IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

HERON THERAPEUTICS, INC.,	)	
	)	
	)	
Plaintiffs,	)	C.A. No. 24-43-WCB
	)	
v.	)	
	)	
MYLAN PHARMACEUTICALS INC.,	)	
	)	
Defendants.	)	

MYLAN PHARMACEUTICALS INC.'S ANSWER,
SEPARATE DEFENSES, AND COUNTERCLAIMS TO COMPLAINT

Mylan Pharmaceuticals Inc. ("MPI"), by its undersigned attorneys, answers and responds to each of the allegations of Plaintiff Heron Therapeutics, Inc. ("Heron") as follows:

THE PARTIES

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

ANSWER: MPI is without knowledge or information sufficient to form a belief as to the allegations set forth in Paragraph 1 and, therefore, denies them.

2. Upon information and belief, Mylan is a corporation organized and existing under the laws of the State of West Virginia, having a place of business at 3711 Collins Ferry Road, Morgantown, West Virginia 26505.

ANSWER: Admitted.

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

ANSWER: MPI admits that it develops and manufactures pharmaceutical products. MPI denies the remaining allegations set forth in Paragraph 3.

NATURE OF THE ACTION

4. 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"), and 11,744,800 ("the '800 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 4 states legal conclusions to which no answer is required. To the extent an answer is required, MPI admits that the Complaint purports to state a cause of action for patent infringement under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq*. MPI denies the remaining allegations set forth in Paragraph 4.

JURISDICTION & VENUE

5. 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 5 states legal conclusions to which no answer is required. To the extent an answer is required, MPI does not dispute the Court's subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a). MPI denies the remaining allegations set forth in Paragraph 5.

6. This Court has personal jurisdiction over Mylan. On information and belief, Mylan intends to market, sell, and/or distribute generic pharmaceutical drug products within this state and to residents of this state, including the generic drug product that is the subject of ANDA No. 218851. The submission of ANDA No. 218851 and the marketing, offer for sale, sale, distribution, and/or importation of the generic drug product that is the subject of ANDA No. 218851 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, Mylan 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. Additionally, on information and belief, Mylan is registered to do business in Delaware (File No. 4809319) and has appointed an agent in Delaware to receive service of process. This Court further has personal jurisdiction over Mylan for other reasons that will be presented to the Court if jurisdiction is challenged.

ANSWER: Paragraph 6 states legal conclusions to which no answer is required. To the extent an answer is required, MPI does not dispute jurisdiction for purposes of this litigation only. MPI denies the remaining allegations set forth in Paragraph 6.

7. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400. Venue is proper in this district with respect to Mylan for the reasons set forth above, including because Mylan has committed acts of infringement in this judicial district, and, upon information and belief, Mylan will commit further acts of infringement in this judicial district. Venue is proper with respect to Mylan for other reasons that will be presented to the Court if venue is challenged.

ANSWER: Paragraph 7 states legal conclusions to which no answer is required. To the extent an answer is required, MPI does not dispute venue for purposes of this litigation only. MPI denies the remaining allegations set forth in Paragraph 7.

THE PATENTS-IN-SUIT

8. 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: MPI admits that a purported copy of the ’229 patent is attached to the Complaint as Exhibit A. MPI further admits that, on its face, the ’229 patent is titled “Emulsion Formulations of Aprepitant,” bears an issuance date of February 7, 2017, and identifies Heron as an assignee. MPI is without knowledge or information sufficient to form a belief as to the remaining allegations set forth in Paragraph 8 and, therefore, denies them.

9. 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: MPI admits that a purported copy of the ’465 patent is attached to the Complaint as Exhibit B. MPI further admits that, on its face, the ’465 patent is titled “Emulsion Formulations of Aprepitant,” bears an issuance date of November 7, 2017, and identifies Heron as an assignee.

MPI is without knowledge or information sufficient to form a belief as to the remaining allegations set forth in Paragraph 9 and, therefore, denies them.

10. 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: MPI admits that a purported copy of the '742 patent is attached to the Complaint as Exhibit C. MPI further admits that, on its face, the '742 patent is titled "Emulsion Formulations of an NK-1 Receptor Antagonist and Uses Thereof," bears an issuance date of May 22, 2018, and identifies Heron as an assignee. MPI is without knowledge or information sufficient to form a belief as to the remaining allegations set forth in Paragraph 10 and, therefore, denies them.

11. 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: MPI admits that a purported copy of the '793 patent is attached to the Complaint as Exhibit D. MPI further admits that, on its face, the '793 patent is titled "Emulsion Formulations of Aprepitant," bears an issuance date of May 22, 2018, and identifies Heron as an assignee. MPI is without knowledge or information sufficient to form a belief as to the remaining allegations set forth in Paragraph 11 and, therefore, denies them.

12. 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: MPI admits that a purported copy of the '794 patent is attached to the Complaint as Exhibit E. MPI further admits that, on its face, the '794 patent is titled "Emulsion Formulations of Aprepitant," bears an issuance date of May 22, 2018, and identifies Heron as an assignee. MPI is without knowledge or information sufficient to form a belief as to the remaining allegations set forth in Paragraph 12 and, therefore, denies them.

13. 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: MPI admits that a purported copy of the ’208 patent is attached to the Complaint as Exhibit F. MPI further admits that, on its face, the ’208 patent is titled “Emulsion Formulations of Aprepitant,” bears an issuance date of December 10, 2019, and identifies Heron as an assignee. MPI is without knowledge or information sufficient to form a belief as to the remaining allegations set forth in Paragraph 13 and, therefore, denies them.

14. 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: MPI admits that a purported copy of the ’850 patent is attached to the Complaint as Exhibit G. MPI further admits that, on its face, the ’850 patent is titled “Emulsion Formulations of an NK-1 Receptor Antagonist and Uses Thereof,” bears an issuance date of April 21, 2020, and identifies Heron as an assignee. MPI is without knowledge and information to form a belief as to the remaining allegations of Paragraph 14 and, therefore, denies them.

15. 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: MPI admits that a purported copy of the ’018 patent is attached to the Complaint as Exhibit H. MPI further admits that, on its face, the ’018 patent is titled “Emulsion Formulations of Aprepitant,” bears an issuance date of March 23, 2021, and identifies Heron as an assignee. MPI is without knowledge or information sufficient to form a belief as to the remaining allegations set forth in Paragraph 15 and, therefore, denies them.

16. 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: MPI admits that a purported copy of the '118 patent is attached to the Complaint as Exhibit I. MPI further admits that, on its face, the '118 patent is titled "Emulsion Formulations of an NK-1 Receptor Antagonist and Uses Thereof," bears an issuance date of November 16, 2021, and identifies Heron as an assignee. MPI is without knowledge or information sufficient to form a belief as to the remaining allegations set forth in Paragraph 16 and, therefore, denies them.

17. 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: MPI admits that a purported copy of the '800 patent is attached to the Complaint as Exhibit I. MPI further admits that, on its face, the '800 patent is titled "Methods of Use of Emulsion Formulations of an NK-1 Receptor Antagonist," bears an issuance date of September 5, 2023, and identifies Heron as an assignee. MPI is without knowledge or information sufficient to form a belief as to the remaining allegations set forth in Paragraph 17 and, therefore, denies them.

ACTS GIVING RISE TO THIS ACTION

18. 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: MPI admits that Heron is listed in FDA's publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") as the holder of NDA No. 216457 for an injectable emulsion for intravenous use containing 32mg/4.4mL (7.2 mg/mL) aprepitant as the active ingredient, indicating an approval date of September 16, 2022. MPI further admits that the electronic version of the Orange Book lists Aponvie® as the brand name for this injectable emulsion. MPI is without knowledge or information sufficient to form a belief as to the remaining allegations set forth in Paragraph 18 and, therefore, denies them.

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

ANSWER: MPI admits that the Full Prescribing Information for Aponvie® (aprepitant) injectable emulsion, revised 09/2022, states that "APONVIE is a substance P/neurokinin-1 (NK_1) receptor antagonist, indicated for the prevention of postoperative nausea and vomiting (PONV) in adults." MPI is without knowledge or information sufficient to form a belief as to the remaining allegations set forth in Paragraph 19 and, therefore, denies them.

20. 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 20 states legal conclusions to which no answer is required. To the extent an answer is required, MPI admits that the Orange Book currently lists the patents-in-suit in conjunction with NDA 216457 for Aponvie®. MPI denies the remaining allegations set forth in Paragraph 20.

21. Upon information and belief, Mylan submitted ANDA No. 218851 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 Mylan Generic Product") prior to the expiration of the patents-in-suit.

ANSWER: MPI admits that it submitted ANDA No. 218851 to FDA seeking approval for an injectable emulsion containing 32mg/4.4mL (7.2 mg/mL) aprepitant. MPI denies the remaining allegations set forth in Paragraph 21.

22. Upon information and belief, by filing ANDA No. 218851, Mylan has certified to the FDA that the Mylan 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: MPI admits that ANDA No. 218851 refers to Aponvie® as the reference listed drug. MPI denies the remaining allegations set forth in Paragraph 22.

23. Upon information and belief, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), Mylan certified in ANDA No. 218851 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 Mylan Generic Product.

ANSWER: MPI admits that ANDA No. 218851 included a Paragraph IV certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) as to the patents-in-suit. MPI denies the remaining allegations set forth in Paragraph 23.

24. On December 18, 2023, Heron received written notification of Mylan's ANDA No. 218851 and its accompanying § 505(j)(2)(A)(vii)(IV) certification by FedEx®470 F. Supp. 2d 435 [*sic*] in a Paragraph IV Certification Notice Letter dated December 15, 2023 ("Mylan's Notice Letter").

ANSWER: MPI admits that it sent a Notice Letter dated December 15, 2023, and, on information and belief, it was delivered via FedEx® on December 18, 2023 to Heron. MPI denies the remaining allegations set forth in Paragraph 24.

25. Upon information and belief, the proposed Mylan 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.

ANSWER: Paragraph 25 contains a legal conclusion to which no answer is required. To the extent an answer is required, MPI denies the allegations set forth in Paragraph 25.

26. This action was filed within 45 days of Heron receiving Mylan's Notice Letter.

ANSWER: MPI admits that it sent a Notice Letter dated December 15, 2023, and, on information and belief, it was delivered on December 18, 2023 to Heron, and that Heron filed suit on January 11, 2023. MPI denies the remaining allegations set forth in Paragraph 25.

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

27. Heron re-alleges paragraphs 1-26 as if fully set forth herein.

ANSWER: MPI incorporates by reference its responses to Paragraphs 1-26 as if fully set forth herein.

28. Mylan's submission of ANDA No. 218851 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 28 contains a legal conclusion to which no answer is required. To the extent an answer is required, MPI denies the allegations set forth in Paragraph 28.

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

ANSWER: Paragraph 29 contains a legal conclusion to which no answer is required. To the extent an answer is required, MPI denies the allegations set forth in Paragraph 29.

30. Upon information and belief, Mylan 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 Mylan Generic Product if it receives FDA approval of ANDA No. 218851.

ANSWER: MPI is without knowledge or information sufficient to form a belief as to the allegations set forth in Paragraph 30 and, therefore, denies them.

31. 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 Mylan 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 31 contains a legal conclusion to which no answer is required. To the extent an answer is required, MPI denies the allegations set forth in Paragraph 31.

32. In Mylan's Notice Letter, Mylan 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: MPI states that its Notice Letter speaks for itself. MPI denies the remaining allegations set forth in Paragraph 32.

33. Heron is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval or Mylan's ANDA No. 218851 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 33 contains a legal conclusion to which no answer is required. To the extent an answer is required, MPI denies that Heron is entitled to the relief described in Paragraph 33.

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

ANSWER: Paragraph 34 contains a legal conclusion to which no answer is required. To the extent an answer is required, MPI denies that Heron is entitled to the declaration described in Paragraph 34.

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

ANSWER: Paragraph 35 contains legal conclusions to which no answer is required. To the extent an answer is required, MPI denies the allegations set forth in Paragraph 35.

36. Upon information and belief, Mylan was aware of the existence of the '229 patent and was aware that the filing of ANDA No. 218851 and the certification with respect to the '229 patent constituted an act of infringement of that patent.

ANSWER: Paragraph 36 contains legal conclusions to which no answer is required. To the extent an answer is required, MPI admits that ANDA No. 218851 included a Paragraph IV certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) as to the '229 patent. MPI denies the remaining allegations set forth in Paragraph 36.

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

37. Heron re-alleges paragraphs 1-36 as if fully set forth herein.

ANSWER: MPI incorporates by reference its responses to Paragraphs 1-36 as if fully set forth herein.

38. Mylan's submission of ANDA No. 218851 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 38 contains a legal conclusion to which no answer is required. To the extent an answer is required, MPI denies the allegations set forth in Paragraph 38.

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

ANSWER: Paragraph 39 contains a legal conclusion to which no answer is required. To the extent an answer is required, MPI denies the allegations set forth in Paragraph 39.

40. Upon information and belief, Mylan 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 Mylan Generic Product if it receives FDA approval of ANDA No. 218851.

ANSWER: MPI is without knowledge or information sufficient to form a belief as to the allegations set forth in Paragraph 40 and, therefore, denies them.

41. 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 Mylan 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 41 contains a legal conclusion to which no answer is required. To the extent an answer is required, MPI denies the allegations set forth in Paragraph 41.

42. In Mylan's Notice Letter, Mylan 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: MPI states that its Notice Letter speaks for itself. MPI denies the remaining allegations set forth in Paragraph 42.

43. Heron is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval or Mylan's ANDA No. 218851 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 43 contains a legal conclusion to which no answer is required. To the extent an answer is required, MPI denies that Heron is entitled to the relief described in Paragraph 43.

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

ANSWER: Paragraph 44 contains a legal conclusion to which no answer is required. To the extent an answer is required, MPI denies that Heron is entitled to the declaration described in Paragraph 44.

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

ANSWER: Paragraph 45 contains legal conclusions to which no answer is required. To the extent an answer is required, MPI denies the allegations set forth in Paragraph 45.

46. Upon information and belief, Mylan was aware of the existence of the '465 patent and was aware that the filing of ANDA No. 218851 and the certification with respect to the '465 patent constituted an act of infringement of that patent.

ANSWER: Paragraph 46 contains legal conclusions to which no answer is required. To the extent an answer is required, MPI admits that ANDA No. 218851 included a Paragraph IV certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) as to the '465 patent. MPI denies the remaining allegations set forth in Paragraph 46.

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

47. Heron re-alleges paragraphs 1-46 as if fully set forth herein.

ANSWER: MPI incorporates by reference its responses to Paragraphs 1-46 as if fully set forth herein.

48. Mylan's submission of ANDA No. 218851 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 48 contains a legal conclusion to which no answer is required. To the extent an answer is required, MPI denies the allegations set forth in Paragraph 48.

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

ANSWER: Paragraph 49 contains a legal conclusion to which no answer is required. To the extent an answer is required, MPI denies the allegations set forth in Paragraph 49.

50. Upon information and belief, Mylan 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 Mylan Generic Product if it receives FDA approval of ANDA No. 218851.

ANSWER: MPI is without knowledge or information sufficient to form a belief as to the allegations set forth in Paragraph 50 and, therefore, denies them.

51. 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 Mylan 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 51 contains a legal conclusion to which no answer is required. To the extent an answer is required, MPI denies the allegations set forth in Paragraph 51.

52. In Mylan's Notice Letter, Mylan did not set forth an opinion of noninfringement for the claims of the '742 patent separate and apart from any assertions of obviousness of those claims.

ANSWER: MPI states that its Notice Letter speaks for itself. MPI denies the remaining allegations set forth in Paragraph 52.

53. Heron is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval or Mylan's ANDA No. 218851 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 53 contains a legal conclusion to which no answer is required. To the extent an answer is required, MPI denies that Heron is entitled to the relief described in Paragraph 53.

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

ANSWER: Paragraph 54 contains a legal conclusion to which no answer is required. To the extent an answer is required, MPI denies that Heron is entitled to the declaration described in Paragraph 54.

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

ANSWER: Paragraph 55 contains legal conclusions to which no answer is required. To the extent an answer is required, MPI denies the allegations set forth in Paragraph 55.

56. Upon information and belief, Mylan was aware of the existence of the '742 patent and was aware that the filing of ANDA No. 218851 and the certification with respect to the '742 patent constituted an act of infringement of that patent.

ANSWER: Paragraph 56 contains legal conclusions to which no answer is required. To the extent an answer is required, MPI admits that ANDA No. 218851 included a Paragraph IV certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) as to the '742 patent. MPI denies the remaining allegations set forth in Paragraph 56.

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

57. Heron re-alleges paragraphs 1-56 as if fully set forth herein.

ANSWER: MPI incorporates by reference its responses to Paragraphs 1-56 as if fully set forth herein.

58. Mylan's submission of ANDA No. 218851 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 58 contains a legal conclusion to which no answer is required. To the extent an answer is required, MPI denies the allegations set forth in Paragraph 58.

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

ANSWER: Paragraph 59 contains a legal conclusion to which no answer is required. To the extent an answer is required, MPI denies the allegations set forth in Paragraph 59.

60. Upon information and belief, Mylan 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 Mylan Generic Product if it receives FDA approval of ANDA No. 218851.

ANSWER: MPI is without knowledge or information sufficient to form a belief as to the allegations set forth in Paragraph 60 and, therefore, denies them.

61. 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 Mylan 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 61 contains a legal conclusion to which no answer is required. To the extent an answer is required, MPI denies the allegations set forth in Paragraph 61.

62. In Mylan's Notice Letter, Mylan 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: MPI states that its Notice Letter speaks for itself. MPI denies the remaining allegations set forth in Paragraph 62.

63. Heron is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval or Mylan's ANDA No. 218851 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 63 contains a legal conclusion to which no answer is required. To the extent an answer is required, MPI denies that Heron is entitled to the relief described in Paragraph 63.

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

ANSWER: Paragraph 64 contains a legal conclusion to which no answer is required. To the extent an answer is required, MPI denies that Heron is entitled to the declaration described in Paragraph 64.

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

ANSWER: Paragraph 65 contains legal conclusions to which no answer is required. To the extent an answer is required, MPI denies the allegations set forth in Paragraph 65.

66. Upon information and belief, Mylan was aware of the existence of the '793 patent and was aware that the filing of ANDA No. 218851 and the certification with respect to the '793 patent constituted an act of infringement of that patent.

ANSWER: Paragraph 66 contains legal conclusions to which no answer is required. To the extent an answer is required, MPI admits that ANDA No. 218851 included a Paragraph IV certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) as to the '793 patent. MPI denies the remaining allegations set forth in Paragraph 66.

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

67. Heron re-alleges paragraphs 1-66 as if fully set forth herein.

ANSWER: MPI incorporates by reference its responses to Paragraphs 1-66 as if fully set forth herein.

68. Mylan's submission of ANDA No. 218851 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 68 contains a legal conclusion to which no answer is required. To the extent an answer is required, MPI denies the allegations set forth in Paragraph 68.

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

ANSWER: Paragraph 69 contains a legal conclusion to which no answer is required. To the extent an answer is required, MPI denies the allegations set forth in Paragraph 69.

70. Upon information and belief, Mylan 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 Mylan Generic Product if it receives FDA approval of ANDA No. 218851.

ANSWER: MPI is without knowledge or information sufficient to form a belief as to the allegations set forth in Paragraph 70 and, therefore, denies them.

71. 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 Mylan 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 71 contains a legal conclusion to which no answer is required. To the extent an answer is required, MPI denies the allegations set forth in Paragraph 71.

72. In Mylan's Notice Letter, Mylan 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: MPI states that its Notice Letter speaks for itself. MPI denies the remaining allegations set forth in Paragraph 72.

73. Heron is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval or Mylan's ANDA No. 218851 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 73 contains a legal conclusion to which no answer is required. To the extent an answer is required, MPI denies that Heron is entitled to the relief described in Paragraph 73.

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

ANSWER: Paragraph 74 contains a legal conclusion to which no answer is required. To the extent an answer is required, MPI denies that Heron is entitled to the declaration described in Paragraph 74.

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

ANSWER: Paragraph 75 contains legal conclusions to which no answer is required. To the extent an answer is required, MPI denies the allegations set forth in Paragraph 75.

76. Upon information and belief, Mylan was aware of the existence of the '794 patent and was aware that the filing of ANDA No. 218851 and the certification with respect to the '794 patent constituted an act of infringement of that patent.

ANSWER: Paragraph 76 contains legal conclusions to which no answer is required. To the extent an answer is required, MPI admits that ANDA No. 218851 included a Paragraph IV certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) as to the '794 patent. MPI denies the remaining allegations set forth in Paragraph 76.

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

77. Heron re-alleges paragraphs 1-76 as if fully set forth herein.

ANSWER: MPI incorporates by reference its responses to Paragraphs 1-76 as if fully set forth herein.

78. Mylan's submission of ANDA No. 218851 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 78 contains a legal conclusion to which no answer is required. To the extent an answer is required, MPI denies the allegations set forth in Paragraph 78.

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

ANSWER: Paragraph 79 contains a legal conclusion to which no answer is required. To the extent an answer is required, MPI denies the allegations set forth in Paragraph 79.

80. Upon information and belief, Mylan 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 Mylan Generic Product if it receives FDA approval of ANDA No. 218851.

ANSWER: MPI is without knowledge or information sufficient to form a belief as to the allegations set forth in Paragraph 80 and, therefore, denies them.

81. 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 Mylan 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 81 contains a legal conclusion to which no answer is required. To the extent an answer is required, MPI denies the allegations set forth in Paragraph 81.

82. In Mylan's Notice Letter, Mylan 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: MPI states that its Notice Letter speaks for itself. MPI denies the remaining allegations set forth in Paragraph 82.

83. Heron is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval or Mylan's ANDA No. 218851 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 83 contains a legal conclusion to which no answer is required. To the extent an answer is required, MPI denies that Heron is entitled to the relief described in Paragraph 83.

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

ANSWER: Paragraph 84 contains a legal conclusion to which no answer is required. To the extent an answer is required, MPI denies that Heron is entitled to the declaration described in Paragraph 84.

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

ANSWER: Paragraph 85 contains legal conclusions to which no answer is required. To the extent an answer is required, MPI denies the allegations set forth in Paragraph 85.

86. Upon information and belief, Mylan was aware of the existence of the '208 patent and was aware that the filing of ANDA No. 218851 and the certification with respect to the '208 patent constituted an act of infringement of that patent.

ANSWER: Paragraph 86 contains legal conclusions to which no answer is required. To the extent an answer is required, MPI admits that ANDA No. 218851 included a Paragraph IV certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) as to the '208 patent. MPI denies the remaining allegations set forth in Paragraph 86.

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

87. Heron re-alleges paragraphs 1-86 as if fully set forth herein.

ANSWER: MPI incorporates by reference its responses to Paragraphs 1-86 as if fully set forth herein.

88. Mylan's submission of ANDA No. 218851 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 88 contains a legal conclusion to which no answer is required. To the extent an answer is required, MPI denies the allegations set forth in Paragraph 88.

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

ANSWER: Paragraph 89 contains a legal conclusion to which no answer is required. To the extent an answer is required, MPI denies the allegations set forth in Paragraph 89.

90. Upon information and belief, Mylan 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 Mylan Generic Product if it receives FDA approval of ANDA No. 218851.

ANSWER: MPI is without knowledge or information sufficient to form a belief as to the allegations set forth in Paragraph 90 and, therefore, denies them.

91. 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 Mylan 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 91 contains a legal conclusion to which no answer is required. To the extent an answer is required, MPI denies the allegations set forth in Paragraph 91.

92. In Mylan's Notice Letter, Mylan did not set forth an opinion of noninfringement for the claims of the '850 patent separate and apart from any assertions of obviousness of those claims.

ANSWER: MPI states that its Notice Letter speaks for itself. MPI denies the remaining allegations set forth in Paragraph 92.

93. Heron is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval or Mylan's ANDA No. 218851 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 93 contains a legal conclusion to which no answer is required. To the extent an answer is required, MPI denies that Heron is entitled to the relief described in Paragraph 93.

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

ANSWER: Paragraph 94 contains a legal conclusion to which no answer is required. To the extent an answer is required, MPI denies that Heron is entitled to the declaration described in Paragraph 94.

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

ANSWER: Paragraph 95 contains legal conclusions to which no answer is required. To the extent an answer is required, MPI denies the allegations set forth in Paragraph 95.

96. Upon information and belief, Mylan was aware of the existence of the '850 patent and was aware that the filing of ANDA No. 218851 and the certification with respect to the '850 patent constituted an act of infringement of that patent.

ANSWER: Paragraph 96 contains legal conclusions to which no answer is required. To the extent an answer is required, MPI admits that ANDA No. 218851 included a Paragraph IV certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) as to the '850 patent. MPI denies the remaining allegations set forth in Paragraph 96.

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

97. Heron re-alleges paragraphs 1-96 as if fully set forth herein.

ANSWER: MPI incorporates by reference its responses to Paragraphs 1-96 as if fully set forth herein.

98. Mylan's submission of ANDA No. 218851 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 98 contains a legal conclusion to which no answer is required. To the extent an answer is required, MPI denies the allegations set forth in Paragraph 98.

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

ANSWER: Paragraph 99 contains a legal conclusion to which no answer is required. To the extent an answer is required, MPI denies the allegations set forth in Paragraph 99.

100. Upon information and belief, Mylan 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 Mylan Generic Product if it receives FDA approval of ANDA No. 218851.

ANSWER: MPI is without knowledge or information sufficient to form a belief as to the allegations set forth in Paragraph 100 and, therefore, denies them.

101. 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 Mylan 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 101 contains a legal conclusion to which no answer is required. To the extent an answer is required, MPI denies the allegations set forth in Paragraph 101.

102. In Mylan's Notice Letter, Mylan 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: MPI states that its Notice Letter speaks for itself. MPI denies the remaining allegations set forth in Paragraph 102.

103. Heron is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval or Mylan's ANDA No. 218851 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 103 contains a legal conclusion to which no answer is required. To the extent an answer is required, MPI denies that Heron is entitled to the relief described in Paragraph 103.

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

ANSWER: Paragraph 104 contains a legal conclusion to which no answer is required. To the extent an answer is required, MPI denies that Heron is entitled to the declaration described in Paragraph 104.

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

ANSWER: Paragraph 105 contains legal conclusions to which no answer is required. To the extent an answer is required, MPI denies the allegations set forth in Paragraph 105.

106. Upon information and belief, Mylan was aware of the existence of the '018 patent and was aware that the filing of ANDA No. 218851 and the certification with respect to the '018 patent constituted an act of infringement of that patent.

ANSWER: Paragraph 106 contains legal conclusions to which no answer is required. To the extent an answer is required, MPI admits that ANDA No. 218851 included a Paragraph IV certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) as to the '018 patent. MPI denies the remaining allegations set forth in Paragraph 106.

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

107. Heron re-alleges paragraphs 1-106 as if fully set forth herein.

ANSWER: MPI incorporates by reference its responses to Paragraphs 1-106 as if fully set forth herein.

108. Mylan's submission of ANDA No. 218851 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 108 contains a legal conclusion to which no answer is required. To the extent an answer is required, MPI denies the allegations set forth in Paragraph 108.

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

ANSWER: Paragraph 109 contains a legal conclusion to which no answer is required. To the extent an answer is required, MPI denies the allegations set forth in Paragraph 109.

110. Upon information and belief, Mylan 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 Mylan Generic Product if it receives FDA approval of ANDA No. 218851.

ANSWER: MPI is without knowledge or information sufficient to form a belief as to the allegations set forth in Paragraph 110 and, therefore, denies them.

111. 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 Mylan 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 111 contains a legal conclusion to which no answer is required. To the extent an answer is required, MPI denies the allegations set forth in Paragraph 111.

112. In Mylan's Notice Letter, Mylan did not set forth an opinion of noninfringement for the claims of the '118 patent separate and apart from any assertions of obviousness of those claims

ANSWER: MPI states that its Notice Letter speaks for itself. MPI denies the remaining allegations set forth in Paragraph 112.

113. Heron is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval or Mylan's ANDA No. 218851 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.

ANSWER: Paragraph 113 contains a legal conclusion to which no answer is required. To the extent an answer is required, MPI denies that Heron is entitled to the relief described in Paragraph 113.

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

ANSWER: Paragraph 114 contains a legal conclusion to which no answer is required. To the extent an answer is required, MPI denies that Heron is entitled to the declaration described in Paragraph 114.

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

ANSWER: Paragraph 115 contains legal conclusions to which no answer is required. To the extent an answer is required, MPI denies the allegations set forth in Paragraph 115.

116. Upon information and belief, Mylan was aware of the existence of the ’118 patent and was aware that the filing of ANDA No. 218851 and the certification with respect to the ’118 patent constituted an act of infringement of that patent.

ANSWER: Paragraph 116 contains legal conclusions to which no answer is required. To the extent an answer is required, MPI admits that ANDA No. 218851 included a Paragraph IV certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) as to the ’118 patent. MPI denies the remaining allegations set forth in Paragraph 116.

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

117. Heron re-alleges paragraphs 1-116 as if fully set forth herein.

ANSWER: MPI incorporates by reference its responses to Paragraphs 1-116 as if fully set forth herein.

118. Mylan's submission of ANDA No. 218851 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 118 contains a legal conclusion to which no answer is required. To the extent an answer is required, MPI denies the allegations set forth in Paragraph 118.

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

ANSWER: Paragraph 119 contains a legal conclusion to which no answer is required. To the extent an answer is required, MPI denies the allegations set forth in Paragraph 119.

120. Upon information and belief, Mylan 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 Mylan Generic Product if it receives FDA approval of ANDA No. 218851.

ANSWER: MPI is without knowledge or information sufficient to form a belief as to the allegations set forth in Paragraph 120 and, therefore, denies them.

121. 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 Mylan 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 121 contains a legal conclusion to which no answer is required. To the extent an answer is required, MPI denies the allegations set forth in Paragraph 121.

122. In Mylan's Notice Letter, Mylan 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: MPI states that its Notice Letter speaks for itself. MPI denies the remaining allegations set forth in Paragraph 122.

123. Heron is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval or Mylan's ANDA No. 218851 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 123 contains a legal conclusion to which no answer is required. To the extent an answer is required, MPI denies that Heron is entitled to the relief described in Paragraph 123.

124. Heron is entitled to a declaration that, if Mylan commercially manufactures, uses, offers for sale, and/or sells the proposed Mylan Generic Product within the United States, imports the proposed Mylan Generic Product into the United States, and/or induces and/or contributes to such conduct, Mylan will infringe one or more claims of the '800 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Paragraph 124 contains a legal conclusion to which no answer is required. To the extent an answer is required, MPI denies that Heron is entitled to the declaration described in Paragraph 124.

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

ANSWER: Paragraph 125 contains legal conclusions to which no answer is required. To the extent an answer is required, MPI denies the allegations set forth in Paragraph 125.

126. Upon information and belief, Mylan was aware of the existence of the '800 patent and was aware that the filing of ANDA No. 218851 and the certification with respect to the '800 patent constituted an act of infringement of that patent.

ANSWER: Paragraph 126 contains legal conclusions to which no answer is required. To the extent an answer is required, MPI admits that ANDA No. 218851 included a Paragraph IV certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) as to the '800 patent. MPI denies the remaining allegations set forth in Paragraph 126.

RESPONSE TO PLAINTIFF'S PRAYER FOR RELIEF

MPI denies that Heron is entitled to the relief requested in the Complaint or to any relief whatsoever. All remaining allegations not specifically admitted herein are denied.

SEPARATE DEFENSES

Without prejudice to the denials set forth in its Answer and without admitting any allegations of the Complaint not expressly admitted, MPI asserts the following separate defenses to the Complaint without assuming the burden of proof on any such defense that would otherwise rest with Heron.

FIRST SEPARATE DEFENSE

The Complaint fails to state a claim upon which relief can be granted.

SECOND SEPARATE DEFENSE

The claims of the ’229, ’465, ’742, ’793, ’794, ’208, ’850, ’018,’118, and ’800 patents are invalid and/or unenforceable for failure to satisfy the requirements of Title 35 of the United States Code, including, without limitation, one or more of 35 U.S.C. §§ 101, 102, 103, 112, and/or double patenting for at least the reasons stated in MPI’s Notice Letter, which is incorporated here by reference.

THIRD SEPARATE DEFENSE

MPI has not infringed, is not infringing, and will not infringe, directly or indirectly, any valid or enforceable claim of the ’229, ’465, ’742, ’793, ’794, ’208, ’850, ’018, ’118, and ’800 patents, either literally or under the doctrine of equivalents. The manufacture, use, sale, offer for sale, or importation of the products that are the subject of ANDA No. 218851 has not infringed, does not infringe, and would not, if marketed, manufactured, used, sold, offered for sale, or imported into the United States, infringe any valid, enforceable claim of the patents-in-suit.

FOURTH SEPARATE DEFENSE

MPI’s activities performed by MPI in relation to its ANDA No. 218851 have solely been for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs. *See* 35 U.S.C. § 271(e)(1).

FIFTH SEPARATE DEFENSE

Neither the filing of MPI's ANDA No. 218851 nor MPI's actions defending this case give rise to an exceptional case under 35 U.S.C. § 285.

SIXTH SEPARATE DEFENSE

The Complaint fails to establish this Court's subject matter jurisdiction over any claim brought pursuant to 35 U.S.C. §§ 271(a), (b), (c), and/or (g).

SEVENTH SEPARATE DEFENSE

Heron is not entitled to any injunctive relief, preliminary, permanent, or otherwise, including at least because Heron cannot show irreparable harm.

EIGHTH SEPARATE DEFENSE

MPI reserves all defenses, at law or equity, which may now exist or in the future be available on discovery and further factual investigation in this case, including, without limitation, all defenses governed by Rules 8, 9, and 12 of the Federal Rules of Civil Procedure. MPI further reserves the right to supplement and/or amend these defenses.

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COUNTERCLAIMS

Counterclaim Plaintiff, Mylan Pharmaceuticals Inc. ("MPI"), by and through its undersigned attorneys, hereby asserts the following counterclaims against Counterclaim Defendant Heron Therapeutics, Inc. ("Heron") for declaratory judgment that the claims of U.S. Patent Nos. 10,828,310 ("'229 patent"); 9,808,465 ("'465 patent"); 9,974,742 ("'742 patent"); 9,974,793 ("'793 patent"); 9,974,794 ("'794 patent"); 10,500,208 ("'208 patent"); 10,624,850 ("'850 patent"); 10,953,018 ("'018 patent"); 11,173,118 ("'118 patent"), and 11,744,800 ("'800 patent") are not infringed and/or invalid.

THE PARTIES

1. MPI is a corporation organized and existing under the laws of the State of West Virginia, having its principal place of business at 3711 Collins Ferry Road, Morgantown, West Virginia 26505.

2. On information and belief, and according to Heron's allegations in the Complaint, Heron is a corporation organized and existing under the laws of Delaware, having a place of business at 4242 Campus Point Court, Suite 200, San Diego, California 92121.

NATURE OF THE ACTION

3. MPI seeks declaratory judgment that the claims of the '229, '465, '742, '793, '794, '208, '850, '018,'118, and '800 patents are not infringed and/or invalid.

JURISDICTION AND VENUE

4. These counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.* and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

5. The Court has jurisdiction over the subject matter of these counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202 because Heron commenced and continues to maintain this action in this judicial district.

6. Further, the Court has jurisdiction over the subject matter of these counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202 because there is an immediate and real controversy regarding the validity of the '229, '465, '742, '793, '794, '208, '850, '018, '118 and '800 patents.

7. The Court has personal jurisdiction over Heron for purposes of these counterclaims at least because Heron commenced and continues to maintain this action in this judicial district.

8. Venue is proper in this judicial district for purposes of these counterclaims at least because Heron commenced and continues to maintain this action in this judicial district.

BACKGROUND

9. Heron has alleged in the instant action that it owns the '229, '465, '742, '793, '794, '208, '850, '018, '118 and '800 patents.

10. On information and belief, and according to Heron's allegations in the Complaint, 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.

11. MPI submitted Abbreviated New Drug Application ("ANDA") No. 218851 to the United States Food and Drug Administration ("FDA") seeking approval for its injectable emulsion containing 32mg/4.4mL (7.2 mg/mL) aprepitant ("MPI's ANDA Product").

12. In accordance with 21 U.S.C. § 355(j)(2)(B), MPI timely notified Heron in writing (the "Notice Letter") that ANDA No. 218851 had been filed with a certification provided for in 21 U.S.C. § 355(j)(2)(A)(vii)(IV) regarding the '229, '465, '742, '793, '794, '208, '850, '018, '118, and '800 patents.

13. In accordance with 21 U.S.C. § 355(j)(2)(B), the Notice Letter included a detailed statement of the factual and legal basis for the certification regarding the '229, '465, '742, '793, '794, '208, '850, '018, '118, '118, and '800 patents in connection with ANDA No. 218851.

14. Heron filed the present action against MPI for infringement of the ’229, ’465, ’742, ’793, ’794, ’208, ’850, ’018, ’118 and ’800 patents.

COUNT I
Declaratory Judgment of Non-Infringement of U.S. Patent No. 9,561,229

15. MPI realleges and incorporates herein by reference the allegations of each of the foregoing paragraphs.

16. MPI’s ANDA Product has not infringed, will not infringe, and is not infringing, directly or indirectly, literally or under the doctrine of equivalents, any valid claim of the ’229 patent.

17. Unless Heron is enjoined, Heron will continue to assert that MPI’s ANDA Product infringes the claims of the ’229 patent and will continue to interfere with MPI’s business with respect to MPI’s ANDA Product and its manufacture, use, offer for sale, and sale.

18. MPI will be irreparably harmed if Heron is not enjoined from continuing to assert the ’229 patent and from interfering with MPI’s business.

19. There is a definite and concrete, real and substantial, justiciable, and continuing case or controversy existing between the parties regarding MPI’s noninfringement of the ’229 patent that is of sufficient immediacy and reality to warrant issuance of a declaratory judgment.

20. MPI is entitled to declaratory judgment that MPI’s ANDA Product has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid claim of the ’229 patent.

COUNT II
Declaratory Judgment of Patent Invalidity of U.S. Patent No. 9,561,229

21. MPI realleges and incorporates herein by reference the allegations of each of the foregoing paragraphs.

22. Heron has asserted the ’229 patent against MPI in the instant action.

23. MPI denies infringement of the ’229 patent and alleges that the ’229 patent is invalid for failure to meet one or more of the statutory requirements for patentability set forth in 35 U.S.C. §§ 101 *et seq.*, including without limitation §§ 101, 102, 103, 112, and/or double patenting.

24. Unless Heron is enjoined, MPI believes that Heron will continue to assert that MPI’s ANDA Product infringes the claims of the ’229 patent and will continue to interfere with MPI’s business with respect to MPI’s ANDA Product and its manufacture, use, offer for sale, and sale.

25. MPI will be irreparably harmed if Heron is not enjoined from continuing to assert the ’229 patent and from interfering with MPI’s business.

26. There is a definite and concrete, real and substantial, justiciable, and continuing case or controversy existing between the parties regarding the invalidity of the ’229 patent that is of sufficient immediacy and reality to warrant issuance of a declaratory judgment.

27. MPI is entitled to declaratory judgment that the claims of the ’229 patent are invalid.

COUNT III
Declaratory Judgment of Non-Infringement of U.S. Patent No. 9,808,465

28. MPI realleges and incorporates herein by reference the allegations of each of the foregoing paragraphs.

29. MPI’s ANDA Product has not infringed, will not infringe, and is not infringing, directly or indirectly, literally or under the doctrine of equivalents, any valid claim of the ’465 patent.

30. Unless Heron is enjoined, Heron will continue to assert that MPI's ANDA Product infringes the claims of the '465 patent and will continue to interfere with MPI's business with respect to MPI's ANDA Product and its manufacture, use, offer for sale, and sale.

31. MPI will be irreparably harmed if Heron is not enjoined from continuing to assert the '465 patent and from interfering with MPI's business.

32. There is a definite and concrete, real and substantial, justiciable, and continuing case or controversy existing between the parties regarding MPI's noninfringement of the '465 patent that is of sufficient immediacy and reality to warrant issuance of a declaratory judgment.

33. MPI is entitled to declaratory judgment that MPI's ANDA Product has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid claim of the '465 patent.

COUNT IV
Declaratory Judgment of Patent Invalidity of U.S. Patent No. 9,808,465

34. MPI realleges and incorporates herein by reference the allegations of each of the foregoing paragraphs.

35. Heron has asserted the '465 patent against MPI in the instant action.

36. MPI denies infringement of the '465 patent and alleges that the '465 patent is invalid for failure to meet one or more of the statutory requirements for patentability set forth in 35 U.S.C. §§ 101 *et seq.*, including without limitation §§ 101, 102, 103, 112, and/or double patenting.

37. Unless Heron is enjoined, MPI believes that Heron will continue to assert that MPI's ANDA Product infringes the claims of the '465 patent and will continue to interfere with MPI's business with respect to MPI's ANDA Product and its manufacture, use, offer for sale, and sale.

38. MPI will be irreparably harmed if Heron is not enjoined from continuing to assert the ’465 patent and from interfering with MPI’s business.

39. There is a definite and concrete, real and substantial, justiciable, and continuing case or controversy existing between the parties regarding the invalidity of the ’465 patent that is of sufficient immediacy and reality to warrant issuance of a declaratory judgment.

40. MPI is entitled to declaratory judgment that the claims of the ’465 patent are invalid.

COUNT V
Declaratory Judgment of Non-Infringement of U.S. Patent No. 9,974,742

41. MPI realleges and incorporates herein by reference the allegations of each of the foregoing paragraphs.

42. MPI’s ANDA Product has not infringed, will not infringe, and is not infringing, directly or indirectly, literally or under the doctrine of equivalents, any valid claim of the ’742 patent.

43. Unless Heron is enjoined, Heron will continue to assert that MPI’s ANDA Product infringes the claims of the ’742 patent and will continue to interfere with MPI’s business with respect to MPI’s ANDA Product and its manufacture, use, offer for sale, and sale.

44. MPI will be irreparably harmed if Heron is not enjoined from continuing to assert the ’742 patent and from interfering with MPI’s business.

45. There is a definite and concrete, real and substantial, justiciable, and continuing case or controversy existing between the parties regarding MPI’s noninfringement of the ’742 patent that is of sufficient immediacy and reality to warrant issuance of a declaratory judgment.

46. MPI is entitled to declaratory judgment that MPI's ANDA Product has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid claim of the '742 patent.

COUNT VI
Declaratory Judgment of Patent Invalidity of U.S. Patent No. 9,974,742

47. MPI realleges and incorporates herein by reference the allegations of each of the foregoing paragraphs.

48. Heron has asserted the '742 patent against MPI in the instant action.

49. MPI denies infringement of the '742 patent and alleges that the '742 patent is invalid for failure to meet one or more of the statutory requirements for patentability set forth in 35 U.S.C. §§ 101 *et seq.*, including without limitation §§ 101, 102, 103, 112, and/or double patenting.

50. Unless Heron is enjoined, MPI believes that Heron will continue to assert that MPI's ANDA Product infringes the claims of the '742 patent and will continue to interfere with MPI's business with respect to MPI's ANDA Product and its manufacture, use, offer for sale, and sale.

51. MPI will be irreparably harmed if Heron is not enjoined from continuing to assert the '742 patent and from interfering with MPI's business.

52. There is a definite and concrete, real and substantial, justiciable, and continuing case or controversy existing between the parties regarding the invalidity of the '742 patent that is of sufficient immediacy and reality to warrant issuance of a declaratory judgment.

53. MPI is entitled to declaratory judgment that the claims of the '742 patent are invalid.

COUNT VII
Declaratory Judgment of Non-Infringement of U.S. Patent No. 9,974,793

54. MPI realleges and incorporates herein by reference the allegations of each of the foregoing paragraphs.

55. MPI's ANDA Product has not infringed, will not infringe, and is not infringing, directly or indirectly, literally or under the doctrine of equivalents, any valid claim of the '793 patent.

56. Unless Heron is enjoined, Heron will continue to assert that MPI's ANDA Product infringes the claims of the '793 patent and will continue to interfere with MPI's business with respect to MPI's ANDA Product and its manufacture, use, offer for sale, and sale.

57. MPI will be irreparably harmed if Heron is not enjoined from continuing to assert the '793 patent and from interfering with MPI's business.

58. There is a definite and concrete, real and substantial, justiciable, and continuing case or controversy existing between the parties regarding MPI's noninfringement of the '793 patent that is of sufficient immediacy and reality to warrant issuance of a declaratory judgment.

59. MPI is entitled to declaratory judgment that MPI's ANDA Product has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid claim of the '793 patent.

COUNT VIII
Declaratory Judgment of Patent Invalidity of U.S. Patent No. 9,974,793

60. MPI realleges and incorporates herein by reference the allegations of each of the foregoing paragraphs.

61. Heron has asserted the '793 patent against MPI in the instant action.

62. MPI denies infringement of the '793 patent and alleges that the '793 patent is invalid for failure to meet one or more of the statutory requirements for patentability set forth in

35 U.S.C. §§ 101 *et seq.*, including without limitation §§ 101, 102, 103, 112, and/or double patenting.

63. Unless Heron is enjoined, MPI believes that Heron will continue to assert that MPI's ANDA Product infringes the claims of the '793 patent and will continue to interfere with MPI's business with respect to MPI's ANDA Product and its manufacture, use, offer for sale, and sale.

64. MPI will be irreparably harmed if Heron is not enjoined from continuing to assert the '793 patent and from interfering with MPI's business.

65. There is a definite and concrete, real and substantial, justiciable, and continuing case or controversy existing between the parties regarding the invalidity of the '793 patent that is of sufficient immediacy and reality to warrant issuance of a declaratory judgment.

66. MPI is entitled to declaratory judgment that the claims of the '793 patent are invalid.

COUNT IX
Declaratory Judgment of Non-Infringement of U.S. Patent No. 9,974,794

67. MPI realleges and incorporates herein by reference the allegations of each of the foregoing paragraphs.

68. MPI's ANDA Product has not infringed, will not infringe, and is not infringing, directly or indirectly, literally or under the doctrine of equivalents, any valid claim of the '794 patent.

69. Unless Heron is enjoined, Heron will continue to assert that MPI's ANDA Product infringes the claims of the '794 patent and will continue to interfere with MPI's business with respect to MPI's ANDA Product and its manufacture, use, offer for sale, and sale.

70. MPI will be irreparably harmed if Heron is not enjoined from continuing to assert the ’794 patent and from interfering with MPI’s business.

71. There is a definite and concrete, real and substantial, justiciable, and continuing case or controversy existing between the parties regarding MPI’s noninfringement of the ’794 patent that is of sufficient immediacy and reality to warrant issuance of a declaratory judgment.

72. MPI is entitled to declaratory judgment that MPI’s ANDA Product has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid claim of the ’794 patent.

COUNT X
Declaratory Judgment of Patent Invalidity of U.S. Patent No. 9,974,794

73. MPI realleges and incorporates herein by reference the allegations of each of the foregoing paragraphs.

74. Heron has asserted the ’794 patent against MPI in the instant action.

75. MPI denies infringement of the ’794 patent and alleges that the ’794 patent is invalid for failure to meet one or more of the statutory requirements for patentability set forth in 35 U.S.C. §§ 101 *et seq.*, including without limitation §§ 101, 102, 103, 112, and/or double patenting.

76. Unless Heron is enjoined, MPI believes that Heron will continue to assert that MPI’s ANDA Product infringes the claims of the ’794 patent and will continue to interfere with MPI’s business with respect to MPI’s ANDA Product and its manufacture, use, offer for sale, and sale.

77. MPI will be irreparably harmed if Heron is not enjoined from continuing to assert the ’794 patent and from interfering with MPI’s business.

78. There is a definite and concrete, real and substantial, justiciable, and continuing case or controversy existing between the parties regarding the invalidity of the ’794 patent that is of sufficient immediacy and reality to warrant issuance of a declaratory judgment.

79. MPI is entitled to declaratory judgment that the claims of the ’794 patent are invalid.

COUNT XI
Declaratory Judgment of Non-Infringement of U.S. Patent No. 10,500,208

80. MPI realleges and incorporates herein by reference the allegations of each of the foregoing paragraphs.

81. MPI’s ANDA Product has not infringed, will not infringe, and is not infringing, directly or indirectly, literally or under the doctrine of equivalents, any valid claim of the ’208 patent.

82. Unless Heron is enjoined, Heron will continue to assert that MPI’s ANDA Product infringes the claims of the ’208 patent and will continue to interfere with MPI’s business with respect to MPI’s ANDA Product and its manufacture, use, offer for sale, and sale.

83. MPI will be irreparably harmed if Heron is not enjoined from continuing to assert the ’208 patent and from interfering with MPI’s business.

84. There is a definite and concrete, real and substantial, justiciable, and continuing case or controversy existing between the parties regarding MPI’s noninfringement of the ’208 patent that is of sufficient immediacy and reality to warrant issuance of a declaratory judgment.

85. MPI is entitled to declaratory judgment that MPI’s ANDA Product has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid claim of the ’208 patent.

COUNT XII
Declaratory Judgment of Patent Invalidity of U.S. Patent No. 10,500,208

86. MPI realleges and incorporates herein by reference the allegations of each of the foregoing paragraphs.

87. Heron has asserted the ’208 patent against MPI in the instant action.

88. MPI denies infringement of the ’208 patent and alleges that the ’208 patent is invalid for failure to meet one or more of the statutory requirements for patentability set forth in 35 U.S.C. §§ 101 *et seq.*, including without limitation §§ 101, 102, 103, 112, and/or double patenting.

89. Unless Heron is enjoined, MPI believes that Heron will continue to assert that MPI’s ANDA Product infringes the claims of the ’208 patent and will continue to interfere with MPI’s business with respect to MPI’s ANDA Product and its manufacture, use, offer for sale, and sale.

90. MPI will be irreparably harmed if Heron is not enjoined from continuing to assert the ’208 patent and from interfering with MPI’s business.

91. There is a definite and concrete, real and substantial, justiciable, and continuing case or controversy existing between the parties regarding the invalidity of the ’208 patent that is of sufficient immediacy and reality to warrant issuance of a declaratory judgment.

92. MPI is entitled to declaratory judgment that the claims of the ’208 patent are invalid.

COUNT XIII
Declaratory Judgment of Non-Infringement of U.S. Patent No. 10,624,850

93. MPI realleges and incorporates herein by reference the allegations of each of the foregoing paragraphs.

94. MPI's ANDA Product has not infringed, will not infringe, and is not infringing, directly or indirectly, literally or under the doctrine of equivalents, any valid claim of the '850 patent.

95. Unless Heron is enjoined, Heron will continue to assert that MPI's ANDA Product infringes the claims of the '850 patent and will continue to interfere with MPI's business with respect to MPI's ANDA Product and its manufacture, use, offer for sale, and sale.

96. MPI will be irreparably harmed if Heron is not enjoined from continuing to assert the '850 patent and from interfering with MPI's business.

97. There is a definite and concrete, real and substantial, justiciable, and continuing case or controversy existing between the parties regarding MPI's noninfringement of the '850 patent that is of sufficient immediacy and reality to warrant issuance of a declaratory judgment.

98. MPI is entitled to declaratory judgment that MPI's ANDA Product has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid claim of the '850 patent.

COUNT XIV
Declaratory Judgment of Patent Invalidity of U.S. Patent No. 10,624,850

99. MPI realleges and incorporates herein by reference the allegations of each of the foregoing paragraphs.

100. Heron has asserted the '850 patent against MPI in the instant action.

101. MPI denies infringement of the '850 patent and alleges that the '850 patent is invalid for failure to meet one or more of the statutory requirements for patentability set forth in 35 U.S.C. §§ 101 *et seq.*, including without limitation §§ 101, 102, 103, 112, and/or double patenting.

102. Unless Heron is enjoined, MPI believes that Heron will continue to assert that MPI's ANDA Product infringes the claims of the '850 patent and will continue to interfere with MPI's business with respect to MPI's ANDA Product and its manufacture, use, offer for sale, and sale.

103. MPI will be irreparably harmed if Heron is not enjoined from continuing to assert the '850 patent and from interfering with MPI's business.

104. There is a definite and concrete, real and substantial, justiciable, and continuing case or controversy existing between the parties regarding the invalidity of the '850 patent that is of sufficient immediacy and reality to warrant issuance of a declaratory judgment.

105. MPI is entitled to declaratory judgment that the claims of the '850 patent are invalid.

COUNT XV
Declaratory Judgment of Non-Infringement of U.S. Patent No. 10,953,018

106. MPI realleges and incorporates herein by reference the allegations of each of the foregoing paragraphs.

107. MPI's ANDA Product has not infringed, will not infringe, and is not infringing, directly or indirectly, literally or under the doctrine of equivalents, any valid claim of the '018 patent.

108. Unless Heron is enjoined, Heron will continue to assert that MPI's ANDA Product infringes the claims of the '018 patent and will continue to interfere with MPI's business with respect to MPI's ANDA Product and its manufacture, use, offer for sale, and sale.

109. MPI will be irreparably harmed if Heron is not enjoined from continuing to assert the '018 patent and from interfering with MPI's business.

110. There is a definite and concrete, real and substantial, justiciable, and continuing case or controversy existing between the parties regarding MPI's noninfringement of the '018 patent that is of sufficient immediacy and reality to warrant issuance of a declaratory judgment.

111. MPI is entitled to declaratory judgment that MPI's ANDA Product has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid claim of the '018 patent.

COUNT XVI
Declaratory Judgment of Patent Invalidity of U.S. Patent No. 10,953,018

112. MPI realleges and incorporates herein by reference the allegations of each of the foregoing paragraphs.

113. Heron has asserted the '018 patent against MPI in the instant action.

114. MPI denies infringement of the '018 patent and alleges that the '018 patent is invalid for failure to meet one or more of the statutory requirements for patentability set forth in 35 U.S.C. §§ 101 *et seq.*, including without limitation §§ 101, 102, 103, 112, and/or double patenting.

115. Unless Heron is enjoined, MPI believes that Heron will continue to assert that MPI's ANDA Product infringes the claims of the '018 patent and will continue to interfere with MPI's business with respect to MPI's ANDA Product and its manufacture, use, offer for sale, and sale.

116. MPI will be irreparably harmed if Heron is not enjoined from continuing to assert the '018 patent and from interfering with MPI's business.

117. There is a definite and concrete, real and substantial, justiciable, and continuing case or controversy existing between the parties regarding the invalidity of the '018 patent that is of sufficient immediacy and reality to warrant issuance of a declaratory judgment.

118. MPI is entitled to declaratory judgment that the claims of the ’018 patent are invalid.

COUNT XVII
Declaratory Judgment of Non-Infringement of U.S. Patent No. 11,173,118

119. MPI realleges and incorporates herein by reference the allegations of each of the foregoing paragraphs.

120. MPI’s ANDA Product has not infringed, will not infringe, and is not infringing, directly or indirectly, literally or under the doctrine of equivalents, any valid claim of the ’118 patent.

121. Unless Heron is enjoined, Heron will continue to assert that MPI’s ANDA Product infringes the claims of the ’118 patent and will continue to interfere with MPI’s business with respect to MPI’s ANDA Product and its manufacture, use, offer for sale, and sale.

122. MPI will be irreparably harmed if Heron is not enjoined from continuing to assert the ’118 patent and from interfering with MPI’s business.

123. There is a definite and concrete, real and substantial, justiciable, and continuing case or controversy existing between the parties regarding MPI’s noninfringement of the ’118 patent that is of sufficient immediacy and reality to warrant issuance of a declaratory judgment.

124. MPI is entitled to declaratory judgment that MPI’s ANDA Product has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid claim of the ’118 patent.

COUNT XVIII
Declaratory Judgment of Patent Invalidity of U.S. Patent No. 11,173,118

125. MPI realleges and incorporates herein by reference the allegations of each of the foregoing paragraphs.

126. Heron has asserted the ’118 patent against MPI in the instant action.

127. MPI denies infringement of the ’118 patent and alleges that the ’118 patent is invalid for failure to meet one or more of the statutory requirements for patentability set forth in 35 U.S.C. §§ 101 *et seq.*, including without limitation §§ 101, 102, 103, 112, and/or double patenting.

128. Unless Heron is enjoined, MPI believes that Heron will continue to assert that MPI’s ANDA Product infringes the claims of the ’118 patent and will continue to interfere with MPI’s business with respect to MPI’s ANDA Product and its manufacture, use, offer for sale, and sale.

129. MPI will be irreparably harmed if Heron is not enjoined from continuing to assert the ’118 patent and from interfering with MPI’s business.

130. There is a definite and concrete, real and substantial, justiciable, and continuing case or controversy existing between the parties regarding the invalidity of the ’118 patent that is of sufficient immediacy and reality to warrant issuance of a declaratory judgment.

131. MPI is entitled to declaratory judgment that the claims of the ’118 patent are invalid.

COUNT XIX
Declaratory Judgment of Non-Infringement of U.S. Patent No. 11,744,800

132. MPI realleges and incorporates herein by reference the allegations of each of the foregoing paragraphs.

133. MPI’s ANDA Product has not infringed, will not infringe, and is not infringing, directly or indirectly, literally or under the doctrine of equivalents, any valid claim of the ’800 patent.

134. Unless Heron is enjoined, Heron will continue to assert that MPI's ANDA Product infringes the claims of the '800 patent and will continue to interfere with MPI's business with respect to MPI's ANDA Product and its manufacture, use, offer for sale, and sale.

135. MPI will be irreparably harmed if Heron is not enjoined from continuing to assert the '800 patent and from interfering with MPI's business.

136. There is a definite and concrete, real and substantial, justiciable, and continuing case or controversy existing between the parties regarding MPI's noninfringement of the '800 patent that is of sufficient immediacy and reality to warrant issuance of a declaratory judgment.

137. MPI is entitled to declaratory judgment that MPI's ANDA Product has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid claim of the '800 patent.

COUNT XX
Declaratory Judgment of Patent Invalidity of U.S. Patent No. 11,744,800

138. MPI realleges and incorporates herein by reference the allegations of each of the foregoing paragraphs.

139. Heron has asserted the '800 patent against MPI in the instant action.

140. MPI denies infringement of the '800 patent and alleges that the '800 patent is invalid for failure to meet one or more of the statutory requirements for patentability set forth in 35 U.S.C. §§ 101 *et seq.*, including without limitation §§ 101, 102, 103, 112, and/or double patenting.

141. Unless Heron is enjoined, MPI believes that Heron will continue to assert that MPI's ANDA Product infringes the claims of the '800 patent and will continue to interfere with MPI's business with respect to MPI's ANDA Product and its manufacture, use, offer for sale, and sale.

142. MPI will be irreparably harmed if Heron is not enjoined from continuing to assert the ’800 patent and from interfering with MPI’s business.

143. There is a definite and concrete, real and substantial, justiciable, and continuing case or controversy existing between the parties regarding the invalidity of the ’800 patent that is of sufficient immediacy and reality to warrant issuance of a declaratory judgment.

144. MPI is entitled to declaratory judgment that the claims of the ’800 patent are invalid.

PRAYER FOR RELIEF

WHEREFORE, Defendant and Counterclaim Plaintiff respectfully requests entry of judgement in its favor and against Plaintiff/Counterclaim Defendant as follows:

A. Ordering that Plaintiff’s Complaint be dismissed with prejudice and judgment entered in favor of Defendant and Counterclaim Plaintiff;

B. Denying the relief sought in Plaintiff’s Complaint in its entirety;

C. Declaring each of the claims of the ’229, ’465, ’742, ’793, ’794, ’208, ’850, ’018, ’118, and ’800 patents invalid and not infringed;

D. Ordering that judgment be entered in favor of Defendant on each of its affirmative defenses and any additional defenses discovery may reveal;

E. Declaring this case exceptional and awarding Defendant and Counterclaim Plaintiff their reasonable attorneys’ fees and costs pursuant to 35 U.S.C. § 285; and

F. Awarding to Defendant and Counterclaim Plaintiff any further relief this Court may deem just, proper, and equitable.

Respectfully submitted,

POTTER ANDERSON & CORROON LLP

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