31, 2022.

87. On information and belief, Defendants continue to seek FDA final approval for Mylan'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 Mylan's ANDA Product, if approved, will infringe the '996 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

88. 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 Mylan's ANDA Product before the '996 patent expires.

89. 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 Mylan's ANDA Product after receiving FDA final approval of ANDA No. 204920 and before the '996 patent expires.

90. Defendants maintain, on information and belief, and Plaintiffs deny that the '996 patent is invalid or unenforceable and that Mylan's ANDA Product does 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 Mylan's ANDA Product.

91. 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.

92. 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 Mylan's ANDA Product will infringe one or more claims of the '996 patent.

COUNT V
(DECLARATORY JUDGMENT AS TO THE '190 PATENT)

93. Plaintiffs incorporate by reference paragraphs 1–92 of this Complaint as if fully set forth herein.

94. The '190 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, sale, or importation of the VIMOVO® product.

95. On information and belief, Mylan's ANDA Product is prepared by a process patented in the '190 patent. On information and belief, Defendants are aware that Mylan's ANDA Product is so made or so adapted.

96. On information and belief, the making, using, selling, or offering for sale in the United States or the importation into the United States of Mylan's ANDA Product before the

expiration of the '190 patent constitutes infringement of the '190 patent under 35 U.S.C. §§ 271(a), (b), (c) and/or (g).

97. On information and belief, Defendants have previously filed patent certifications in association with their ANDA No. 204920 seeking, *inter alia*, FDA final approval to market Mylan's ANDA Product before February 28, 2023.

98. The May 2013 ANDA Notice Letter and the February 2015 ANDA Notice Letter show Defendants' intent to market Mylan's ANDA Product before the '190 patent expires on May 31, 2022.

99. On information and belief, Defendants continue to seek FDA final approval for Mylan'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 Mylan's ANDA Product, if approved, will infringe the '190 patent under 35 U.S.C. §§ 271(a), (b), (c) and/or (g).

100. 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 Mylan's ANDA Product before the '190 patent expires.

101. 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 Mylan's ANDA Product after receiving FDA final approval of ANDA No. 204920 and before the '190 patent expires.

102. Accordingly, a definite and concrete, real and substantial, justiciable case or controversy exists between Plaintiffs and Defendants concerning infringement of the '190 patent by Mylan's ANDA Product.

103. 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.

104. 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 Mylan's ANDA Product will infringe one or more claims of the '190 patent.

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

105. Plaintiffs incorporate by reference paragraphs 1–104 of this Complaint as if fully set forth herein.

106. 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, sale, or importation of the VIMOVO® product.

107. Accordingly, pursuant to 21 U.S.C. § 355(c)(2), Plaintiffs timely submitted patent information for the '920 patent to the FDA in connection with NDA No. 022511 for the VIMOVO® product. This information has been published in the FDA's Orange Book.

108. 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."

109. On information and belief, Defendants were aware of the statutory provisions and regulations referred to in paragraph 108 above when they served the May 2013 ANDA Notice Letter regarding certain patents including the '907 patent and when they served the February 2015 ANDA Notice Letter regarding the '285 patent.

110. On information and belief, Defendants have previously filed patent certifications in association with their ANDA No. 204920 seeking, *inter alia*, FDA final approval prior to February 28, 2023. The '920 patent has an expiration date of May 31, 2022. Therefore, on further information and belief, Defendants are currently pursuing FDA final approval of ANDA No. 204920 before the '920 patent expires.

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

112. 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. 204920 and continuing to seek approval from the FDA to engage in the commercial manufacture, use, sale, or importation of a drug to be used as claimed in the '920 patent before the expiration of the '920 patent.

113. On information and belief, Mylan's 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 Mylan's ANDA Product is so made or so adapted. On information and belief, Defendants are aware that Mylan's ANDA Product, if approved, will be used in contravention of Plaintiffs' rights under the '920 patent.

114. 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).

115. 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 VII
(DECLARATORY JUDGMENT AS TO THE '920 PATENT)

116. Plaintiffs incorporate by reference paragraphs 1–115 of this Complaint as if fully set forth herein.

117. 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, sale, or importation of the VIMOVO® product.

118. On information and belief, Mylan's 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 Mylan's ANDA Product is so made or so adapted.

119. On information and belief, the making, using, selling, or offering for sale in the United States or the importation into the United States of Mylan's 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).

120. On information and belief, Defendants have previously filed patent certifications in association with their ANDA No. 204920 seeking, *inter alia*, FDA final approval to market Mylan's ANDA Product before February 28, 2023.

121. The May 2013 ANDA Notice Letter and the February 2015 ANDA Notice Letter show Defendants' intent to market Mylan's ANDA Product before the '920 patent expires on May 31, 2022.

122. On information and belief, Defendants continue to seek FDA final approval for Mylan'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 Mylan's ANDA Product, if approved, will infringe the '920 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

123. 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 Mylan's ANDA Product before the '920 patent expires.

124. 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 Mylan's ANDA Product after receiving FDA final approval of ANDA No. 204920 and before the '920 patent expires.

125. Defendants maintain, on information and belief, and Plaintiffs deny that the '920 patent is invalid or unenforceable and that Mylan's ANDA Product does 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 Mylan's ANDA Product.

126. 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.

127. 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 Mylan's ANDA Product will infringe one or more claims of the '920 patent.

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

128. Plaintiffs incorporate by reference paragraphs 1–127 of this Complaint as if fully set forth herein.

129. 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, sale, or importation of the VIMOVO® product.

130. Accordingly, pursuant to 21 U.S.C. § 355(c)(2), Plaintiffs timely submitted patent information for the '888 patent to the FDA in connection with NDA No. 022511 for the VIMOVO® product. This information has been published in the FDA's Orange Book.

131. 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."

132. On information and belief, Defendants were aware of the statutory provisions and regulations referred to in paragraph 131 above when they served the May 2013 ANDA Notice Letter regarding certain patents including the '907 patent and when they served the February 2015 ANDA Notice Letter regarding the '285 patent.

133. On information and belief, Defendants have previously filed patent certifications in association with their ANDA No. 204920 seeking, *inter alia*, FDA final approval prior to February 28, 2023. The '888 patent has an expiration date of May 31, 2022. Therefore, on further information and belief, Defendants are currently pursuing FDA final approval of ANDA No. 204920 before the '888 patent expires.

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

135. 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. 204920 and continuing to seek

approval from the FDA to engage in the commercial manufacture, use, sale, or importation of a drug to be used as claimed in the ’888 patent before the expiration of the ’888 patent.

136. On information and belief, Mylan’s 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 Mylan’s ANDA Product is so made or so adapted. On information and belief, Defendants are aware that Mylan’s ANDA Product, if approved, will be used in contravention of Plaintiffs’ rights under the ’888 patent.

137. 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).

138. 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 IX
(DECLARATORY JUDGMENT AS TO THE ’888 PATENT)

139. Plaintiffs incorporate by reference paragraphs 1–138 of this Complaint as if fully set forth herein.

140. 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, sale, or importation of the VIMOVO® product.

141. On information and belief, Mylan’s 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 Mylan’s ANDA Product is so made or so adapted.

142. On information and belief, the making, using, selling, or offering for sale in the United States or the importation into the United States of Mylan’s 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).

143. On information and belief, Defendants have previously filed patent certifications in association with their ANDA No. 204920 seeking, *inter alia*, FDA final approval to market Mylan’s ANDA Product before February 28, 2023.

144. The May 2013 ANDA Notice Letter and the February 2015 ANDA Notice Letter show Defendants’ intent to market Mylan’s ANDA Product before the ’888 patent expires on May 31, 2022.

145. On information and belief, Defendants continue to seek FDA final approval for Mylan’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 Mylan’s ANDA Product, if approved, will infringe the ’888 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

146. 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 Mylan’s ANDA Product before the ’888 patent expires.

147. 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 Mylan's ANDA Product after receiving FDA final approval of ANDA No. 204920 and before the '888 patent expires.

148. Defendants maintain, on information and belief, and Plaintiffs deny that the '888 patent is invalid or unenforceable and that Mylan's ANDA Product does 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 Mylan's ANDA Product.

149. 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.

150. 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 Mylan's ANDA Product will infringe one or more claims of the '888 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that the claims of the '636, '996,'190, '920, and '888 patents are valid and enforceable;

B. A judgment that the submission of ANDA No. 204920 by Defendants infringes one or more claims of the '636, '996, '920, and '888 patents under 35 U.S.C. § 271(e)(2)(A);

C. A judgment providing that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any FDA approval of Defendants' ANDA No. 204920 shall be no earlier than the

expiration date of the '636,'996, '920, and '888 patents or any later exclusivity to which Plaintiffs are or become entitled;

D. 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. 204920 no earlier than the expiration date of the '636,'996, '920, and '888 patents or any later exclusivity to which Plaintiffs are or become entitled;

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

F. 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 No. 204920 would infringe the patents-in-suit;

G. 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. 204920 no earlier than the expiration date of the patents-in-suit or any later exclusivity to which Plaintiffs are or become entitled;

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

I. Costs and expenses in this action; and

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

Dated: February 10, 2016

Respectfully submitted,

By: *s/ John E. Flaherty*
John E. Flaherty

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that true copies of the foregoing SECOND AMENDED COMPLAINT were caused to be served on February 10, 2016, by electronic mail and/or the ECF system upon all counsel of record.

By: *s/ John E. Flaherty*

John E. Flaherty