

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

FRESENIUS KABI USA, LLC and
FRESENIUS KABI DEUTSCHLAND GMBH,

Plaintiffs,

v.

BAXTER HEALTHCARE CORPORATION
and BAXTER INTERNATIONAL, 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 Baxter Healthcare Corporation and Baxter International, Inc. (collectively, “Baxter” or “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 ’7,802 patent”); 8,118,802 (“the ’8,802 patent”); and 8,162,915 (“the ’915 patent”) (collectively, “the Patents-in-Suit”). This action arises out of Defendant Baxter Healthcare Corporation’s filing of an Abbreviated New Drug Application (“ANDA”) seeking approval by the United States Food and Drug Administration (“FDA”) to sell a generic version 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, Defendant Baxter Healthcare Corporation is a corporation organized and existing under the laws of Delaware, with its principal place of business at One Baxter Parkway, Deerfield, Illinois 60015.
5. Upon information and belief, Baxter Healthcare Corporation is a pharmaceutical company that develops, manufactures, markets and/or distributes generic pharmaceutical products around the world, including in this Judicial District.
6. Upon information and belief, Baxter Healthcare Corporation is a wholly-owned subsidiary of Baxter International, Inc.
7. Upon information and belief, Defendant Baxter International, Inc. is a corporation organized and existing under the laws of Delaware, with its principal place of business at One Baxter Parkway, Deerfield, Illinois 60015.
8. Upon information and belief, Baxter International, Inc. is a pharmaceutical company that develops, manufactures, markets and/or distributes generic pharmaceutical products around the world, including in this Judicial District.

JURISDICTION AND VENUE

Subject Matter Jurisdiction

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

11. This Court has personal jurisdiction over Defendants because, *inter alia*, Defendants have maintained continuous and systematic contacts with the State of Delaware.
12. Upon information and belief, Defendants Baxter Healthcare Corporation and Baxter International, Inc. are corporations organized and existing under the laws of the State of Delaware, are qualified to do business in Delaware, and have appointed registered agents for service of process in Delaware. Defendants have therefore consented to general jurisdiction in Delaware.

13. This Court also has personal jurisdiction over Defendants because, *inter alia*, Defendants 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 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 have previously availed themselves of this Judicial District by not contesting personal jurisdiction in at least the following actions:
Millennium Pharmaceuticals Inc. v. Baxter Healthcare Corporation, No. 1:20-cv-00682-CFC (D. Del. filed May 20, 2020); *Mallinckrodt Hospital Products IP Limited et al. v. Baxter Healthcare Corporation*, No. 1:20-cv-00434-LPS (D. Del. filed Mar. 27, 2020); *Helsinn Healthcare S.A. et al. v. Baxter Healthcare Corporation*, No. 1:18-cv-01674-RGA (D. Del. filed Oct. 25, 2018); *May*

v. Baxter Healthcare Corporation et al., No. 1:09-cv-00839-GMS (D. Del. filed Nov. 5, 2009); *Nock v. Baxter Healthcare Corporation et al.*, No. 1:09-cv-00832-GMS (D. Del. filed Nov. 4, 2009); *Talecris Biotherapeutics Inc. v. Baxter International Inc. et al.*, No. 1:05-cv-00349-GMS (D. Del. filed June 1, 2005).

15. Upon information and belief, Defendants have engaged in continuous and systematic contacts with the State of Delaware and/or purposefully has availed themselves of this forum by, *inter alia*, making, marketing, shipping, using, offering to sell or selling Baxter pharmaceutical products in this Judicial District, and deriving substantial revenue from such activities.

16. Upon information and belief, Defendants have engaged in and maintained systematic and continuous business contacts within the State of Delaware, and have purposefully availed themselves of the benefits and protections of the laws of Delaware, rendering them at home in Delaware.

17. Upon information and belief, Defendants have 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.

18. Upon information and belief, Defendants have applied for FDA approval to market and sell a generic version of Naropin® throughout the United States, including in Delaware.

19. Upon information and belief, Defendants will market, sell, and offer for sale Baxter's proposed generic version of Naropin® in the State of Delaware following FDA approval of that product.

20. Upon information and belief, as a result of Defendants' marketing, selling, or offering for sale of Baxter's generic version of Naropin® in the State of Delaware, Fresenius will lose sales of Naropin® and be injured in the State of Delaware.

21. Upon information and belief, Defendants' systematic and continuous business contacts within Delaware render them at home in Delaware.

22. Upon information and belief, this Court has personal jurisdiction over Defendants for the reasons stated herein, including, *inter alia*, Defendants' activities in the forum, activities directed at the forum, and significant contacts with the forum, all of which render Defendants at home in the forum.

Venue

23. Venue is proper in this district under 28 U.S.C. § 1391 and 1400(b). *In re HTC Corp.*, 889 F.3d 1349, 1354 (Fed. Cir. 2018).

24. Venue is proper in this district as to Baxter Healthcare Corporation and Baxter International, Inc. under 28 U.S.C. § 1400(b) because Baxter Healthcare Corporation and Baxter International, Inc. are corporations organized and existing under the laws of the State of Delaware and are subject to personal jurisdiction in this Judicial District.

25. Upon information and belief, Defendants have previously not contested venue in this Judicial District in at least the following actions: *Millennium Pharmaceuticals Inc. v. Baxter Healthcare Corporation*, No. 1:20-cv-00682-CFC (D. Del. filed May 20, 2020); *Mallinckrodt Hospital Products IP Limited et al. v. Baxter Healthcare Corporation*, No. 1:20-cv-00434-LPS (D. Del. filed Mar. 27, 2020); *Helsinn Healthcare S.A. et al. v. Baxter Healthcare Corporation*, No. 1:18-cv-01674-RGA (D. Del. filed Oct. 25, 2018); *May v. Baxter Healthcare Corporation et al.*, No. 1:09-cv-00839-GMS (D. Del. filed Nov. 5, 2009); *Nock v. Baxter Healthcare Corporation et al.*, No. 1:09-cv-00832-GMS (D. Del. filed Nov. 4, 2009); *Talecris*

Biotherapeutics Inc. v. Baxter International Inc. et al., No. 1:05-cv-00349-GMS (D. Del. filed June 1, 2005).

26. Defendants have a regular and established place of business in this Judicial District at least because, upon information and belief: (1) Defendants Baxter Healthcare Corporation and Baxter International, Inc. are organized under the laws of Delaware; (2) Defendant Baxter Healthcare Corporation has sought approval from the FDA to market and sell its proposed generic Naropin® in this Judicial District; and (3) Defendants have engaged in regular and established business contacts with Delaware by, *inter alia*, marketing, making, shipping, using, offering to sell or selling Baxter products in this Judicial District, and deriving substantial revenue from such activities.

BACKGROUND

The Patents-in-Suit

27. 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 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.

28. The '7,802 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 '7,802 Patent to Fresenius Kabi Deutschland GmbH. The '7,802 Patent is listed in the Orange Book with respect to Naropin®. The '7,802 Patent will expire on November 28, 2026. A true and accurate copy of the '7,802 Patent is attached hereto as Exhibit B.

29. The '8,802 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 '8,802 Patent to Fresenius Kabi Deutschland GmbH. The '8,802 Patent is listed in the Orange Book with respect to Naropin®. The '8,802 Patent will expire on May 18, 2023. A true and accurate copy of the '8,802 Patent is attached hereto as Exhibit C.

30. 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

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

32. 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®.

Defendant Baxter Healthcare Corporation's ANDA

33. Defendant Baxter Healthcare Corporation 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 that Defendants assert is a generic copy of Naropin® ("Defendants' proposed generic Naropin® product") prior to the expiration of the Patents-in-Suit.

34. The FDA assigned Defendant Baxter Healthcare Corporation’s ANDA number 215691.

35. Defendant Baxter Healthcare Corporation 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’ proposed generic Naropin® product (“Defendant’s Paragraph IV Certification”).

36. Defendant Baxter Healthcare Corporation notified Fresenius of this certification in a letter dated June 4, 2021 (the “Notice Letter”) sent by Federal Express. Fresenius received the Notice Letter on June 7, 2021. The Notice Letter stated that Defendant Baxter Healthcare Corporation had filed ANDA No. 215691 seeking FDA approval to market a generic Naropin® product prior to the expiration of the Patents-in-Suit.

37. A document entitled “Baxter’s Detailed Factual and Legal Bases in Support of its Paragraph IV Certification for Ropivacaine Hydrochloride Injection USP (“Detailed Statement”) was attached to the Notice Letter.

38. In the Notice Letter, Defendant Baxter Healthcare Corporation offered Fresenius confidential access to ANDA No. 215691 on terms and conditions set forth in an attached “Offer of Confidential Access to Application and Confidential Disclosure Agreement” (“OCA”). The OCA provided by Defendant Baxter Healthcare Corporation contained various terms and conditions, several of which went above and beyond protections typically afforded in an offer of confidential access or a protective order.

39. On June 17, 2021, Fresenius provided Defendant Baxter Healthcare Corporation with a revised draft of the OCA. On June 30, 2021, and in response to Defendant Baxter

Healthcare Corporation's proposed revisions, Fresenius provided Defendant Baxter Healthcare Corporation with a second revised draft of the OCA.

40. Defendant Baxter Healthcare Corporation did not respond to Fresenius's proposed compromise draft until July 9, 2021. Defendant Baxter Healthcare Corporation continued to insist on provisions that go above and beyond protections typically afforded in an offer of confidential access or a protective order. As of the filing of this Complaint, Fresenius has still not received any samples of Defendants' proposed generic Naropin® product or documentation from Defendants' ANDA.

41. 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 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' proposed 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

42. The allegations of paragraphs 1-41 are realleged and incorporated herein by reference.

43. Baxter's proposed generic Naropin® product is covered by one or more claims of the '787 Patent.

44. Upon information and belief, the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Baxter's proposed generic Naropin® product would infringe one or more claims of the '787 Patent.

45. Defendants have infringed the '787 Patent under 35 U.S.C. § 271(e)(2)(A) by, individually and/or in concert, submitting and maintaining Baxter's ANDA before the FDA seeking approval to market Defendants' proposed generic Naropin® product before the expiration of the '787 Patent.

46. Upon information and belief, Defendants 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 Defendant Baxter Healthcare Corporation's ANDA to the FDA.

47. Upon information and belief, Defendants induced the infringement of the '787 Patent by actively and knowingly aiding and abetting the preparation, submission, and maintenance of Defendant Baxter Healthcare Corporation's ANDA with the Paragraph IV Certification and the preparation to sell Defendants' proposed generic Naropin® product in the United States.

48. Upon information and belief, Defendants were aware of the '787 Patent when engaging in these knowing and purposeful activities and were aware that filing Defendant Baxter Healthcare Corporation's ANDA with the Paragraph IV Certification with respect to the '787 Patent constituted an act of infringement of the '787 Patent.

49. Upon information and belief, use of Defendant Baxter Healthcare Corporation's proposed generic Naropin® product in accordance with and as directed by Baxter's proposed labeling for that product would infringe one or more claims of the '787 Patent.

50. Upon information and belief, Defendants intend to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Defendants' proposed generic

Naropin® product with its proposed labeling immediately and imminently upon approval of Defendant Baxter Healthcare Corporation's ANDA.

51. Upon information and belief, Defendants plan and intend to, and will, actively induce infringement of the '787 Patent when Defendant Baxter Healthcare Corporation's ANDA is approved, and plan and intend to, and will, do so immediately and imminently upon approval.

52. Upon information and belief, Defendants know that their generic Naropin® product and the proposed labeling for Defendants' proposed generic Naropin® product are especially made or adapted for use in infringing the '787 Patent and that Defendants' proposed 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 Defendant Baxter Healthcare Corporation's ANDA.

53. 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.

54. 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.

55. 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' proposed generic Naropin® product.

56. 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**

57. The allegations of paragraphs 1-56 are realleged and incorporated herein by reference.

58. Baxter's proposed generic Naropin® product is covered by one or more claims of the '7,802 Patent.

59. Upon information and belief, the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Baxter's proposed generic Naropin® product would infringe one or more claims of the '7,802 Patent.

60. Defendants have infringed the '7,802 Patent under 35 U.S.C. § 271(e)(2)(A) by, individually and/or in concert, submitting and maintaining Baxter's ANDA before the FDA seeking approval to market Defendants' proposed generic Naropin® product before the expiration of the '7,802 Patent.

61. Upon information and belief, Defendants 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 Defendant Baxter Healthcare Corporation's ANDA to the FDA.

62. Upon information and belief, Defendants induced the infringement of the '7,802 Patent by actively and knowingly aiding and abetting the preparation, submission, and maintenance of Defendant Baxter Healthcare Corporation's ANDA with the Paragraph IV Certification and the preparation to sell Defendants' proposed generic Naropin® product in the United States.

63. Upon information and belief, Defendants were aware of the '7,802 Patent when engaging in these knowing and purposeful activities and were aware that filing Defendant Baxter Healthcare Corporation's ANDA with the Paragraph IV Certification with respect to the '7,802 Patent constituted an act of infringement of the '7,802 Patent.

64. Upon information and belief, use of Defendants' proposed generic Naropin® product in accordance with and as directed by Baxter's proposed labeling for that product would infringe one or more claims of the '7,802 Patent.

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

66. Upon information and belief, Defendants plan and intend to, and will, actively induce infringement of the '7,802 Patent when Defendant Baxter Healthcare Corporation's ANDA is approved, and plan and intend to, and will, do so immediately and imminently upon approval.

67. Upon information and belief, Defendants know that their generic Naropin® product and the proposed labeling for Defendants' proposed generic Naropin® product are especially made or adapted for use in infringing the '7,802 Patent and that Defendants' proposed 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 '7,802 Patent immediately and imminently upon approval of Defendant Baxter Healthcare Corporation's ANDA.

68. The foregoing actions by Defendants constitute and/or would constitute infringement of the '7,802 Patent, active inducement of infringement of the '7,802 Patent and/or contribution to the infringement by others of the '7,802 Patent.

69. Upon information and belief, Defendants acted without a reasonable basis for believing that they would not be liable for infringing the '7,802 Patent, actively inducing infringement of the '7,802 Patent, and/or contributing to the infringement by others of the '7,802 Patent.

70. 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' proposed generic Naropin® product.

71. 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**

72. The allegations of paragraphs 1-71 are realleged and incorporated herein by reference.

73. Baxter's proposed generic Naropin® product is covered by one or more claims of the '8,802 Patent.

74. Upon information and belief, the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Baxter's proposed generic Naropin® product would infringe one or more claims of the '8,802 Patent.

75. Defendants have infringed the '8,802 Patent under 35 U.S.C. § 271(e)(2)(A) by, individually and/or in concert, submitting and maintaining Baxter's ANDA before the FDA

seeking approval to market Defendants' proposed generic Naropin® product before the expiration of the '8,802 Patent.

76. Upon information and belief, Defendants 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 Defendant Baxter Healthcare Corporation's ANDA to the FDA.

77. Upon information and belief, Defendants induced the infringement of the '8,802 Patent by actively and knowingly aiding and abetting the preparation, submission, and maintenance of Defendant Baxter Healthcare Corporation's ANDA with the Paragraph IV Certification and the preparation to sell Defendants' proposed generic Naropin® product in the United States.

78. Upon information and belief, Defendants were aware of the '8,802 Patent when engaging in these knowing and purposeful activities and were aware that filing Defendant Baxter Healthcare Corporation's ANDA with the Paragraph IV Certification with respect to the '8,802 Patent constituted an act of infringement of the '8,802 Patent.

79. Upon information and belief, use of Defendants' proposed generic Naropin® product in accordance with and as directed by Baxter's proposed labeling for that product would infringe one or more claims of the '8,802 Patent.

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

81. Upon information and belief, Defendants plan and intend to, and will, actively induce infringement of the '8,802 Patent when Defendant Baxter Healthcare Corporation's ANDA is approved, and plan and intend to, and will, do so immediately and imminently upon approval.

82. Upon information and belief, Defendants know that their generic Naropin® product and the proposed labeling for Defendants' proposed generic Naropin® product are especially made or adapted for use in infringing the '8,802 Patent and that Defendants' proposed 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 '8,802 Patent immediately and imminently upon approval of Defendant Baxter Healthcare Corporation's ANDA.

83. The foregoing actions by Defendants constitute and/or would constitute infringement of the '8,802 Patent, active inducement of infringement of the '8,802 Patent and/or contribution to the infringement by others of the '8,802 Patent.

84. Upon information and belief, Defendants acted without a reasonable basis for believing that they would not be liable for infringing the '8,802 Patent, actively inducing infringement of the '8,802 Patent, and/or contributing to the infringement by others of the '8,802 Patent.

85. 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' proposed generic Naropin® product.

86. 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**

87. The allegations of paragraphs 1-86 are realleged and incorporated herein by reference.

88. Baxter's proposed generic Naropin® product is covered by one or more claims of the '915 Patent.

89. Upon information and belief, the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Baxter's proposed generic Naropin® product would infringe one or more claims of the '915 Patent.

90. Defendants have infringed the '915 Patent under 35 U.S.C. § 271(e)(2)(A) by, individually and/or in concert, submitting and maintaining Baxter's ANDA before the FDA seeking approval to market Defendants' proposed generic Naropin® product before the expiration of the '915 Patent.

91. Upon information and belief, Defendants 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 Defendant Baxter Healthcare Corporation's ANDA to the FDA.

92. Upon information and belief, Defendants induced the infringement of the '915 Patent by actively and knowingly aiding and abetting the preparation, submission, and maintenance of Defendant Baxter Healthcare Corporation's ANDA with the Paragraph IV Certification and the preparation to sell Defendants' proposed generic Naropin® product in the United States.

93. Upon information and belief, Defendants were aware of the '915 Patent when engaging in these knowing and purposeful activities and were aware that filing Defendant Baxter Healthcare Corporation's ANDA with the Paragraph IV Certification with respect to the '915 Patent constituted an act of infringement of the '915 Patent.

94. Upon information and belief, use of Defendants' proposed generic Naropin® product in accordance with and as directed by Baxter's proposed labeling for that product would infringe one or more claims of the '915 Patent.

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

96. 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.

97. Upon information and belief, Defendants know that their generic Naropin® product and the proposed labeling for Defendants' proposed generic Naropin® product are especially made or adapted for use in infringing the '915 Patent and that Defendants' proposed 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 Defendant Baxter Healthcare Corporation's ANDA.

98. 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.

99. 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.

100. 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' proposed generic Naropin® product.

101. 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 Patents-in-Suit are valid and enforceable;
- b. a judgment that Baxter Healthcare Corporations' submission of the ANDA No.

215691, was an act of infringement of one or more claims of the Patents-in-Suit and that the making, using, offering to sell, selling, marketing, distributing, or importing of Defendants' proposed generic Naropin® product prior to the expiration of the Patents-in-Suit will infringe, actively induce infringement and/or contribute to the infringement of one or more claims of the Patents-in-Suit;

- 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. 215691 or any product the use of which infringes the Patents-in-Suit, shall be a date that is not earlier than the expiration of the Patents-in-Suit;
- 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' proposed generic Naropin® product, or any product the use of which infringes the Patents-in-Suit, or inducing or contributing to the infringement of the Patents-in-Suit until after the expiration of the Patents-in-Suit;
- 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' proposed generic Naropin® product, or any product or compound the use of which infringes the Patents-in-Suit, or inducing or contributing to the infringement of the Patents-in-Suit, until after the expiration of the Patents-in-Suit;
- f. an Order enjoining Defendants and all persons acting in concert with Defendants from seeking, obtaining, or maintaining approval of Defendant Baxter Healthcare Corporation's ANDA No. 215691 before the expiration of the Patents-in-Suit;
- g. an award of Fresenius's damages or other monetary relief to compensate Fresenius if Defendants engage in the commercial manufacture, use, offer to sell, sale or marketing or distribution in, or importation into the United States of Defendants' proposed generic Naropin® product, or any product or compound the use of which infringes the Patents-

in-Suit, or the inducement or contribution of the foregoing, prior to the expiration of the Patents-in-Suit 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.

Date: July 16, 2021

Respectfully submitted,

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