IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

HQ SPECIALTY PHARMA CORP. and WG CRITICAL CARE, LLC,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
FRESENIUS KABI USA, L.L.C.,	)	
Defendant.	)	

COMPLAINT

Plaintiffs, HQ Specialty Pharma Corp. ("HQ Specialty Pharma") and WG Critical Care, LLC ("WG Critical Care") (collectively "Plaintiffs"), for their Complaint against Defendant Fresenius Kabi USA, LLC ("Fresenius USA"), allege as follows:

NATURE OF ACTION

1. This is an action arising under the patent laws of the United States, 35 U.S.C. § 100 et seq., including 35 U.S.C. §§ 271(a), (b), (c), and (e), for infringement by Defendants of United States Patent No. 10,130,646 (the "'646 patent") and United States Patent No. 10,342,813 (the "'813 patent") (together, the "Asserted Patents") and for a declaratory judgment of infringement under 28 U.S.C. §§ 2201 and 2202.

2. This action arises out of Fresenius USA's submission of its supplemental New Drug Application ("sNDA") No. 208418/S-007 ("Fresenius USA's sNDA") under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 355(b)(2), to the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell calcium gluconate in sodium chloride injection solution in a bag prior to the expiration of the '646 patent and the '813 patent.

3. The FDA approved Fresenius USA's sNDA on June 17, 2021.

PARTIES

4. Plaintiff HQ Specialty Pharma is a corporation organized and existing under the laws of the state of New Jersey, having a place of business at 120 Route 17 North, Suite 130, Paramus, New Jersey 07652.

5. Plaintiff WG Critical Care is a limited liability company organized and existing under the laws of the state of New Jersey, having a principal place of business at 120 Route 17 North, Paramus, New Jersey 07652.

6. Upon information and belief, Defendant Fresenius USA is a limited liability company organized and existing under the laws of the state of Delaware, having its principal place of business at 3 Corporate Drive, Lake Zurich, Illinois 60047.

7. Upon information and belief, Fresenius USA is in the business of manufacturing, marketing, and selling generic drug products. As a part of this business, upon information and belief, Fresenius USA, directly or through agents, regularly files New Drug Applications ("NDAs"), sNDAs, and abbreviated new drug applications ("ANDAs") with the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of generic versions of drug products that are covered by United States patents. Upon information and belief, Fresenius USA's ordinary business operations include litigating and filing claims in the courts of the United States, including this Court, regarding infringement, validity, and/or enforceability of United States patents that cover or are alleged to cover generic drug products that are the subject of NDAs, sNDAs, and ANDAs filed by Fresenius USA.

8. Upon information and belief, Fresenius USA manufactures and/or imports drug products for the purpose of sale within the United States, including Delaware.

9. Upon information and belief, Fresenius USA derives substantial revenue from services or things used or consumed in the Delaware.

JURISDICTION AND VENUE

10. Jurisdiction and venue are proper in this District pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, 2202, 1391, and 1400(b).

11. Fresenius USA is subject to personal jurisdiction in Delaware because, among other things, Fresenius USA is a limited liability company formed under the laws of the state of Delaware.

12. Upon information and belief, Fresenius USA has a registered agent in Delaware (Corporation Service Company, 251 Little Falls Drive, Wilmington, Delaware 19808); it is in the business of manufacturing drug products, which it manufactures, distributes, sells, or offers to sell throughout the United States, including in Delaware; it derives substantial revenue from services or things used or consumed in Delaware; it transacts business with companies located and/or headquartered in Delaware; as part of its ordinary business practice of engaging in U.S. patent litigation, it has regularly and routinely litigated ANDA and NDA cases without contesting jurisdiction in this District; it has, directly or through an agent, filed an NDA, and/or been actively involved in the preparation and submission of an NDA, for the purpose of approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the generic product described in sNDA No. 208418/S-007 in the United States, including in Delaware; and it intends to offer to sell and sell the generic product described in sNDA No. 208418/S-007 in the United States, including in Delaware.

13. Upon information and belief, Fresenius USA has availed itself of the legal protections of Delaware by filing claims or counterclaims affirmatively seeking relief in other prior

actions in this Court, including in *Millennium Pharmaceuticals, Inc. v. Fresenius Kabi USA, LLC, et al.*, 13-467-GMS (D. Del.); *Fresenius Kabi USA, LLC v. Dr. Reddy's Laboratories Ltd., et al.*, 13-925-SLR (D. Del.); *Fresenius Kabi USA, LLC v. Watson Laboratories Inc., et al.*, 13-1015-SLR (D. Del.); *Celgene Corp. v. Fresenius Kabi USA, LLC, et al.*, 14-571-RGA (D. Del.); and *Shire Orphan Therapies, LLC v. Fresenius Kabi USA, LLC, et al.*, 15-1102-GMS (D. Del).

14. Venue is proper in this district pursuant to 28 U.S.C. § 1391(b) and (c) and § 1400(b) because Fresenius USA is organized, and thus resides, in Delaware.

BACKGROUND

15. On October 29, 2018, Plaintiff HQ Specialty Pharma received FDA approval for its NDA 210906. NDA 210906 covers calcium gluconate in sodium chloride solution in bags for intravenous administration.

16. Plaintiffs' calcium gluconate in sodium chloride injection is a solution indicated for the treatment of acute symptomatic hypocalcemia. It is provided in a ready-to-use flexible plastic bag to be administered intravenously without dilution.

17. The '646 patent, entitled "Calcium Gluconate Solutions in Flexible Containers" (Exhibit A hereto), was duly and legally issued on November 20, 2018 to HQ Specialty Pharma as assignee. HQ Specialty Pharma is the owner and assignee of the '646 patent. Calcium gluconate in sodium chloride solution and the use thereof are covered by one or more claims of the '646 patent, and HQ Specialty Pharma has caused the '646 patent to be listed in connection with calcium gluconate in sodium chloride solutions in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the "Orange Book."

18. The '646 has one independent claim. Independent claim 1 of the '646 patent states:

1. A terminally sterilized aqueous calcium gluconate solution comprising:

sodium chloride; and

1 to 15 wt. % calcium gluconate and from 1 to 19 wt. parts of calcium saccharate per 100 wt. parts of calcium gluconate packaged in a flexible plastic container with the remainder water,

wherein

the flexible plastic container is a bag, and

the solution has a pH of from 6 to 8.2.

19. The ’813 patent, entitled “Calcium Gluconate Solutions in Flexible Containers” (Exhibit B hereto), was duly and legally issued on July 9, 2019 to HQ Specialty Pharma as assignee. HQ Specialty Pharma is the owner and assignee of the ’813 patent. Calcium gluconate in sodium chloride solution and the use thereof are covered by one or more claims of the ’813 patent. HQ Specialty Pharma has caused the ’813 patent to be listed in connection with calcium gluconate in sodium chloride solutions in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the “Orange Book.”

20. The ’813 has one independent claim. Independent claim 1 states:

1. A terminally sterilized aqueous calcium gluconate solution comprising 1 to 15 wt.% calcium gluconate and from 1 to 19 wt. parts of calcium saccharate per 100 wt. parts of calcium gluconate packaged in a flexible plastic container with the remainder water,

wherein the solution has a pH of from 6.0 to 8.2.

21. WG Critical Care has an exclusive license from HQ Specialty Pharma to sell products covered by the Asserted Patents in the United States. WG Critical Care also has the right to enforce the Asserted Patents. WG Critical Care is responsible for the marketing and sale of HQ Specialty Pharma’s calcium gluconate in sodium chloride solution in the United States.

22. HQ Specialty Pharma retains all other right, title, and interest in the '646 patent and the '813 patent.

23. On August 5, 2019, HQ Specialty Pharma sent a cease and desist letter entitled "Notice to Discontinue Compounding of Calcium Gluconate in Sodium Chloride Premix in Bags, FDA Approval of HQ Specialty Pharma's New Drug Application 210906," informing Fresenius USA of the FDA's approval of NDA 210906 for Calcium in Sodium Chloride Injection in premixed bags, of the '646 patent, and of the '813 patent.[1]

24. In that letter, HQ Specialty Pharma requested written confirmation from Fresenius USA of the absence of manufacturing, distributing, or selling of products that were "essentially a copy" of HQ Specialty Pharma's approved drug products or that were infringing HQ Specialty Pharma's '646 patent. On information and belief, Fresenius USA did not respond to that letter.

25. On December 17, 2020, Fresenius USA submitted its sNDA for calcium gluconate in sodium chloride injection solution in Freeflex bags to the FDA.

26. On June 17, 2021, Fresenius USA received FDA approval for its sNDA 208418/S-007 for calcium gluconate in sodium chloride injection (the "Approved Fresenius Product"), and Fresenius USA is therefore now permitted by the FDA to sell the Approved Fresenius Product in the United States.

27. The approved package insert for Fresenius USA's sNDA product (Exhibit C hereto) is substantially identical in all respects relevant to the Asserted Patents to the approved package insert for calcium gluconate in sodium chloride injection sold by WG Critical Care.

[1] At the time of the cease and desist letter, the '813 patent had not yet issued. However, Fresenius USA was informed of the Application Publication (No. US 2019/0076454), and that HQ Specialty Pharma was expecting the patent to issue shortly.

28. The Approved Fresenius Product as described in Fresenius USA's approved labeling meets each and every limitation of at least claim 1 of '646 patent because, *inter alia*, it is a terminally sterilized aqueous calcium gluconate solution including sodium chloride with the required amount of calcium gluconate and calcium saccharate in a flexible plastic container that is a bag and is within the required pH range.

29. The Approved Fresenius Product as described in Fresenius USA's approved labeling meets each and every limitation of at least claim 1 of '813 patent because, *inter alia*, it is a terminally sterilized aqueous calcium gluconate solution with the required amount of calcium gluconate and calcium saccharate in a flexible plastic container with the remainder water and is within the required pH range.

30. There is an actual, real, immediate, and justiciable controversy between Plaintiffs and Fresenius USA regarding the infringement of the Asserted Patents by the Approved Fresenius Product.

COUNT I – INFRINGEMENT OF U.S. PATENT NO. 10,130,646 UNDER 35 U.S.C. §§ 271(a), (b), AND (c)

31. Plaintiffs incorporate each of the preceding paragraphs 1-30 as if fully set forth herein.

32. Fresenius USA has knowledge of the '646 patent.

33. Upon information and belief, the Approved Fresenius Product and the use of the Approved Fresenius Product are covered by at least claim 1 of the '646 patent.

34. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Approved Fresenius Product will infringe one or more claims of the '646 patent, either literally or under the doctrine of equivalents under 35 U.S.C. §§ 271(a), (b), and/or (c).

35. Upon information and belief, Fresenius USA either has already, or intends imminently, to engage in the importation, manufacture, use, offer for sale, sale, marketing and/or distribution of the Approved Fresenius Product with its approved labeling of sNDA 208418/S-007.

36. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution and/or importation of the Approved Fresenius Product in accordance with and as directed by Fresenius USA's approved labeling for that product will infringe one or more claims of the '646 patent, including, but not limited to, claim 1.

37. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of the Approved Fresenius Product in accordance with and as directed by Fresenius USA's approved labeling for that product will infringe one or more claims of the '646 patent, including, but not limited to claim 1 under 35 U.S.C. § 271(a).

38. Upon information and belief, Fresenius USA plans and intends to, and will, actively induce infringement of the '646 patent, including, but not limited to claim 1, under 35 U.S.C. § 271(b). Fresenius USA's activities will be done with knowledge of the '646 patent and specific intent to infringe that patent.

39. Upon information and belief, Fresenius USA knows that Approved Fresenius Product and its proposed labeling are especially made or adapted for use in infringing the '646 patent, are not staple articles or commodities of commerce, and that the Approved Fresenius Product and its approved labeling are not suitable for substantial non-infringing use. Upon information and belief, Fresenius USA plans and intends to, and will, contribute to infringement of the '646 patent under 35 U.S.C. § 271(c).

40. Upon information and belief, Fresenius USA has already or will, without authority, import into the United States and/or offer to sell, sell, and/or use within the United States, a product

that infringes one or more claims of the '646 patent, and contributes to the infringement by others of the '646 patent under 35 U.S.C. § 271(c).

41. The foregoing actions by Fresenius USA constitute and/or will constitute infringement of the '646 patent, active inducement of infringement of the '646 patent, and contribution to the infringement by others of the '646 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

42. Upon information and belief, Fresenius USA has acted with full knowledge of the '646 patent and without reasonable basis for believing that it would not be liable for infringing the '646 patent, actively inducing infringement of the '646 patent, and contributing to the infringement by others of the '646 patent.

43. Plaintiffs will be substantially and irreparably damaged by infringement of the '646 patent.

44. Unless Fresenius USA is enjoined from infringing the '646 patent, actively inducing infringement of the '646 patent, and contributing to the infringement by others of the '646 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT II – DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 10,130,646

45. Plaintiffs incorporate each of the preceding paragraphs 1-30 as if fully set forth herein.

46. Fresenius USA has knowledge of the '646 patent.

47. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiffs on the one hand and Fresenius USA on the other regarding Fresenius USA's infringement, active

inducement of infringement, and contribution to the infringement by others of the '646 patent, and/or validity or the '646 patent.

48. Upon information and belief, the Approved Fresenius Product and the use of the Approved Fresenius Product are covered by at least claim 1 of the '646 patent.

49. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Approved Fresenius Product will infringe one or more claims of the '646 patent, including, but not limited to claim 1, either literally or under the doctrine of equivalents.

50. Upon information and belief, Fresenius USA plans and intends to, and will, engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Approved Fresenius Product with its approved labeling, and intends to do so immediately and imminently because the Approved Fresenius Product has already received FDA approval for marketing and sale within the United States.

51. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Approved Fresenius Product in accordance with and as directed by Fresenius USA's approved labeling for that product will infringe one or more of the claims of the '646 patent, including, but not limited to claim 1.

52. Upon information and belief, Fresenius USA plans and intends to, and will, actively induce infringement of the '646 patent. Fresenius USA's activities will be done with knowledge of the '646 patent and specific intent to infringe that patent.

53. Upon information and belief, Fresenius USA knows that Fresenius USA's sNDA Product and its approved labeling are especially made or adapted for use in infringing the '646 patent, are not staple articles or commodities of commerce, and that the Approved Fresenius

Product and its approved labeling are not suitable for substantial non-infringing use. Upon information and belief, Fresenius USA plans and intends to, and will, contribute to infringement of the ’646 patent.

54. Upon information and belief, Fresenius USA will, without authority, import into the United States and/or offer to sell, sell, and/or use within the United States, a product which infringes one or more claims of the ’646 patent prior to the expiration of the patent.

55. The foregoing actions by Fresenius USA constitute and/or will constitute infringement of the ’646 patent, active inducement of infringement of the ’646 patent, and contribution to the infringement by others of the ’646 patent.

56. Upon information and belief, Fresenius USA acted without a reasonable basis for believing that it would not be liable for infringing the ’646 patent, actively inducing infringement of the ’646 patent, and contributing to the infringement by others of the ’646 patent.

57. Plaintiffs will be substantially and irreparably damaged by infringement of the ’646 patent.

58. Unless Fresenius USA is enjoined from infringing the ’646 patent, actively inducing infringement of the ’646 patent and contributing to the infringement by others of the ’646 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

59. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Approved Fresenius Product in accordance with and as directed by Fresenius USA’s approved labeling for that product, or any other Fresenius USA product that is covered by or whose use is covered by the ’646 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the ’646 patent, and that the claims of the ’813 patent are not invalid.

COUNT III – INFRINGEMENT OF U.S. PATENT NO. 10,130,646 UNDER 35 U.S.C. § 271(e)(2)

60. Plaintiffs incorporate each of the preceding paragraphs 1-30 as if fully set forth herein.

61. Upon information and belief, the Approved Fresenius Product and the use of the Approved Fresenius Product are covered by at least claim 1 of the '646 patent.

62. Fresenius USA's submission of sNDA 208418/S-007 to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Fresenius USA's sNDA Product prior to the expiration of the '646 patent was an act of infringement of the '646 patent under 35 U.S.C. § 271(e)(2)(A).

63. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Approved Fresenius Product will infringe one or more claims of the '646 patent, either literally or under the doctrine of equivalents.

64. Upon information and belief, Fresenius USA either has already, or intends imminently, to engage in the importation, manufacture, use, offer for sale, sale, marketing and/or distribution of the Approved Fresenius Product with its approved labeling of sNDA 208418/S-007.

65. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution and/or importation of the Approved Fresenius Product in accordance with and as directed by Fresenius USA's approved labeling for that product will infringe one or more claims of the '646 patent, including, but not limited to, claim 1.

66. Upon information and belief, Fresenius USA plans and intends to, and will, actively induce infringement of the '646 patent, including, but not limited to claim 1. Fresenius USA's activities will be done with knowledge of the '646 patent and specific intent to infringe that patent.

67. Upon information and belief, Fresenius USA knows that Approved Fresenius Product and its proposed labeling are especially made or adapted for use in infringing the ’646 patent, are not staple articles or commodities of commerce, and that the Approved Fresenius Product and its approved labeling are not suitable for substantial non-infringing use. Upon information and belief, Fresenius USA plans and intends to, and will, contribute to infringement of the ’646 patent.

68. Upon information and belief, Fresenius USA has already or will, without authority, import into the United States and/or offer to sell, sell, and/or use within the United States, a product that infringes one or more claims of the ’646 patent, and contributes to the infringement by others of the ’646 patent.

69. The foregoing actions by Fresenius USA constitute and/or will constitute infringement of the ’646 patent, active inducement of infringement of the ’646 patent, and contribution to the infringement by others of the ’646 patent.

70. Upon information and belief, Fresenius USA has acted with full knowledge of the ’646 patent and without reasonable basis for believing that it would not be liable for infringing the ’646 patent, actively inducing infringement of the ’646 patent, and contributing to the infringement by others of the ’646 patent.

71. Plaintiffs will be substantially and irreparably damaged by infringement of the ’646 patent.

72. Unless Fresenius USA is enjoined from infringing the ’646 patent, actively inducing infringement of the ’646 patent, and contributing to the infringement by others of the ’646 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT IV – INFRINGEMENT OF U.S. PATENT NO. 10,342,813 UNDER 35 U.S.C. §§ 271(a), (b), AND (c)

73. Plaintiffs incorporate each of the preceding paragraphs 1-30 as if fully set forth herein.

74. Fresenius USA has knowledge of the '813 patent.

75. Upon information and belief, the Approved Fresenius Product and the use of the Approved Fresenius Product are covered by at least claim 1 of the '813 patent

76. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Approved Fresenius Product will infringe one or more claims of the '813 patent, either literally or under the doctrine of equivalents under 35 U.S.C. §§ 271(a), (b), and/or (c).

77. Upon information and belief, Fresenius USA either has already, or intends imminently, to engage in the importation, manufacture, use, offer for sale, sale, marketing and/or distribution of the Approved Fresenius Product with its approved labeling of sNDA 208418/S-007.

78. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution and/or importation of the Approved Fresenius Product in accordance with and as directed by Fresenius USA's approved labeling for that product will infringe one or more claims of the '813 patent, including, but not limited to, claim 1.

79. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of the Approved Fresenius Product in accordance with and as directed by Fresenius USA's approved labeling for that product will infringe one or more claims of the '813 patent, including, but not limited to claim 1 under 35 U.S.C. § 271(a).

80. Upon information and belief, Fresenius USA plans and intends to, and will, actively induce infringement of the '813 patent, including, but not limited to claim 1, under 35 U.S.C.

§ 271(b). Fresenius USA's activities will be done with knowledge of the '813 patent and specific intent to infringe that patent.

81. Upon information and belief, Fresenius USA knows that Approved Fresenius Product and its proposed labeling are especially made or adapted for use in infringing the '813 patent, are not staple articles or commodities of commerce, and that the Approved Fresenius Product and its approved labeling are not suitable for substantial non-infringing use. Upon information and belief, Fresenius USA plans and intends to, and will, contribute to infringement of the '813 patent under 35 U.S.C. § 271(c).

82. Upon information and belief, Fresenius USA has already or will, without authority, import into the United States and/or offer to sell, sell, and/or use within the United States, a product that infringes one or more claims of the '813 patent, and contributes to the infringement by others of the '813 patent under 35 U.S.C. § 271(c).

83. The foregoing actions by Fresenius USA constitute and/or will constitute infringement of the '813 patent, active inducement of infringement of the '813 patent, and contribution to the infringement by others of the '813 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

84. Upon information and belief, Fresenius USA has acted with full knowledge of the '813 patent and without reasonable basis for believing that it would not be liable for infringing the '813 patent, actively inducing infringement of the '813 patent, and contributing to the infringement by others of the '813 patent.

85. Plaintiffs will be substantially and irreparably damaged by infringement of the '646 patent.

86. Unless Fresenius USA is enjoined from infringing the ’813 patent, actively inducing infringement of the ’813 patent, and contributing to the infringement by others of the ’813 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT V – DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 10,342,813

87. Plaintiffs incorporate each of the preceding paragraphs 1-30 as if fully set forth herein.

88. Fresenius USA has knowledge of the ’813 patent.

89. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiffs on the one hand and Fresenius USA on the other regarding Fresenius USA’s infringement, active inducement of infringement, and contribution to the infringement by others of the ’831 patent, and/or validity of the ’831 patent.

90. The Approved Fresenius Product and the use of the Approved Fresenius Product are covered by at least claim 1 of the ’831 patent.

91. The manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Approved Fresenius Product will infringe one or more claims of the ’813 patent, including, but not limited to, claim 1, either literally or under the doctrine of equivalents.

92. Upon information and belief, Fresenius USA plans and intends to, and will, engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Fresenius USA’s sNDA Product with its approved labeling, and intends to do so immediately and imminently because the Approved Fresenius Product has already received FDA approval for marketing and sale within the United States.

93. The use of the Approved Fresenius Product in accordance with and as directed by Fresenius USA's approved labeling for that product will infringe one or more of the claims of the '813 patent, including, but not limited to, claim 1.

94. Upon information and belief, Fresenius USA plans and intends to, and will, actively induce infringement of the '813 patent. Fresenius USA's activities will be done with knowledge of the '813 patent and specific intent to infringe that patent.

95. Upon information and belief, Fresenius USA knows that Fresenius USA's sNDA Product and its approved labeling are especially made or adapted for use in infringing the '813 patent, are not staple articles or commodities of commerce, and that Fresenius USA's sNDA Product and its approved labeling are not suitable for substantial non-infringing use. Upon information and belief, Fresenius USA plans and intends to, and will, contribute to infringement of the '813 patent.

96. Upon information and belief, Fresenius USA will, without authority, import into the United States and/or offer to sell, sell, and/or use within the United States, a product which is made by a process that infringes one or more claims of the '813 patent prior to the expiration of the patent.

97. The foregoing actions by Fresenius USA constitute and/or will constitute infringement of the '813 patent, active inducement of infringement of the '813 patent, and contribution to the infringement by others of the '813 patent.

98. Upon information and belief, Fresenius USA acted without a reasonable basis for believing that it would not be liable for infringing the '813 patent, actively inducing infringement of the '813 patent, and contributing to the infringement by others of the '813 patent.

99. Plaintiffs will be substantially and irreparably damaged by infringement of the '913 patent.

100. Unless Fresenius USA is enjoined from infringing the '813 patent, actively inducing infringement of the '813 patent and contributing to the infringement by others of the '813 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Approved Fresenius Product in accordance with and as directed by Fresenius USA's approved labeling for that product, or any other Fresenius USA product that is covered by or whose use is covered by the '813 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the '813 patent, and that the claims of the '813 patent are not invalid.

COUNT VI – INFRINGEMENT OF U.S. PATENT NO. 10,342,813 UNDER 35 U.S.C. § 271(e)(2)

101. Plaintiffs incorporate each of the preceding paragraphs 1-30 as if fully set forth herein.

102. Upon information and belief, the Approved Fresenius Product and the use of the Approved Fresenius Product are covered by at least claim 1 of the '813 patent.

103. Fresenius USA's submission of sNDA 208418/S-007 to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Fresenius USA's sNDA Product prior to the expiration of the '813 patent was an act of infringement of the '813 patent under 35 U.S.C. § 271(e)(2)(A).

104. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Approved Fresenius Product will infringe one or more claims of the '813 patent, either literally or under the doctrine of equivalents.

105. Upon information and belief, Fresenius USA either has already, or intends imminently, to engage in the importation, manufacture, use, offer for sale, sale, marketing and/or distribution of the Approved Fresenius Product with its approved labeling of sNDA 208418/S-007.

106. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution and/or importation of the Approved Fresenius Product in accordance with and as directed by Fresenius USA's approved labeling for that product will infringe one or more claims of the '813 patent, including, but not limited to, claim 1.

107. Upon information and belief, Fresenius USA plans and intends to, and will, actively induce infringement of the '813 patent, including, but not limited to claim 1. Fresenius USA's activities will be done with knowledge of the '813 patent and specific intent to infringe that patent.

108. Upon information and belief, Fresenius USA knows that Fresenius Approved Product and its proposed labeling are especially made or adapted for use in infringing the '813 patent, are not staple articles or commodities of commerce, and that Fresenius USA's sNDA Product and its approved labeling are not suitable for substantial non-infringing use. Upon information and belief, Fresenius USA plans and intends to, and will, contribute to infringement of the '813 patent.

109. Upon information and belief, Fresenius USA has already or will, without authority, import into the United States and/or offer to sell, sell, and/or use within the United States, a product that infringes one or more claims of the '813 patent, and contributes to the infringement by others of the '813 patent.

110. The foregoing actions by Fresenius USA constitute and/or will constitute infringement of the '813 patent, active inducement of infringement of the '813 patent, and contribution to the infringement by others of the '813 patent.

111. Upon information and belief, Fresenius USA has acted with full knowledge of the '813 patent and without reasonable basis for believing that it would not be liable for infringing the '813 patent, actively inducing infringement of the '813 patent, and contributing to the infringement by others of the '813 patent.

112. Plaintiffs will be substantially and irreparably damaged by infringement of the '646 patent.

113. Unless Fresenius USA is enjoined from infringing the '813 patent, actively inducing infringement of the '813 patent, and contributing to the infringement by others of the '813 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court grant the following relief:

A. A judgment that Fresenius USA has infringed the '646 patent and the '813 patent;

B. A preliminary and permanent injunction enjoining Fresenius USA, its officers and directors, and all persons acting in concert with Fresenius USA, from making, using, selling, offering for sale, marketing, distributing, or importing the Approved Fresenius Product, or any product or compound the making, using, offering for sale, sale, marketing, distributing, or importation of which infringes the '646 patent or the '813 patent, or the inducement of or the contribution to any of the foregoing, prior to the expiration date of the '646 patent or the '813 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

C. A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing the Approved Fresenius Product, or any product or compound the making, using, offering for sale, sale, marketing, distributing, or

importation of which infringes the ’646 patent or the ’813 patent, prior to the expiration date of the ’646 patent or the ’813 patent will infringe, actively induce infringement of, and/or contribute to the infringement by others of the ’646 patent or the ’813 patent;

D. An order that the FDA withdraw its approval of the Approved Fresenius Product until a date which is not earlier than the date of the expiration of the ’646 and the ’813 patents, inclusive of any extension(s) and additional period(s) of exclusivity, pursuant to 35 U.S.C. § 271(e)(4);

E. A judgment awarding Plaintiffs damages if Defendant commercially manufactures, uses, offers to sell, or sells the Approved Fresenius Product within the United States, or imports the Approved Fresenius Product into the United States, prior to the expiration of the ’646 patent or the ’813 patent, inclusive of any extension(s) and additional period(s) of exclusivity, along with prejudgment and post-judgment interest;

F. A declaration that this is an exceptional case and an award of attorneys’ fees pursuant to 35 U.S.C. § 285;

G. An award of Plaintiffs’ costs and expenses in this action; and

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

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