IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

HERON THERAPEUTICS, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
	)	
FRESENIUS KABI USA, LLC, and FRESENIUS KABI AG,	)	
	)	
	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Heron Therapeutics, Inc. ("Heron"), for its Complaint against Defendants Fresenius Kabi USA, LLC ("Fresenius USA") and Fresenius Kabi AG ("Fresenius AG") (collectively, "Fresenius"), hereby alleges as follows:

THE PARTIES

1. Heron is a corporation organized and existing under the laws of Delaware, having a principal place of business at 4242 Campus Point Court, Suite 200, San Diego, California 92121.

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

3. Upon information and belief, Fresenius AG is a corporation organized and existing under the laws of Germany, with its principal place of business at Else-Kröner-Straße 1, 61352 Bad Homburg, Germany.

4. Upon information and belief, Fresenius USA is a wholly-owned subsidiary of Fresenius AG and one or more of the board members of Fresenius AG is also a board member of Fresenius USA.

5. Upon information and belief, Fresenius USA develops, manufactures, markets, sells, distributes, and/or imports generic pharmaceutical versions of branded products throughout the United States, including in this judicial district.

6. Upon information and belief, Fresenius AG, itself and through its subsidiaries and agents, including Fresenius USA, develops, manufactures, markets, sells, distributes, and/or imports generic drugs for sale and use throughout the United States, including in this judicial district.

NATURE OF THE ACTION

7. This is a civil action for infringement of United States Patent Nos. 9,561,229 ("the '229 patent"), 9,808,465 ("the '465 patent"), 9,974,742 ("the '742 patent"), 9,974,793 ("the '793 patent"), 9,974,794 ("the '794 patent"), 10,500,208 ("the '208 patent"), 10,624,850 ("the '850 patent"), 10,953,018 ("the '018 patent"), and 11,173,118 ("the '118 patent") (collectively, "the patents-in-suit"). This action arises under the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq.*, as well as the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

JURISDICTION & VENUE

8. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, 2202, and 35 U.S.C. § 271. This Court may declare the rights and other legal relations of the parties under 28 U.S.C. §§ 2201-02 because this case is an actual controversy within the Court's jurisdiction.

9. This Court has personal jurisdiction over Fresenius USA because, on information and belief, it is a limited liability company organized and existing under Delaware law.

10. This Court has personal jurisdiction over Fresenius AG in this action pursuant to Fed. R. Civ. P. 4(k)(2) because, upon information and belief, Fresenius AG is organized under the

laws of Germany and is not subject to any state's courts of general jurisdiction, and exercising jurisdiction over Fresenius AG is consistent with the United States Constitution and laws.

11. Upon information and belief, Fresenius AG, itself and/or through its subsidiaries, agents, and/or alter egos, including Fresenius USA, develops, manufactures, sells, distributes, and/or imports for sale drug products throughout the United States, including in this judicial district.

12. Upon information and belief, Fresenius AG directs the operations, management, and activities of Fresenius USA.

13. Upon information and belief, Fresenius AG, directly or through Fresenius USA, routinely directs the submission, makes the submission, and/or contributes to the submission of Abbreviated New Drug Applications ("ANDA") seeking FDA approval to market drug products in the United States.

14. Upon information and belief, Fresenius USA and Fresenius AG collaborate in the marketing, sale, and/or distribution of many pharmaceutical products (including generic drug products manufactured and sold pursuant to approved ANDAs) throughout the United States, including in this judicial district.

15. This Court has personal jurisdiction over Fresenius USA and Fresenius AG at least because they intend to market, sell, and/or distribute generic pharmaceutical drug products within this state and to residents of this state, including the generic drug product that is the subject of ANDA No. 214639. The submission of ANDA No. 214639 and the marketing, offer for sale, sale, distribution, and/or importation of the generic drug product that is the subject of ANDA No. 214639 infringes the patents-in-suit and will lead to foreseeable harm and injury to Heron in this state.

16. This Court also has personal jurisdiction over Fresenius USA and Fresenius AG by virtue of, *inter alia*, the fact that they have committed, aided, abetted, contributed to, and/or participated in the commission of a tortious act of patent infringement that has led to and/or will lead to foreseeable harm and injury to Heron, a Delaware corporation, in the State of Delaware.

17. This Court also has personal jurisdiction over Fresenius USA because it has previously purposefully availed itself of the rights and benefits of this Court by bringing suit within this judicial district. *See, e.g.*, *Fresenius Kabi USA, LLC v. Sintetica S.A.*, C.A. No. 22-217-MN, D.I. 1 (D. Del. Feb. 18, 2022); *Fresenius Kabi USA, LLC v. Baxter Healthcare Corp.*, C.A. No. 21-1040-MN, D.I. 1 (D. Del. Jul. 16, 2021). This Court further has personal jurisdiction over Fresenius Kabi USA, LLC because it has previously been sued in this judicial district and has not challenged personal jurisdiction, and it has purposefully availed itself of the rights and benefits of this Court by asserting counterclaims in Delaware in previous suits without challenging personal jurisdiction. *See, e.g.*, *Millennium Pharms. Inc. v. Fresenius Kabi USA, LLC*, C.A. No. 19-2252-CFC, D.I. 8 (D. Del. Feb. 10, 2020); *Hoffmann-La Roche, Inc. v. Fresenius Kabi USA, LLC*, C.A. No. 20-394-RGA, D.I. 12 (D. Del. Jun. 8, 2020); *Novartis Pharms. Corp. v. Fresenius Kabi USA, LLC*, C.A. No. 21-00870-LPS, D.I. 14 (D. Del. Aug. 27, 2021).

18. This Court has personal jurisdiction over Fresenius USA and Fresenius AG for other reasons that will be presented to the Court if jurisdiction is challenged.

19. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400.

20. Venue is proper in this district with respect to Fresenius USA because it is incorporated in the State of Delaware, it has committed acts of infringement in this judicial district, and, upon information and belief, it will commit further acts of infringement in this judicial district.

21. Venue is proper in this district with respect to Fresenius AG because it is not a resident of the United States, it has committed acts of infringement in this judicial district, and, upon information and belief, it will commit further acts of infringement in this judicial district.

22. Venue is proper for the additional reasons set forth above, and for other reasons that will be presented to the Court if such venue is challenged.

THE PATENTS-IN-SUIT

23. Heron is the owner of the ’229 patent, titled “Emulsion Formulations of Aprepitant.” The ’229 patent was duly and legally issued on February 7, 2017. A copy of the ’229 patent is attached as Exhibit A.

24. Heron is the owner of the ’465 patent, titled “Emulsion Formulations of Aprepitant.” The ’465 patent was duly and legally issued on November 7, 2017. A copy of the ’465 patent is attached as Exhibit B.

25. Heron is the owner of the ’742 patent, titled “Emulsion Formulations of an NK-1 Receptor Antagonist and Uses Thereof.” The ’742 patent was duly and legally issued on May 22, 2018. A copy of the ’742 patent is attached as Exhibit C.

26. Heron is the owner of the ’793 patent, titled “Emulsion Formulations of Aprepitant.” The ’793 patent was duly and legally issued on May 22, 2018. A copy of the ’793 patent is attached as Exhibit D.

27. Heron is the owner of the ’794 patent, titled “Emulsion Formulations of Aprepitant.” The ’794 patent was duly and legally issued on May 22, 2018. A copy of the ’794 patent is attached as Exhibit E.

28. Heron is the owner of the ’208 patent, titled “Emulsion Formulations of Aprepitant.” The ’208 patent was duly and legally issued on December 10, 2019. A copy of the ’208 patent is attached as Exhibit F.

29. Heron is the owner of the '850 patent, titled "Emulsion Formulations of an NK-1 Receptor Antagonist and Uses Thereof." The '850 patent was duly and legally issued on April 21, 2020. A copy of the '850 patent is attached as Exhibit G.

30. Heron is the owner of the '018 patent, titled "Emulsion Formulations of Aprepitant." The '018 patent was duly and legally issued on March 23, 2021. A copy of the '018 patent is attached as Exhibit H.

31. Heron is the owner of the '118 patent, titled "Emulsion Formulations of an NK-1 Receptor Antagonist and Uses Thereof." The '118 patent was duly and legally issued on November 16, 2021. A copy of the '118 patent is attached as Exhibit I.

ACTS GIVING RISE TO THIS ACTION

32. Heron holds New Drug Application ("NDA") No. 209296 for an injectable emulsion for intravenous use containing 130mg/18mL (7.2 mg/mL) aprepitant as the active ingredient, which was approved by the Food and Drug Administration ("FDA") on November 9, 2017. Heron markets and sells this injectable emulsion in the United States under the brand name Cinvanti®.

33. Cinvanti® (aprepitant) is indicated for the treatment in adults, in combination of other antiemetic agents, for the prevention of (1) acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy including high dose cisplatin as a single-dose regimen, (2) delayed nausea and vomiting with initial and repeat courses of moderately emetogenic cancer chemotherapy as a single-dose regimen, and (3) nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy as a 3-day regimen.

34. Pursuant to 21 U.S.C. § 355(b)(1), the patents-in-suit are listed in the FDA publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") for Cinvanti®.

35. Upon information and belief, Fresenius submitted ANDA No. 214639 to the FDA under 21 U.S.C. § 355(j) seeking FDA approval to engage in the commercial manufacture, use, sale, and/or offer for sale within the United States, and/or importation into the United States, of an injectable emulsion containing 130mg/18mL (7.2 mg/mL) aprepitant ("the Fresenius Generic Product") prior to the expiration of the patents-in-suit.

36. Upon information and belief, by filing ANDA No. 214639, Fresenius has certified to the FDA that the Fresenius Generic Product has the same active ingredient as Cinvanti®, the same or substantially the same indications as Cinvanti®, and the same or substantially the same proposed labeling directing the use thereof as Cinvanti®.

37. Upon information and belief, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), Fresenius certified in ANDA No. 214639 that the claims of the patents-in-suit are invalid and/or would not be infringed by the commercial manufacture, use, sale, or offer for sale of the Fresenius Generic Product.

38. On June 14, 2022, Heron received written notification of Fresenius's ANDA No. 214639 and its accompanying § 505(j)(2)(A)(vii)(IV) certification by FedEx® in a Paragraph IV Certification Notice Letter dated June 13, 2022 ("Fresenius's Notice Letter").

39. Upon information and belief, the proposed Fresenius Generic Product, any commercial manufacture, use, sale, and/or offer to sell this product for sale within the United States, and/or any importation this product into the United States, meets or embodies all elements of one or more claims of each of the patents-in-suit.

40. This action was filed within 45 days of Heron receiving Fresenius's Notice Letter.

COUNT I
INFRINGEMENT BY FRESENIUS OF U.S. PATENT NO. 9,561,229

41. Heron re-alleges paragraphs 1-40 as if fully set forth herein.

42. Fresenius's submission of ANDA No. 214639 to the FDA, including its § 505(j)(2)(A)(vii)(IV) certification, constituted infringement of the '229 patent under 35 U.S.C. § 271(e)(2)(A).

43. Upon information and belief, the manufacture, use, sale, and/or offer for sale within the United States, and/or importation into the United States, of the proposed Fresenius Generic Product meets or embodies all elements of one or more claims of the '229 patent.

44. Upon information and belief, Fresenius intends to and will engage in the commercial manufacture use, sale, and/or offer for sale, within the United States, and/or import into the United States of the Fresenius Generic Product if it receives FDA approval of ANDA No. 214639.

45. Upon information and belief, the commercial manufacture, use, sale, and/or offer for sale, within the United States, and/or import into the United States of the Fresenius Generic Product prior to the expiration of the '229 patent will infringe and/or induce and/or contribute to the infringement of the '229 patent under 35 U.S.C. §§ 271(a), (b), and/or (c) either literally or under the doctrine of equivalents.

46. In Fresenius's Notice Letter, Fresenius did not set forth an opinion of noninfringement for claims 1-11 of the '229 patent separate and apart from any assertions of invalidity of those claims.

47. In Fresenius's Notice Letter, separate and apart from any assertions of invalidity of claims 12-21 of the '229 patent, Fresenius did not deny infringement of those claims other than on

the grounds that Fresenius will not treat subjects and does not have a specific intent for liability under any indirect infringement allegation.

48. Heron is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval or Fresenius's ANDA No. 214639 be a date that is not earlier than the expiration of the '229 patent, or any later expiration of exclusivity for the '229 patent to which Heron is or becomes entitled.

49. Heron is entitled to a declaration that, if Fresenius commercially manufactures, uses, offers for sale, and/or sells the proposed Fresenius Generic Product within the United States, imports the proposed Fresenius Generic Product into the United States, and/or induces and/or contributes to such conduct, Fresenius will infringe one or more claims of the '229 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

50. Heron will be irreparably harmed by Fresenius's infringing activities unless those activities are enjoined by this Court. Heron does not have an adequate remedy at law.

51. Upon information and belief, Fresenius was aware of the existence of the '229 patent and was aware that the filing of ANDA No. 214639 and the certification with respect to the '229 patent constituted an act of infringement of that patent.

COUNT II
INFRINGEMENT BY FRESENIUS OF U.S. PATENT NO. 9,808,465

52. Heron re-alleges paragraphs 1-51 as if fully set forth herein.

53. Fresenius's submission of ANDA No. 214639 to the FDA, including its § 505(j)(2)(A)(vii)(IV) certification, constituted infringement of the '465 patent under 35 U.S.C. § 271(e)(2)(A).

54. Upon information and belief, the manufacture, use, sale, and/or offer for sale within the United States, and/or importation into the United States, of the proposed Fresenius ANDA Products meets or embodies all elements of one or more claims of the '465 patent.

55. Upon information and belief, Fresenius intends to and will engage in the commercial manufacture use, sale, and/or offer for sale, within the United States, and/or import into the United States of the Fresenius Generic Product if it receives FDA approval of ANDA No. 214639.

56. Upon information and belief, the commercial manufacture, use, sale, and/or offer for sale, within the United States, and/or import into the United States of the Fresenius Generic Product prior to the expiration of the '465 patent will infringe and/or induce and/or contribute to the infringement of the '465 patent under 35 U.S.C. §§ 271(a), (b), and/or (c) either literally or under the doctrine of equivalents.

57. In Fresenius's Notice Letter, separate and apart from any assertions of invalidity of claims 1-6 and 8-15 of the '465 patent, Fresenius did not deny infringement of those claims other than on the grounds that Fresenius will not treat subjects and does not have a specific intent for liability under any indirect infringement allegation.

58. Heron is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval or Fresenius's ANDA No. 214639 be a date that is not earlier than the expiration of the '465 patent, or any later expiration of exclusivity for the '465 patent to which Heron is or becomes entitled.

59. Heron is entitled to a declaration that, if Fresenius commercially manufactures, uses, offers for sale, and/or sells the proposed Fresenius Generic Product within the United States, imports the proposed Fresenius Generic Product into the United States, and/or induces and/or

contributes to such conduct, Fresenius will infringe one or more claims of the '465 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

60. Heron will be irreparably harmed by Fresenius's infringing activities unless those activities are enjoined by this Court. Heron does not have an adequate remedy at law.

61. Upon information and belief, Fresenius was aware of the existence of the '465 patent and was aware that the filing of ANDA No. 214639 and the certification with respect to the '465 patent constituted an act of infringement of that patent.

COUNT III
INFRINGEMENT BY FRESENIUS OF U.S. PATENT NO. 9,974,742

62. Heron re-alleges paragraphs 1-61 as if fully set forth herein.

63. Fresenius's submission of ANDA No. 214639 to the FDA, including its § 505(j)(2)(A)(vii)(IV) certification, constituted infringement of the '742 patent under 35 U.S.C. § 271(e)(2)(A).

64. Upon information and belief, the manufacture, use, sale, and/or offer for sale within the United States, and/or importation into the United States, of the proposed Fresenius ANDA Products meets or embodies all elements of one or more claims of the '742 patent.

65. Upon information and belief, Fresenius intends to and will engage in the commercial manufacture use, sale, and/or offer for sale, within the United States, and/or import into the United States of the Fresenius Generic Product if it receives FDA approval of ANDA No. 214639.

66. Upon information and belief, the commercial manufacture, use, sale, and/or offer for sale, within the United States, and/or import into the United States of the Fresenius Generic Product prior to the expiration of the '742 patent will infringe and/or induce and/or contribute to

the infringement of the '742 patent under 35 U.S.C. §§ 271(a), (b), (c), and/or (g) either literally or under the doctrine of equivalents.

67. In Fresenius's Notice Letter, Fresenius did not set forth an opinion of noninfringement for claims 1-6, 9, 10, 12-14, or 16-20 of the '742 patent separate and apart from any assertions of invalidity of those claims.

68. Heron is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval or Fresenius's ANDA No. 214639 be a date that is not earlier than the expiration of the '742 patent, or any later expiration of exclusivity for the '742 patent to which Heron is or becomes entitled.

69. Heron is entitled to a declaration that, if Fresenius commercially manufactures, uses, offers for sale, and/or sells the proposed Fresenius Generic Product within the United States, imports the proposed Fresenius Generic Product into the United States, and/or induces and/or contributes to such conduct, Fresenius will infringe one or more claims of the '742 patent under 35 U.S.C. §§ 271(a), (b), (c), and/or (g).

70. Heron will be irreparably harmed by Fresenius's infringing activities unless those activities are enjoined by this Court. Heron does not have an adequate remedy at law.

71. Upon information and belief, Fresenius was aware of the existence of the '742 patent and was aware that the filing of ANDA No. 214639 and the certification with respect to the '742 patent constituted an act of infringement of that patent.

COUNT IV
INFRINGEMENT BY FRESENIUS OF U.S. PATENT NO. 9,974,793

72. Heron re-alleges paragraphs 1-71 as if fully set forth herein.

73. Fresenius's submission of ANDA No. 214639 to the FDA, including its § 505(j)(2)(A)(vii)(IV) certification, constituted infringement of the '793 patent under 35 U.S.C. § 271(e)(2)(A).

74. Upon information and belief, the manufacture, use, sale, and/or offer for sale within the United States, and/or importation into the United States, of the proposed Fresenius ANDA Products meets or embodies all elements of one or more claims of the '793 patent.

75. Upon information and belief, Fresenius intends to and will engage in the commercial manufacture use, sale, and/or offer for sale, within the United States, and/or import into the United States of the Fresenius Generic Product if it receives FDA approval of ANDA No. 214639.

76. Upon information and belief, the commercial manufacture, use, sale, and/or offer for sale, within the United States, and/or import into the United States of the Fresenius Generic Product prior to the expiration of the '793 patent will infringe and/or induce and/or contribute to the infringement of the '793 patent under 35 U.S.C. §§ 271(a), (b), and/or (c) either literally or under the doctrine of equivalents.

77. In Fresenius's Notice Letter, Fresenius did not set forth an opinion of noninfringement the claims of the '793 patent separate and apart from any assertions of invalidity of those claims.

78. Heron is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval or Fresenius's ANDA No. 214639 be a date that is not earlier than the expiration of the '793 patent, or any later expiration of exclusivity for the '793 patent to which Heron is or becomes entitled.

79. Heron is entitled to a declaration that, if Fresenius commercially manufactures, uses, offers for sale, and/or sells the proposed Fresenius Generic Product within the United States, imports the proposed Fresenius Generic Product into the United States, and/or induces and/or contributes to such conduct, Fresenius will infringe one or more claims of the '793 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

80. Heron will be irreparably harmed by Fresenius's infringing activities unless those activities are enjoined by this Court. Heron does not have an adequate remedy at law.

81. Upon information and belief, Fresenius was aware of the existence of the '793 patent and was aware that the filing of ANDA No. 214639 and the certification with respect to the '793 patent constituted an act of infringement of that patent.

COUNT V
INFRINGEMENT BY FRESENIUS OF U.S. PATENT NO. 9,974,794

82. Heron re-alleges paragraphs 1-81 as if fully set forth herein.

83. Fresenius's submission of ANDA No. 214639 to the FDA, including its § 505(j)(2)(A)(vii)(IV) certification, constituted infringement of the '794 patent under 35 U.S.C. § 271(e)(2)(A).

84. Upon information and belief, the manufacture, use, sale, and/or offer for sale within the United States, and/or importation into the United States, of the proposed Fresenius ANDA Products meets or embodies all elements of one or more claims of the '794 patent.

85. Upon information and belief, Fresenius intends to and will engage in the commercial manufacture use, sale, and/or offer for sale, within the United States, and/or import into the United States of the Fresenius Generic Product if it receives FDA approval of ANDA No. 214639.

86. Upon information and belief, the commercial manufacture, use, sale, and/or offer for sale, within the United States, and/or import into the United States of the Fresenius Generic Product prior to the expiration of the '794 patent will infringe and/or induce and/or contribute to the infringement of the '794 patent under 35 U.S.C. §§ 271(a), (b), and/or (c) either literally or under the doctrine of equivalents.

87. In Fresenius's Notice Letter, Fresenius did not set forth an opinion of noninfringement for claims 1-11 of the '794 patent separate and apart from any assertions of invalidity of those claims.

88. In Fresenius's Notice Letter, separate and apart from any assertions of invalidity of claims 12-21 of the '794 patent, Fresenius did not deny infringement of those claims other than on the grounds that Fresenius will not treat subjects and does not have a specific intent for liability under any indirect infringement allegation.

89. Heron is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval or Fresenius's ANDA No. 214639 be a date that is not earlier than the expiration of the '794 patent, or any later expiration of exclusivity for the '794 patent to which Heron is or becomes entitled.

90. Heron is entitled to a declaration that, if Fresenius commercially manufactures, uses, offers for sale, and/or sells the proposed Fresenius Generic Product within the United States, imports the proposed Fresenius Generic Product into the United States, and/or induces and/or contributes to such conduct, Fresenius will infringe one or more claims of the '794 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

91. Heron will be irreparably harmed by Fresenius's infringing activities unless those activities are enjoined by this Court. Heron does not have an adequate remedy at law.

92. Upon information and belief, Fresenius was aware of the existence of the '794 patent and was aware that the filing of ANDA No. 214639 and the certification with respect to the '794 patent constituted an act of infringement of that patent.

COUNT VI
INFRINGEMENT BY FRESENIUS OF U.S. PATENT NO. 10,500,208

93. Heron re-alleges paragraphs 1-92 as if fully set forth herein.

94. Fresenius's submission of ANDA No. 214639 to the FDA, including its § 505(j)(2)(A)(vii)(IV) certification, constituted infringement of the '208 patent under 35 U.S.C. § 271(e)(2)(A).

95. Upon information and belief, the manufacture, use, sale, and/or offer for sale within the United States, and/or importation into the United States, of the proposed Fresenius ANDA Products meets or embodies all elements of one or more claims of the '208 patent.

96. Upon information and belief, Fresenius intends to and will engage in the commercial manufacture use, sale, and/or offer for sale, within the United States, and/or import into the United States of the Fresenius Generic Product if it receives FDA approval of ANDA No. 214639.

97. Upon information and belief, the commercial manufacture, use, sale, and/or offer for sale, within the United States, and/or import into the United States of the Fresenius Generic Product prior to the expiration of the '208 patent will infringe and/or induce and/or contribute to the infringement of the '208 patent under 35 U.S.C. §§ 271(a), (b), (c), and/or (g) either literally or under the doctrine of equivalents.

98. In Fresenius's Notice Letter, Fresenius did not set forth an opinion of noninfringement for claims 1-5, 7-9, or 11-16 of the '208 patent separate and apart from any assertions of invalidity of those claims.

99. Heron is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval or Fresenius's ANDA No. 214639 be a date that is not earlier than the expiration of the '208 patent, or any later expiration of exclusivity for the '208 patent to which Heron is or becomes entitled.

100. Heron is entitled to a declaration that, if Fresenius commercially manufactures, uses, offers for sale, and/or sells the proposed Fresenius Generic Product within the United States, imports the proposed Fresenius Generic Product into the United States, and/or induces and/or contributes to such conduct, Fresenius will infringe one or more claims of the '208 patent under 35 U.S.C. §§ 271(a), (b), (c), and/or (g).

101. Heron will be irreparably harmed by Fresenius's infringing activities unless those activities are enjoined by this Court. Heron does not have an adequate remedy at law.

102. Upon information and belief, Fresenius was aware of the existence of the '208 patent and was aware that the filing of ANDA No. 214639 and the certification with respect to the '208 patent constituted an act of infringement of that patent.

COUNT VII
INFRINGEMENT BY FRESENIUS OF U.S. PATENT NO. 10,624,850

103. Heron re-alleges paragraphs 1-102 as if fully set forth herein.

104. Fresenius's submission of ANDA No. 214639 to the FDA, including its § 505(j)(2)(A)(vii)(IV) certification, constituted infringement of the '850 patent under 35 U.S.C. § 271(e)(2)(A).

105. Upon information and belief, the manufacture, use, sale, and/or offer for sale within the United States, and/or importation into the United States, of the proposed Fresenius ANDA Products meets or embodies all elements of one or more claims of the '850 patent.

106. Upon information and belief, Fresenius intends to and will engage in the commercial manufacture use, sale, and/or offer for sale, within the United States, and/or import into the United States of the Fresenius Generic Product if it receives FDA approval of ANDA No. 214639.

107. Upon information and belief, the commercial manufacture, use, sale, and/or offer for sale, within the United States, and/or import into the United States of the Fresenius Generic Product prior to the expiration of the '850 patent will infringe and/or induce and/or contribute to the infringement of the '850 patent under 35 U.S.C. §§ 271(a), (b), and/or (c) either literally or under the doctrine of equivalents.

108. In Fresenius's Notice Letter, separate and apart from any assertions of invalidity of claims 1-6, 9, 10, 12-14, or 16 of the '850 patent, Fresenius did not deny infringement of those claims other than on the grounds that Fresenius will not treat subjects and does not have a specific intent for liability under any indirect infringement allegation.

109. Heron is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval or Fresenius's ANDA No. 214639 be a date that is not earlier than the expiration of the '850 patent, or any later expiration of exclusivity for the '850 patent to which Heron is or becomes entitled.

110. Heron is entitled to a declaration that, if Fresenius commercially manufactures, uses, offers for sale, and/or sells the proposed Fresenius Generic Product within the United States, imports the proposed Fresenius Generic Product into the United States, and/or induces and/or contributes to such conduct, Fresenius will infringe one or more claims of the '850 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

111. Heron will be irreparably harmed by Fresenius's infringing activities unless those activities are enjoined by this Court. Heron does not have an adequate remedy at law.

112. Upon information and belief, Fresenius was aware of the existence of the '850 patent and was aware that the filing of ANDA No. 214639 and the certification with respect to the '850 patent constituted an act of infringement of that patent.

COUNT VIII
INFRINGEMENT BY FRESENIUS OF U.S. PATENT NO. 10,953,018

113. Heron re-alleges paragraphs 1-112 as if fully set forth herein.

114. Fresenius's submission of ANDA No. 214639 to the FDA, including its § 505(j)(2)(A)(vii)(IV) certification, constituted infringement of the '018 patent under 35 U.S.C. § 271(e)(2)(A).

115. Upon information and belief, the manufacture, use, sale, and/or offer for sale within the United States, and/or importation into the United States, of the proposed Fresenius ANDA Products meets or embodies all elements of one or more claims of the '018 patent.

116. Upon information and belief, Fresenius intends to and will engage in the commercial manufacture use, sale, and/or offer for sale, within the United States, and/or import into the United States of the Fresenius Generic Product if it receives FDA approval of ANDA No. 214639.

117. Upon information and belief, the commercial manufacture, use, sale, and/or offer for sale, within the United States, and/or import into the United States of the Fresenius Generic Product prior to the expiration of the '018 patent will infringe and/or induce and/or contribute to the infringement of the '018 patent under 35 U.S.C. §§ 271(a), (b), and/or (c) either literally or under the doctrine of equivalents.

118. In Fresenius's Notice Letter, separate and apart from any assertions of invalidity of the claims of the '018 patent, Fresenius did not deny infringement of those claims other than on the grounds that Fresenius will not treat subjects and does not have a specific intent for liability under any indirect infringement allegation.

119. Heron is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval or Fresenius's ANDA No. 214639 be a date that is not earlier than the expiration of the '018 patent, or any later expiration of exclusivity for the '018 patent to which Heron is or becomes entitled.

120. Heron is entitled to a declaration that, if Fresenius commercially manufactures, uses, offers for sale, and/or sells the proposed Fresenius Generic Product within the United States, imports the proposed Fresenius Generic Product into the United States, and/or induces and/or contributes to such conduct, Fresenius will infringe one or more claims of the '018 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

121. Heron will be irreparably harmed by Fresenius's infringing activities unless those activities are enjoined by this Court. Heron does not have an adequate remedy at law.

122. Upon information and belief, Fresenius was aware of the existence of the '018 patent and was aware that the filing of ANDA No. 214639 and the certification with respect to the '018 patent constituted an act of infringement of that patent.

COUNT IX
INFRINGEMENT BY FRESENIUS OF U.S. PATENT NO. 11,173,118

123. Heron re-alleges paragraphs 1-122 as if fully set forth herein.

124. Fresenius's submission of ANDA No. 214639 to the FDA, including its § 505(j)(2)(A)(vii)(IV) certification, constituted infringement of the '118 patent under 35 U.S.C. § 271(e)(2)(A).

125. Upon information and belief, the manufacture, use, sale, and/or offer for sale within the United States, and/or importation into the United States, of the proposed Fresenius ANDA Products meets or embodies all elements of one or more claims of the ’118 patent.

126. Upon information and belief, Fresenius intends to and will engage in the commercial manufacture use, sale, and/or offer for sale, within the United States, and/or import into the United States of the Fresenius Generic Product if it receives FDA approval of ANDA No. 214639.

127. Upon information and belief, the commercial manufacture, use, sale, and/or offer for sale, within the United States, and/or import into the United States of the Fresenius Generic Product prior to the expiration of the ’118 patent will infringe and/or induce and/or contribute to the infringement of the ’118 patent under 35 U.S.C. §§ 271(a), (b), and/or (c) either literally or under the doctrine of equivalents.

128. In Fresenius’s Notice Letter, Fresenius did not set forth an opinion of noninfringement for claims 1-8, 11, 12, or 14-17 of the ’118 patent separate and apart from any assertions of invalidity of those claims.

129. Heron is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval or Fresenius’s ANDA No. 214639 be a date that is not earlier than the expiration of the ’118 patent, or any later expiration of exclusivity for the ’118 patent to which Heron is or becomes entitled.

130. Heron is entitled to a declaration that, if Fresenius commercially manufactures, uses, offers for sale, and/or sells the proposed Fresenius Generic Product within the United States, imports the proposed Fresenius Generic Product into the United States, and/or induces and/or

contributes to such conduct, Fresenius will infringe one or more claims of the '118 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

131. Heron will be irreparably harmed by Fresenius's infringing activities unless those activities are enjoined by this Court. Heron does not have an adequate remedy at law.

132. Upon information and belief, Fresenius was aware of the existence of the '118 patent and was aware that the filing of ANDA No. 214639 and the certification with respect to the '118 patent constituted an act of infringement of that patent.

PRAYER FOR RELIEF

WHEREFORE, Heron requests that the Court grant the following relief:

A. A judgment decreeing that Fresenius has infringed one or more claims of each patent-in-suit by submitting ANDA No. 214639;

B. A judgment decreeing that Fresenius will infringe one or more claims of each patent-in-suit if it commercially manufactures, uses, offers for sale, or sells the proposed Fresenius Generic Product within the United States, imports the proposed Fresenius Generic Product into the United States, or induces and/or contributes to such conduct;

C. An order pursuant to 35 U.S.C. § 271(e)(4)(A) decreeing that the effective date of any FDA approval of Fresenius's ANDA No. 214639 be a date not earlier than the latest expiration date of the patents-in-suit, or any later expiration of any patent term extension or exclusivity for the patents-in-suit to which Heron is or becomes entitled;

D. A permanent injunction pursuant to 35 U.S.C. § 271(e)(4)(B) or 35 U.S.C. § 283 restraining and enjoining Fresenius, its directors, officers, agents, attorneys, affiliates, divisions, successors, and employees, and those acting in privity or concert with them, from commercially manufacturing, using, offering to sell, and/or selling within the United States, or importing into the United States the Fresenius Generic Product and any other product that infringes or induces or

contributes to the infringement of one or more of the patents-in-suit, prior to the expiration of the patents-in-suit, including any exclusivities or extensions to which Heron is or become entitled;

E. A declaration that this case is an exceptional case pursuant to 35 U.S.C. §285 and Heron be awarded its attorneys' fees; and

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

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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