IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

HERON THERAPEUTICS, INC., *Plaintiff*, v. QILU PHARMACEUTICAL CO., LTD., QILU PHARMACEUTICAL (HAINAN) CO., LTD., and QILU PHARMA, INC., *Defendants*.	Civil Action No. 1:25-cv-357-WCB

DEFENDANTS QILU PHARMACEUTICAL CO., LTD., QILU PHARMACEUTICAL (HAINAN) CO., LTD., AND QILU PHARMA INC.'S ANSWER TO COMPLAINT AND COUNTERCLAIMS

Defendants Qilu Pharmaceutical Co., Ltd. ("Qilu Ltd."), Qilu Pharmaceutical (Hainan) Co., Ltd. ("Qilu Hainan Ltd."), and Qilu Pharma, Inc. ("Qilu Inc."), (collectively, "Qilu" or "Defendants"), by their undersigned attorneys, for their Answer to the Complaint for Patent Infringement filed by Plaintiff Heron Therapeutics, Inc. ("Heron" or "Plaintiff"), state as follows. Pursuant to Fed. R. Civ. P. 8(b)(3), Qilu denies all allegations in Plaintiff's Complaint except those expressly admitted below.

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.

ANSWER: Paragraph 1 contains legal conclusions and allegations to which no answer is required. Qilu lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this Paragraph, and therefore denies the same.

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.

ANSWER: Paragraph 2 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Qilu admits that Qilu Ltd. is a corporation organized and existing under the laws of China, having a place of business at 8888 Lvyou Road, High-Tech Zone, Jinan, 250104, China. Qilu denies any and all remaining allegations contained in this paragraph

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 Room A, No. 273, Nanhai Boulevard, State Hi-and-New Tech Park Haikou, Hainan, 570314, China.

ANSWER: Paragraph 3 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Qilu admits that Qilu Hainan Ltd. is a corporation organized and existing under the laws of China, having a place of business at No. 273-A, Nanhai Avenue, National High-Tech Zone, Haikou, Hainan 570314, China. Qilu denies any and all remaining allegations contained in this paragraph.

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.

ANSWER: Paragraph 4 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Qilu admits that Qilu Inc. is a company organized and existing under the laws of the State of Pennsylvania, having a principal place of business at 101 Lindenwood Drive, Suite 225, Malvern, PA 19355. Qilu denies any and all remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 5 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Qilu admits that Qilu Inc. is the U.S. agent for Qilu Hainan Ltd. with respect to ANDA No. 220259. Qilu denies any and all remaining allegations of this paragraph

6. Upon information and belief, Qilu Inc. is the designated U.S. agent for Qilu Hainan Ltd. in connection with Qilu's ANDA No. 220259.

ANSWER: Paragraph 6 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Qilu admits that Qilu Inc. is the U.S. agent for Qilu Hainan Ltd. with respect to ANDA No. 220259. Qilu denies any and all remaining allegations of this paragraph.

7. Upon information and belief, Qilu Hainan Ltd., Qilu Ltd., and Qilu Inc. acted in concert to prepare and submit Qilu's ANDA No. 220259.

ANSWER: Paragraph 7 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits that it filed ANDA No. 220259 with the FDA for approval to engage in the commercial manufacture, use or sale of Qilu's aprepitant intravenous emulsion, 32 mg/4.4 ml (7.2mg/ml), (the "Qilu ANDA Product"), which is a generic version of Aponvie®. Qilu further admits that Qilu Inc. is the U.S. agent for Qilu Hainan Ltd. with respect to ANDA No. 220259. Qilu denies any and all remaining allegations contained in this paragraph.

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.

ANSWER: Paragraph 8 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Qilu admits that Qilu Ltd. manufactures and sells generic pharmaceutical products. Qilu denies any and all remaining allegations contained in this paragraph.

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.

ANSWER: Paragraph 9 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Qilu admits that Qilu Hainan Ltd. manufactures and sells generic pharmaceutical products. Qilu denies any and all remaining allegations contained in this paragraph.

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.

ANSWER: Paragraph 10 contains legal conclusions and allegations to which no answer is required. Qilu admits that Qilu Inc. is the U.S. agent for Qilu Hainan Ltd. with respect to ANDA No. 220259. Qilu denies any and all remaining allegations contained in this paragraph.

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"), 11,878,074 ("the '074 patent"), 12,115,254 ("the '254 patent"), and 12,115,255 ("the '255 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.

ANSWER: Paragraph 11 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits Plaintiff purports to bring this 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"), 11,878,074 ("the '074 patent"), 12,115,254 ("the '254 patent"), and 12,115,255 ("the '255 patent") (collectively, the "Patents-in-Suit"). Qilu admits that it filed Abbreviated New Drug Application ("ANDA") No. 220259 with the FDA with a paragraph IV certification to obtain approval to engage in the commercial manufacture, use or sale of the Qilu ANDA Product, which is a generic version of Aponvie®, prior to expiration of the Patents-in-Suit. Qilu denies any and all remaining allegations contained in this paragraph.

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.

ANSWER: Paragraph 12 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits that Plaintiff's Complaint is for alleged patent infringement and for declaratory judgment of patent infringement, but denies that Plaintiff is entitled to any relief. Qilu denies any and all remaining allegations contained in this paragraph.

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.

ANSWER: Paragraph 13 contains legal conclusions to which no answer is required. To the extent an answer may be required, solely to conserve the resources of the parties and the Court, Qilu does not contest personal jurisdiction in this Judicial District solely for the limited purposes of this action only. Qilu denies any and all remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 14 contains legal conclusions to which no answer is required. To the extent an answer may be required, solely to conserve the resources of the parties and the Court, Qilu does not contest personal jurisdiction in this Judicial District solely for the limited purposes of this action only. Qilu denies any and all remaining allegations contained in this paragraph.

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.

ANSWER: Paragraph 15 contains legal conclusions to which no answer is required. To the extent an answer may be required, solely to conserve the resources of the parties and the Court, Qilu does not contest personal jurisdiction in this Judicial District solely for the limited purposes of this action only. Qilu denies any and all remaining allegations contained in this paragraph.

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.

ANSWER: Paragraph 16 contains legal conclusions to which no answer is required. To the extent an answer may be required, solely to conserve the resources of the parties and the Court, Qilu does not contest personal jurisdiction in this Judicial District solely for the limited purposes of this action only. Qilu denies any and all remaining allegations contained in this paragraph.

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. 220259. The submission of ANDA No. 220259 and the marketing, offer for sale, sale, distribution, and/or importation of the generic drug product that is the subject of ANDA No. 220259 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.

ANSWER: Paragraph 17 contains legal conclusions to which no answer is required. To the extent an answer may be required, solely to conserve the resources of the parties and the Court, Qilu does not contest personal jurisdiction in this Judicial District solely for the limited purposes of this action only. Qilu denies any and all remaining allegations contained in this paragraph.

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. 220259. The submission of ANDA No. 220259 and the marketing, offer for sale, sale, distribution, and/or importation of the generic drug product that is the subject of ANDA No. 220259 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.

ANSWER: Paragraph 18 contains legal conclusions to which no answer is required. To the extent an answer may be required, solely to conserve the resources of the parties and the Court, Qilu does not contest personal jurisdiction in this Judicial District solely for the limited purposes of this action only. Qilu denies any and all remaining allegations contained in this paragraph.

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. 220259. The submission of ANDA No. 220259 and the marketing, offer for sale, sale, distribution, and/or importation of the generic drug product that is the subject of ANDA No. 220259 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.

ANSWER: Paragraph 19 contains legal conclusions to which no answer is required. To the extent an answer may be required, solely to conserve the resources of the parties and the Court, Qilu does not contest personal jurisdiction in this Judicial District solely for the limited purposes of this action only. Qilu denies any and all remaining allegations contained in this paragraph.

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.

ANSWER: Paragraph 20 contains legal conclusions to which no answer is required. To the extent an answer may be required, solely to conserve the resources of the parties and the Court,

Qilu does not contest personal jurisdiction in this Judicial District solely for the limited purposes of this action only. Qilu denies any and all remaining allegations contained in this paragraph.

21. This Court further has personal jurisdiction over Qilu 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.*, 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. 9 (D. Del. 2017).

ANSWER: Paragraph 21 contains legal conclusions to which no answer is required. To the extent an answer may be required, solely to conserve the resources of the parties and the Court, Qilu does not contest personal jurisdiction in this Judicial District solely for the limited purposes of this action only. Qilu denies any and all remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 22 contains legal conclusions to which no answer is required. To the extent an answer may be required, solely to conserve the resources of the parties and the Court, Qilu does not contest personal jurisdiction in this Judicial District solely for the limited purposes of this action only. Qilu denies any and all remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 23 contains legal conclusions to which no answer is required. To the extent an answer may be required, solely to conserve the resources of the parties and the Court, Qilu does not contest venue in this Judicial District solely for the limited purposes of this action only. Qilu denies any and all remaining allegations contained in this paragraph.

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.

ANSWER: Paragraph 24 contains legal conclusions to which no answer is required. To the extent an answer may be required, solely to conserve the resources of the parties and the Court, Qilu does not contest venue in this Judicial District solely for the limited purposes of this action only. Qilu denies any and all remaining allegations contained in this paragraph.

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.

ANSWER: Paragraph 25 contains legal conclusions to which no answer is required. To the extent an answer may be required, solely to conserve the resources of the parties and the Court, Qilu does not contest venue in this Judicial District solely for the limited purposes of this action only. Qilu denies any and all remaining allegations contained in this paragraph.

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.

ANSWER: Paragraph 26 contains legal conclusions to which no answer is required. To the extent an answer may be required, solely to conserve the resources of the parties and the Court, Qilu does not contest venue in this Judicial District solely for the limited purposes of this action only. Qilu denies any and all remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 27 contains legal conclusions to which no answer is required. To the extent an answer may be required, solely to conserve the resources of the parties and the Court, Qilu does not contest venue in this Judicial District solely for the limited purposes of this action only. Qilu denies any and all remaining allegations contained in this paragraph.

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.

ANSWER: Paragraph 28 contains legal conclusions to which no answer is required. To the extent Qilu is required to answer, Qilu admits that what purports to be a copy of the ’229 patent is attached to the Complaint as Exhibit A, that the patent is entitled “Emulsion Formulations of Aprepitant,” and that it bears an issue date of February 7, 2017. Qilu denies that the ’229 patent was duly and legally issued and further denies any suggestion that the ’229 patent is valid or enforceable.

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.

ANSWER: Paragraph 29 contains legal conclusions to which no answer is required. To the extent Qilu is required to answer, Qilu admits that what purports to be a copy of the ’465 patent is attached to the Complaint as Exhibit B, that the patent is entitled “Emulsion Formulations of Aprepitant,” and that it bears an issue date of November 7, 2017. Qilu denies that the ’465 patent was duly and legally issued and further denies any suggestion that the ’465 patent is valid or enforceable.

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.

ANSWER: Paragraph 30 contains legal conclusions to which no answer is required. To the extent Qilu is required to answer, Qilu admits that what purports to be a copy of the ’742 patent is attached to the Complaint as Exhibit C, that the patent is entitled “Emulsion Formulations of an NK-1 Receptor Antagonist and Uses Thereof,” and that it bears an issue date of May 22, 2018. Qilu denies that the ’742 patent was duly and legally issued and further denies any suggestion that the ’742 patent is valid or enforceable.

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.

ANSWER: Paragraph 31 contains legal conclusions to which no answer is required. To the extent Qilu is required to answer, Qilu admits that what purports to be a copy of the ’793 patent is attached to the Complaint as Exhibit D, that the patent is entitled “Emulsion Formulations of Aprepitant,” and that it bears an issue date of May 22, 2018. Qilu denies that the ’793 patent was duly and legally issued and further denies any suggestion that the ’793 patent is valid or enforceable.

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.

ANSWER: Paragraph 32 contains legal conclusions to which no answer is required. To the extent Qilu is required to answer, Qilu admits that what purports to be a copy of the ’794 patent is attached to the Complaint as Exhibit E, that the patent is entitled “Emulsion Formulations of Aprepitant,” and that it bears an issue date of May 22, 2018. Qilu denies that the ’794 patent was

duly and legally issued and further denies any suggestion that the ’794 patent is valid or enforceable.

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.

ANSWER: Paragraph 33 contains legal conclusions to which no answer is required. To the extent Qilu is required to answer, Qilu admits that what purports to be a copy of the ’208 patent is attached to the Complaint as Exhibit F, that the patent is entitled “Emulsion Formulations of Aprepitant,” and that it bears an issue date of December 10, 2019. Qilu denies that the ’208 patent was duly and legally issued and further denies any suggestion that the ’208 patent is valid or enforceable.

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.

ANSWER: Paragraph 34 contains legal conclusions to which no answer is required. To the extent Qilu is required to answer, Qilu admits that what purports to be a copy of the ’850 patent is attached to the Complaint as Exhibit G, that the patent is entitled “Emulsion Formulations of an NK-1 Receptor Antagonist and Uses Thereof,” and that it bears an issue date of April 21, 2020. Qilu denies that the ’850 patent was duly and legally issued and further denies any suggestion that the ’850 patent is valid or enforceable.

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.

ANSWER: Paragraph 35 contains legal conclusions to which no answer is required. To the extent Qilu is required to answer, Qilu admits that what purports to be a copy of the ’018 patent

is attached to the Complaint as Exhibit H, that the patent is entitled "Emulsion Formulations of Aprepitant," and that it bears an issue date of March 23, 2021. Qilu denies that the '018 patent was duly and legally issued and further denies any suggestion that the '018 patent is valid or enforceable.

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.

ANSWER: Paragraph 36 contains legal conclusions to which no answer is required. To the extent Qilu is required to answer, Qilu admits that what purports to be a copy of the '118 patent is attached to the Complaint as Exhibit I, that the patent is entitled "Emulsion Formulations of an NK-1 Receptor Antagonist and Uses Thereof," and that it bears an issue date of November 16, 2021. Qilu denies that the '118 patent was duly and legally issued and further denies any suggestion that the '118 patent is valid or enforceable.

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.

ANSWER: Paragraph 37 contains legal conclusions to which no answer is required. To the extent Qilu is required to answer, Qilu admits that what purports to be a copy of the '800 patent is attached to the Complaint as Exhibit J, that the patent is entitled "Methods of Use of Emulsion Formulations of an NK-1 Receptor Antagonist," and that it bears an issue date of September 5, 2023. Qilu denies that the '800 patent was duly and legally issued and further denies any suggestion that the '800 patent is valid or enforceable.

38. Heron is the owner of the ’074 patent, titled “Methods of Use of Emulsion Formulations of an NK-1 Receptor Antagonist.” the ’074 patent was duly and legally issued on January 23, 2024. A copy of the ’074 patent is attached as Exhibit K.

ANSWER: Paragraph 38 contains legal conclusions to which no answer is required. To the extent Qilu is required to answer, Qilu admits that what purports to be a copy of the ’074 patent is attached to the Complaint as Exhibit K, that the patent is entitled “Methods of Use of Emulsion Formulations of an NK-1 Receptor Antagonist,” and that it bears an issue date of January 23, 2024. Qilu denies that the ’074 patent was duly and legally issued and further denies any suggestion that the ’074 patent is valid or enforceable.

39. 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 L.

ANSWER: Paragraph 39 contains legal conclusions to which no answer is required. To the extent Qilu is required to answer, Qilu admits that what purports to be a copy of the ’254 patent is attached to the Complaint as Exhibit L, that the patent is entitled “Methods of Use of Emulsion Formulations of an NK-1 Receptor Antagonist,” and that it bears an issue date of October 15, 2024. Qilu denies that the ’254 patent was duly and legally issued and further denies any suggestion that the ’254 patent is valid or enforceable.

40. 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 M.

ANSWER: Paragraph 40 contains legal conclusions to which no answer is required. To the extent Qilu is required to answer, Qilu admits that what purports to be a copy of the ’255 patent is attached to the Complaint as Exhibit M, that the patent is entitled “Methods of Use of Emulsion

Formulations of an NK-1 Receptor Antagonist," and that it bears an issue date of October 15, 2024. Qilu denies that the '255 patent was duly and legally issued and further denies any suggestion that the '255 patent is valid or enforceable.

ACTS GIVING RISE TO THIS ACTION

41. Heron holds New Drug Application ("NDA") No. 216457 for an injectable emulsion for intravenous use containing 32mg/4.4mL (7.2 mg/mL) aprepitant as the active ingredient, which was approved by the Food and Drug Administration ("FDA") on September 16, 2022. Heron markets and sells this injectable emulsion in the United States under the brand name Aponvie®.

ANSWER: Paragraph 41 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits that, according to FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations* (the "Orange Book"), the applicant holder's full name for NDA 216457 for Aponvie® (aprepitant) injectable emulsion, 32mg/4.4mL (7.2 mg/mL) is Heron, and the approval date is September 16, 2022. Qilu denies any and all remaining allegations contained in this paragraph.

42. Aponvie® (aprepitant) is indicated for the prevention of postoperative nausea and vomiting in adults.

ANSWER: Paragraph 42 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits that, the Aponvie® injectable emulsion prescribing information (revised March 2024),states that it is indicated for the prevention of postoperative nausea and vomiting (PONV) in adults, with limitations of use: APONVIE has not been studied for treatment of established nausea and vomiting. Qilu denies any and all remaining allegations contained in this paragraph.

43. The composition of Aponvie® 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 Aponvie®.

ANSWER: Paragraph 43 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits that the Patents-in-Suit are listed in the Orange Book in connection with NDA 216457 for Aponvie® (aprepitant) injectable emulsion, 32mg/4.4mL (7.2 mg/mL). Qilu denies any and all remaining allegations contained in this paragraph.

44. Upon information and belief, Qilu submitted ANDA No. 220259 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 32mg/4.4mL (7.2 mg/mL) aprepitant ("the Qilu Generic Product") prior to the expiration of the patents-in-suit.

ANSWER: Paragraph 44 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits that it filed ANDA No. 220259 with the FDA with a paragraph IV certification to obtain approval to engage in the commercial manufacture, use or sale of the Qilu ANDA Product prior to expiration of the Patents-in-Suit. Qilu denies any and all remaining allegations contained in this paragraph.

45. Upon information and belief, by filing ANDA No. 220259, Qilu has certified to the FDA that the Qilu Generic Product has the same active ingredient as Aponvie®, the same or substantially the same indications as Aponvie®, and the same or substantially the same proposed labeling directing the use thereof as Aponvie®.

ANSWER: Paragraph 45 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits that it filed ANDA No. 220259 with the FDA with a paragraph IV certification to obtain approval to engage in the commercial manufacture, use

or sale of the Qilu ANDA Product prior to expiration of the Patents-in-Suit. Qilu denies any and all remaining allegations contained in this paragraph.

46. Upon information and belief, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), Qilu certified in ANDA No. 220259 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.

ANSWER: Paragraph 46 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits that it filed ANDA No. 220259 with the FDA with a paragraph IV certification to obtain approval to engage in the commercial manufacture, use or sale of the Qilu ANDA Product prior to expiration of the Patents-in-Suit, and sent a notice letter to Plaintiff, dated February 6, 2025, which served as written notification to Plaintiff pursuant to U.S.C. § 355(j)(2)(B) that Qilu submitted ANDA No. 220259 and certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to the FDA as to the Patents-in-Suit, which satisfied all statutory, legal, and regulatory requirements. Qilu denies any and all remaining allegations contained in this paragraph.

47. On February 7, 2025, Heron received written notification of Qilu's ANDA No. 220259 and its accompanying § 505(j)(2)(A)(vii)(IV) certification by FedEx® in a Paragraph IV Certification Notice Letter dated February 6, 2025 ("Qilu's Notice Letter").

ANSWER: Paragraph 47 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits that it sent a notice letter to Plaintiff, dated February 6, 2025, which served as written notification to Plaintiff pursuant to U.S.C. § 355(j)(2)(B) that Qilu submitted ANDA No. 220259 and certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to the FDA as to the Patents-in-Suit, which satisfied all statutory, legal, and regulatory requirements. Qilu denies any and all remaining allegations contained in this paragraph.

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, either literally and/or under the doctrine of equivalents.

ANSWER: Paragraph 48 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies any and all remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 49 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits that it sent a notice letter to Plaintiff, dated February 6, 2025, which served as written notification to Plaintiff pursuant to U.S.C. § 355(j)(2)(B) that Qilu submitted ANDA No. 220259 and certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to the FDA as to the Patents-in-Suit, which satisfied all statutory, legal, and regulatory requirements, and that Plaintiff filed its Complaint on March 21, 2025. Qilu denies any and all remaining allegations contained in this paragraph.

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.

ANSWER: Qilu incorporates its answers to Paragraphs 1 through 49 as if fully set forth herein.

51. Qilu's submission of ANDA No. 220259 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).

ANSWER: Paragraph 51 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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.

ANSWER: Paragraph 52 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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. 220259.

ANSWER: Paragraph 53 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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.

ANSWER: Paragraph 54 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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.

ANSWER: Paragraph 55 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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. 220259 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.

ANSWER: Paragraph 56 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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).

ANSWER: Paragraph 57 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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.

ANSWER: Paragraph 58 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

59. Upon information and belief, Qilu was aware of the existence of the '229 patent and was aware that the filing of ANDA No. 220259 and the certification with respect to the '229 patent constituted an act of infringement of that patent.

ANSWER: Paragraph 59 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits that it was aware of the '229 patent and its listing in the Orange Book as of the date of mailing of Qilu's February 6, 2025 notice letter. Qilu denies any and all remaining allegations contained in this paragraph.

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.

ANSWER: Qilu incorporates its answers to Paragraphs 1 through 59 as if fully set forth herein.

61. Qilu's submission of ANDA No. 220259 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).

ANSWER: Paragraph 61 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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.

ANSWER: Paragraph 62 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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. 220259.

ANSWER: Paragraph 63 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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.

ANSWER: Paragraph 64 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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.

ANSWER: Paragraph 65 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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. 220259 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.

ANSWER: Paragraph 66 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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).

ANSWER: Paragraph 67 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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.

ANSWER: Paragraph 68 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

69. Upon information and belief, Qilu was aware of the existence of the '465 patent and was aware that the filing of ANDA No. 220259 and the certification with respect to the '465 patent constituted an act of infringement of that patent.

ANSWER: Paragraph 69 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits that it was aware of the '465 patent and its listing in the Orange Book as of the date of mailing of Qilu's February 6, 2025 notice letter. Qilu denies any and all remaining allegations contained in this paragraph.

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.

ANSWER: Qilu incorporates its answers to Paragraphs 1 through 69 as if fully set forth herein.

71. Qilu's submission of ANDA No. 220259 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).

ANSWER: Paragraph 71 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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.

ANSWER: Paragraph 72 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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. 220259.

ANSWER: Paragraph 73 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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.

ANSWER: Paragraph 74 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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.

ANSWER: Paragraph 75 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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. 220259 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.

ANSWER: Paragraph 76 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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).

ANSWER: Paragraph 77 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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.

ANSWER: Paragraph 78 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

79. Upon information and belief, Qilu was aware of the existence of the ’742 patent and was aware that the filing of ANDA No. 220259 and the certification with respect to the ’742 patent constituted an act of infringement of that patent.

ANSWER: Paragraph 79 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits that it was aware of the ’742 patent and its listing in the Orange Book as of the date of mailing of Qilu’s February 6, 2025 notice letter. Qilu denies any and all remaining allegations contained in this paragraph.

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.

ANSWER: Qilu incorporates its answers to Paragraphs 1 through 79 as if fully set forth herein.

81. Qilu's submission of ANDA No. 220259 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).

ANSWER: Paragraph 81 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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.

ANSWER: Paragraph 82 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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. 220259.

ANSWER: Paragraph 83 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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.

ANSWER: Paragraph 84 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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.

ANSWER: Paragraph 85 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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. 220259 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.

ANSWER: Paragraph 86 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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).

ANSWER: Paragraph 87 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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.

ANSWER: Paragraph 88 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

89. Upon information and belief, Qilu was aware of the existence of the '793 patent and was aware that the filing of ANDA No. 220259 and the certification with respect to the '793 patent constituted an act of infringement of that patent.

ANSWER: Paragraph 89 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits that it was aware of the '793 patent and its listing in the Orange Book as of the date of mailing of Qilu's February 6, 2025 notice letter. Qilu denies any and all remaining allegations contained in this paragraph.

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.

ANSWER: Qilu incorporates its answers to Paragraphs 1 through 89 as if fully set forth herein.

91. Qilu's submission of ANDA No. 220259 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).

ANSWER: Paragraph 91 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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.

ANSWER: Paragraph 92 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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. 220259.

ANSWER: Paragraph 93 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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.

ANSWER: Paragraph 94 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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.

ANSWER: Paragraph 95 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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. 220259 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.

ANSWER: Paragraph 96 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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).

ANSWER: Paragraph 97 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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.

ANSWER: Paragraph 98 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

99. Upon information and belief, Qilu was aware of the existence of the '794 patent and was aware that the filing of ANDA No. 220259 and the certification with respect to the '794 patent constituted an act of infringement of that patent.

ANSWER: Paragraph 99 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits that it was aware of the '794 patent and its listing in the Orange Book as of the date of mailing of Qilu's February 6, 2025 notice letter. Qilu denies any and all remaining allegations contained in this paragraph.

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.

ANSWER: Qilu incorporates its answers to Paragraphs 1 through 99 as if fully set forth herein.

101. Qilu's submission of ANDA No. 220259 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).

ANSWER: Paragraph 101 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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.

ANSWER: Paragraph 102 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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. 220259.

ANSWER: Paragraph 103 contains legal conclusions to which no answer is required.

To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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.

ANSWER: Paragraph 104 contains legal conclusions to which no answer is required.

To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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.

ANSWER: Paragraph 105 contains legal conclusions to which no answer is required.

To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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. 220259 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.

ANSWER: Paragraph 106 contains legal conclusions to which no answer is required.

To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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).

ANSWER: Paragraph 107 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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.

ANSWER: Paragraph 108 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

109. Upon information and belief, Qilu was aware of the existence of the ’208 patent and was aware that the filing of ANDA No. 220259 and the certification with respect to the ’208 patent constituted an act of infringement of that patent.

ANSWER: Paragraph 109 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits that it was aware of the ’208 patent and its listing in the Orange Book as of the date of mailing of Qilu’s February 6, 2025 notice letter. Qilu denies any and all remaining allegations contained in this paragraph.

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.

ANSWER: Qilu incorporates its answers to Paragraphs 1 through 109 as if fully set forth herein.

111. Qilu's submission of ANDA No. 220259 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).

ANSWER: Paragraph 111 contains legal conclusions to which no answer is required.

To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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.

ANSWER: Paragraph 112 contains legal conclusions to which no answer is required.

To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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. 220259.

ANSWER: Paragraph 113 contains legal conclusions to which no answer is required.

To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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.

ANSWER: Paragraph 114 contains legal conclusions to which no answer is required.

To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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.

ANSWER: Paragraph 115 contains legal conclusions to which no answer is required.

To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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. 220259 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.

ANSWER: Paragraph 116 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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).

ANSWER: Paragraph 117 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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.

ANSWER: Paragraph 118 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

119. Upon information and belief, Qilu was aware of the existence of the '850 patent and was aware that the filing of ANDA No. 220259 and the certification with respect to the '850 patent constituted an act of infringement of that patent.

ANSWER: Paragraph 119 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits that it was aware of the '850 patent and its listing in the Orange Book as of the date of mailing of Qilu's February 6, 2025 notice letter. Qilu denies any and all remaining allegations contained in this paragraph.

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.

ANSWER: Qilu incorporates its answers to Paragraphs 1 through 119 as if fully set forth herein.

121. Qilu's submission of ANDA No. 220259 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).

ANSWER: Paragraph 121 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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.

ANSWER: Paragraph 122 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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. 220259.

ANSWER: Paragraph 123 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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.

ANSWER: Paragraph 124 contains legal conclusions to which no answer is required.

To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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.

ANSWER: Paragraph 125 contains legal conclusions to which no answer is required.

To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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. 220259 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.

ANSWER: Paragraph 126 contains legal conclusions to which no answer is required.

To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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).

ANSWER: Paragraph 127 contains legal conclusions to which no answer is required.

To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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.

ANSWER: Paragraph 128 contains legal conclusions to which no answer is required.

To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

129. Upon information and belief, Qilu was aware of the existence of the '018 patent and was aware that the filing of ANDA No. 220259 and the certification with respect to the '018 patent constituted an act of infringement of that patent.

ANSWER: Paragraph 129 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits that it was aware of the '018 patent and its listing in the Orange Book as of the date of mailing of Qilu's February 6, 2025 notice letter. Qilu denies any and all remaining allegations contained in this paragraph.

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.

ANSWER: Qilu incorporates its answers to Paragraphs 1 through 129 as if fully set forth herein.

131. Qilu's submission of ANDA No. 220259 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).

ANSWER: Paragraph 131 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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.

ANSWER: Paragraph 132 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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. 220259.

ANSWER: Paragraph 133 contains legal conclusions to which no answer is required.

To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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.

ANSWER: Paragraph 134 contains legal conclusions to which no answer is required.

To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

135. In Qilu's Notice Letter, Qilu did not set forth an opinion of noninfringement for claims 1-9 and 11-18 of the '118 patent separate and apart from any assertions of obviousness of those claims.

ANSWER: Paragraph 135 contains legal conclusions to which no answer is required.

To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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. 220259 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.2

ANSWER: Paragraph 136 contains legal conclusions to which no answer is required.

To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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).

ANSWER: Paragraph 137 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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.

ANSWER: Paragraph 138 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

139. Upon information and belief, Qilu was aware of the existence of the ’118 patent and was aware that the filing of ANDA No. 220259 and the certification with respect to the ’118 patent constituted an act of infringement of that patent.

ANSWER: Paragraph 139 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits that it was aware of the ’118 patent and its listing in the Orange Book as of the date of mailing of Qilu’s February 6, 2025 notice letter. Qilu denies any and all remaining allegations contained in this paragraph.

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.

ANSWER: Qilu incorporates its answers to Paragraphs 1 through 139 as if fully set forth herein.

141. Qilu's submission of ANDA No. 220259 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).

ANSWER: Paragraph 141 contains legal conclusions to which no answer is required.

To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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.

ANSWER: Paragraph 142 contains legal conclusions to which no answer is required.

To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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. 220259.

ANSWER: Paragraph 143 contains legal conclusions to which no answer is required.

To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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.

ANSWER: Paragraph 144 contains legal conclusions to which no answer is required.

To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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.

ANSWER: Paragraph 145 contains legal conclusions to which no answer is required.

To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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. 220259 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.

ANSWER: Paragraph 146 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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).

ANSWER: Paragraph 147 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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.

ANSWER: Paragraph 148 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

149. Upon information and belief, Qilu was aware of the existence of the '800 patent and was aware that the filing of ANDA No. 220259 and the certification with respect to the '800 patent constituted an act of infringement of that patent.

ANSWER: Paragraph 149 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits that it was aware of the '800 patent and its listing in the Orange Book as of the date of mailing of Qilu's February 6, 2025 notice letter. Qilu denies any and all remaining allegations contained in this paragraph.

COUNT XI

INFRINGEMENT BY QILU OF U.S. PATENT NO. 11,878,074

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

ANSWER: Qilu incorporates its answers to Paragraphs 1 through 149 as if fully set forth herein.

151. Qilu's submission of ANDA No. 220259 to the FDA, including its § 505(j)(2)(A)(vii)(IV) certification, constituted infringement of the '074 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Paragraph 151 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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 '074 patent.

ANSWER: Paragraph 152 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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. 220259.

ANSWER: Paragraph 153 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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 '074 patent will infringe and/or induce and/or contribute to the infringement of the '074

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

ANSWER: Paragraph 154 contains legal conclusions to which no answer is required.

To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

155. In Qilu's Notice Letter, Qilu did not set forth an opinion of noninfringement for claims 1-6 and 8-13 of the '074 patent separate and apart from any assertions of obviousness of those claims.

ANSWER: Paragraph 155 contains legal conclusions to which no answer is required.

To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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. 220259 be a date that is not earlier than the expiration of the '074 patent, or any later expiration of exclusivity for the '074 patent to which Heron is or becomes entitled.

ANSWER: Paragraph 156 contains legal conclusions to which no answer is required.

To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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 '074 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Paragraph 157 contains legal conclusions to which no answer is required.

To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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.

ANSWER: Paragraph 158 contains legal conclusions to which no answer is required.

To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

159. Upon information and belief, Qilu was aware of the existence of the '074 patent and was aware that the filing of ANDA No. 220259 and the certification with respect to the '074 patent constituted an act of infringement of that patent.

ANSWER: Paragraph 159 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits that it was aware of the '074 patent and its listing in the Orange Book as of the date of mailing of Qilu's February 6, 2025 notice letter. Qilu denies any and all remaining allegations contained in this paragraph.

COUNT XII

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

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

ANSWER: Qilu incorporates its answers to Paragraphs 1 through 159 as if fully set forth herein.

161. Qilu's submission of ANDA No. 220259 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).

ANSWER: Paragraph 161 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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 '254 patent.

ANSWER: Paragraph 162 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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. 220259.

ANSWER: Paragraph 163 contains legal conclusions to which no answer is required.

To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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 '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.

ANSWER: Paragraph 164 contains legal conclusions to which no answer is required.

To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

165. 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.

ANSWER: Paragraph 165 contains legal conclusions to which no answer is required.

To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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. 220259 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.

ANSWER: Paragraph 166 contains legal conclusions to which no answer is required.

To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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 ’254 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Paragraph 167 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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.

ANSWER: Paragraph 168 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

169. Upon information and belief, Qilu was aware of the existence of the ’254 patent and was aware that the filing of ANDA No. 220259 and the certification with respect to the ’254 patent constituted an act of infringement of that patent.

ANSWER: Paragraph 169 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits that it was aware of the ’254 patent and its listing in the Orange Book as of the date of mailing of Qilu’s February 6, 2025 notice letter. Qilu denies any and all remaining allegations contained in this paragraph.

COUNT XIII

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

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

ANSWER: Qilu incorporates its answers to Paragraphs 1 through 169 as if fully set forth herein.

171. Qilu's submission of ANDA No. 220259 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).

ANSWER: Paragraph 171 contains legal conclusions to which no answer is required.

To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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 '255 patent.

ANSWER: Paragraph 172 contains legal conclusions to which no answer is required.

To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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. 220259.

ANSWER: Paragraph 173 contains legal conclusions to which no answer is required.

To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

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 '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.,

ANSWER: Paragraph 174 contains legal conclusions to which no answer is required.

To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

175. In Qilu's Notice Letter, Qilu did not set forth an opinion of invalidity or unenforceability for all of the claims of the '255 patent.

ANSWER: Paragraph 175 contains legal conclusions to which no answer is required.

To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

176. In Qilu's Notice Letter, Qilu did not set forth an opinion of noninfringement for all of the claims of the '255 patent.

ANSWER: Paragraph 176 contains legal conclusions to which no answer is required.

To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

177. 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. 220259 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.

ANSWER: Paragraph 177 contains legal conclusions to which no answer is required.

To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

178. 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).

ANSWER: Paragraph 178 contains legal conclusions to which no answer is required.

To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

179. 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.

ANSWER: Paragraph 179 contains legal conclusions to which no answer is required.

To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

180. Upon information and belief, Qilu was aware of the existence of the '255 patent and was aware that the filing of ANDA No. 220259 and the certification with respect to the '255 patent constituted an act of infringement of that patent.

ANSWER: Paragraph 180 contains legal conclusions to which no answer is required.

To the extent an answer may be required, Qilu admits that it was aware of the '255 patent and its

listing in the Orange Book as of the date of mailing of Qilu's February 6, 2025 notice letter. Qilu denies any and all remaining allegations contained in this paragraph.

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. 220259;

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. 220259 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.

RESPONSE TO PRAYER FOR RELIEF

Qilu denies all allegations not expressly admitted herein. Qilu further denies that Plaintiff are entitled to any of the relief requested in paragraphs (A) through (F), and requests that Plaintiff's Complaint be dismissed with prejudice and that Qilu be awarded its fees and costs incurred defending this suit under 35. U.S.C. § 285.

QILU'S ADDITIONAL DEFENSES

Qilu asserts the following additional defenses without prejudice to the denials in this Answer and without admitting any allegations of the Complaint not otherwise admitted. Qilu asserts these additional defenses without conceding that it bears a burden of proof on them, and reserves the right to assert additional defenses as warranted.

FIRST ADDITIONAL DEFENSE
(Invalidity of the Patents-in-Suit)

The claims of the Patents-in-Suit are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq*. or under other judicially created bases for invalidation.

SECOND ADDITIONAL DEFENSE
(No Direct Infringement of the Patents-in-Suit)

Qilu does not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the Patents-in-Suit and Qilu's products that are the subject of ANDA No. 220259 do not infringe any valid and enforceable claim of the Patents-in-Suit.

THIRD ADDITIONAL DEFENSE

(No Infringement of the Patents-in-Suit)

Qilu has not, does not, and will not induce the infringement of, or contribute to the infringement of, any valid and enforceable claim of the Patents-in-Suit, and the marketing, sale, and/or distribution of Qilu's products that are the subject of ANDA No. 220259 does not induce the infringement of, or contribute to the infringement of any valid and enforceable claim of the Patents-in-Suit.

FOURTH ADDITIONAL DEFENSE

(Failure to State a Claim)

Plaintiff's Complaint, in whole and/or in part, fails to state a claim upon which relief can be granted.

FIFTH ADDITIONAL DEFENSE

(Failure to State a Claim for Exceptional or Willful Infringement)

Plaintiff fails to state a proper claim for an exceptional case and/or willful infringement.

RESERVATION OF ADDITIONAL DEFENSES

Qilu reserves the right to plead additional affirmative defenses or counterclaims that may be revealed through the course of discovery, including unenforceability.

COUNTERCLAIMS

Pursuant to Rule 13 of the Federal Rules of Civil Procedure, Defendants Qilu Pharmaceutical Co., Ltd. ("Qilu Ltd."), Qilu Pharmaceutical (Hainan) Co., Ltd. ("Qilu Hainan Ltd."), and Qilu Pharma, Inc. ("Qilu Inc."), (together "Defendants/Counterclaim-Plaintiffs" or "Qilu"), by way of their attorneys, hereby state for their Counterclaims against Heron Therapeutics, Inc. ("Heron" or "Plaintiff/Counterclaim-Defendant"), the following, without prejudice to the denials in this Answer, without admitting any allegations of the Complaint not otherwise admitted, and without assuming the burden when such burden would otherwise be on Plaintiff/Counterclaim-Defendant:

THE PARTIES

1. Qilu repeats and incorporates by reference each of the foregoing paragraphs of Qilu's Answer and Separate Defenses to the Complaint.

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

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

4. Qilu Inc. is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, having a place of business at 101 Lindenwood Drive, Suite 225, Malvern, PA 19355

5. Upon information and belief, Plaintiff/Counterclaim-Defendant Heron is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, having a place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560.

JURISDICTION

6. These Counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq*., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) ("MMA") (21 U.S.C. § 355(j) and 35 U.S.C. § 271(e)(5)).

7. This Court has original jurisdiction over the subject matter of these Counterclaims under 28 U.S.C. §§ 1331 and 1338(a); under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and under the MMA (21 U.S.C. § 355(j) and 35 U.S.C. § 271(e)(5)).

8. This Court has subject matter jurisdiction over these Counterclaims for declaratory judgment pursuant to 28 U.S.C. §§ 1331, 1337(a), 1338(a), 2201(a) and (b), and 2202, based on an actual controversy between Qilu, and Plaintiff/Counterclaim-Defendant, arising under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq*.

9. This Court has personal jurisdiction over Plaintiff/Counterclaim-Defendant based, *inter alia*, on the filing of this lawsuit in this jurisdiction and because Plaintiff/Counterclaim-Defendant is doing business in this jurisdiction.

10. Venue is proper in this judicial district under 28 U.S. C. §§ 1391(b) and (c), and 1400(b).

FACTS COMMON TO ALL COUNTS

11. This is an action for a declaratory judgment of invalidity and noninfringement of one or more claims 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"), 11,878,074 ("the '074

patent"), 12,115,254 ("the '254 patent"), and 12,115,255 ("the '255 patent") (collectively, the "Patents-in-Suit"). Upon information and belief, true and correct copies of the Patents-in-Suit are attached to the Complaint as Exhibits A-M.

12. On or about February 7, 2017, the U.S. Patent & Trademark Office ("USPTO") issued the '229 patent.

13. On or about November 7, 2017, the USPTO issued the '465 patent.

14. On or about May 22, 2018, the USPTO issued the '742 patent.

15. On or about May 22, 2018, the USPTO issued the '793 patent.

16. On or about May 22, 2018, the USPTO issued the '794 patent.

17. On or about December 10, 2019, the USPTO issued the '208 patent.

18. On or about April 21, 2020, the USPTO issued the '850 patent.

19. On or about March 23, 2021, the USPTO issued the '018 patent.

20. On or about November 16, 2021, the USPTO issued the '118 patent.

21. On or about September 5, 2023, the USPTO issued the '800 patent.

22. On or about January 23, 2024, the USPTO issued the '074 patent.

23. On or about October 15, 2024, the USPTO issued the '254 patent.

24. On or about October 15, 2024, the USPTO issued the '255 patent.

25. Upon information and belief, Plaintiff/Counterclaim-Defendant Heron is the assignee of the Patents-in-Suit.

26. Plaintiff/Counterclaim-Defendant Heron purports to be the holder of New Drug Application ("NDA") No. 216457 for aprepitant intravenous emulsion, 32 mg/4.4 ml (7.2mg/ml). Heron sells its aprepitant intravenous emulsion in the United States under the trademark APONVIE®.

27. Plaintiff/Counterclaim-Defendant purports and claims to have the rights to enforce the Patents-in-Suit, and have listed the Patents-in-Suit in the FDA's *Approved Drug Products and Therapeutic Equivalence Evaluations* (the "Orange Book") in connection with APONVIE®.

28. Qilu has filed Abbreviated New Drug Application ("ANDA") No. 220259 with the U.S. Food and Drug Administration (the "FDA") seeking approval for Qilu's proposed aprepitant intravenous emulsion, 32 mg/4.4 ml (7.2mg/ml) described therein (the "Qilu ANDA Product").

29. Qilu's ANDA seeks FDA approval to market the Qilu ANDA Product described within ANDA No. 220259 before the expiration of the Patents-in-Suit listed in the Orange Book, and Qilu's ANDA includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (also called a "Paragraph IV Certification") as to the Patents-in-Suit.

30. Plaintiff/Counterclaim-Defendant sued Qilu in this District for alleged infringement of the Patents-in-Suit.

COUNT I
(Declaratory Judgment of Invalidity of the '229 Patent)

31. Qilu realleges and incorporates by reference the allegations of paragraphs 1-30 as though full set forth herein.

32. There is an actual, substantial, and continuing case or controversy between Qilu and the Plaintiff/Counterclaim-Defendant regarding *inter alia*, the invalidity of the '229 patent,

and a judicial declaration of invalidity is necessary and appropriate at this time so that the parties may ascertain their respective rights and duties regarding the invalidity of the claims of the ’229 patent.

33. The claims of the ’229 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, or under judicially created bases for invalidation.

34. The claims of the ’229 patent are invalid under 35 U.S.C. § 103 because they would have been obvious to a person of ordinary skill in the art, as set forth in Qilu’s Notice Letter to Plaintiff/Counterclaim-Defendant, because each and every element of each and every claim of the ’229 patent was disclosed expressly in one or more references and/or products which were publicly available before the earliest possible priority date of the ’229 patent, including, but not limited to:

i. Chinese Application No. CN102379845, “Aprepitant Microemulsion for Injection and Preparation Method thereof”;

ii. Swarbrick, J., *et al.*, “Coarse Dispersions,” in Remington: The Science and Practice of Pharmacy, Gennaro, A. (ed), Lippincot, Wilkins & Williams, (2005), pp. 319, 325-326, and 330-331;

iii. Colon-Gonzalez, F., *et al.*, “Pharmacokinetic Evaluation of Fosaprepitant Dimeglumine” Expert Opin. Drug Metab. Toxicol. (2010); 6(10): 1277–1286;

iv. Toshiaki T., *et al.*, “Pharmacokinetics of aprepitant and dexamethasone after administration of chemotherapeutic agents and effects of plasma substance P concentration on chemotherapy-induced nausea and vomiting in Japanese cancer patients” Cancer Chemother Pharmacol (2011) 68:653–659; and

v. U.S. Patent Publication No. 2011/0038925, “Intravenous Formulations of Neurokinin-1 Antagonists.”

35. Pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act, dated September 12, 2016, any person of ordinary skill in the art would have been motivated to combine

those references and/or products as of the earliest possible priority date of the ’229 patent, and would have had a reasonable expectation of success in doing so.

36. There is no objective evidence of non-obviousness of the claims of the ’229 patent, nor would any such evidence, should it exist, have any nexus to the claimed purported inventions of the ’229 patent.

37. Qilu is entitled to a judicial declaration that the claims of the ’229 patent are invalid.

38. Qilu reserves the right to provide additional bases for invalidity of each claim of the ’229 patent in its contentions, responses to discovery requests, expert reports or pleadings filed or served as this action progresses.

COUNT II

(Declaratory Judgment of Noninfringement of the ’229 Patent)

39. Qilu realleges and incorporates by reference the allegations of paragraphs 1-38 as though fully set forth herein.

40. There is an actual, substantial, and continuing case or controversy between Qilu and Plaintiff/Counterclaim-Defendant regarding, *inter alia*, non-infringement of the claims of the ’229 patent.

41. The manufacture, use, offer for sale, sale, importation, and/or marketing of the Qilu ANDA Product described in Qilu’s ANDA has not infringed, does not infringe, and would not — if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the ’229 patent, either literally or under the doctrine of equivalents.

42. Qilu is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, importation, and/or marketing of the Qilu ANDA Product described in Qilu's ANDA has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the '229 patent, either literally or under the doctrine of equivalents.

COUNT III

(Declaratory Judgment of Invalidity of the '465 Patent)

43. Qilu realleges and incorporates by reference the allegations of paragraphs 1-42 as though full set forth herein.

44. There is an actual, substantial, and continuing case or controversy between Qilu and the Plaintiff/Counterclaim-Defendant regarding *inter alia*, the invalidity of the '465 patent, and a judicial declaration of invalidity is necessary and appropriate at this time so that the parties may ascertain their respective rights and duties regarding the invalidity of the claims of the '465 patent.

45. The claims of the '465 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, or under judicially created bases for invalidation.

46. The claims of the '465 patent are invalid under 35 U.S.C. § 103 because they would have been obvious to a person of ordinary skill in the art, as set forth in Qilu's Notice Letter to Plaintiff/Counterclaim-Defendant, because each and every element of each and every claim of the '465 patent was disclosed expressly in one or more references and/or products which were publicly available before the earliest possible priority date of the '465 patent, including, but not limited to:

i. Chinese Application No. CN102379845, "Aprepitant Microemulsion for Injection and Preparation Method thereof";

ii. Swarbrick, J. *et al.*, "Coarse Dispersions," in Remington: The Science and Practice of Pharmacy, Gennaro, A. (ed), Lippincot, Wilkins & Williams, (2005), pp. 319, 325-326, and 330-331;

iii. Colon-Gonzalez, F., *et al.*, "Pharmacokinetic Evaluation of Fosaprepitant Dimeglumine" Expert Opin Drug Metab. Toxicol. (2010); 6(10): 1277–1286;

iv. Toshiaki T., *et al.*, "Pharmacokinetics of aprepitant and dexamethasone after administration of chemotherapeutic agents and effects of plasma substance P concentration on chemotherapy-induced nausea and vomiting in Japanese cancer patients" Cancer Chemother Pharmacol (2011) 68:653–659; and

v. U.S. Patent Publication No. 2011/0038925, "Intravenous Formulations of Neurokinin-1 Antagonists."

47. Pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act, dated September 12, 2016, any person of ordinary skill in the art would have been motivated to combine those references and/or products as of the earliest possible priority date of the '465 patent, and would have had a reasonable expectation of success in doing so.

48. There is no objective evidence of non-obviousness of the claims of the '465 patent, nor would any such evidence, should it exist, have any nexus to the claimed purported inventions of the '465 patent.

49. Qilu is entitled to a judicial declaration that the claims of the '465 patent are invalid.

50. Qilu reserves the right to provide additional bases for invalidity of each claim of the '465 patent in its contentions, responses to discovery requests, expert reports or pleadings filed or served as this action progresses.

COUNT IV

(Declaratory Judgment of Noninfringement of the ’465 Patent)

51. Qilu realleges and incorporates by reference the allegations of paragraphs 1-50 as though fully set forth herein.

52. There is an actual, substantial, and continuing case or controversy between Qilu and Plaintiff/Counterclaim-Defendant regarding, *inter alia*, non-infringement of the claims of the ’465 patent.

53. The manufacture, use, offer for sale, sale, importation, and/or marketing of the Qilu ANDA Product described in Qilu’s ANDA has not infringed, does not infringe, and would not — if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the ’465 patent, either literally or under the doctrine of equivalents.

54. Qilu is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, importation, and/or marketing of the Qilu ANDA Product described in Qilu’s ANDA has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the ’465 patent, either literally or under the doctrine of equivalents.

COUNT V

(Declaratory Judgment of Invalidity of the ’742 Patent)

55. Qilu realleges and incorporates by reference the allegations of paragraphs 1-54 as though full set forth herein.

56. There is an actual, substantial, and continuing case or controversy between Qilu and the Plaintiff/Counterclaim-Defendant regarding *inter alia*, the invalidity of the ’742 patent,

and a judicial declaration of invalidity is necessary and appropriate at this time so that the parties may ascertain their respective rights and duties regarding the invalidity of the claims of the ’742 patent.

57. The claims of the ’742 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, or under judicially created bases for invalidation.

58. The claims of the ’742 patent are invalid under 35 U.S.C. § 103 because they would have been obvious to a person of ordinary skill in the art, as set forth in Qilu’s Notice Letter to Plaintiff/Counterclaim-Defendant, because each and every element of each and every claim of the ’742 patent was disclosed expressly in one or more references and/or products which were publicly available before the earliest possible priority date of the ’742 patent, including, but not limited to:

i. Chinese Application No. CN102379845, “Aprepitant Microemulsion for Injection and Preparation Method thereof”;

ii. Swarbrick, J. *et al.*, “Coarse Dispersions,” in Remington: The Science and Practice of Pharmacy, Gennaro, A. (ed), Lippincot, Wilkins & Williams, (2005), pp. 319, 325-326, and 330-331;

iii. Colon-Gonzalez, F., *et al.*, “Pharmacokinetic Evaluation of Fosaprepitant Dimeglumine” Expert Opin Drug Metab. Toxicol. (2010); 6(10): 1277–1286;

iv. Toshiaki T., *et al.*, “Pharmacokinetics of aprepitant and dexamethasone after administration of chemotherapeutic agents and effects of plasma substance P concentration on chemotherapy-induced nausea and vomiting in Japanese cancer patients” Cancer Chemother Pharmacol (2011) 68:653–659;

v. U.S. Patent Publication No. 2011/0038925, “Intravenous Formulations of Neurokinin-1 Antagonists”; and

vi. Curran, M. P., *et al.* “Aprepitant A Review of its Use in the Prevention of Nausea and Vomiting” Drugs (2009), 69 (13):1853-1878.

59. Pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act, dated September 12, 2016, any person of ordinary skill in the art would have been motivated to combine

those references and/or products as of the earliest possible priority date of the '742 patent, and would have had a reasonable expectation of success in doing so.

60. There is no objective evidence of non-obviousness of the claims of the '742 patent, nor would any such evidence, should it exist, have any nexus to the claimed purported inventions of the '742 patent.

61. Qilu is entitled to a judicial declaration that the claims of the '742 patent are invalid.

62. Qilu reserves the right to provide additional bases for invalidity of each claim of the '742 patent in its contentions, responses to discovery requests, expert reports or pleadings filed or served as this action progresses.

COUNT VI

(Declaratory Judgment of Noninfringement of the '742 Patent)

63. Qilu realleges and incorporates by reference the allegations of paragraphs 1-62 as though fully set forth herein.

64. There is an actual, substantial, and continuing case or controversy between Qilu and Plaintiff/Counterclaim-Defendant regarding, *inter alia*, non-infringement of the claims of the '742 patent.

65. The manufacture, use, offer for sale, sale, importation, and/or marketing of the Qilu ANDA Product described in Qilu's ANDA has not infringed, does not infringe, and would not — if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the '742 patent, either literally or under the doctrine of equivalents.

66. Qilu is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, importation, and/or marketing of the Qilu ANDA Product described in Qilu's ANDA has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the '742 patent, either literally or under the doctrine of equivalents.

COUNT VII

(Declaratory Judgment of Invalidity of the '793 Patent)

67. Qilu realleges and incorporates by reference the allegations of paragraphs 1-66 as though full set forth herein.

68. There is an actual, substantial, and continuing case or controversy between Qilu and the Plaintiff/Counterclaim-Defendant regarding *inter alia*, the invalidity of the '793 patent, and a judicial declaration of invalidity is necessary and appropriate at this time so that the parties may ascertain their respective rights and duties regarding the invalidity of the claims of the '793 patent.

69. The claims of the '793 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, or under judicially created bases for invalidation.

70. The claims of the '793 patent are invalid under 35 U.S.C. § 103 because they would have been obvious to a person of ordinary skill in the art, as set forth in Qilu's Notice Letter to Plaintiff/Counterclaim-Defendant, because each and every element of each and every claim of the '793 patent was disclosed expressly in one or more references and/or products which were publicly available before the earliest possible priority date of the '793 patent, including, but not limited to:

i. Chinese Application No. CN102379845, "Aprepitant Microemulsion for Injection and Preparation Method thereof";

ii. Swarbrick, J. *et al.*, "Coarse Dispersions," in Remington: The Science and Practice of Pharmacy, Gennaro, A. (ed), Lippincot, Wilkins & Williams, (2005), pp. 319, 325-326, and 330-331;

iii. Colon-Gonzalez, F., *et al.*, "Pharmacokinetic Evaluation of Fosaprepitant Dimeglumine" Expert Opin Drug Metab Toxicol. (2010); 6(10): 1277–1286; and

iv. U.S. Patent Publication No. 2011/0038925, "Intravenous Formulations of Neurokinin-1 Antagonists."

71. Pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act, dated September 12, 2016, any person of ordinary skill in the art would have been motivated to combine those references and/or products as of the earliest possible priority date of the '793 patent, and would have had a reasonable expectation of success in doing so.

72. There is no objective evidence of non-obviousness of the claims of the '793 patent, nor would any such evidence, should it exist, have any nexus to the claimed purported inventions of the '793 patent.

73. Qilu is entitled to a judicial declaration that the claims of the '793 patent are invalid.

74. Qilu reserves the right to provide additional bases for invalidity of each claim of the '793 patent in its contentions, responses to discovery requests, expert reports or pleadings filed or served as this action progresses.

COUNT VIII

(Declaratory Judgment of Noninfringement of the '793 Patent)

75. Qilu realleges and incorporates by reference the allegations of paragraphs 1-74 as though fully set forth herein.

76. There is an actual, substantial, and continuing case or controversy between Qilu and Plaintiff/Counterclaim-Defendant regarding, *inter alia*, non-infringement of the claims of the ’793 patent.

77. The manufacture, use, offer for sale, sale, importation, and/or marketing of the Qilu ANDA Product described in Qilu’s ANDA has not infringed, does not infringe, and would not — if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the ’793 patent, either literally or under the doctrine of equivalents.

78. Qilu is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, importation, and/or marketing of the Qilu ANDA Product described in Qilu’s ANDA has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the ’793 patent, either literally or under the doctrine of equivalents.

COUNT IX

(Declaratory Judgment of Invalidity of the ’794 Patent)

79. Qilu realleges and incorporates by reference the allegations of paragraphs 1-78 as though full set forth herein.

80. There is an actual, substantial, and continuing case or controversy between Qilu and the Plaintiff/Counterclaim-Defendant regarding *inter alia*, the invalidity of the ’794 patent, and a judicial declaration of invalidity is necessary and appropriate at this time so that the parties may ascertain their respective rights and duties regarding the invalidity of the claims of the ’794 patent.

81. The claims of the '794 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, or under judicially created bases for invalidation.

82. The claims of the '794 patent are invalid under 35 U.S.C. § 103 because they would have been obvious to a person of ordinary skill in the art, as set forth in Qilu's Notice Letter to Plaintiff/Counterclaim-Defendant, because each and every element of each and every claim of the '794 patent was disclosed expressly in one or more references and/or products which were publicly available before the earliest possible priority date of the '794 patent, including, but not limited to:

i. Chinese Application No. CN102379845, "Aprepitant Microemulsion for Injection and Preparation Method thereof";

ii. Swarbrick, J. *et al.*, "Coarse Dispersions," in Remington: The Science and Practice of Pharmacy, Gennaro, A. (ed), Lippincot, Wilkins & Williams, (2005), pp. 319, 325-326, and 330-331;

iii. Colon-Gonzalez, F., *et al.*, "Pharmacokinetic Evaluation of Fosaprepitant Dimeglumine" Expert Opin Drug Metab Toxicol. (2010); 6(10): 1277–1286; and

iv. U.S. Patent Publication No. 2011/0038925, "Intravenous Formulations of Neurokinin-1 Antagonists."

83. Pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act, dated September 12, 2016, any person of ordinary skill in the art would have been motivated to combine those references and/or products as of the earliest possible priority date of the '794 patent, and would have had a reasonable expectation of success in doing so.

84. There is no objective evidence of non-obviousness of the claims of the '794 patent, nor would any such evidence, should it exist, have any nexus to the claimed purported inventions of the '794 patent.

85. Qilu is entitled to a judicial declaration that the claims of the '794 patent are invalid.

86. Qilu reserves the right to provide additional bases for invalidity of each claim of the ’794 patent in its contentions, responses to discovery requests, expert reports or pleadings filed or served as this action progresses.

COUNT X

(Declaratory Judgment of Noninfringement of the ’794 Patent)

87. Qilu realleges and incorporates by reference the allegations of paragraphs 1-86 as though fully set forth herein.

88. There is an actual, substantial, and continuing case or controversy between Qilu and Plaintiff/Counterclaim-Defendant regarding, *inter alia*, non-infringement of the claims of the ’794 patent.

89. The manufacture, use, offer for sale, sale, importation, and/or marketing of the Qilu ANDA Product described in Qilu’s ANDA has not infringed, does not infringe, and would not — if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the ’794 patent, either literally or under the doctrine of equivalents.

90. Qilu is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, importation, and/or marketing of the Qilu ANDA Product described in Qilu’s ANDA has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the ’794 patent, either literally or under the doctrine of equivalents.

COUNT XI

(Declaratory Judgment of Invalidity of the '208 Patent)

91. Qilu realleges and incorporates by reference the allegations of paragraphs 1-90 as though full set forth herein.

92. There is an actual, substantial, and continuing case or controversy between Qilu and the Plaintiff/Counterclaim-Defendant regarding *inter alia*, the invalidity of the '208 patent, and a judicial declaration of invalidity is necessary and appropriate at this time so that the parties may ascertain their respective rights and duties regarding the invalidity of the claims of the '208 patent.

93. The claims of the '208 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, or under judicially created bases for invalidation.

94. The claims of the '208 patent are invalid under 35 U.S.C. § 103 because they would have been obvious to a person of ordinary skill in the art, as set forth in Qilu's Notice Letter to Plaintiff/Counterclaim-Defendant, because each and every element of each and every claim of the '208 patent was disclosed expressly in one or more references and/or products which were publicly available before the earliest possible priority date of the '208 patent, including, but not limited to:

i. Chinese Application No. CN102379845, "Aprepitant Microemulsion for Injection and Preparation Method thereof";

ii. Swarbrick, J. *et al.*, "Coarse Dispersions," in Remington: The Science and Practice of Pharmacy, Gennaro, A. (ed), Lippincot, Wilkins & Williams, (2005), pp. 319, 325-326, and 330-331;

iii. Colon-Gonzalez, F., *et al.*, "Pharmacokinetic Evaluation of Fosaprepitant Dimeglumine" Expert Opin Drug Metab Toxicol. (2010); 6(10): 1277–1286; and

iv. U.S. Patent Publication No. 2011/0038925, "Intravenous Formulations of Neurokinin-1 Antagonists."

95. Pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act, dated September 12, 2016, any person of ordinary skill in the art would have been motivated to combine those references and/or products as of the earliest possible priority date of the ’208 patent, and would have had a reasonable expectation of success in doing so.

96. There is no objective evidence of non-obviousness of the claims of the ’208 patent, nor would any such evidence, should it exist, have any nexus to the claimed purported inventions of the ’208 patent.

97. Qilu is entitled to a judicial declaration that the claims of the ’208 patent are invalid.

98. Qilu reserves the right to provide additional bases for invalidity of each claim of the ’208 patent in its contentions, responses to discovery requests, expert reports or pleadings filed or served as this action progresses.

COUNT XII

(Declaratory Judgment of Noninfringement of the ’208 Patent)

99. Qilu realleges and incorporates by reference the allegations of paragraphs 1-98 as though fully set forth herein.

100. There is an actual, substantial, and continuing case or controversy between Qilu and Plaintiff/Counterclaim-Defendant regarding, *inter alia*, non-infringement of the claims of the ’208 patent.

101. The manufacture, use, offer for sale, sale, importation, and/or marketing of the Qilu ANDA Product described in Qilu’s ANDA has not infringed, does not infringe, and would not — if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly,

any valid or enforceable claim of the ’208 patent, either literally or under the doctrine of equivalents.

102. Qilu is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, importation, and/or marketing of the Qilu ANDA Product described in Qilu’s ANDA has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the ’208 patent, either literally or under the doctrine of equivalents.

COUNT XIII

(Declaratory Judgment of Invalidity of the ’850 Patent)

103. Qilu realleges and incorporates by reference the allegations of paragraphs 1-102 as though full set forth herein.

104. There is an actual, substantial, and continuing case or controversy between Qilu and the Plaintiff/Counterclaim-Defendant regarding *inter alia*, the invalidity of the ’850 patent, and a judicial declaration of invalidity is necessary and appropriate at this time so that the parties may ascertain their respective rights and duties regarding the invalidity of the claims of the ’850 patent.

105. The claims of the ’850 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, or under judicially created bases for invalidation.

106. The claims of the ’850 patent are invalid under 35 U.S.C. § 103 because they would have been obvious to a person of ordinary skill in the art, as set forth in Qilu’s Notice Letter to Plaintiff/Counterclaim-Defendant, because each and every element of each and every claim of the

'850 patent was disclosed expressly in one or more references and/or products which were publicly available before the earliest possible priority date of the '850 patent, including, but not limited to:

i. Chinese Application No. CN102379845, "Aprepitant Microemulsion for Injection and Preparation Method thereof";

ii. Swarbrick, J. *et al.*, "Coarse Dispersions," in Remington: The Science and Practice of Pharmacy, Gennaro, A. (ed), Lippincot, Wilkins & Williams, (2005), pp. 319, 325-326, and 330-331;

iii. Colon-Gonzalez, F., *et al.*, "Pharmacokinetic Evaluation of Fosaprepitant Dimeglumine" Expert Opin Drug Metab Toxicol. (2010); 6(10): 1277–1286;

iv. Toshiaki T., *et al.*, "Pharmacokinetics of aprepitant and dexamethasone after administration of chemotherapeutic agents and effects of plasma substance P concentration on chemotherapy-induced nausea and vomiting in Japanese cancer patients" Cancer Chemother Pharmacol (2011) 68:653–659; and

v. U.S. Patent Publication No. 2011/0038925, "Intravenous Formulations of Neurokinin-1 Antagonists."

107. Pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act, dated September 12, 2016, any person of ordinary skill in the art would have been motivated to combine those references and/or products as of the earliest possible priority date of the '850 patent, and would have had a reasonable expectation of success in doing so.

108. There is no objective evidence of non-obviousness of the claims of the '850 patent, nor would any such evidence, should it exist, have any nexus to the claimed purported inventions of the '850 patent.

109. Qilu is entitled to a judicial declaration that the claims of the '850 patent are invalid.

110. Qilu reserves the right to provide additional bases for invalidity of each claim of the '850 patent in its contentions, responses to discovery requests, expert reports or pleadings filed or served as this action progresses.

COUNT XIV

(Declaratory Judgment of Noninfringement of the ’850 Patent)

111. Qilu realleges and incorporates by reference the allegations of paragraphs 1-110 as though fully set forth herein.

112. There is an actual, substantial, and continuing case or controversy between Qilu and Plaintiff/Counterclaim-Defendant regarding, *inter alia*, non-infringement of the claims of the ’850 patent.

113. The manufacture, use, offer for sale, sale, importation, and/or marketing of the Qilu ANDA Product described in Qilu’s ANDA has not infringed, does not infringe, and would not — if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the ’850 patent, either literally or under the doctrine of equivalents.

114. Qilu is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, importation, and/or marketing of the Qilu ANDA Product described in Qilu’s ANDA has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the ’850 patent, either literally or under the doctrine of equivalents.

COUNT XV

(Declaratory Judgment of Invalidity of the ’018 Patent)

115. Qilu realleges and incorporates by reference the allegations of paragraphs 1-114 as though full set forth herein.

116. There is an actual, substantial, and continuing case or controversy between Qilu and the Plaintiff/Counterclaim-Defendant regarding *inter alia*, the invalidity of the ’018 patent,

and a judicial declaration of invalidity is necessary and appropriate at this time so that the parties may ascertain their respective rights and duties regarding the invalidity of the claims of the ’018 patent.

117. The claims of the ’018 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, or under judicially created bases for invalidation.

118. The claims of the ’018 patent are invalid under 35 U.S.C. § 103 because they would have been obvious to a person of ordinary skill in the art, as set forth in Qilu’s Notice Letter to Plaintiff/Counterclaim-Defendant, because each and every element of each and every claim of the ’018 patent was disclosed expressly in one or more references and/or products which were publicly available before the earliest possible priority date of the ’018 patent, including, but not limited to:

i. Chinese Application No. CN102379845, “Aprepitant Microemulsion for Injection and Preparation Method thereof”;

ii. Swarbrick, J. *et al.*, “Coarse Dispersions,” in Remington: The Science and Practice of Pharmacy, Gennaro, A. (ed), Lippincot, Wilkins & Williams, (2005), pp. 319, 325-326, and 330-331;

iii. Colon-Gonzalez, F., *et al.*, “Pharmacokinetic Evaluation of Fosaprepitant Dimeglumine” Expert Opin Drug Metab. Toxicol. (2010); 6(10): 1277–1286; and

iv. U.S. Patent Publication No. 2011/0038925, “Intravenous Formulations of Neurokinin-1 Antagonists.”

119. Pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act, dated September 12, 2016, any person of ordinary skill in the art would have been motivated to combine those references and/or products as of the earliest possible priority date of the ’018 patent, and would have had a reasonable expectation of success in doing so.

120. There is no objective evidence of non-obviousness of the claims of the ’018 patent, nor would any such evidence, should it exist, have any nexus to the claimed purported inventions of the ’018 patent.

121. Qilu is entitled to a judicial declaration that the claims of the ’018 patent are invalid.

122. Qilu reserves the right to provide additional bases for invalidity of each claim of the ’018 patent in its contentions, responses to discovery requests, expert reports or pleadings filed or served as this action progresses.

COUNT XVI

(Declaratory Judgment of Noninfringement of the ’018 Patent)

123. Qilu realleges and incorporates by reference the allegations of paragraphs 1-122 as though fully set forth herein.

124. There is an actual, substantial, and continuing case or controversy between Qilu and Plaintiff/Counterclaim-Defendant regarding, *inter alia*, non-infringement of the claims of the ’018 patent.

125. The manufacture, use, offer for sale, sale, importation, and/or marketing of the Qilu ANDA Product described in Qilu’s ANDA has not infringed, does not infringe, and would not — if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the ’018 patent, either literally or under the doctrine of equivalents.

126. Qilu is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, importation, and/or marketing of the Qilu ANDA Product described in Qilu’s ANDA has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported or

marketed—infringe, either directly or indirectly, any valid or enforceable claim of the ’018 patent, either literally or under the doctrine of equivalents.

COUNT XVII

(Declaratory Judgment of Invalidity of the ’118 Patent)

127. Qilu realleges and incorporates by reference the allegations of paragraphs 1-126 as though full set forth herein.

128. There is an actual, substantial, and continuing case or controversy between Qilu and the Plaintiff/Counterclaim-Defendant regarding *inter alia*, the invalidity of the ’118 patent, and a judicial declaration of invalidity is necessary and appropriate at this time so that the parties may ascertain their respective rights and duties regarding the invalidity of the claims of the ’118 patent.

129. The claims of the ’118 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, or under judicially created bases for invalidation.

130. The claims of the ’118 patent are invalid under 35 U.S.C. § 103 because they would have been obvious to a person of ordinary skill in the art, as set forth in Qilu’s Notice Letter to Plaintiff/Counterclaim-Defendant, because each and every element of each and every claim of the ’118 patent was disclosed expressly in one or more references and/or products which were publicly available before the earliest possible priority date of the ’118 patent, including, but not limited to:

i. Chinese Application No. CN102379845, “Aprepitant Microemulsion for Injection and Preparation Method thereof”;

ii. Swarbrick, J. *et al.*, “Coarse Dispersions,” in Remington: The Science and Practice of Pharmacy, Gennaro, A. (ed), Lippincot, Wilkins & Williams, (2005), pp. 319, 325-326, and 330-331;

iii. Colon-Gonzalez, F., *et al.*, "Pharmacokinetic Evaluation of Fosaprepitant Dimeglumine" Expert Opin Drug Metab Toxicol. (2010); 6(10): 1277–1286;

iv. Toshiaki T., *et al.*, "Pharmacokinetics of aprepitant and dexamethasone after administration of chemotherapeutic agents and effects of plasma substance P concentration on chemotherapy-induced nausea and vomiting in Japanese cancer patients" Cancer Chemother Pharmacol (2011) 68:653–659; and

v. U.S. Patent Publication No. 2011/0038925, "Intravenous Formulations of Neurokinin-1 Antagonists."

131. Pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act, dated September 12, 2016, any person of ordinary skill in the art would have been motivated to combine those references and/or products as of the earliest possible priority date of the '118 patent, and would have had a reasonable expectation of success in doing so.

132. There is no objective evidence of non-obviousness of the claims of the '118 patent, nor would any such evidence, should it exist, have any nexus to the claimed purported inventions of the '118 patent.

133. Qilu is entitled to a judicial declaration that the claims of the '118 patent are invalid.

134. Qilu reserves the right to provide additional bases for invalidity of each claim of the '118 patent in its contentions, responses to discovery requests, expert reports or pleadings filed or served as this action progresses.

COUNT XVIII

(Declaratory Judgment of Noninfringement of the '118 Patent)

135. Qilu realleges and incorporates by reference the allegations of paragraphs 1-134 as though fully set forth herein.

136. There is an actual, substantial, and continuing case or controversy between Qilu and Plaintiff/Counterclaim-Defendant regarding, *inter alia*, non-infringement of the claims of the ’118 patent.

137. The manufacture, use, offer for sale, sale, importation, and/or marketing of the Qilu ANDA Product described in Qilu’s ANDA has not infringed, does not infringe, and would not — if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the ’118 patent, either literally or under the doctrine of equivalents.

138. Qilu is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, importation, and/or marketing of the Qilu ANDA Product described in Qilu’s ANDA has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the ’118 patent, either literally or under the doctrine of equivalents.

COUNT XIX

(Declaratory Judgment of Invalidity of the ’800 Patent)

139. Qilu realleges and incorporates by reference the allegations of paragraphs 1-138 as though full set forth herein.

140. There is an actual, substantial, and continuing case or controversy between Qilu and the Plaintiff/Counterclaim-Defendant regarding *inter alia*, the invalidity of the ’800 patent, and a judicial declaration of invalidity is necessary and appropriate at this time so that the parties may ascertain their respective rights and duties regarding the invalidity of the claims of the ’800 patent.

141. The claims of the ’800 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, or under judicially created bases for invalidation.

142. The claims of the ’800 patent are invalid under 35 U.S.C. § 103 because they would have been obvious to a person of ordinary skill in the art, as set forth in Qilu’s Notice Letter to Plaintiff/Counterclaim-Defendant, because each and every element of each and every claim of the ’800 patent was disclosed expressly in one or more references and/or products which were publicly available before the earliest possible priority date of the ’800 patent, including, but not limited to:

i. Chinese Application No. CN102379845, “Aprepitant Microemulsion for Injection and Preparation Method thereof”;

ii. Swarbrick, J. *et al.*, “Coarse Dispersions,” in Remington: The Science and Practice of Pharmacy, Gennaro, A. (ed), Lippincot, Wilkins & Williams, (2005), pp. 319, 325-326, and 330-331;

iii. Colon-Gonzalez, F., *et al.*, “Pharmacokinetic Evaluation of Fosaprepitant Dimeglumine” Expert Opin Drug Metab. Toxicol. (2010); 6(10): 1277–1286;

iv. Toshiaki T., *et al.*, “Pharmacokinetics of aprepitant and dexamethasone after administration of chemotherapeutic agents and effects of plasma substance P concentration on chemotherapy-induced nausea and vomiting in Japanese cancer patients” Cancer Chemother Pharmacol (2011) 68:653–659; and

v. U.S. Patent Publication No. 2011/0038925, “Intravenous Formulations of Neurokinin-1 Antagonists.”

143. Pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act, dated September 12, 2016, any person of ordinary skill in the art would have been motivated to combine those references and/or products as of the earliest possible priority date of the ’800 patent, and would have had a reasonable expectation of success in doing so.

144. There is no objective evidence of non-obviousness of the claims of the ’800 patent, nor would any such evidence, should it exist, have any nexus to the claimed purported inventions of the ’800 patent.

145. Qilu is entitled to a judicial declaration that the claims of the ’800 patent are invalid.

146. Qilu reserves the right to provide additional bases for invalidity of each claim of the ’800 patent in its contentions, responses to discovery requests, expert reports or pleadings filed or served as this action progresses.

COUNT XX

(Declaratory Judgment of Noninfringement of the ’800 Patent)

147. Qilu realleges and incorporates by reference the allegations of paragraphs 1-146 as though fully set forth herein.

148. There is an actual, substantial, and continuing case or controversy between Qilu and Plaintiff/Counterclaim-Defendant regarding, *inter alia*, non-infringement of the claims of the ’800 patent.

149. The manufacture, use, offer for sale, sale, importation, and/or marketing of the Qilu ANDA Product described in Qilu’s ANDA has not infringed, does not infringe, and would not — if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the ’800 patent, either literally or under the doctrine of equivalents.

150. Qilu is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, importation, and/or marketing of the Qilu ANDA Product described in Qilu’s ANDA has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported or

marketed—infringe, either directly or indirectly, any valid or enforceable claim of the ’800 patent, either literally or under the doctrine of equivalents.

COUNT XXI

(Declaratory Judgment of Invalidity of the ’074 Patent)

151. Qilu realleges and incorporates by reference the allegations of paragraphs 1-150 as though full set forth herein.

152. There is an actual, substantial, and continuing case or controversy between Qilu and the Plaintiff/Counterclaim-Defendant regarding *inter alia*, the invalidity of the ’074 patent, and a judicial declaration of invalidity is necessary and appropriate at this time so that the parties may ascertain their respective rights and duties regarding the invalidity of the claims of the ’074 patent.

153. The claims of the ’074 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, or under judicially created bases for invalidation.

154. The claims of the ’074 patent are invalid under 35 U.S.C. § 103 because they would have been obvious to a person of ordinary skill in the art, as set forth in Qilu’s Notice Letter to Plaintiff/Counterclaim-Defendant, because each and every element of each and every claim of the ’074 patent was disclosed expressly in one or more references and/or products which were publicly available before the earliest possible priority date of the ’074 patent, including, but not limited to:

i. Chinese Application No. CN102379845, “Aprepitant Microemulsion for Injection and Preparation Method thereof”;

ii. Swarbrick, J. *et al.*, “Coarse Dispersions,” in Remington: The Science and Practice of Pharmacy, Gennaro, A. (ed), Lippincot, Wilkins & Williams, (2005), pp. 319, 325-326, and 330-331;

iii. Colon-Gonzalez, F., *et al.*, "Pharmacokinetic Evaluation of Fosaprepitant Dimeglumine" Expert Opin Drug Metab Toxicol. (2010); 6(10): 1277–1286;

iv. Toshiaki T., *et al.*, "Pharmacokinetics of aprepitant and dexamethasone after administration of chemotherapeutic agents and effects of plasma substance P concentration on chemotherapy-induced nausea and vomiting in Japanese cancer patients" Cancer Chemother Pharmacol (2011) 68:653–659; and

v. U.S. Patent Publication No. 2011/0038925, "Intravenous Formulations of Neurokinin-1 Antagonists."

155. Pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act, dated September 12, 2016, any person of ordinary skill in the art would have been motivated to combine those references and/or products as of the earliest possible priority date of the '074 patent, and would have had a reasonable expectation of success in doing so.

156. There is no objective evidence of non-obviousness of the claims of the '074 patent, nor would any such evidence, should it exist, have any nexus to the claimed purported inventions of the '074 patent.

157. Qilu is entitled to a judicial declaration that the claims of the '074 patent are invalid.

158. Qilu reserves the right to provide additional bases for invalidity of each claim of the '074 patent in its contentions, responses to discovery requests, expert reports or pleadings filed or served as this action progresses.

COUNT XXII

(Declaratory Judgment of Noninfringement of the '074 Patent)

159. Qilu realleges and incorporates by reference the allegations of paragraphs 1-158 as though fully set forth herein.

160. There is an actual, substantial, and continuing case or controversy between Qilu and Plaintiff/Counterclaim-Defendant regarding, *inter alia*, non-infringement of the claims of the ’074 patent.

161. The manufacture, use, offer for sale, sale, importation, and/or marketing of the Qilu ANDA Product described in Qilu’s ANDA has not infringed, does not infringe, and would not — if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the ’074 patent, either literally or under the doctrine of equivalents.

162. Qilu is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, importation, and/or marketing of the Qilu ANDA Product described in Qilu’s ANDA has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the ’074 patent, either literally or under the doctrine of equivalents.

COUNT XXIII

(Declaratory Judgment of Invalidity of the ’254 Patent)

163. Qilu realleges and incorporates by reference the allegations of paragraphs 1-162 as though full set forth herein.

164. There is an actual, substantial, and continuing case or controversy between Qilu and the Plaintiff/Counterclaim-Defendant regarding *inter alia*, the invalidity of the ’254 patent, and a judicial declaration of invalidity is necessary and appropriate at this time so that the parties may ascertain their respective rights and duties regarding the invalidity of the claims of the ’254 patent.

165. The claims of the ’254 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, or under judicially created bases for invalidation.

166. The claims of the ’254 patent are invalid under 35 U.S.C. § 103 because they would have been obvious to a person of ordinary skill in the art, as set forth in Qilu’s Notice Letter to Plaintiff/Counterclaim-Defendant, because each and every element of each and every claim of the ’254 patent was disclosed expressly in one or more references and/or products which were publicly available before the earliest possible priority date of the ’254 patent, including, but not limited to:

i. Chinese Application No. CN102379845, “Aprepitant Microemulsion for Injection and Preparation Method thereof”;

ii. Swarbrick, J. *et al.*, “Coarse Dispersions,” in Remington: The Science and Practice of Pharmacy, Gennaro, A. (ed), Lippincot, Wilkins & Williams, (2005), pp. 319, 325-326, and 330-331;

iii. Colon-Gonzalez, F., *et al.*, “Pharmacokinetic Evaluation of Fosaprepitant Dimeglumine” Expert Opin Drug Metab Toxicol. (2010); 6(10): 1277–1286;

iv. Toshiaki T., *et al.*, “Pharmacokinetics of aprepitant and dexamethasone after administration of chemotherapeutic agents and effects of plasma substance P concentration on chemotherapy-induced nausea and vomiting in Japanese cancer patients” Cancer Chemother Pharmacol (2011) 68:653–659; and

v. U.S. Patent Publication No. 2011/0038925, “Intravenous Formulations of Neurokinin-1 Antagonists.”

167. Pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act, dated September 12, 2016, any person of ordinary skill in the art would have been motivated to combine those references and/or products as of the earliest possible priority date of the ’254 patent, and would have had a reasonable expectation of success in doing so.

168. There is no objective evidence of non-obviousness of the claims of the ’254 patent, nor would any such evidence, should it exist, have any nexus to the claimed purported inventions of the ’254 patent.

169. Qilu is entitled to a judicial declaration that the claims of the ’254 patent are invalid.

170. Qilu reserves the right to provide additional bases for invalidity of each claim of the ’254 patent in its contentions, responses to discovery requests, expert reports or pleadings filed or served as this action progresses.

COUNT XXIV

(Declaratory Judgment of Noninfringement of the ’254 Patent)

171. Qilu realleges and incorporates by reference the allegations of paragraphs 1-170 as though fully set forth herein.

172. There is an actual, substantial, and continuing case or controversy between Qilu and Plaintiff/Counterclaim-Defendant regarding, *inter alia*, non-infringement of the claims of the ’254 patent.

173. The manufacture, use, offer for sale, sale, importation, and/or marketing of the Qilu ANDA Product described in Qilu’s ANDA has not infringed, does not infringe, and would not — if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the ’254 patent, either literally or under the doctrine of equivalents.

174. Qilu is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, importation, and/or marketing of the Qilu ANDA Product described in Qilu’s ANDA has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported or

marketed—infringe, either directly or indirectly, any valid or enforceable claim of the ’254 patent, either literally or under the doctrine of equivalents.

COUNT XXV

(Declaratory Judgment of Invalidity of the ’255 Patent)

175. Qilu realleges and incorporates by reference the allegations of paragraphs 1-174 as though full set forth herein.

176. There is an actual, substantial, and continuing case or controversy between Qilu and the Plaintiff/Counterclaim-Defendant regarding *inter alia*, the invalidity of the ’255 patent, and a judicial declaration of invalidity is necessary and appropriate at this time so that the parties may ascertain their respective rights and duties regarding the invalidity of the claims of the ’255 patent.

177. The claims of the ’255 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, or under judicially created bases for invalidation.

178. The claims of the ’255 patent are invalid under 35 U.S.C. § 103 because they would have been obvious to a person of ordinary skill in the art, as set forth in Qilu’s Notice Letter to Plaintiff/Counterclaim-Defendant, because each and every element of each and every claim of the ’255 patent was disclosed expressly in one or more references and/or products which were publicly available before the earliest possible priority date of the ’255 patent, including, but not limited to:

i. Chinese Application No. CN102379845, “Aprepitant Microemulsion for Injection and Preparation Method thereof”;

ii. Swarbrick, J. *et al.*, “Coarse Dispersions,” in Remington: The Science and Practice of Pharmacy, Gennaro, A. (ed), Lippincot, Wilkins & Williams, (2005), pp. 319, 325-326, and 330-331;

iii. Colon-Gonzalez, F., *et al.*, "Pharmacokinetic Evaluation of Fosaprepitant Dimeglumine" Expert Opin Drug Metab Toxicol. (2010); 6(10): 1277–1286;

iv. Toshiaki T., *et al.*, "Pharmacokinetics of aprepitant and dexamethasone after administration of chemotherapeutic agents and effects of plasma substance P concentration on chemotherapy-induced nausea and vomiting in Japanese cancer patients" Cancer Chemother Pharmacol (2011) 68:653–659; and

v. U.S. Patent Publication No. 2011/0038925, "Intravenous Formulations of Neurokinin-1 Antagonists."

179. Pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act, dated September 12, 2016, any person of ordinary skill in the art would have been motivated to combine those references and/or products as of the earliest possible priority date of the '255 patent, and would have had a reasonable expectation of success in doing so.

180. There is no objective evidence of non-obviousness of the claims of the '255 patent, nor would any such evidence, should it exist, have any nexus to the claimed purported inventions of the '255 patent.

181. Qilu is entitled to a judicial declaration that the claims of the '255 patent are invalid.

182. Qilu reserves the right to provide additional bases for invalidity of each claim of the '255 patent in its contentions, responses to discovery requests, expert reports or pleadings filed or served as this action progresses.

COUNT XXVI

(Declaratory Judgment of Noninfringement of the '255 Patent)

183. Qilu realleges and incorporates by reference the allegations of paragraphs 1-182 as though fully set forth herein.

184. There is an actual, substantial, and continuing case or controversy between Qilu and Plaintiff/Counterclaim-Defendant regarding, *inter alia*, non-infringement of the claims of the '255 patent.

185. The manufacture, use, offer for sale, sale, importation, and/or marketing of the Qilu ANDA Product described in Qilu's ANDA has not infringed, does not infringe, and would not — if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the '255 patent, either literally or under the doctrine of equivalents.

186. Qilu is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, importation, and/or marketing of the Qilu ANDA Product described in Qilu's ANDA has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the '255 patent, either literally or under the doctrine of equivalents.

PRAYER FOR RELIEF

WHEREFORE, Qilu respectfully requests that the Court enter judgment in its favor and against Plaintiff/Counterclaim Defendant Heron Therapeutics, Inc. as follows:

A. Dismissing Plaintiff's Complaint, and each and every claim by Plaintiff against Qilu for relief contained therein, with prejudice;

B. Declaring that Qilu does not infringe any valid claim of the Patents-in-Suit, and that the claims of the Patents-in-Suit are invalid for failure to comply with one or more provisions of 35 U.S.C. § 101, *et seq.*;

C. Declaring that the manufacture, use, sale, offer for sale, importation, and/or marketing of the Qilu ANDA Product described in Qilu's ANDA No. 220259 has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported, or marketed—infringe, either directly or indirectly, any valid and/or enforceable claim of the Patents-in-Suit, either literally or under the doctrine of equivalents;

D. Declaring this case exceptional and awarding Qilu reasonable attorneys' fees and costs under 35 U.S.C. § 285;

E. Awarding Qilu its costs and expenses

F. Ordering that Plaintiff/Counterclaim-Defendant and its officers, agents, servants, employees, attorneys, successors and any person who acts in concert or participation with it or any of them, be preliminarily and permanently enjoined from using the Patents-in-Suit to block, hamper, hinder or obstruct FDA approval of the products described in Qilu's ANDA No. 220259; and

G. Awarding Qilu such other and further relief as the Court may deem just and proper.

Dated: June 9, 2025

/s/ Kenneth L. Dorsney
Kenneth L. Dorsney (#3726)
Cortlan S. Hitch (#6720)
MORRIS JAMES LLP
500 Delaware Avenue, Suite 1500
Wilmington, DE 19801
(302) 888-6800
kdorsney@morrisjames.com
chitch@morrisjames.com

Attorneys for Defendants
Qilu Pharmaceutical Co., Ltd.,
Qilu Pharmaceutical (Hainan) Co., Ltd., and
Qilu Pharma, Inc.

OF COUNSEL:

Ian Scott
TAFT STETTINIUS & HOLLISTER LLP
111 East Wacker Drive, Suite 2600
Chicago, IL 60601
(312) 527-4000
iscott@taftlaw.com