

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

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FRESENIUS KABI USA, LLC and )  
FRESENIUS KABI DEUTSCHLAND GMBH )

*Plaintiffs,* )

v. )

MYLAN LABORATORIES LIMITED, )  
MYLAN INC., AGILA SPECIALTIES INC., )  
MYLAN PHARMACEUTICALS INC., and )  
TECHNOFLEX )

*Defendants.* )  
\_\_\_\_\_

C. A. No. 15-cv-942-LPS

**AMENDED 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”), Mylan Pharmaceuticals Inc. (“Mylan Pharma”) (collectively, “Mylan Defendants”), and Technoflex (collectively, “Defendants”).

**NATURE OF THE ACTION**

1. This is an action by Fresenius against Defendants for infringement of United States Patent Nos. 8,118,802 (“the ’8802 patent”) and 8,162,915 (“the ’915 patent”) (collectively, “the Patents-in-Suit”). This action arises out of Mylan 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. Additionally, the

action arises out of Technoflex's plans to sell infusion bags within the United States, including in connection with the sale of the generic product described in the ANDA, which would also infringe 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, Technoflex is a French company with its principal place of business at ZA de Bassilour, 64210 Bidart, France.

10. Upon information and belief, the Mylan 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**

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

12. 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**

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

14. 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.

15. 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.

16. 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.

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

18. 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.

19. 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.

20. 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.

21. 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.

22. 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.

23. 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”).

24. 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.

25. 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.

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

27. 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.

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

29. 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.

30. 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.

31. 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.

32. 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.

33. 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.

34. 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.

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

36. 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.

37. 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.

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

39. 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.

40. 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.

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

42. 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.

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

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

45. 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.

46. 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.

47. 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.

48. 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.

49. 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.

50. 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.

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

52. 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.

53. Upon information and belief, Technoflex filed DMF No. 19057 and provided it to Mylan Defendants in connection with their ANDA filing, indicating its intent to sell the infusion bags described therein (the "Technoflex Bags") within United States jurisdictions including Delaware.

54. Upon information and belief, Technoflex collaborated and/or acted in concert with the Mylan Defendants to market and sell a generic version of Naropin® throughout the United States, including in Delaware.

55. Upon information and belief, Technoflex sells, offers for sale and/or imports the Technoflex Bags within the United States, including Delaware.

56. Upon information and belief, Technoflex 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.

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

58. In the alternative, upon information and belief, Technoflex is not subject to jurisdiction in any United States state's courts of general jurisdiction, and personal jurisdiction is proper under Fed. R. Civ. P. 4(k)(2).

### **Venue**

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

## **BACKGROUND**

### **The Patents-in-Suit**

60. 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 A.

61. 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 B.

### **The Naropin® Drug Product**

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

63. 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®.

### **Mylan Defendants' ANDA**

64. Mylan 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.

65. The FDA assigned Mylan Defendants’ ANDA the number 206091.

66. Mylan 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 ( the “Paragraph IV Certification”). Mylan Defendants notified Fresenius of this certification, in a letter dated September 3, 2015 sent by Federal Express.

67. In the Notice Letter, Mylan 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 Mylan Defendants contained various terms and conditions, several of which went above and beyond protections typically afforded in a protective order.

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

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

70. Mylan Defendants' ANDA indicates that the infusion bags used in the generic version of Naropin® will be the product produced by Technoflex and described in DMF No. 19057.

71. 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.

72. 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®.

### **The Technoflex Bags**

73. Technoflex is the manufacturer of infusion bags and infusion brand connectors under the Inerta® brand name. The Technoflex Bags are designed for intravenous delivery of drugs, parenteral nutrition and rehydration solutions. The connectors sold with the Technoflex Bags are intended for use with pre-mixed drugs and infusion therapy, and are designed to be compatible with the infusion systems used in the United States. On information and belief, Technoflex produces over 100 million infusion bags and over 500 million connectors for the North American and European markets.

74. Technoflex holds DMF No. 19057, covering the infusion bags and infusion bag connectors sold under the Inerta<sup>®</sup> brand name.

75. On information and belief Technoflex sells, offers for sale and imports the Technoflex Bag in the United States.

**COUNT I FOR INFRINGEMENT OF U.S. PATENT NO. 8,118,802 BY MYLAN DEFENDANTS**

76. The allegations of paragraphs 1-75 are realleged and incorporated herein by reference.

77. The use of Mylan Defendants' generic Naropin<sup>®</sup> product is covered by one or more claims of the '8802 patent.

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

79. Mylan Defendants have infringed the '8802 patent by submitting and maintaining Mylan Defendants' ANDA before the FDA seeking approval to market Defendants' generic Naropin<sup>®</sup> product before the expiration of the '8802 patent.

80. Upon information and belief, Mylan 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 Mylan Defendants' ANDA to the FDA.

81. Mylan Defendants induced the infringement of the '8802 patent by actively and knowingly aiding and abetting the preparation, submission, and maintenance of Mylan Defendants' ANDA with the Paragraph IV Certification and in the preparation to sell Defendants' generic Naropin<sup>®</sup> product in the United States.

82. Mylan Defendants were aware of the '8802 patent when engaging in these knowing and purposeful activities and were aware that filing Mylan Defendants' ANDA with the Paragraph IV Certification with respect to the '8802 patent constituted an act of infringement of the '787 patent.

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

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

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

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

87. The foregoing actions by Mylan 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.

88. Upon information and belief, Mylan 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.

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

90. Mylan 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. 8,118,802 BY  
TECHNOFLEX**

91. The allegations of paragraphs 1-90 are realleged and incorporated herein by reference.

92. The commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Technoflex Bag infringes or would infringe one or more claims of the '8802 patent.

93. Upon information and belief, Technoflex has acted and is acting in concert with the Mylan Defendants in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Technoflex Bag.

94. By manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Technoflex Bag, Technoflex has directly infringed and is continuing to infringe under 35 U.S.C. § 271(a) one or more claims of the '8802 patent, either literally or under the doctrine of equivalents.

95. Upon information and belief, Technoflex plans and intends to, and will, actively induce infringement of the '8802 patent, including in connection with the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan Defendants' generic Naropin® product.

96. Upon information and belief, Technoflex knows that the Technoflex Bag is especially made or adapted for use in infringing the '8802 patent and that the Technoflex Bag is not suitable for substantial noninfringing use.

97. The foregoing actions by Technoflex 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.

98. Upon information and belief, Technoflex acted without a reasonable basis for believing that it would not be liable for infringing the '8802 patent, actively inducing infringement of the '915 patent, and/or contributing to the infringement by others of the '8802 patent.

99. Technoflex's actions constitute knowing and willful infringement of the '8802 patent.

100. Fresenius will be substantially and irreparably harmed by Technoflex's infringing activities unless the Court enjoins those activities. Fresenius will have no adequate remedy at law if Technoflex is not enjoined from the commercial manufacture, use, offer to sell, sale in, and importation into the United States of the Technoflex Bag.

101. Technoflex's 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. 8,162,915 BY MYLAN DEFENDANTS**

102. The allegations of paragraphs 1-101 are realleged and incorporated herein by reference.

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

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

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

106. Upon information and belief, Mylan 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 Mylan Defendants' ANDA to the FDA.

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

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

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

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

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

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

113. The foregoing actions by Mylan 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.

114. Upon information and belief, Mylan 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.

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

116. Mylan 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  
TECHNOFLEX**

117. The allegations of paragraphs 1-116 are realleged and incorporated herein by reference.

118. The commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Technoflex Bag infringes or would infringe one or more claims of the '915 patent.

119. Upon information and belief, Technoflex has acted and is acting in concert with the Mylan Defendants in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Technoflex Bag.

120. By manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Technoflex Bag, Technoflex has directly infringed and is continuing to infringe under 35 U.S.C. § 271(a) one or more claims of the '915 patent, either literally or under the doctrine of equivalents.

121. Upon information and belief, Technoflex plans and intends to, and will, actively induce infringement of the '915 patent, including in connection with the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan Defendants' generic Naropin® product.

122. Upon information and belief, Technoflex knows that the Technoflex Bag is especially made or adapted for use in infringing the '915 patent and that the Technoflex Bag is not suitable for substantial noninfringing use.

123. The foregoing actions by Technoflex 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.

124. Upon information and belief, Technoflex acted without a reasonable basis for believing that it 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.

125. Technoflex's actions constitute knowing and willful infringement of the '915 patent.

126. Fresenius will be substantially and irreparably harmed by Technoflex's infringing activities unless the Court enjoins those activities. Fresenius will have no adequate remedy at law if Technoflex is not enjoined from the commercial manufacture, use, offer to sell, sale in, and importation into the United States of the Technoflex Bag.

127. Technoflex's 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 '8802 and '915 patents are valid and enforceable;
- b. a judgment that Mylan Defendants' submission of the ANDA No. 206091, was an act of infringement of one or more claims of the '8802 and '915 patents and that the making, using, offering to sell, selling, marketing, distributing, or importing of Mylan Defendants' generic Naropin® product prior to the expiration of the '8802 and '915 patents will infringe, actively induce infringement and/or contribute to the infringement of one or more claims of the '8802 and '915 patents;
- c. a declaratory judgment that Technoflex's making, using, offering to sell, selling, marketing, distributing, or importing of the Technoflex Bag prior to the expiration of the '8802

and '915 patents will infringe, actively induce infringement and/or contribute to the infringement of one or more claims of the '8802 and '915 patents;

d. 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 '8802, and '915 patents, shall be a date that is not earlier than the expiration of the '8802 and '915 patents;

e. an Order pursuant to 35 U.S.C. § 271(e)(4)(B) permanently enjoining Mylan Defendants and all persons acting in concert with Mylan Defendants from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Mylan Defendants' generic Naropin® product, or any product the use of which infringes the '8802 and '915 patents, or inducing or contributing to the infringement of the '8802 and '915 patents until after the expiration of the '8802 and '915 patents;

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

g. an Order pursuant to 35 U.S.C. § 283 permanently enjoining Technoflex and all persons acting in concert with Technoflex from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing the Technoflex Bag, or any product or compound the use of which infringes the '8802 and '915 patents, or inducing or contributing to

the infringement of the '8802 and '915 patents, until after the expiration of the '8802 and '915 patents;

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

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

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

k. an award of Fresenius's reasonable costs and expenses in this action; and

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

Dated: May 16, 2016

Respectfully submitted,

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