UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

FRESENIUS KABI USA, LLC and FRESENIUS KABI DEUTSCHLAND GMBH *Plaintiffs*, v. MYLAN LABORATORIES LIMITED, MYLAN INC., AGILA SPECIALTIES INC., and MYLAN PHARMACEUTICALS INC. *Defendants*.	)	Civil Action No. _____

COMPLAINT

Fresenius Kabi USA, LLC and Fresenius Kabi Deutschland GmbH (collectively, "Fresenius" or "Plaintiffs") bring this action for patent infringement against Mylan Laboratories Limited ("Mylan Labs"), Mylan Inc., Agila Specialties Inc. ("Agila"), and Mylan Pharmaceuticals Inc. ("Mylan Pharma") (collectively, "Defendants").

NATURE OF THE ACTION

1. This is an action by Fresenius against Defendants for infringement of United States Patent Nos. 7,828,787 ("the '787 patent"); 7,857,802 ("the '7802 patent"); 8,118,802 ("the '8802 patent"); and 8,162,915 ("the '915 patent") (collectively, "the Patents-in-Suit"). This action arises out of Defendants' filing of an Abbreviated New Drug Application ("ANDA") seeking approval by the United States Food and Drug Administration ("FDA") to sell generic versions of Fresenius's ropivacaine hydrochloride injection product, Naropin®, prior to the expiration of the Patents-in-Suit.

THE PARTIES

Plaintiffs

2. Fresenius Kabi USA, LLC is a Delaware limited liability company with its principal place of business at Three Corporate Drive, Lake Zurich, Illinois 60047.

3. Fresenius Kabi Deutschland GmbH is a limited liability company organized and existing under the laws of Germany with a principal place of business at Else-Kröner-Straße 1, 61352 Bad Homburg, Germany.

Defendants

4. Upon information and belief, Mylan Labs is a corporation organized and existing under the laws of India, with its principal place of business at Opp. IIM, Bilekahalli, Bannerghatta Road, Bangalore, Karnataka 560076, India.. Mylan Labs was formerly known as Agila Specialties Private Ltd. Upon information and belief, Mylan Labs is a wholly-owned subsidiary of and is controlled by Mylan, Inc.

5. Upon information and belief, 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.

6. Upon information and belief, Agila is a corporation incorporated in New Jersey with its principal place of business at 201 South Main Street, Suite 3, Lambertville, NJ 08530. Agila was formerly known as Strides Inc. Upon information and belief, Agila is a wholly-owned subsidiary of and is controlled by Mylan Inc.

7. Upon information and belief, Mylan Pharma is a corporation organized and existing under the laws of West Virginia with its principal place of business at 781 Chestnut

Ridge Rd., Morgantown, WV 26505. Upon information and belief, Mylan Pharma is a wholly-owned subsidiary of and is controlled by Mylan Inc.

8. Upon information and belief, Mylan Labs conducts its business through and with Agila and/or Mylan Pharma. On information and belief, Mylan Labs, Agila, and Mylan Pharma conduct their business under the direction and on behalf of Mylan Inc.

9. Upon information and belief, Defendants acted in concert to develop the proposed generic product that is the subject of ANDA No. 206091 ("Defendants' ANDA"), to seek regulatory approval from the FDA to market and sell the proposed ANDA product throughout the United States, including within this District, and to prepare and/or file Defendants' ANDA.

JURISDICTION AND VENUE

Subject Matter Jurisdiction

10. This action for patent infringement arises under 35 U.S.C. § 271.

11. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

Personal Jurisdiction Over Defendants

12. This Court has personal jurisdiction over Defendants because, *inter alia*, they have maintained continuous and systematic contacts with the State of Delaware.

13. This Court also has personal jurisdiction over Defendants because, *inter alia*, they have committed, or aided, abetted, contributed to, or participated in the commission of, tortious conduct which will lead to foreseeable harm and injury to Fresenius Kabi USA, LLC, a Delaware Limited Liability Company, in the State of Delaware, and by doing so, Defendants have purposefully directed their activities at the residents of this forum.

14. Upon information and belief, Defendants collaborate to market and sell generic pharmaceutical products, pursuant to the Abbreviated New Drug Application process, throughout the United States, including in the State of Delaware, at least by making and shipping into this judicial district, or by offering to sell or selling, or causing others to offer to sell or sell, generic pharmaceutical products. Defendants derive substantial revenue from goods used or consumed or services rendered in this judicial district.

15. Upon information and belief, Defendants operate as a single vertically-integrated business with respect to the regulatory approval, manufacturing, marketing, sale, and distribution of pharmaceutical products throughout the United States including in this judicial district.

16. Upon information and belief, Mylan Labs markets, distributes and/or sells generic drugs throughout the United States and within the State of Delaware.

17. Upon information and belief, Mylan Labs has engaged in and maintained systematic and continuous business contacts within the State of Delaware, and has purposefully availed itself of the benefits and protections of the laws of Delaware, rendering it at home in Delaware.

18. Upon information and belief, Mylan Labs routinely files ANDAs in the United States and markets numerous generic injectable pharmaceutical products, including, *inter alia*, adenosine, ampicillin sodium, dexamethasone sodium phosphate, doxycycline hyclate, etomidate, famotidine, flumazenil, haloperidol lactate, lidocaine hydrochloride, nafcillin sodium, rifampin, vancomycin hydrochloride, and zoledronic acid.

19. Upon information and belief, Mylan Labs has agreements with pharmaceutical retailers, wholesalers or distributors providing for the distribution of its products in the State of Delaware, including, *inter alia*, adenosine, ampicillin sodium, dexamethasone sodium phosphate,

doxycycline hyclate, etomidate, famotidine, flumazenil, haloperidol lactate, lidocaine hydrochloride, nafcillin sodium, rifampin, vancomycin hydrochloride, and zoledronic acid.

20. Upon information and belief, Mylan Labs has committed, or aided, abetted, contributed to and/or participated in the commission of the tortious action of patent infringement that has led to foreseeable harm and injury to Fresenius, which manufactures Naropin® for sale and use throughout the United States, including the State of Delaware.

21. Upon information and belief, Mylan Labs has applied for FDA approval to market and sell a generic version of Naropin® throughout the United States, including in Delaware.

22. Mylan Labs sent a letter dated September 3, 2015 to Fresenius Kabi USA, LLC, a Delaware Limited Liability Company, stating that it had filed ANDA No. 206091 seeking FDA approval to market a generic Naropin® product prior to the expiration of the Patents-in-Suit (the "Notice Letter").

23. Upon information and belief, Mylan Labs will market, sell, and offer for sale its proposed generic version of Naropin® in the State of Delaware following FDA approval of that product.

24. Upon information and belief, as a result of Mylan Labs' marketing, selling, or offering for sale of its generic version of Naropin® in the State of Delaware, Fresenius will lose sales of Naropin® and be injured in the State of Delaware.

25. Upon information and belief, Mylan Labs' systematic and continuous business contacts within Delaware render it at home in Delaware.

26. Upon information and belief, this Court has personal jurisdiction over Mylan Labs for the reasons stated herein, including, *inter alia,* Mylan Labs' activities in the forum, activities

directed at the forum, and significant contacts with the forum, all of which render Mylan Labs at home in the forum.

27. This Court also has personal jurisdiction over Mylan Labs under Federal Rule of Civil Procedure 4(k)(2).

28. Upon information and belief, Mylan Inc. (through its wholly-owned subsidiaries including Mylan Pharma, Agila, and Mylan Labs) markets, distributes and/or sells generic drugs throughout the United States and within the State of Delaware.

29. Upon information and belief, Mylan Inc. has engaged in and maintained systematic and continuous business contacts within the State of Delaware, and has purposefully availed itself of the benefits and protections of the laws of Delaware.

30. Upon information and belief, Mylan Inc. collaborated and/or acted in concert with Mylan Labs to apply for FDA approval to market and sell a generic version of Naropin® throughout the United States, including in Delaware.

31. Upon information and belief, Mylan Inc. collaborated in the decision to send the Notice Letter to Fresenius Kabi USA, LLC, a Delaware Limited Liability Company.

32. Upon information and belief, as a result of Mylan Inc.'s conduct, Mylan Labs will market, sell, and offer for sale its generic version of Naropin® in the State of Delaware following FDA approval of that product.

33. Upon information and belief, Mylan Inc. has committed, or aided, abetted, contributed to and/or participated in the commission of the tortious action of patent infringement that has led to foreseeable harm and injury to Fresenius Kabi USA, LLC, a Delaware Limited Liability Company, which manufactures Naropin® for sale and use throughout the United States, including the State of Delaware.

34. Upon information and belief, Mylan Inc.'s systematic and continuous business contacts within Delaware render it at home in Delaware.

35. Upon information and belief, this Court has personal jurisdiction over Mylan Inc. for the reasons stated herein, including by virtue of Mylan Inc.'s activities in the forum, activities directed at the forum, and significant contacts with the forum, all of which render Mylan Inc. at home in the forum.

36. Upon information and belief, Agila collaborated and/or acted in concert with Mylan Labs to apply for FDA approval to market and sell a generic version of Naropin® throughout the United States, including in Delaware.

37. Upon information and belief, Agila collaborated in the decision to send the Notice Letter to Fresenius Kabi USA, LLC, a Delaware Limited Liability Company.

38. Upon information and belief, as a result of Agila's conduct, Mylan Labs will market, sell, and offer for sale its generic version of Naropin® in the State of Delaware following FDA approval of that product.

39. Upon information and belief, Agila has committed, or aided, abetted, contributed to and/or participated in the commission of the tortious action of patent infringement that has led to foreseeable harm and injury to Fresenius, which manufactures Naropin® for sale and use throughout the United States, including the State of Delaware.

40. Upon information and belief, Agila's systematic and continuous business contacts within Delaware render it at home in Delaware.

41. Upon information and belief, this Court has personal jurisdiction over Agila for the reasons stated herein, including by virtue of Agila's activities in the forum, activities directed

at the forum, and significant contacts with the forum, all of which render Agila at home in the forum.

42. Upon information and belief, Mylan Pharma is primarily responsible for the marketing, distribution, and sales of Mylan Inc.'s products.

43. Upon information and belief, Mylan Pharma has consented to suit in the state of Delaware by registering to do business in Delaware.

44. Upon information and belief, Mylan Pharma is registered with the Delaware Department of State Division of Corporations as a foreign corporation and has appointed Corporation Service Company, 2711 Centerville Road, Suite 400, Wilmington, DE 19808, as its registered agent for the receipt of service of process.

45. Upon information and belief, Mylan Pharma is registered with the Delaware Board of Pharmacy as an active Pharmacy – Wholesale under license number A4-0001719 and as a Distributor/Manufacturer CSR under license number DM-0007571.

46. Upon information and belief, Mylan Pharma collaborated and/or acted in concert with Mylan Labs to apply for FDA approval to market and sell a generic version of Naropin® throughout the United States, including in Delaware.

47. Upon information and belief, Mylan Pharma collaborated in the decision to send the Notice Letter to Fresenius Kabi USA, LLC, a Delaware Limited Liability Company.

48. Upon information and belief, as a result of Mylan Pharma's conduct, Mylan Labs will market, sell, and offer for sale its generic version of Naropin® in the State of Delaware following FDA approval of that product.

49. Upon information and belief, Mylan Pharma has committed, or aided, abetted, contributed to and/or participated in the commission of the tortious action of patent infringement

that has led to foreseeable harm and injury to Fresenius, which manufactures Naropin® for sale and use throughout the United States, including the State of Delaware.

50. Upon information and belief, Mylan Pharma's systematic and continuous business contacts within Delaware render it at home in Delaware.

51. Upon information and belief, this Court has personal jurisdiction over Mylan Pharma for the reasons stated herein, including by virtue of Mylan Pharma's activities in the forum, activities directed at the forum, significant contacts with the forum, and consent, all of which render Mylan Pharma at home in the forum.

Venue

52. Venue is proper in this Judicial District under 28 U.S.C. §§ 1391 and 1400(b).

BACKGROUND

The Patents-in-Suit

53. The '787 patent, entitled "Connector for packaging containing medical fluids and packaging for medical fluids," was duly and lawfully issued on November 9, 2010 to inventors Torsten Brandenburger and Ismael Rahimy. The named inventors assigned the '787 patent to Fresenius Kabi Deutschland GmbH. The '787 patent is listed in the FDA publication "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly referred to as "The Orange Book" ("Orange Book") with respect to Naropin®. The '787 patent will expire on October 18, 2025. A true and accurate copy of the '787 patent is attached hereto as Exhibit A.

54. The ’7802 patent, entitled “Connector for medical liquid-containing packages and medical liquid-containing packages,” was duly and lawfully issued on December 28, 2010 to inventors Torsten Brandenburger and Ismael Rahimy. The named inventors assigned the ’7802 patent to Fresenius Kabi Deutschland GmbH. The ’7802 patent is listed in the Orange Book with respect to Naropin®. The ’7802 patent will expire on November 28, 2026. A true and accurate copy of the ’7802 patent is attached hereto as Exhibit B.

55. The ’8802 patent, entitled “Connector for packaging containing medical fluids and packaging for medical fluids,” was duly and lawfully issued on February 21, 2012 to inventors Torsten Brandenburger and Ismael Rahimy. The named inventors assigned the ’8802 patent to Fresenius Kabi Deutschland GmbH. The ’8802 patent is listed in the Orange Book with respect to Naropin®. The ’8802 patent will expire on May 18, 2023. A true and accurate copy of the ’8802 patent is attached hereto as Exhibit C.

56. The ’915 patent, entitled “Connector for packings containing medical liquids, and corresponding packing for medical liquids,” was duly and lawfully issued on April 24, 2012 to inventors Torsten Brandenburger, Klaus Heilmann, and Bernd Knierbein. The named inventors assigned the ’915 patent to Fresenius Kabi Deutschland GmbH. The ’915 patent is listed in the Orange Book with respect to Naropin®. The ’915 patent will expire on May 23, 2024. A true and accurate copy of the ’915 patent is attached hereto as Exhibit D.

The Naropin® Drug Product

57. Fresenius Kabi USA, LLC currently sells, promotes, distributes, and markets Naropin® in the United States.

58. Fresenius Kabi USA, LLC holds an approved New Drug Application ("NDA") No. 20553 under Section 505(b) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(a) in connection with Naropin®.

Defendants' ANDA

59. Defendants filed with the FDA an ANDA under 21 U.S.C. § 355(j) seeking approval to manufacture, use, offer for sale, sell in and import into the United States a ropivacaine hydrochloride injection product containing 2 mg ropivacaine hydrochloride per 1 mL formulation, in 100 mL and 200 mL infusion bags, that Defendants assert is a generic copy of Naropin® ("Defendants' generic Naropin® product") prior to the expiration of the Patents-in-Suit.

60. The FDA assigned Defendants' ANDA the number 206091.

61. Defendants filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), a certification alleging that the claims of the Patents-In-Suit are invalid, unenforceable and/or would not be infringed by the manufacture, use, importation, sale or offer for sale of Defendants' generic Naropin® product ("Defendants' Paragraph IV Certification"). Defendants notified Fresenius of this certification, in a letter dated September 3, 2015 sent by Federal Express.

62. In the Notice Letter, Defendants offered Fresenius confidential access to ANDA No. 206091 on terms and conditions set forth in an attached "Offer of Confidential Access" ("OCA"). The OCA provided by Defendants contained various terms and conditions, several of which went above and beyond protections typically afforded in a protective order.

63. On September 29, 2015, Fresenius provided Defendants with a revised draft of the OCA, but despite Fresenius's repeated attempts to contact Defendants to finalize the OCA, a final OCA was only signed on October 14, 2015. Defendants refused to produce a complete copy of their ANDA file as part of the OCA process.

64. On the evening of October 14, 2015, Fresenius was provided with small excerpts of Defendants' ANDA.

65. Given the 45-day statutory deadline to file suit set forth in 21 U.S.C. § 355(j)(5)(B)(iii) and the limited information provided by the Defendants to date, Fresenius turns to the judicial process and the aid of discovery to obtain, under appropriate judicial safeguards, such information as is required to further confirm their allegations of infringement and to present to the Court evidence that Defendants' generic Naropin® product falls within the scope of one or more claims of the Patents-in-Suit.

COUNT I FOR INFRINGEMENT OF U.S. PATENT NO. 7,828,787 BY DEFENDANTS

66. The allegations of paragraphs 1-65 are realleged and incorporated herein by reference.

67. The use of Defendants' generic Naropin® product is covered by one or more claims of the '787 patent.

68. The commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Defendants' generic Naropin® product would infringe one or more claims of the '787 patent.

69. Defendants have infringed the '787 patent by submitting and maintaining Defendants' ANDA before the FDA seeking approval to market Defendants' generic Naropin® product before the expiration of the '787 patent.

70. Upon information and belief, Defendants acted in concert and actively and knowingly caused to be submitted, assisted with, participated in, encouraged, contributed to, aided and abetted, and/or directed the submission and maintenance of Defendants' ANDA to the FDA.

71. Defendants induced the infringement of the '787 patent by actively and knowingly aiding and abetting the preparation, submission, and maintenance of Defendants' ANDA with the Paragraph IV Certification and in the preparation to sell Defendants' generic Naropin® product in the United States.

72. Defendants were aware of the '787 patent when engaging in these knowing and purposeful activities and were aware that filing Defendants' ANDA with the Paragraph IV Certification with respect to the '787 patent constituted an act of infringement of the '787 patent.

73. Use of Defendants' generic Naropin® product in accordance with and as directed by Defendants' proposed labeling for that product would infringe one or more claims of the '787 patent.

74. Upon information and belief, Defendants intend to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Defendants' generic Naropin® product with its proposed labeling immediately and imminently upon approval of Defendants' ANDA.

75. Upon information and belief, Defendants plan and intend to, and will, actively induce infringement of the '787 patent when Defendants' ANDA is approved, and plan and intend to, and will, do so immediately and imminently upon approval.

76. Upon information and belief, Defendants know that Defendants' generic Naropin® product and the proposed labeling for Defendants' generic Naropin® product is especially made or adapted for use in infringing the '787 patent and that Defendants' generic Naropin® product and the proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Defendants plan and intend to, and will, contribute to the infringement of the '787 patent immediately and imminently upon approval of Defendants' ANDA.

77. The foregoing actions by Defendants constitute and/or would constitute infringement of the '787 patent, active inducement of infringement of the '787 patent and/or contribution to the infringement by others of the '787 patent.

78. Upon information and belief, Defendants acted without a reasonable basis for believing that they would not be liable for infringing the '787 patent, actively inducing infringement of the '787 patent, and/or contributing to the infringement by others of the '787 patent.

79. Fresenius will be substantially and irreparably harmed by Defendants' infringing activities unless the Court enjoins those activities. Fresenius will have no adequate remedy at law if Defendants are not enjoined from the commercial manufacture, use, offer to sell, sale in, and importation into the United States of Defendants' generic Naropin® product.

80. Defendants' activities render this case an exceptional one, and Fresenius is entitled to an award of its reasonable attorney fees under 35 U.S.C. § 285.

COUNT II FOR INFRINGEMENT OF U.S. PATENT NO. 7,857,802 BY DEFENDANTS

81. The allegations of paragraphs 1-80 are realleged and incorporated herein by reference.

82. The use of Defendants' generic Naropin® product is covered by one or more claims of the '7802 patent.

83. The commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Defendants' generic Naropin® product would infringe one or more claims of the '7802 patent.

84. Defendants have infringed the '7802 patent by submitting and maintaining Defendants' ANDA before the FDA seeking approval to market Defendants' generic Naropin® product before the expiration of the '7802 patent.

85. Upon information and belief, Defendants acted in concert and actively and knowingly caused to be submitted, assisted with, participated in, encouraged, contributed to, aided and abetted, and/or directed the submission and maintenance of Defendants' ANDA to the FDA.

86. Defendants induced the infringement of the '7802 patent by actively and knowingly aiding and abetting the preparation, submission, and maintenance of Defendants' ANDA with the Paragraph IV Certification and in the preparation to sell Defendants' generic Naropin® product in the United States.

87. Defendants were aware of the '7802 patent when engaging in these knowing and purposeful activities and were aware that filing Defendants' ANDA with the Paragraph IV Certification with respect to the '7802 patent constituted an act of infringement of the '7802 patent.

88. Use of Defendants' generic Naropin® product in accordance with and as directed by Defendants' proposed labeling for that product would infringe one or more claims of the '7802 patent.

89. Upon information and belief, Defendants intend to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Defendants' generic Naropin® product with its proposed labeling immediately and imminently upon approval of Defendants' ANDA.

90. Upon information and belief, Defendants plan and intend to, and will, actively induce infringement of the '7802 patent when Defendants' ANDA is approved, and plan and intend to, and will, do so immediately and imminently upon approval.

91. Upon information and belief, Defendants know that Defendants' generic Naropin® product and the proposed labeling for Defendants' generic Naropin® product is especially made or adapted for use in infringing the '7802 patent and that Defendants' generic Naropin® product and the proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Defendants plan and intend to, and will, contribute to the infringement of the '7802 patent immediately and imminently upon approval of Defendants' ANDA.

92. The foregoing actions by Defendants constitute and/or would constitute infringement of the '7802 patent, active inducement of infringement of the '7802 patent and/or contribution to the infringement by others of the '7802 patent.

93. Upon information and belief, Defendants acted without a reasonable basis for believing that they would not be liable for infringing the '7802 patent, actively inducing infringement of the '7802 patent, and/or contributing to the infringement by others of the '7802 patent.

94. Fresenius will be substantially and irreparably harmed by Defendants' infringing activities unless the Court enjoins those activities. Fresenius will have no adequate remedy at law if Defendants are not enjoined from the commercial manufacture, use, offer to sell, sale in, and importation into the United States of Defendants' generic Naropin® product.

95. Defendants' activities render this case an exceptional one, and Fresenius is entitled to an award of its reasonable attorney fees under 35 U.S.C. § 285.

COUNT III FOR INFRINGEMENT OF U.S. PATENT NO. 8,118,802 BY DEFENDANTS

96. The allegations of paragraphs 1-95 are realleged and incorporated herein by reference.

97. The use of Defendants' generic Naropin® product is covered by one or more claims of the '8802 patent.

98. The commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Defendants' generic Naropin® product would infringe one or more claims of the '8802 patent.

99. Defendants have infringed the '8802 patent by submitting and maintaining Defendants' ANDA before the FDA seeking approval to market Defendants' generic Naropin® product before the expiration of the '8802 patent.

100. Upon information and belief, Defendants acted in concert and actively and knowingly caused to be submitted, assisted with, participated in, encouraged, contributed to, aided and abetted, and/or directed the submission and maintenance of Defendants' ANDA to the FDA.

101. Defendants induced the infringement of the ’8802 patent by actively and knowingly aiding and abetting the preparation, submission, and maintenance of Defendants’ ANDA with the Paragraph IV Certification and in the preparation to sell Defendants’ generic Naropin® product in the United States.

102. Defendants were aware of the ’8802 patent when engaging in these knowing and purposeful activities and were aware that filing Defendants’ ANDA with the Paragraph IV Certification with respect to the ’8802 patent constituted an act of infringement of the ’8802 patent.

103. Use of Defendants’ generic Naropin® product in accordance with and as directed by Defendants’ proposed labeling for that product would infringe one or more claims of the ’8802 patent.

104. Upon information and belief, Defendants intend to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Defendants’ generic Naropin® product with its proposed labeling immediately and imminently upon approval of Defendants’ ANDA.

105. Upon information and belief, Defendants plan and intend to, and will, actively induce infringement of the ’8802 patent when Defendants’ ANDA is approved, and plan and intend to, and will, do so immediately and imminently upon approval.

106. Upon information and belief, Defendants know that Defendants' generic Naropin® product and the proposed labeling for Defendants' generic Naropin® product is especially made or adapted for use in infringing the '8802 patent and that Defendants' generic Naropin® product and the proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Defendants plan and intend to, and will, contribute to the infringement of the '8802 patent immediately and imminently upon approval of Defendants' ANDA.

107. The foregoing actions by Defendants constitute and/or would constitute infringement of the '8802 patent, active inducement of infringement of the '8802 patent and/or contribution to the infringement by others of the '8802 patent.

108. Upon information and belief, Defendants acted without a reasonable basis for believing that they would not be liable for infringing the '8802 patent, actively inducing infringement of the '8802 patent, and/or contributing to the infringement by others of the '8802 patent.

109. Fresenius will be substantially and irreparably harmed by Defendants' infringing activities unless the Court enjoins those activities. Fresenius will have no adequate remedy at law if Defendants are not enjoined from the commercial manufacture, use, offer to sell, sale in, and importation into the United States of Defendants' generic Naropin® product.

110. Defendants' activities render this case an exceptional one, and Fresenius is entitled to an award of its reasonable attorney fees under 35 U.S.C. § 285.

COUNT IV FOR INFRINGEMENT OF U.S. PATENT NO. 8,162,915 BY DEFENDANTS

111. The allegations of paragraphs 1-110 are realleged and incorporated herein by reference.

112. The use of Defendants' generic Naropin® product is covered by one or more claims of the '915 patent.

113. The commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Defendants' generic Naropin® product would infringe one or more claims of the '915 patent.

114. Defendants have infringed the '915 patent by submitting and maintaining Defendants' ANDA before the FDA seeking approval to market Defendants' generic Naropin® product before the expiration of the '915 patent.

115. Upon information and belief, Defendants acted in concert and actively and knowingly caused to be submitted, assisted with, participated in, encouraged, contributed to, aided and abetted, and/or directed the submission and maintenance of Defendants' ANDA to the FDA.

116. Defendants induced the infringement of the '915 patent by actively and knowingly aiding and abetting the preparation, submission, and maintenance of Defendants' ANDA with the Paragraph IV Certification and in the preparation to sell Defendants' generic Naropin® product in the United States.

117. Defendants were aware of the '915 patent when engaging in these knowing and purposeful activities and were aware that filing Defendants' ANDA with the Paragraph IV Certification with respect to the '915 patent constituted an act of infringement of the '915 patent.

118. Use of Defendants' generic Naropin® product in accordance with and as directed by Defendants' proposed labeling for that product would infringe one or more claims of the '915 patent.

119. Upon information and belief, Defendants intend to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Defendants' generic Naropin® product with its proposed labeling immediately and imminently upon approval of Defendants' ANDA.

120. Upon information and belief, Defendants plan and intend to, and will, actively induce infringement of the '915 patent when Defendants' ANDA is approved, and plan and intend to, and will, do so immediately and imminently upon approval.

121. Upon information and belief, Defendants know that Defendants' generic Naropin® product and the proposed labeling for Defendants' generic Naropin® product is especially made or adapted for use in infringing the '915 patent and that Defendants' generic Naropin® product and the proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Defendants plan and intend to, and will, contribute to the infringement of the '915 patent immediately and imminently upon approval of Defendants' ANDA.

122. The foregoing actions by Defendants constitute and/or would constitute infringement of the '915 patent, active inducement of infringement of the '915 patent and/or contribution to the infringement by others of the '915 patent.

123. Upon information and belief, Defendants acted without a reasonable basis for believing that they would not be liable for infringing the '915 patent, actively inducing infringement of the '915 patent, and/or contributing to the infringement by others of the '915 patent.

124. Fresenius will be substantially and irreparably harmed by Defendants' infringing activities unless the Court enjoins those activities. Fresenius will have no adequate remedy at law if Defendants are not enjoined from the commercial manufacture, use, offer to sell, sale in, and importation into the United States of Defendants' generic Naropin® product.

125. Defendants' activities render this case an exceptional one, and Fresenius is entitled to an award of its reasonable attorney fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Fresenius respectfully requests the following relief:

a. a judgment that the '787, '7802, '8802, and '915 patents are valid and enforceable;

b. a judgment that Defendants' submission of the ANDA No. 206091, was an act of infringement of one or more claims of the '787, '7802, '8802, and '915 patents and that the making, using, offering to sell, selling, marketing, distributing, or importing of Defendants' generic Naropin® product prior to the expiration of the '787, '7802, '8802, and '915 patents will infringe, actively induce infringement and/or contribute to the infringement of one or more claims of the '787, '7802, '8802, and '915 patents;

c. an Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of ANDA No. 206091 or any product the use of which infringes the '787, '7802, '8802, and '915 patents, shall be a date that is not earlier than the expiration of the '787, '7802, '8802, and '915 patents;

d. an Order pursuant to 35 U.S.C. § 271(e)(4)(B) permanently enjoining Defendants and all persons acting in concert with Defendants from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Defendants' generic Naropin®

product, or any product the use of which infringes the ’787, ’7802, ’8802, and ’915 patents, or inducing or contributing to the infringement of the ’787, ’7802, ’8802, and ’915 patents until after the expiration of the ’787, ’7802, ’8802, and ’915 patents;

e. an Order pursuant to 35 U.S.C. § 283 permanently enjoining Defendants and all persons acting in concert with Defendants from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Defendants’ generic Naropin® product, or any product or compound the use of which infringes the ’787, ’7802, ’8802, and ’915 patents, or inducing or contributing to the infringement of the ’787, ’7802, ’8802, and ’915 patents, until after the expiration of the ’787, ’7802, ’8802, and ’915 patents;

f. an Order enjoining Defendants and all persons acting in concert with Defendants from seeking, obtaining, or maintaining approval of the Defendants ANDA No. 206091 before the expiration of the ’787, ’7802, ’8802, and ’915 patents;

g. an award of Fresenius’s damages or other monetary relief to compensate Fresenius if Defendants engages in the commercial manufacture, use, offer to sell, sale or marketing or distribution in, or importation into the United States of Defendants’ generic Naropin® product, or any product or compound the use of which infringes the ’787, ’7802, ’8802, and ’915 patents, or the inducement or contribution of the foregoing, prior to the expiration of the ’787, ’7802, ’8802, and ’915 patents in accordance with 35 U.S.C. § 271(e)(4)(C);

h. a judgment that this is an exceptional case and awarding Fresenius its attorneys’ fees under 35 U.S.C. § 285;

i. an award of Fresenius’s reasonable costs and expenses in this action; and

j. an award of any further and additional relief to Fresenius as this Court deems just and proper.

Dated: October 19, 2015

Respectfully submitted,

FARNAN LLP

/s/ Brian E. Farnan

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