IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB, Plaintiffs, v. FRESENIUS KABI USA, LLC, Defendant.	Case No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, and AstraZeneca AB (collectively "Plaintiffs" or "AstraZeneca") bring this action for patent infringement against Fresenius Kabi USA, LLC ("Defendant" or "Fresenius").

THE PARTIES

1. Plaintiff AstraZeneca Pharmaceuticals LP is a limited partnership organized under the laws of the State of Delaware, with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19850, U.S.A.

2. Plaintiff AstraZeneca UK Limited is a private limited company organized under the laws of England and Wales, with its registered office at 2 Kingdom St, London W2 6BD, United Kingdom.

3. Plaintiff AstraZeneca AB is a public limited liability company organized under the laws of Sweden with its principal place of business at Karlebyhus, Astraallén, Södertälje, S-151 85, Sweden.

4. On information and belief, Fresenius is a limited liability company organized and

existing under the laws of the State of Delaware, with its principal place of business at Three Corporate Drive, Lake Zurich, Illinois 60047.

5. On information and belief, Fresenius is in the business of manufacturing, marketing, and selling generic copies of branded pharmaceutical products throughout the United States, including within this District.

6. On information and belief, Fresenius filed New Drug Application ("NDA") No. 210326 seeking regulatory approval from the U.S. Food and Drug Administration ("FDA") to market and sell a proposed Fulvestrant Injection, 250 mg/5ml (50 mg/ml) product throughout the United States, including within this District.

NATURE OF THE ACTION

7. This is a civil action for patent infringement under the patent laws of the United States, Title 35, United States Code, arising out of Fresenius's filing of NDA No. 210326 with the FDA.

8. Fresenius is seeking approval to engage in the commercial manufacture, use and sale of a proposed Fulvestrant Injection, 250 mg/5ml (50 mg/ml) product (the "Proposed NDA Product") prior to the expiration of AstraZeneca's U.S. Patent Nos. 6,774,122, 7,456,160, 8,329,680, and 8,466,139.

JURISDICTION AND VENUE

9. This Court has jurisdiction over the subject matter of this action, which arises under the patent laws of the United States, pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

10. This Court has personal jurisdiction over Fresenius because Fresenius has maintained continuous and systematic contacts with the State of Delaware and this District.

11. On information and belief, Fresenius markets and sells brand and generic pharmaceutical products 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, brand and generic pharmaceutical products. Fresenius derives substantial revenue from goods used or consumed or services rendered in this judicial district.

12. More specifically, this Court has personal jurisdiction over Fresenius by virtue of its conduct of business in this District, its purposeful availment of the rights and benefits of Delaware law, and its substantial, continuous, and systematic contacts with the State of Delaware. On information and belief, Fresenius: (i) is registered with the Delaware Department of State, Division of Corporations and is incorporated as a Delaware Limited Liability Company under File Number 4373141 and (ii) intentionally markets and sells generic pharmaceutical products, pursuant to the New Drug Application process, throughout the United States, including in the State of Delaware, at least by making and shipping into this District, or by offering to sell and selling, or causing others to offer to sell or sell, generic pharmaceutical products in this District. On information and belief, Fresenius derives substantial revenue from goods used or consumed or services rendered in this District.

13. On information and belief, Fresenius intends to distribute and sell its Proposed NDA Product in this judicial district. Fresenius's filing of NDA No. 210326 confirms this intention and additionally subjects Fresenius to the specific personal jurisdiction of this Court. *See Acorda Therapeutics Inc. v. Mylan Pharms. Inc.*, 817 F.3d 755 (Fed. Cir. 2016).

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

15. On December 14, 2017, AstraZeneca filed a complaint against Fresenius in the United States District Court for the District of New Jersey (the "Fresenius New Jersey Action").

The complaint in the Fresenius New Jersey Action alleged the same acts of infringement as the present complaint. A copy of the complaint is attached as **Appendix A**. Pursuant to Local Civil Rule 11.2 of that Court, the Fresenius New Jersey action was certified as related to thirteen other Hatch-Waxman litigations also involving the FASLODEX® (fulvestrant) intramuscular injection product, the same product at issue here, and the same Patents-in-Suit.[1]

16. On information and belief, based on Fresenius's continuous and systematic business contacts with New Jersey, Fresenius should be subject to personal jurisdiction in the District of New Jersey; however, Fresenius may assert that it is not subject to such jurisdiction.

17. AstraZeneca is therefore filing the instant complaint, which has identical infringement claims against Defendant as the Fresenius New Jersey Complaint, a so-called

[1] The Hatch-Waxman litigations pending before the Hon. Renee Marie Bumb of the United States District Court of the District of New Jersey, and certified as related litigations in the Fresenius New Jersey Complaint under L.Civ.R. 11.2, are the following: *ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB v. SANDOZ INC., and SANDOZ INTERNATIONAL GmbH, C.A. No. 1:14-cv-03547-RMB-KMW ("AstraZeneca v. Sandoz")*; *ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB v. SAGENT PHARMACEUTICALS, INC., C.A. No. 1:14-cv-05539-RMB-KMW ("AstraZeneca v. Sagent")*; *ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB v. GLENMARK PHARMACEUTICALS INC., USA, C.A. No. 1:15-cv-00615-RMB-KMW ("AstraZeneca v. Glenmark")*; *ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB v. AGILA SPECIALTIES, INC. F/K/A STRIDES INC., ONCO THERAPIES LIMITED, MYLAN PHARMACEUTICALS INC., MYLAN LABORATORIES LIMITED, and MYLAN INC., C.A. No. 1:15-cv- 06039-RMB-KMW ("AstraZeneca v. Agila")*; *ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB v. MYLAN PHARMACEUTICALS INC., MYLAN LABORATORIES LIMITED, and MYLAN INC., C.A. No. 1:15-cv-07009-RMB-KMW ("AstraZeneca v. Mylan")*; *ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB v. TEVA PHARMACEUTICALS USA, INC., C.A. No. 1:15-cv-07889-RMB-KMW ("AstraZeneca v. Teva Second Wave")*; *ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB v. INNOPHARMA, INC., C.A. No. 1:16-cv-00894-RMB-KMW ("AstraZeneca v. InnoPharma Inc.")*; *ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB v. INNOPHARMA LICENSING LLC, C.A. No. 1:16-cv-01962-RMB-KMW ("AstraZeneca v. InnoPharma Licensing")*; *ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB v. MYLAN INSTITUTIONAL LLC, C.A. No. 1:16-cv-04612-RMB-KMW ("AstraZeneca v. Mylan Institutional")*; *ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB v. DR. REDDY'S LABORATORIES, INC. and DR. REDDY'S LABORATORIES, LTD., C.A. No. 1:17-cv-00926-RMB-KMW ("AstraZeneca v. Dr. Reddy's")*; *ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB v. AMNEAL PHARMACEUTICALS LLC, C.A. No. 1:17-cv-01968-RMB-KMW ("AstraZeneca v. Amneal"); ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB v. HBT LABS, INC., C.A. No. 1:17-cv-02652-RMB-KMW ("AstraZeneca v. HBT"); ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB v. TEVA PHARMACEUTICALS USA, INC., C.A. No. 1:17-cv-02448-RMB-KMW ("AstraZeneca v. Teva").*

Hatch-Waxman "protective suit," to preserve its right to a 30-month stay under 21 U.S.C. § 355(j)(5)(B)(iii).

THE PATENTS-IN-SUIT

18. United States Patent No. 6,774,122 (the "'122 Patent"), entitled "Formulation," was duly and legally issued on August 10, 2004 and will expire on January 9, 2021, with an additional six months of pediatric exclusivity that will expire July 9, 2021. AstraZeneca AB is the legal owner of the '122 Patent. AstraZeneca UK Limited is the beneficial owner of the '122 Patent. A copy of the '122 Patent is attached as **Appendix B**.

19. United States Patent No. 7,456,160 (the "'160 Patent"), entitled "Formulation," was duly and legally issued on November 25, 2008 and will expire on January 9, 2021, with an additional six months of pediatric exclusivity that will expire July 9, 2021. AstraZeneca AB is the legal owner of the '160 Patent. AstraZeneca UK Limited is the beneficial owner of the '160 Patent. A copy of the '160 Patent is attached as **Appendix C**.

20. United States Patent No. 8,329,680 (the "'680 Patent"), entitled "Formulation," was duly and legally issued on December 11, 2012 and will expire on January 9, 2021, with an additional six months of pediatric exclusivity that will expire July 9, 2021. AstraZeneca AB is the legal owner of the '680 Patent. AstraZeneca UK Limited is the beneficial owner of the '680 Patent. A copy of the '680 Patent is attached as **Appendix D**.

21. United States Patent No. 8,466,139 (the "'139 Patent"), entitled "Formulation," was duly and legally issued on June 18, 2013 and will expire on January 9, 2021, with an additional six months of pediatric exclusivity that will expire July 9, 2021. AstraZeneca AB is the legal owner of the '139 Patent. AstraZeneca UK Limited is the beneficial owner of the '139 Patent. A copy of the '139 Patent is attached as **Appendix E**.

FACTUAL BACKGROUND

FASLODEX® (fulvestrant) intramuscular injection

22. FASLODEX® (fulvestrant) intramuscular injection is an estrogen receptor antagonist approved by the FDA for the treatment of: (a) hormone receptor positive metastatic breast cancer in postmenopausal women with disease progression following antiestrogen therapy; and (b) hormone receptor positive, HER2-negative advanced or metastatic breast cancer in combination with palbociclib in women with disease progression following endocrine therapy.

23. FDA regulatory exclusivity for the treatment of hormone receptor positive, HER2-negative advanced or metastatic breast cancer in combination with palbociclib in women with disease progression following endocrine therapy will expire on February 19, 2019.

24. AstraZeneca UK Limited is the holder of approved New Drug Application ("NDA") No. 21-344 for FASLODEX® (fulvestrant) intramuscular injection, in 50 mg/mL dosage forms. AstraZeneca Pharmaceuticals LP is the authorized agent for matters related to NDA No. 21-344 in the United States.

25. The use of FASLODEX® (fulvestrant) intramuscular injection is covered by one or more Claims of the '122, '160, '680, and '139 Patents.

26. The '122, '160, '680, and '139 Patents have been listed for NDA No. 21-344 in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is referred to as the "Orange Book."

27. AstraZeneca Pharmaceuticals LP sells and distributes FASLODEX® (fulvestrant) intramuscular injection in the United States pursuant to NDA No. 21-344.

FRESENIUS'S NDA

28. By Notice Letter dated October 31, 2017, Fresenius notified AstraZeneca that

Fresenius's NDA No. 210326 ("Fresenius's NDA") was submitted to the FDA and that Fresenius is seeking approval to engage in the commercial manufacture, use and sale of the Proposed NDA Product prior to the expiration of the '122, '160, '680, and '139 Patents, and included within NDA No. 210326 a certification pursuant to 21 U.S.C. § 355(b)(2)(A)(iv) ("Paragraph IV Certification") that the '122, '160, '680, and '139 Patents are invalid and/or will not be infringed by the manufacture, use, importation, sale or offer for sale of the Proposed NDA Product.

29. Fresenius was aware of the Patents-in-Suit when NDA No. 210326 was filed with a Paragraph IV Certification.

30. With its Notice Letter, Fresenius offered to provide AstraZeneca with confidential access to certain information from Fresenius's NDA No. 210326, pursuant to 21 U.S.C. 355(b)(3)(D)(i)(III), for the sole and exclusive purpose of determining whether an infringement action as to the Patents-in-Suit could be brought. AstraZeneca was only provided access to limited materials in Fresenius's NDA No. 210326 on December 8, 2017. In the absence of sufficient information and the ability to meaningfully evaluate information related to Fresenius's NDA No. 210326, AstraZeneca must resort to the judicial process and the aid of discovery to obtain under appropriate judicial safeguards such information as is required to confirm its belief and to present to the Court evidence that Fresenius infringes one or more claims of the Patents-in-Suit. *See Hoffman-La Roche Inc. v. Invamed Inc.*, 213 F.3d 1359, 1364 (Fed. Cir. 2000).

31. The Notice Letter contains one narrow allegation of non-infringement, but does not otherwise deny: (a) that the Proposed NDA Product, when offered for sale, sold, and/or imported, and when used as directed, will be used in a manner that would directly infringe at least one or more Claims of the '122, '160, '680, and '139 Patents under 35 U.S.C. § 271(a); or

(b) that Fresenius will actively induce and/or contribute to infringement by others of one or more Claims of the ’122, ’160, ’680, and ’139 Patents under 35 U.S.C. § 271(b) and/or (c).

32. On information and belief, Fresenius’s NDA refers to and relies upon AstraZeneca’s FASLODEX® (fulvestrant) intramuscular injection as the reference product.

33. On information and belief, the proposed label will also have instructions for use that substantially copy the instructions for FASLODEX® (fulvestrant) intramuscular injection, including instructions for administering the Proposed NDA Product by intramuscular injection to treat hormone dependent breast cancer. The instructions accompanying the Proposed NDA Product will induce others to use and/or contribute to others’ use of the Proposed NDA Product in the manner set forth in the instructions.

34. On information and belief, based on Fresenius’s assertions to the FDA, every limitation of the patent claims is met by Fresenius’s Proposed NDA Product with its instructions, either literally or by equivalents by performing substantially the same function, in substantially the same way, to obtain substantially the same results; any difference is insubstantial.

COUNT I: INFRINGEMENT OF U.S. PATENT NO. 6,774,122

35. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1–34 of this Complaint.

36. The use of the Proposed NDA Product is covered by one or more Claims of the ’122 Patent.

37. Fresenius's submission of NDA No. 210326 under 21 U.S.C. § 355(b)(2) for the purpose of obtaining approval to engage in the commercial manufacture, use, importation, sale and/or offer for sale of the Proposed NDA Product before the expiration of the '122 Patent constitutes infringement of one or more Claims of the '122 Patent under 35 U.S.C. § 271(e)(2).

38. On information and belief, Fresenius plans to, intends to, and will engage in the commercial manufacture, use, importation, sale and/or offer for sale of the Proposed NDA Product immediately upon approval of NDA No. 210326 and will direct physicians and patients on the use of the Proposed NDA Product through product labeling.

39. The Proposed NDA Product, when offered for sale, sold, and/or imported, and when used as directed, will be used in a manner that would directly infringe at least one or more Claims of the '122 Patent under 35 U.S.C. § 271(a).

40. Upon FDA approval of NDA No. 210326, Fresenius will infringe the '122 Patent by making, using, offering to sell, selling, and/or importing the Proposed NDA Product in the United States, and by actively inducing and/or contributing to infringement by others under 35 U.S.C. § 271(b) and/or (c).

41. Fresenius had knowledge of the '122 Patent when it submitted NDA No. 210326 to the FDA and Fresenius knows or should have known that it will aid and abet another's direct infringement of at least one of the Claims of the '122 Patent.

42. As discussed above in paragraphs 31-34, the Notice Letter lacks any legitimate legal or factual basis for non-infringement of any Claims of the '122 Patent.

43. Fresenius had knowledge of the '122 Patent and is knowingly and willfully infringing the '122 Patent.

44. Plaintiffs will be substantially and irreparably harmed by the infringing activities

described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

45. On information and belief, Fresenius lacked a good faith basis for alleging invalidity and/or non-infringement of the '122 Patent when it filed its Paragraph IV Certification. Accordingly, Fresenius's Paragraph IV Certification was wholly unjustified, and this case is exceptional under 35 U.S.C. § 285.

COUNT II: DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 6,774,122

46. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1–45 of this Complaint.

47. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

48. On information and belief, Fresenius has taken and plans to, intends to, and will take active steps to induce, or contribute to, the infringement of one or more Claims of the '122 Patent under 35 U.S.C. § 271(b) and/or § 271(c), after NDA No. 210326 is approved.

COUNT III: INFRINGEMENT OF U.S. PATENT NO. 7,456,160

49. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1–48 of this Complaint.

50. The use of the Proposed NDA Product is covered by one or more Claims of the '160 Patent.

51. Fresenius's submission of NDA No. 210326 under 21 U.S.C. § 355(b)(2) for the purpose of obtaining approval to engage in the commercial manufacture, use, importation, sale and/or offer for sale of the Proposed NDA Product before the expiration of the '160 Patent

constitutes infringement of one or more Claims of the ’160 Patent under 35 U.S.C. § 271(e)(2).

52. On information and belief, Fresenius plans to, intends to, and will engage in the commercial manufacture, use, importation, sale and/or offer for sale of the Proposed NDA Product immediately upon approval of NDA No. 210326 and will direct physicians and patients on the use of the Proposed NDA Product through product labeling.

53. On information and belief, the Proposed NDA Product, when offered for sale, sold, and/or imported, and when used as directed, will be used in a manner that would directly infringe at least one or more Claims of the ’160 Patent under 35 U.S.C. § 271(a).

54. Upon FDA approval of NDA No. 210326, Fresenius will infringe the ’160 Patent by making, using, offering to sell, selling, and/or importing the Proposed NDA Product in the United States, and by actively inducing and/or contributing to infringement by others under 35 U.S.C. § 271(b) and/or (c).

55. Fresenius had knowledge of the ’160 Patent when it submitted NDA No. 210326 to the FDA and Fresenius knows or should have known that it will aid and abet another’s direct infringement of at least one of the Claims of the ’160 Patent.

56. As discussed above in paragraphs 31-34, the Notice Letter lacks any legitimate legal or factual basis for non-infringement of any Claims of the ’160 Patent.

57. Fresenius had knowledge of the ’160 Patent and is knowingly and willfully infringing the ’160 Patent.

58. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

59. On information and belief, Fresenius lacked a good faith basis for alleging

invalidity and/or non-infringement of the ’160 Patent when it filed its Paragraph IV Certification. Accordingly, Defendant’s Paragraph IV Certification was wholly unjustified, and this case is exceptional under 35 U.S.C. § 285.

COUNT IV: DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 7,456,160

60. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1–59 of this Complaint.

61. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

62. On information and belief, Fresenius has taken and plans to, intends to, and will take active steps to induce, or contribute to, the infringement of one or more Claims of the ’160 Patent under 35 U.S.C. § 271(b) and/or § 271(c), after NDA No. 210326 is approved.

COUNT V: INFRINGEMENT OF U.S. PATENT NO. 8,329,680

63. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1–62 of this Complaint.

64. The use of the Proposed NDA Product is covered by one or more Claims of the ’680 Patent.

65. Fresenius’s submission of NDA No. 210326 under 21 U.S.C. § 355(b)(2) for the purpose of obtaining approval to engage in the commercial manufacture, use, importation, sale and/or offer for sale of the Proposed NDA Product before the expiration of the ’680 Patent constitutes infringement of one or more Claims of the ’680 Patent under 35 U.S.C. § 271(e)(2).

66. On information and belief, Fresenius plans to, intends to, and will engage in the commercial manufacture, use, importation, sale and/or offer for sale of the Proposed NDA

Product immediately upon approval of NDA No. 210326 and will direct physicians and patients on the use of the Proposed NDA Product through product labeling.

67. On information and belief, the Proposed NDA Product, when offered for sale, sold, and/or imported, and when used as directed, will be used in a manner that would directly infringe at least one or more Claims of the ’680 Patent under 35 U.S.C. § 271(a).

68. Upon FDA approval of NDA No. 210326, Fresenius will infringe the ’680 Patent by making, using, offering to sell, selling, and/or importing the Proposed NDA Product in the United States, and by actively inducing and/or contributing to infringement by others under 35 U.S.C. § 271(b) and/or (c).

69. Fresenius had knowledge of the ’680 Patent when Fresenius submitted NDA No. 210326 to the FDA and Fresenius knows or should have known that it will aid and abet another’s direct infringement of at least one of the Claims of the ’680 Patent.

70. As discussed above in paragraphs 31-34, the Notice Letter lacks any legitimate legal or factual basis for non-infringement of any Claims of the ’680 Patent.

71. Fresenius has knowledge of the ’680 Patent and is knowingly and willfully infringing the ’680 Patent.

72. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

73. On information and belief, Fresenius lacked a good faith basis for alleging invalidity and/or non-infringement of the ’680 Patent when it filed its Paragraph IV Certification. Accordingly, Fresenius’s Paragraph IV Certification was wholly unjustified, and this case is exceptional under 35 U.S.C. § 285.

COUNT VI: DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,329,680

74. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1–73 of this Complaint.

75. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

76. On information and belief, Fresenius has taken and plans to, intends to, and will take active steps to induce, or contribute to, the infringement of one or more Claims of the '680 Patent under 35 U.S.C. § 271(b) and/or § 271(c), after NDA No. 210326 is approved.

COUNT VII: INFRINGEMENT OF U.S. PATENT NO. 8,466,139

77. Plaintiffs hereby reallege and incorporate by reference the allegations of paragraphs 1–76 of this Complaint.

78. The use of the Proposed NDA Product is covered by one or more Claims of the '139 Patent.

79. Fresenius's submission of NDA No. 210326 under 21 U.S.C. § 355(b)(2) for the purpose of obtaining approval to engage in the commercial manufacture, use, importation, sale and/or offer for sale of the Proposed NDA Product before the expiration of the '139 Patent constitutes infringement of one or more Claims of the '139 Patent under 35 U.S.C. § 271(e)(2).

80. On information and belief, Fresenius plans to, intends to, and will engage in the commercial manufacture, use, importation, sale and/or offer for sale of the Proposed NDA Product immediately upon approval of NDA No. 210326 and will direct physicians and patients on the use of the Proposed NDA Product through product labeling.

81. On information and belief, the Proposed NDA Product, when offered for sale,

sold, and/or imported, and when used as directed, will be used in a manner that would directly infringe at least one or more Claims of the '139 Patent under 35 U.S.C. § 271(a).

82. Upon FDA approval of NDA No. 210326, Fresenius will infringe the '139 Patent by making, using, offering to sell, selling, and/or importing the Proposed NDA Product in the United States, and by actively inducing and/or contributing to infringement by others under 35 U.S.C. § 271(b) and/or (c).

83. Fresenius had knowledge of the '139 Patent when it submitted NDA No. 210326 to the FDA and Fresenius knows or should have known that it will aid and abet another's direct infringement of at least one of the Claims of the '139 Patent.

84. As discussed above in paragraphs 31-34, the Notice Letter lacks any legitimate legal or factual basis for non-infringement of any Claims of the '139 Patent.

85. Fresenius has knowledge of the '139 Patent and is knowingly and willfully infringing the '139 Patent.

86. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

87. On information and belief, Fresenius lacked a good faith basis for alleging invalidity and/or non-infringement of the '139 Patent when it filed its Paragraph IV Certification. Accordingly, Fresenius's Paragraph IV Certification was wholly unjustified, and this case is exceptional under 35 U.S.C. § 285.

COUNT VIII: DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,466,139

88. Plaintiffs hereby reallege and incorporate by reference the allegations of

paragraphs 1–87 of this Complaint.

89. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

90. On information and belief, Fresenius has taken and plans to, intends to, and will take active steps to induce, or contribute to, the infringement of one or more Claims of the '139 Patent under 35 U.S.C. § 271(b) and/or § 271(c), after NDA No. 210326 is approved.

PRAYER FOR RELIEF

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

a) Judgment that the '122, '160, '680, and '139 Patents are valid and enforceable;

b) Judgment that Fresenius's submission of NDA No. 210326 was an act of infringement of one or more Claims of the '122, '160, '680, and '139 Patents under 35 U.S.C. § 271(e)(2);

c) Judgment that Fresenius's making, using, offering to sell, selling, or importing into the United States of the Proposed NDA Product prior to the expiration of the '122, '160, '680, and '139 Patents, will infringe, will actively induce infringement, and/or will contribute to the infringement of one or more Claims of the '122, '160, '680, and/or '139 Patents;

d) An Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of NDA No. 210326 shall be a date that is not earlier than the expiration of the '122, '160, '680, and '139 Patents plus any other exclusivity to which Plaintiffs are or become entitled;

e) An Order permanently enjoining Fresenius, its affiliates and subsidiaries, each of their officers, agents, servants and employees, and any person acting in concert with Fresenius, from making, using, offering to sell, selling, marketing, distributing, or importing

into the United States the Proposed NDA Product until after the expiration of the '122, '160, '680, and '139 Patents plus any other exclusivity to which Plaintiffs are or become entitled;

f) Judgment declaring that infringement, inducement or contributory infringement of the '122, '160, '680, and/or '139 Patents by Fresenius is willful should Fresenius commercially manufacture, use, offer to sell, sell, or import into the United States the Proposed NDA Product;

g) A declaration that this case is an exceptional case within the meaning of 35 U.S.C. § 285 and an award of reasonable attorneys' fees, expenses, and disbursements of this action;

h) Plaintiffs' reasonable costs and expenses in this action; and

i) Such further and other relief as this Court deems proper and just.

Dated: December 14, 2017

McCARTER & ENGLISH

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