IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

HERON THERAPEUTICS, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
QILU PHARMACEUTICAL CO., LTD., QILU PHARMACEUTICAL (HAINAN) CO., LTD., and QILU PHARMA, INC.,	)	
	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Heron Therapeutics, Inc. ("Heron"), for its Complaint against Defendants Qilu Pharmaceutical Co., Ltd. ("Qilu Ltd."), Qilu Pharmaceutical (Hainan) Co., Ltd. ("Qilu Hainan Ltd."), and Qilu Pharma, Inc. ("Qilu Inc.") (collectively, "Qilu") hereby alleges as follows:

THE PARTIES

1. Heron is a corporation organized and existing under the laws of Delaware, having a place of business at 100 Regency Forest Drive, Suite 300, Cary, NC 27518.

2. Upon information and belief, Qilu Ltd. is a corporation organized and existing under the laws of China with its principal place of business at 8888 Lvyou Road, High-Tech Zone, Jinan, 250104, China.

3. Upon information and belief, Qilu Hainan Ltd. is a corporation organized and existing under the laws of China with its principal place of business at No. 273-A, Nanhai Avenue, National High-Tech Zone, Haikou, Hainan 570314, China.

4. Upon information and belief, Qilu Inc. is a corporation organized and existing under the laws of the State of Pennsylvania with its principal place of business at 101 Lindenwood Drive, Suite 225, Malvern, Pennsylvania 19355.

5. Upon information and belief, Qilu Hainan Ltd. and Qilu Inc. are wholly owned subsidiaries of Qilu Ltd.

6. Upon information and belief, Qilu Inc. is the designated U.S. agent for Qilu Hainan Ltd. in connection with Qilu's ANDA No. 220608.

7. Upon information and belief, Qilu Hainan Ltd., Qilu Ltd., and Qilu Inc. acted in concert to prepare and submit Qilu's ANDA No. 220608.

8. Upon information and belief, Qilu Ltd., itself and/or in cooperation with Qilu Hainan Ltd. and Qilu Inc., develops, manufactures, markets, sells, distributes, and/or imports generic pharmaceutical versions of branded products throughout the United States, including in this judicial district.

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

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

NATURE OF THE ACTION

11. 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"), 11,173,118 ("the '118 patent"), 11,744,800 ("the '800 patent"), 12,115,254 ("the '254 patent"), 12,115,255 ("the '255 patent"), and 12,290,520 ("the '520 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

12. 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.

13. Upon information and belief, Qilu Ltd., itself and/or through its subsidiaries, agents, and/or alter egos, including Qilu Hainan Ltd. and Qilu Inc., develops manufactures, sells, distributes, and/or imports for sale drug products throughout the United States, including in Delaware.

14. Upon information and belief, Qilu Ltd. directs the operations, management, and activities of Qilu Hainan Ltd. and Qilu Inc.

15. Upon information and belief, Qilu Ltd., directly or through Qilu Hainan Ltd. and Qilu Inc., routinely directs, makes, and/or contributes to the submission of Abbreviated New Drug Applications ("ANDA") seeking FDA approval to market drug products in the United States.

16. Upon information and belief, Qilu Ltd., Qilu Hainan Ltd., and Qilu Inc. collaborate in the marketing, sale, and/or distribution of many pharmaceutical productions (including generic drug products manufacturing and sold pursuant to approved ANDAs) throughout the United States, including within Delaware.

17. This Court has personal jurisdiction over Qilu Ltd. because, on information and belief, Qilu Ltd. intends to market, sell, and/or distribute generic pharmaceutical drug products within Delaware and to residents of Delaware, including the generic drug product that is the subject of ANDA No. 220608. The submission of ANDA No. 220608 and the marketing, offer for sale,

sale, distribution, and/or importation of the generic drug product that is the subject of ANDA No. 220608 infringes the patents-in-suit and will lead to foreseeable harm and injury to Heron, a Delaware corporation, in the State of Delaware. On information and belief, Qilu Ltd. has 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.

18. This Court has personal jurisdiction over Qilu Hainan Ltd. because, on information and belief, Qilu Hainan Ltd. intends to market, sell, and/or distribute generic pharmaceutical drug products within Delaware and to residents of Delaware, including the generic drug product that is the subject of ANDA No. 220608. The submission of ANDA No. 220608 and the marketing, offer for sale, sale, distribution, and/or importation of the generic drug product that is the subject of ANDA No. 220608 infringes the patents-in-suit and will lead to foreseeable harm and injury to Heron, a Delaware corporation, in the State of Delaware. On information and belief, Qilu Hainan Ltd. has 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.

19. This Court has personal jurisdiction over Qilu Inc. because, on information and belief, Qilu Inc. intends to market, sell, and/or distribute generic pharmaceutical drug products within Delaware and to residents of Delaware, including the generic drug product that is the subject of ANDA No. 220608. The submission of ANDA No. 220608 and the marketing, offer for sale, sale, distribution, and/or importation of the generic drug product that is the subject of ANDA No. 220608 infringes the patents-in-suit and will lead to foreseeable harm and injury to Heron, a Delaware corporation, in the State of Delaware. On information and belief, Qilu Inc. has

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.

20. This Court further has jurisdiction over Qilu Hainan Ltd. and Qilu Ltd. in this action pursuant to Fed. R. Civ. P. 4(k)(2) because, on information and belief, Qilu Hainan Ltd. and Qilu Ltd. are organized under the laws of China and is not subject to any state's courts of general jurisdiction, and exercising jurisdiction over Qilu Hainan Ltd. and Qilu Ltd. is consistent with the Constitution and laws of the United States.

21. This Court further has personal jurisdiction over Qilu Ltd., Qilu Hainan Ltd., and Qilu Inc. because they have previously availed themselves to the rights and benefits of this Court by asserting counterclaims in this Judicial District and because they have consented to and not challenged personal jurisdiction in this Judicial District. *E.g.*, *Heron Therapeutics, Inc. v. Qilu Pharm. Co., Ltd., Qilu Pharm. (Hainan) Co., Ltd., and Qilu Pharma, Inc.*, C.A. No. 1:25-cv-357-WCB, D.I. 19 (D. Del. 2025); *Pfizer Inc., et al. v. Qilu Pharm. Co., Ltd. and Qilu Pharma, Inc.*, C.A. No. 1:21-cv-00929-CFC, D.I. 11 (D. Del. 2021); *Pfizer Inc., et al. v. Qilu Pharm. Co., Ltd. and Qilu Pharma, Inc.*, C.A. No. 1:19-cv-00754-CFC, D.I. 10 (D. Del. 2019); *Millennium Pharms., Inc. v. Qilu Pharm. Co., Ltd. and Qilu Pharma Inc.*, C.A. No. 17-1830-GMS, D.I. 11 (D. Del. 2018); *Onyx Therapeutics, Inc. v. Qilu Pharma, Inc. and Qilu Pharm. Co., Ltd.*, C.A. No. 16-1013-LPS, D.I. 13 (D. Del. 2017).

22. This Court further has personal jurisdiction over Qilu for other reasons that will be presented to the Court if jurisdiction is challenged.

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

24. Venue is proper in this district with respect to Qilu Ltd. for the reasons set forth above, including 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.

25. Venue is proper in this district with respect to Qilu Hainan Ltd. for the reasons set forth above, including 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.

26. Venue is proper in this district with respect to Qilu Inc. for the reasons set forth above, including because Qilu Inc. 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.

27. Venue is proper with respect to Qilu for other reasons that will be presented to the Court if venue is challenged.

THE PATENTS-IN-SUIT

28. 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.

29. 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.

30. 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.

31. 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.

32. 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.

33. 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.

34. 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.

35. 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.

36. 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.

37. Heron is the owner of the ’800 patent, titled “Methods of Use of Emulsion Formulations of an NK-1 Receptor Antagonist.” The ’800 patent was duly and legally issued on September 5, 2023. A copy of the ’800 patent is attached as Exhibit J.

38. Heron is the owner of the '254 patent, titled "Methods of Use of Emulsion Formulations of an NK-1 Receptor Antagonist." The '254 patent was duly and legally issued on October 15, 2024. A copy of the '254 patent is attached as Exhibit K.

39. Heron is the owner of the '255 patent, titled "Methods of Use of Emulsion Formulations of an NK-1 Receptor Antagonist." The '255 patent was duly and legally issued on October 15, 2024. A copy of the '255 patent is attached as Exhibit L.

40. Heron is the owner of the '520 patent, titled "Methods of Use of Emulsion Formulations of Aprepitant." The '520 patent was duly and legally issued on May 6, 2025. A copy of the '520 patent is attached as Exhibit M.

ACTS GIVING RISE TO THIS ACTION

41. 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®.

42. 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.

43. The composition of Cinvanti® is an embodiment of one or more claims of the patents-in-suit. 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®.

44. Upon information and belief, Qilu submitted ANDA No. 220608 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 Qilu Generic Product") prior to the expiration of the patents-in-suit.

45. Upon information and belief, by filing ANDA No. 220608, Qilu has certified to the FDA that the Qilu 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®.

46. Upon information and belief, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), Qilu certified in ANDA No. 220608 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 Qilu Generic Product.

47. On June 11, 2025, Heron received written notification of Qilu's ANDA No. 220608 and its accompanying § 505(j)(2)(A)(vii)(IV) certification by FedEx® in a Paragraph IV Certification Notice Letter dated June 10, 2025 ("Qilu's Notice Letter").

48. Upon information and belief, the proposed Qilu 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, literally and/or under the doctrine of equivalents.

49. This action was filed within 45 days of Heron receiving Qilu's Notice Letter.

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

50. Heron re-alleges paragraphs 1-49 as if fully set forth herein.

51. Qilu's submission of ANDA No. 220608 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).

52. 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 Qilu Generic Product meets or embodies all elements of one or more claims of the '229 patent.

53. Upon information and belief, Qilu 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 Qilu Generic Product if it receives FDA approval of ANDA No. 220608.

54. 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 Qilu 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.

55. In Qilu's Notice Letter, Qilu did not set forth an opinion of noninfringement for the claims of the '229 patent separate and apart from any assertions of obviousness of those claims.

56. 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 of Qilu's ANDA No. 220608 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.

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

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

59. Upon information and belief, Qilu was aware of the existence of the '229 patent and was aware that the filing of ANDA No. 220608 and the certification with respect to the '229 patent constituted an act of infringement of that patent.

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

60. Heron re-alleges paragraphs 1-59 as if fully set forth herein.

61. Qilu's submission of ANDA No. 220608 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).

62. 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 Qilu Generic Product meets or embodies all elements of one or more claims of the '465 patent.

63. Upon information and belief, Qilu 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 Qilu Generic Product if it receives FDA approval of ANDA No. 220608.

64. 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 Qilu 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.

65. In Qilu's Notice Letter, Qilu did not set forth an opinion of noninfringement for the claims of the '465 patent separate and apart from any assertions of obviousness of those claims.

66. 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 of Qilu's ANDA No. 220608 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.

67. Heron is entitled to a declaration that, if Qilu commercially manufactures, uses, offers for sale, and/or sells the proposed Qilu Generic Product within the United States, imports the proposed Qilu Generic Product into the United States, and/or induces and/or contributes to such conduct, Qilu will infringe one or more claims of the '465 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

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

69. Upon information and belief, Qilu was aware of the existence of the '465 patent and was aware that the filing of ANDA No. 220608 and the certification with respect to the '465 patent constituted an act of infringement of that patent.

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

70. Heron re-alleges paragraphs 1-69 as if fully set forth herein.

71. Qilu's submission of ANDA No. 220608 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).

72. 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 Qilu Generic Product meets or embodies all elements of one or more claims of the '742 patent.

73. Upon information and belief, Qilu 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 Qilu Generic Product if it receives FDA approval of ANDA No. 220608.

74. 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 Qilu 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.

75. In Qilu's Notice Letter, Qilu did not set forth an opinion of noninfringement for claims 1-7, 9-14, and 16-21 of the '742 patent separate and apart from any assertions of obviousness of those claims.

76. 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 of Qilu's ANDA No. 220608 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.

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

the proposed Qilu Generic Product into the United States, and/or induces and/or contributes to such conduct, Qilu will infringe one or more claims of the '742 patent under 35 U.S.C. §§ 271(a), (b), (c), and/or (g).

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

79. Upon information and belief, Qilu was aware of the existence of the '742 patent and was aware that the filing of ANDA No. 220608 and the certification with respect to the '742 patent constituted an act of infringement of that patent.

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

80. Heron re-alleges paragraphs 1-79 as if fully set forth herein.

81. Qilu's submission of ANDA No. 220608 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).

82. 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 Qilu Generic Product meets or embodies all elements of one or more claims of the '793 patent.

83. Upon information and belief, Qilu 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 Qilu Generic Product if it receives FDA approval of ANDA No. 220608.

84. 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 Qilu 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.

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

86. 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 of Qilu's ANDA No. 220608 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.

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

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

89. Upon information and belief, Qilu was aware of the existence of the '793 patent and was aware that the filing of ANDA No. 220608 and the certification with respect to the '793 patent constituted an act of infringement of that patent.

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

90. Heron re-alleges paragraphs 1-89 as if fully set forth herein.

91. Qilu's submission of ANDA No. 220608 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).

92. 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 Qilu Generic Product meets or embodies all elements of one or more claims of the '794 patent.

93. Upon information and belief, Qilu 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 Qilu Generic Product if it receives FDA approval of ANDA No. 220608.

94. 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 Qilu 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.

95. In Qilu's Notice Letter, Qilu did not set forth an opinion of noninfringement the claims of the '794 patent separate and apart from any assertions of obviousness of those claims.

96. 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 of Qilu's ANDA No. 220608 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.

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

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

99. Upon information and belief, Qilu was aware of the existence of the '794 patent and was aware that the filing of ANDA No. 220608 and the certification with respect to the '794 patent constituted an act of infringement of that patent.

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

100. Heron re-alleges paragraphs 1-99 as if fully set forth herein.

101. Qilu's submission of ANDA No. 220608 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).

102. 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 Qilu Generic Product meets or embodies all elements of one or more claims of the '208 patent.

103. Upon information and belief, Qilu 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 Qilu Generic Product if it receives FDA approval of ANDA No. 220608.

104. 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 Qilu 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.

105. In Qilu's Notice Letter, Qilu did not set forth an opinion of noninfringement for the claims of the '208 patent separate and apart from any assertions of obviousness of those claims.

106. 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 of Qilu's ANDA No. 220608 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.

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

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

109. Upon information and belief, Qilu was aware of the existence of the '208 patent and was aware that the filing of ANDA No. 220608 and the certification with respect to the '208 patent constituted an act of infringement of that patent.

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

110. Heron re-alleges paragraphs 1-109 as if fully set forth herein.

111. Qilu's submission of ANDA No. 220608 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).

112. 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 Qilu Generic Product meets or embodies all elements of one or more claims of the '850 patent.

113. Upon information and belief, Qilu 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 Qilu Generic Product if it receives FDA approval of ANDA No. 220608.

114. 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 Qilu 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.

115. In Qilu's Notice Letter, Qilu did not set forth an opinion of noninfringement for claims 1-7 and 9-16 of the '850 patent separate and apart from any assertions of obviousness of those claims.

116. 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 of Qilu's ANDA No. 220608 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.

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

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

119. Upon information and belief, Qilu was aware of the existence of the '850 patent and was aware that the filing of ANDA No. 220608 and the certification with respect to the '850 patent constituted an act of infringement of that patent.

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

120. Heron re-alleges paragraphs 1-119 as if fully set forth herein.

121. Qilu's submission of ANDA No. 220608 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).

122. 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 Qilu Generic Product meets or embodies all elements of one or more claims of the '018 patent.

123. Upon information and belief, Qilu 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 Qilu Generic Product if it receives FDA approval of ANDA No. 220608.

124. 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 Qilu 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.

125. In Qilu's Notice Letter, Qilu did not set forth an opinion of noninfringement for the claims of the '018 patent separate and apart from any assertions of obviousness of those claims.

126. 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 of Qilu's ANDA No. 220608 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.

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

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

129. Upon information and belief, Qilu was aware of the existence of the '018 patent and was aware that the filing of ANDA No. 220608 and the certification with respect to the '018 patent constituted an act of infringement of that patent.

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

130. Heron re-alleges paragraphs 1-129 as if fully set forth herein.

131. Qilu's submission of ANDA No. 220608 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).

132. 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 Qilu Generic Product meets or embodies all elements of one or more claims of the '118 patent.

133. Upon information and belief, Qilu 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 Qilu Generic Product if it receives FDA approval of ANDA No. 220608.

134. 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 Qilu 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.

135. In Qilu's Notice Letter, Qilu did not set forth an opinion of noninfringement for claims 1-9 and 11-17 of the '118 patent separate and apart from any assertions of obviousness of those claims.

136. 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 of Qilu's ANDA No. 220608 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.

137. Heron is entitled to a declaration that, if Qilu commercially manufactures, uses, offers for sale, and/or sells the proposed Qilu Generic Product within the United States, imports the proposed Qilu Generic Product into the United States, and/or induces and/or contributes to such conduct, Qilu will infringe one or more claims of the '118 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

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

139. Upon information and belief, Qilu was aware of the existence of the '118 patent and was aware that the filing of ANDA No. 220608 and the certification with respect to the '118 patent constituted an act of infringement of that patent.

COUNT X
INFRINGEMENT BY QILU OF U.S. PATENT NO. 11,744,800

140. Heron re-alleges paragraphs 1-139 as if fully set forth herein.

141. Qilu's submission of ANDA No. 220608 to the FDA, including its § 505(j)(2)(A)(vii)(IV) certification, constituted infringement of the '800 patent under 35 U.S.C. § 271(e)(2)(A).

142. 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 Qilu Generic Product meets or embodies all elements of one or more claims of the '800 patent.

143. Upon information and belief, Qilu 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 Qilu Generic Product if it receives FDA approval of ANDA No. 220608.

144. 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 Qilu Generic Product prior to the expiration of the '800 patent will infringe and/or induce and/or contribute to the infringement of the '800 patent under 35 U.S.C. §§ 271(a), (b), and/or (c) either literally or under the doctrine of equivalents.

145. In Qilu's Notice Letter, Qilu did not set forth an opinion of noninfringement for the claims of the '800 patent separate and apart from any assertions of obviousness of those claims.

146. 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 of Qilu's ANDA No. 220608 be a date that is not earlier than the expiration of the '800 patent, or any later expiration of exclusivity for the '800 patent to which Heron is or becomes entitled.

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

the proposed Qilu Generic Product into the United States, and/or induces and/or contributes to such conduct, Qilu will infringe one or more claims of the '800 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

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

149. Upon information and belief, Qilu was aware of the existence of the '800 patent and was aware that the filing of ANDA No. 220608 and the certification with respect to the '800 patent constituted an act of infringement of that patent.

COUNT XI
INFRINGEMENT BY QILU OF U.S. PATENT NO. 12,115,254

150. Heron re-alleges paragraphs 1-149 as if fully set forth herein.

151. Qilu's submission of ANDA No. 220608 to the FDA, including its § 505(j)(2)(A)(vii)(IV) certification, constituted infringement of the '254 patent under 35 U.S.C. § 271(e)(2)(A).

152. 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 Qilu Generic Product meets or embodies all elements of one or more claims of the '254 patent.

153. Upon information and belief, Qilu 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 Qilu Generic Product if it receives FDA approval of ANDA No. 220608.

154. 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 Qilu Generic Product prior to the expiration of the '254 patent will infringe and/or induce and/or contribute to the

infringement of the '254 patent under 35 U.S.C. §§ 271(a), (b), and/or (c) either literally or under the doctrine of equivalents.

155. In Qilu's Notice Letter, Qilu did not set forth an opinion of noninfringement for the claims of the '254 patent separate and apart from any assertions of obviousness of those claims.

156. 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 of Qilu's ANDA No. 220608 be a date that is not earlier than the expiration of the '254 patent, or any later expiration of exclusivity for the '254 patent to which Heron is or becomes entitled.

157. Heron is entitled to a declaration that, if Qilu commercially manufactures, uses, offers for sale, and/or sells the proposed Qilu Generic Product within the United States, imports the proposed Qilu Generic Product into the United States, and/or induces and/or contributes to such conduct, Qilu will infringe one or more claims of the '254 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

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

159. Upon information and belief, Qilu was aware of the existence of the '254 patent and was aware that the filing of ANDA No. 220608 and the certification with respect to the '254 patent constituted an act of infringement of that patent.

COUNT XII
INFRINGEMENT BY QILU OF U.S. PATENT NO. 12,115,255

160. Heron re-alleges paragraphs 1-159 as if fully set forth herein.

161. Qilu's submission of ANDA No. 220608 to the FDA, including its § 505(j)(2)(A)(vii)(IV) certification, constituted infringement of the '255 patent under 35 U.S.C. § 271(e)(2)(A).

162. 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 Qilu Generic Product meets or embodies all elements of one or more claims of the '255 patent.

163. Upon information and belief, Qilu 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 Qilu Generic Product if it receives FDA approval of ANDA No. 220608.

164. 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 Qilu Generic Product prior to the expiration of the '255 patent will infringe and/or induce and/or contribute to the infringement of the '255 patent under 35 U.S.C. §§ 271(a), (b), and/or (c) either literally or under the doctrine of equivalents.

165. In Qilu's Notice Letter, Qilu did not set forth an opinion of noninfringement for the claims of the '255 patent separate and apart from any assertions of obviousness of those claims.

166. 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 of Qilu's ANDA No. 220608 be a date that is not earlier than the expiration of the '255 patent, or any later expiration of exclusivity for the '255 patent to which Heron is or becomes entitled.

167. Heron is entitled to a declaration that, if Qilu commercially manufactures, uses, offers for sale, and/or sells the proposed Qilu Generic Product within the United States, imports the proposed Qilu Generic Product into the United States, and/or induces and/or contributes to such conduct, Qilu will infringe one or more claims of the '255 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

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

169. Upon information and belief, Qilu was aware of the existence of the '255 patent and was aware that the filing of ANDA No. 220608 and the certification with respect to the '255 patent constituted an act of infringement of that patent.

COUNT XIII
INFRINGEMENT BY QILU OF U.S. PATENT NO. 12,290,520

170. Heron re-alleges paragraphs 1-169 as if fully set forth herein.

171. Qilu's submission of ANDA No. 220608 to the FDA, including its § 505(j)(2)(A)(vii)(IV) certification, constituted infringement of the '520 patent under 35 U.S.C. § 271(e)(2)(A).

172. 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 Qilu Generic Product meets or embodies all elements of one or more claims of the '520 patent.

173. Upon information and belief, Qilu 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 Qilu Generic Product if it receives FDA approval of ANDA No. 220608.

174. 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 Qilu Generic Product prior to the expiration of the '520 patent will infringe and/or induce and/or contribute to the infringement of the '520 patent under 35 U.S.C. §§ 271(a), (b), and/or (c) either literally or under the doctrine of equivalents.

175. In Qilu's Notice Letter, Qilu did not set forth an opinion of noninfringement for the claims of the '520 patent separate and apart from any assertions of obviousness of those claims.

176. 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 of Qilu's ANDA No. 220608 be a date that is not earlier than the expiration of the '520 patent, or any later expiration of exclusivity for the '520 patent to which Heron is or becomes entitled.

177. Heron is entitled to a declaration that, if Qilu commercially manufactures, uses, offers for sale, and/or sells the proposed Qilu Generic Product within the United States, imports the proposed Qilu Generic Product into the United States, and/or induces and/or contributes to such conduct, Qilu will infringe one or more claims of the '520 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

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

179. Upon information and belief, Qilu was aware of the existence of the '520 patent and was aware that the filing of ANDA No. 220608 and the certification with respect to the '520 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 Qilu has infringed one or more claims of each patent-in-suit by submitting ANDA No. 220608;

B. A judgment decreeing that Qilu will infringe one or more claims of each patent-in-suit if it commercially manufactures, uses, offers for sale, or sells the proposed Qilu Generic Product within the United States, imports the proposed Qilu 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 Qilu's ANDA No. 220608 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 Qilu, 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 Qilu 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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