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(a/k/a Deva Holdings A.S.)

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

Teva Branded Pharmaceutical Products R&D, Inc., Norton (Waterford) Ltd., and Teva Pharmaceuticals USA, Inc., Plaintiffs, v. Deva Holding A.S. (a/k/a Deva Holdings A.S.) Defendant.	C.A. No.: 2:24-cv-04404-SRC-MAH

DEFENDANT DEVA HOLDING A.S. ANSWER, SEPARATE DEFENSES AND COUNTERCLAIMS

Deva Holding A.S. a/k/a Deva Holdings A.S. ("Deva" or "Defendant") by and through its counsel, hereby respond to the allegations set forth in Plaintiffs Teva Branded Pharmaceutical Products R&D, Inc. ("Teva Branded"), Norton (Waterford) Ltd. ("Norton"), and Teva Pharmaceuticals USA, Inc.' ("Teva USA") (collectively, "Plaintiffs") Complaint for Patent Infringement. (D.I. 1). This Answer is based on Deva's current knowledge as to its own activities, and on information and belief as to the activities of others. If not specifically admitted herein, the allegations of the Complaint are denied. The headings in Plaintiffs' Complaint are copied herein for convenience only, and any allegations in such headings are denied.

NATURE OF THIS ACTION

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100 et seq., including 35 U.S.C. § 271, the Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. § 355(j) ("Hatch-Waxman Act"), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, that arises out of Deva's submission of Abbreviated New Drug Application ("ANDA") No. 21-3818 to the U.S. Food and Drug Administration ("FDA") seeking approval to commercially manufacture, use, offer for sale, sell, and/or import a generic version of ProAir® HFA (albuterol sulfate) Inhalation Aerosol prior to the expiration of U.S. Patent Nos. 8,132,712 ("the '712 patent"), 9,463,289 ("the '289 patent"), 9,808,587 ("the '587 patent"), 10,022,509 ("the '509 patent"), 10,022,510 ("the '510 patent"), 10,086,156 ("the '156 patent"), 10,561,808 ("the '808 patent"), 10,695,512 ("the '512 patent"), 11,395,889 ("the '889 patent"). Collectively, the '712 patent, the '289 patent, the '587 patent, the '509 patent, the '510 patent, the '156 patent, the '808 patent, the '512 patent, and the '889 patent are referred to herein as the "Patents-in-Suit."

ANSWER: Defendant admits that this action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100 et seq., including 35 U.S.C. § 271, the Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. § 355(j) ("Hatch-Waxman Act"), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, that arises out of Deva's submission of Abbreviated New Drug Application ("ANDA") No. 21-3818 to the U.S. Food and Drug Administration ("FDA") seeking approval to commercially manufacture, use, offer for sale, sell, and/or import a generic version of ProAir® HFA (albuterol sulfate) Inhalation Aerosol prior to the expiration of U.S. Patent Nos. 8,132,712 ("the '712 patent"), 9,463,289 ("the '289 patent"), 9,808,587 ("the '587 patent"), 10,022,509 ("the '509 patent"), 10,022,510 ("the '510 patent"), 10,086,156 ("the '156 patent"), 10,561,808 ("the '808 patent"), 10,695,512 ("the '512 patent"), 11,395,889 ("the '889 patent"). Collectively, the '712 patent, the '289 patent, the '587 patent, the '509 patent, the '510 patent, the '156 patent, the '808 patent, the '512 patent, and the '889 patent are referred to herein as the "Patents-in-Suit." Defendant is otherwise without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 1 of the Complaint and therefore denies them.

THE PARTIES

Plaintiffs

2. Plaintiff Teva Branded is a company organized under the laws of the State of Delaware with its principal place of business at 145 Brandywine Parkway, West Chester, Pennsylvania 19380. In addition, Teva Branded has a place of business at 400 Interpace Parkway #3, Parsippany, New Jersey 07054.

ANSWER: On information and belief, and based upon the Complaint filed in this case, Plaintiff Teva Branded is a company organized under the laws of the State of Delaware with its

principal place of business at 145 Brandywine Parkway, West Chester, Pennsylvania 19380. In addition, Teva Branded has a place of business at 400 Interpace Parkway #3, Parsippany, New Jersey 07054. Defendant is otherwise without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 2 of the Complaint and therefore denies them.

3. Plaintiff Norton is a private limited company organized under the laws of the Republic of Ireland and having its registered office at Unit 301, IDA Industrial Park, Waterford X91 WK68, Republic of Ireland. Norton trades, i.e., does business, as Ivax Pharmaceuticals Ireland and as Teva Pharmaceuticals Ireland.

ANSWER: On information and belief, and based upon the Complaint filed in this case, Plaintiff Norton is a private limited company organized under the laws of the Republic of Ireland and having its registered office at Unit 301, IDA Industrial Park, Waterford X91 WK68, Republic of Ireland. Norton trades, i.e., does business, as Ivax Pharmaceuticals Ireland and as Teva Pharmaceuticals Ireland. Defendant is otherwise without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 3 of the Complaint and therefore denies them.

4. Plaintiff Teva USA is a company organized and existing under the laws of the State of Delaware, with a principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054.

ANSWER: On information and belief, and based upon the Complaint filed in this case, Plaintiff Teva USA is a company organized and existing under the laws of the State of Delaware, with a principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054.. Defendant is otherwise without knowledge or information sufficient to form a belief as to the truth

of the allegations in paragraph 4 of the Complaint and therefore denies them.

Defendant

5. On information and belief, Defendant Deva Holding A.S. (a/k/a Deva Holdings A.S.)[1] is a corporation organized and existing under the laws of Turkey, having a principal place of business at Halkalı Merkez Mah. Basın Ekspres Cad. No: 1 34303 Küçükçekmece - Istanbul Sicil No: 70061.

ANSWER: Defendant Deva Holding A.S. (a/k/a Deva Holdings A.S.) is a corporation organized and existing under the laws of Turkey, having a principal place of business at Halkalı Merkez Mah. Basın Ekspres Cad. No: 1 34303 Küçükçekmece - Istanbul Sicil No: 70061.

6. By a letter dated February 19, 2024 ("Deva Notice Letter"), Defendant notified Plaintiffs that Deva had submitted to FDA ANDA No. 21-3818 ("Deva's ANDA") for a purported generic version of ProAir® HFA (albuterol sulfate) Inhalation Aerosol, 90 mcg (EQ 0.09 mg base) per actuation ("Deva ANDA Product"), seeking FDA approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Deva ANDA Product in and/or into the United States prior to the expiration of the Patents-in-Suit.

ANSWER: Deva admits that by a letter dated February 19, 2024 ("Deva Notice Letter"),

[1] The Deva Notice Letter referred to "Deva" as "Deva Holdings A.S." (emphasis added). Based on publicly available information, this appears to be a misspelling. The name of the Deva entity located at the principal place of business referenced in the Deva Notice Letter appears to be "Deva Holding A.S." See, e.g., Deva Holding A.S., Annual Report 2022, https://www.deva.com.tr/uploads/pdf_files/nNZrwMz5BcxOkrKDGhiy.pdf (last visited March 29, 2024); DEVA, Contact Us, https://www.deva.com.tr/en/contact (last visited March 29, 2024). For the avoidance of doubt, the named Defendant in this action is the Deva entity that is identified in the Deva Notice Letter as the entity that submitted ANDA No. 21-3818 and that sent the Deva Notice Letter.

Defendant notified Plaintiffs that Deva had submitted to FDA ANDA No. 21-3818 ("Deva's ANDA") for a purported generic version of ProAir® HFA (albuterol sulfate) Inhalation Aerosol, 90 mcg (EQ 0.09 mg base) per actuation ("Deva ANDA Product"), seeking FDA approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Deva ANDA Product in and/or into the United States prior to the expiration of the Patents-in-Suit.

7. On information and belief, following any FDA approval of Deva's ANDA, Deva will commercially manufacture, use, offer for sale, sell, market, distribute, and/or import the Deva ANDA Product in and/or into the United States, including New Jersey.

ANSWER: Deva cannot respond as to its actions should it receive approval for the ANDA, as intervening events, including but not limited to competition by others, changes in the marketplace, and FDA actions with respect to the brand product, can affect the actions Deva ultimately does undertake. To the extent an answer is required, Deva denies the allegations in Paragraph 7.

8. On information and belief, following any FDA approval of Deva's ANDA, Deva knows and intends that the Deva ANDA Product will be commercially manufactured, used, offered for sale, sold, marketed, distributed, and/or imported in and/or into the United States, including New Jersey.

ANSWER: Deva cannot respond as to its actions should it receive approval for the ANDA, as intervening events, including but not limited to competition by others, changes in the marketplace, and FDA actions with respect to the brand product, can affect the actions Deva ultimately does undertake. To the extent an answer is required, Deva denies the allegations in Paragraph 8.

JURISDICTION AND VENUE

Subject Matter Jurisdiction

9. Plaintiffs incorporate each of the preceding paragraphs 1–8 as if fully set forth herein.

ANSWER: Defendant repeats, reiterates and re-alleges the responses to paragraphs 1 through and including 8 of the Complaint with the same force and effect as if hereinafter set forth at length.

10. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100 et seq., including 35 U.S.C. § 271.

ANSWER: Paragraph 10 states a legal conclusion to which no response is required. To the extent an answer is required, Defendant Deva will not contest subject matter jurisdiction solely for the purposes of Plaintiffs' Complaint in this case.

11. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

ANSWER: Paragraph 11 states a legal conclusion to which no response is required. To the extent an answer is required, Defendant Deva will not contest subject matter jurisdiction solely for the purposes of Plaintiffs' Complaint in this case.

Personal Jurisdiction

12. Plaintiffs incorporate each of the preceding paragraphs 1–11 as if fully set forth herein.

ANSWER: Defendant repeats, reiterates and re-alleges the responses to paragraphs 1 through and including 11 of the Complaint with the same force and effect as if hereinafter set forth at length.

13. Based on the facts and causes alleged herein, and for additional reasons to be further developed through discovery, if necessary, this Court has personal jurisdiction over Deva.

ANSWER: Paragraph 13 states a legal conclusion to which no response is required. To the extent an answer is required, Defendant Deva will not contest personal jurisdiction solely for the purposes of Plaintiffs' Complaint in this case. With respect to any remaining allegations of Paragraph 13, Deva denies the same.

14. On information and belief, Deva is in the business of, among other things, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products, including generic drug products, throughout the United States, including in this District.

ANSWER: Deva is in the business of, among other things, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products, including generic drug products, To the extent an answer is required, Deva denies any remaining allegations of Paragraph 14.

15. On information and belief, this District is a likely destination for the Deva ANDA Product.

ANSWER: Paragraph 15 states a legal conclusion to which no response is required. To the extent an answer is required, Deva will not contest personal jurisdiction solely for the purposes of Plaintiffs' Complaint in this case. With respect to any remaining allegations of Paragraph 15, Deva denies the same.

16. On information and belief, Deva has (1) engaged in patent litigation concerning its

ANDA products in this District, and (2) consented to personal jurisdiction in this District. See Consent Judgment (D.E. 12) ¶¶ 1, 2, 6, Celgene Corp. v. Deva Holding A.S., No. 23-cv-02992 (Oct. 24, 2023) ("[T]he parties in the above-captioned action, hereby stipulate and consent to entry of judgment and an injunction in this action as follows: . . . This Court . . . has personal jurisdiction over the parties for purposes of this action only . . . .").

ANSWER: Deva admits that it has engaged in patent litigation concerning its ANDA products in this District and consented to personal jurisdiction in this District.

17. This Court has personal jurisdiction over Deva because the requirements of Federal Rule of Civil Procedure 4(k)(2) are met, including because (a) Plaintiffs' claims arise under federal law; (b) Deva is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Deva has sufficient contacts in the United States as a whole, including, but not limited to, by preparing and submitting ANDAs to the FDA (including Deva's ANDA), and/or manufacturing, importing, offering to sell, or selling pharmaceutical products that are distributed throughout the United States, including in this Judicial District, such that this Court's exercise of jurisdiction over Deva satisfies due process.

ANSWER: Paragraph 17 states a legal conclusion to which no response is required. To the extent an answer is required, Deva will not contest personal jurisdiction solely for the purposes of Plaintiffs' Complaint in this case. With respect to any remaining allegations of Paragraph 17, Deva denies the same.

Venue

18. Plaintiffs incorporate each of the preceding paragraphs 1–17 as if fully set forth herein.

ANSWER: Defendant repeats, reiterates and re-alleges the responses to paragraphs 1 through and including 17 of the Complaint with the same force and effect as if hereinafter set forth at length.

19. Venue is proper in this Judicial District under 28 U.S.C. §§ 1391 and 1400(b).

ANSWER: Paragraph 19 sets forth legal conclusions to which no response is required. To the extent an answer is required, Deva admits only that it will not contest venue for the purposes of this action. With respect to any remaining allegations of Paragraph 19, Deva Pharma denies the same.

20. Venue is proper in this District for Deva at least because, among other things, Deva is a foreign corporation organized and existing under the laws of Turkey and may be sued in any judicial district, including in New Jersey. See 28 U.S.C. § 1391(c)(3); see also 28 U.S.C. § 1400(b).

ANSWER: Paragraph 20 sets forth legal conclusions to which no response is required. To the extent an answer is required, Deva admits only that it will not contest venue for the purposes of this action. With respect to any remaining allegations of Paragraph 20, Deva denies the same.

BACKGROUND
NDA No. 021457

21. Teva Branded is the holder of New Drug Application ("NDA") No. 021457, under which FDA approved the commercial marketing of ProAir® HFA (albuterol sulfate) Inhalation Aerosol on October 29, 2004. ProAir® HFA (albuterol sulfate) Inhalation Aerosol is indicated for the treatment or prevention of bronchospasm in patients 4 years of age and older with reversible obstructive airway disease and for the prevention of exercise-induced bronchospasm in patients 4

years of age and older.

ANSWER: Teva Branded is the holder of New Drug Application ("NDA") No. 021457, under which FDA approved the commercial marketing of ProAir® HFA (albuterol sulfate) Inhalation Aerosol on October 29, 2004. Defendant is otherwise without knowledge or information sufficient to form a belief as to the truth of the other allegations of Paragraph 21.

22. On October 1, 2022, the manufacturing of branded ProAir® HFA (albuterol sulfate) Inhalation Aerosol was discontinued. Teva USA currently distributes an authorized generic of ProAir® HFA (albuterol sulfate) Inhalation Aerosol under NDA No. 021457 in the United States.

ANSWER: Deva lacks information sufficient to form a belief as to the truth of this allegation of this Paragraph 22, and on that basis denies the same.

The '712 Patent

23. The '712 patent, titled "Metered-Dose Inhaler," duly and legally issued on March 13, 2012. A true and correct copy of the '712 patent is attached hereto as Exhibit A.

ANSWER: Deva admits that Exhibit A to Plaintiffs' Complaint contains what purports to be a copy of the '712 patent, which purported copy bears the title "Metered-Dose Inhaler." Deva denies that the '712 patent was "duly and legally issued" and deny any remaining allegations in Paragraph 23.

24. Norton is the owner and assignee of the '712 patent.

ANSWER: Deva lacks information sufficient to form a belief as to the truth of this allegation, and on that basis denies the same.

25. The ’712 patent is listed in connection with ProAir® HFA (NDA No. 021457) in FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations (“Orange Book”).

ANSWER: Deva admits the ’712 patent is improperly listed in connection with ProAir® HFA (NDA No. 021457) in FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations (“Orange Book”).

26. The Orange Book currently lists the expiration of the ’712 patent as September 7, 2028.

ANSWER: Deva admits that the Orange Book currently lists the expiration of the ’712 patent as September 7, 2028.

The ’289 Patent

27. The ’289 patent, titled “Dose Counters for Inhalers, Inhalers and Methods of Assembly Thereof,” duly and legally issued on October 11, 2016. A true and correct copy of the ’289 patent is attached hereto as Exhibit B.

ANSWER: Deva admits that Exhibit B to Plaintiffs’ Complaint contains what purports to be a copy of the ’289 patent, which purported copy bears the title “Dose Counters for Inhalers, Inhalers and Methods of Assembly Thereof,” Deva denies that the ’289 patent was “duly and legally issued” and deny any remaining allegations in Paragraph 27.

28. Norton is the owner and assignee of the ’289 patent.

ANSWER: Deva lacks information sufficient to form a belief as to the truth of this allegation, and on that basis denies the same.

29. The ’289 patent is listed in connection with ProAir® HFA (NDA No. 021457) in

the Orange Book.

ANSWER: Deva admits that the '289 patent is improperly listed in connection with ProAir® HFA (NDA No. 021457) in the Orange Book.

30. The Orange Book currently lists the expiration of the '289 patent as May 18, 2031.

ANSWER: Deva admits the Orange Book currently lists the expiration of the '289 patent as May 18, 2031.

The '587 Patent

31. The '587 patent, titled "Dose Counter for Inhaler Having an Anti-Reverse Rotation Actuator," duly and legally issued on November 7, 2017. A true and correct copy of the '587 patent is attached hereto as Exhibit C.

ANSWER: Deva admits that Exhibit C to Plaintiffs' Complaint contains what purports to be a copy of the '587 patent, which purported copy bears the title "Dose Counter for Inhaler Having an Anti-Reverse Rotation Actuator." Deva denies that the '587 patent was "duly and legally issued" and deny any remaining allegations in Paragraph 31.

32. Norton is the owner and assignee of the '587 patent.

ANSWER: Deva lacks information sufficient to form a belief as to the truth of this allegation, and on that basis denies the same.

33. The '587 patent is listed in connection with ProAir® HFA (NDA No. 021457) in the Orange Book.

ANSWER: Deva admits that the'587 patent is improperly listed in connection with ProAir® HFA (NDA No. 021457) in the Orange Book.

34. The Orange Book currently lists the expiration of the ’587 patent as May 18, 2031.

ANSWER: Deva admits that the Orange Book currently lists the expiration of the ’587 patent as May 18, 2031.

The ’509 Patent

35. The ’509 patent, titled “Dose Counter for Inhaler Having a Bore and Shaft Arrangement,” duly and legally issued on July 17, 2018. A true and correct copy of the ’509 patent is attached hereto as Exhibit D.

ANSWER: Deva admits that Exhibit D to Plaintiffs’ Complaint contains what purports to be a copy of the ’712 patent, which purported copy bears the title “Dose Counter for Inhaler Having a Bore and Shaft Arrangement.” Deva denies that the ’509 patent was “duly and legally issued” and deny any remaining allegations in Paragraph 35.

36. Norton is the owner and assignee of the ’509 patent.

ANSWER: Defendant lacks information sufficient to form a belief as to the truth of this allegation, and on that basis denies the same.

37. The ’509 patent is listed in connection with ProAir® HFA (NDA No. 021457) in the Orange Book.

ANSWER: Deva admits that the’509 patent is improperly listed in connection with ProAir® HFA (NDA No. 021457) in the Orange Book.

38. The Orange Book currently lists the expiration of the ’509 patent as May 18, 2031.

ANSWER: Deva admits that the Orange Book currently lists the expiration of the ’509 patent as May 18, 2031.

The ’510 Patent

39. The ’510 patent, titled “Dose Counters for Inhalers, Inhalers and Methods of Assembly Thereof,” duly and legally issued on July 17, 2018. A true and correct copy of the ’510 patent is attached hereto as Exhibit E.

ANSWER: Deva admits that Exhibit E to Plaintiffs’ Complaint contains what purports to be a copy of the ’510 patent, which purported copy bears the title “Dose Counters for Inhalers, Inhalers and Methods of Assembly Thereof.” Deva denies that the ’510 patent was “duly and legally issued” and deny any remaining allegations in Paragraph 39.

40. Norton is the owner and assignee of the ’510 patent.

ANSWER: Defendant lacks information sufficient to form a belief as to the truth of this allegation, and on that basis denies the same.

41. The ’510 patent is listed in connection with ProAir® HFA (NDA No. 021457) in the Orange Book.

ANSWER: Deva admits that the ’510 patent is improperly listed in connection with ProAir® HFA (NDA No. 021457) in the Orange Book.

42. The Orange Book currently lists the expiration of the ’510 patent as May 18, 2031.

ANSWER: Deva admits that the Orange Book currently lists the expiration of the ’510 patent as May 18, 2031.

The ’156 Patent

43. The ’156 patent, titled “Dose Counter for Inhaler and Method for Counting Doses,” duly and legally issued on October 2, 2018. A true and correct copy of the ’156 patent is

attached hereto as Exhibit F.

ANSWER: Deva admits that Exhibit F to Plaintiffs' Complaint contains what purports to be a copy of the '156 patent, which purported copy bears the title "Dose Counter for Inhaler and Method for Counting Doses." Deva denies that the '156 patent was "duly and legally issued" and deny any remaining allegations in Paragraph 43.

44. Norton is the owner and assignee of the '156 patent.

ANSWER: Deva lacks information sufficient to form a belief as to the truth of this allegation, and on this basis denies the same.

45. The '156 patent is listed in connection with ProAir® HFA (NDA No. 021457) in the Orange Book.

ANSWER: Deva admits that the '156 patent is improperly listed in connection with ProAir® HFA (NDA No. 021457) in the Orange Book.

46. The Orange Book currently lists the expiration of the '156 patent as May 18, 2031.

ANSWER: Deva admits that the Orange Book currently lists the expiration of the '156 patent as May 18, 2031

The '808 Patent

47. The '808 patent, titled "Dose Counter for Inhaler Having an Anti-Reverse Rotation Actuator," duly and legally issued on February 18, 2020. A true and correct copy of the '808 patent is attached hereto as Exhibit G.

ANSWER: Deva admits that Exhibit G to Plaintiffs' Complaint contains what purports to be a copy of the '808 patent, which purported copy bears the title "Dose Counter for Inhaler Having

an Anti-Reverse Rotation Actuator," Deva denies that the '808 patent was "duly and legally issued" and deny any remaining allegations in Paragraph 47.

48. Norton is the owner and assignee of the '808 patent.

ANSWER: Deva lacks information sufficient to form a belief as to the truth of this allegation, and on this basis denies the same.

49. The '808 patent is listed in connection with ProAir® HFA (NDA No. 021457) in the Orange Book.

ANSWER: Deva admits that the '808 patent is improperly listed in connection with ProAir® HFA (NDA No. 021457) in the Orange Book.

50. The Orange Book currently lists the expiration of the '808 patent as January 1, 2032.

ANSWER: Deva admits that the Orange Book currently lists the expiration of the '808 patent as January 1, 2032.

The '512 Patent

51. The '512 patent, titled "Dose Counter for Inhaler Having an Anti-Reverse Rotation Actuator," duly and legally issued on June 30, 2020. A true and correct copy of the '512 patent is attached hereto as Exhibit H.

ANSWER: Deva admits that Exhibit H to Plaintiffs' Complaint contains what purports to be a copy of the '512 patent, which purported copy bears the title "Dose Counter for Inhaler Having an Anti-Reverse Rotation Actuator." Deva denies that the '512 patent was "duly and legally issued" and deny any remaining allegations in Paragraph 51.

52. Norton is the owner and assignee of the '512 patent.

ANSWER: Deva lacks information sufficient to form a belief as to the truth of this allegation, and on this basis denies the same.

53. The '512 patent is listed in connection with ProAir® HFA (NDA No. 021457) in the Orange Book.

ANSWER: Deva admits that the '512 patent is improperly listed in connection with ProAir® HFA (NDA No. 021457) in the Orange Book.

54. The Orange Book currently lists the expiration of the '512 patent as May 18, 2031.

ANSWER: Deva admits that the Orange Book currently lists the expiration of the '512 patent as May 18, 2031.

The '889 Patent

55. The '889 patent, titled "Dose Counter for Inhaler Having an Anti-Reverse Rotation Actuator," duly and legally issued on July 26, 2022. A true and correct copy of the '889 patent is attached hereto as Exhibit I.

ANSWER: Deva admits that Exhibit I to Plaintiffs' Complaint contains what purports to be a copy of the '889 patent, which purported copy bears the title "Dose Counter for Inhaler Having an Anti-Reverse Rotation Actuator." Deva denies that the '889 patent was "duly and legally issued" and deny any remaining allegations in Paragraph 55.

56. Norton is the owner and assignee of the '889 patent.

ANSWER: Deva lacks information sufficient to form a belief as to the truth of this allegation, and on this basis denies the same.

57. The '889 patent is listed in connection with ProAir® HFA (NDA No. 021457) in the

Orange Book.

ANSWER: Deva admits that the '889 patent is improperly listed in connection with ProAir® HFA (NDA No. 021457) in the Orange Book.

58. The Orange Book currently lists the expiration of the '889 patent as May 18, 2031.

ANSWER: Deva admits that the Orange Book currently lists the expiration of the '889 patent as May 18, 2031.

Deva's ANDA and Notice of Paragraph IV Certification

59. On information and belief, Deva has submitted or caused the submission of Deva's ANDA to FDA under 21 U.S.C. § 355(j) to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of the Deva ANDA Product prior to the expiration of the Patents-in-Suit.

ANSWER: Deva admits it has submitted or caused the submission of Deva's ANDA to FDA under 21 U.S.C. § 355(j) to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of the Deva ANDA Product prior to the expiration of the Patents-in-Suit.

60. On information and belief, FDA has not yet approved Deva's ANDA.

ANSWER: Deva admits that FDA has not yet approved Deva's ANDA.

61. In the Deva Notice Letter, Deva notified Plaintiffs of the submission of Deva's ANDA to FDA.

ANSWER: Deva admits that in the Deva Notice Letter, Deva notified Plaintiffs of the submission of Deva's ANDA to FDA.

62. In the Deva Notice Letter, Deva stated the ANDA No. for Deva's ANDA is 21-3818.

ANSWER: Deva admits that in the Deva Notice Letter, Deva stated the ANDA No. for Deva's ANDA is 21-3818.

63. In the Deva Notice Letter, Deva notified Plaintiffs that Deva had filed a Paragraph IV Certification with respect to each of the Patents-in-Suit and was seeking approval from FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Deva ANDA Product prior to the expiration of the Patents-in-Suit.

ANSWER: Deva admits that in the Deva Notice Letter, Deva notified Plaintiffs that Deva had filed a Paragraph IV Certification with respect to each of the Patents-in-Suit and was seeking approval from FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Deva ANDA Product prior to the expiration of the Patents-in-Suit.

64. The purpose of Deva's submission of Deva's ANDA to FDA was to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Deva ANDA Product prior to the expiration of the Patents-in-Suit.

ANSWER: Deva admits that the purpose of Deva's submission of Deva's ANDA to FDA was to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Deva ANDA Product prior to the expiration of the Patents-in-Suit.

65. On information and belief, Deva prepared and submitted Deva's ANDA and intends to further prosecute Deva's ANDA.

ANSWER: Deva admits that it prepared and submitted Deva's ANDA and intends to further

prosecute Deva's ANDA.

66. On information and belief, if FDA approves Deva's ANDA, Deva will manufacture, offer for sale, or sell the Deva ANDA Product within the United States, or will import the Deva ANDA Product into the United States.

ANSWER: Deva cannot respond as to its actions should the FDA approve its ANDA, as intervening events, including but not limited to competition by others, changes in the marketplace, and FDA actions with respect to the brand product, can affect the actions Deva ultimately undertakes. To the extent an answer is required, Deva denies the allegations of Paragraph 66.

67. On information and belief, if FDA approves Deva's ANDA, Deva will actively induce or contribute to the manufacture, use, offer for sale, sale, or importation of the Deva ANDA Product in or into the United States.

ANSWER: Deva cannot respond as to its actions should the FDA approve its ANDA, as intervening events, including but not limited to competition by others, changes in the marketplace, and FDA actions with respect to the brand product, can affect the actions Deva ultimately undertakes. To the extent an answer is required, Deva denies the allegations of Paragraph 67.

68. In the Deva Notice Letter, Deva stated that the subject of Deva's ANDA is "Albuterol sulphate inhalation aerosol 90 mcg (EQ 0.09 mg base) per actuation."

ANSWER: Defendant directs Plaintiffs to the Deva Notice Letter for the best description of the Deva ANDA Product.

69. In the Deva Notice Letter, Deva stated that the active ingredient of the Deva ANDA Product is "albuterol sulphate."

ANSWER: Deva directs Plaintiffs to the Deva Notice Letter for the best description of the Deva ANDA Product.

70. In the Deva Notice Letter, Deva stated that the dosage form of the Deva ANDA Product is "an inhaler."

ANSWER: Deva directs Plaintiffs to the Deva Notice Letter for the best description of the Deva ANDA Product.

71. In the Deva Notice Letter, Deva stated that the strength of the Deva ANDA Product is "90 mcg (EQ 0.09 mg base)."

ANSWER: Deva directs Plaintiffs to the Deva Notice Letter for the best description of the Deva ANDA Product.

72. On information and belief, Deva's ANDA contains a Paragraph IV Certification with respect to each of the Patents-in-Suit asserting that the Patents-in-Suit are unenforceable, invalid, and/or will not be infringed by the manufacture, use, offer for sale, sale, or importation of the Deva ANDA Product ("Deva's Paragraph IV Certification"). Deva notified Plaintiffs of Deva's Paragraph IV Certification in the Deva Notice Letter, dated February 19, 2024.

ANSWER: Deva admits that Deva's ANDA contains a Paragraph IV Certification with respect to each of the Patents-in-Suit asserting that the Patents-in-Suit are unenforceable, invalid, and/or will not be infringed by the manufacture, use, offer for sale, sale, or importation of the Deva ANDA Product ("Deva's Paragraph IV Certification"). Deva notified Plaintiffs of Deva's Paragraph IV Certification in the Deva Notice Letter, dated February 19, 2024.

73. In the Deva Notice Letter, Deva offered Plaintiffs confidential access to certain limited information from ANDA No. 21-3818 on terms and conditions set forth in an attached "Offer

of Confidential Access" ("OCA").

ANSWER: Deva admits that in the Deva Notice Letter, Deva offered Plaintiffs confidential access to certain limited information from ANDA No. 21-3818 on terms and conditions set forth in an attached "Offer of Confidential Access" ("OCA").

74. The OCA provided by Deva in the Deva Notice Letter contained various unreasonably restrictive terms and conditions—many of which went above and beyond protections typically afforded in a protective order—including, but not limited to, broad restrictions on Teva's outside counsel from engaging in any patent prosecution for Teva, or any FDA counseling, litigation or other work before or involving FDA; prohibitions on providing information to scientific consultants; choice of law; and limitations on the scope of documents Deva would provide Teva.

ANSWER: Deva directs Plaintiffs to the Notice Letter for the best description of the offer of confidential access. Otherwise, denied.

75. On March 8, 2024, Plaintiffs' counsel sent Deva's counsel an email identifying various unreasonably restrictive terms in Deva's OCA and included a revised draft of the OCA.

ANSWER: Deva directs Plaintiffs to Plaintiffs' counsel's email for the best descriptions of the identified allegedly restrictive terms and the revised draft of the OCA. Otherwise, denied.

76. On March 18, 2024, Plaintiffs' counsel sent Deva's counsel another email regarding the revised draft of the OCA because Deva's counsel had not responded to the March 8, 2024 email.

ANSWER: Deva directs Plaintiffs to Plaintiffs' counsel's email for the best descriptions of this email regarding the revised draft of the OCA.

77. On March 20, 2024, Plaintiffs' counsel sent Deva's counsel a third email regarding the revised draft of the OCA because Deva's counsel had not responded to either the March 8, 2024 or March 18, 2024 emails.

ANSWER: Deva directs Plaintiffs to Plaintiffs' counsel's email for the best description of the contents of this third email.

78. On March 21, 2024, Deva's counsel sent an email to Plaintiffs' counsel stating that Deva did not agree to the changes in the revised draft of the OCA. Deva's counsel did not provide any proposed counter-revisions to the draft of the OCA. Instead, Deva's counsel stated that Deva considered the OCA offer revoked.

ANSWER: Deva directs Plaintiffs to Deva counsel's email for the best description of its content.

79. The Deva Notice Letter appends a document titled "Detailed Factual and Legal Bases for Deva's Paragraph IV Certification that [the Patents-in-Suit] are Invalid, Unenforceable, and/or Will Not Be Infringed" asserting that the commercial manufacture, use, offer for sale, sale, or importation of the Deva ANDA Product will not infringe any of the Patents-in-Suit ("Detailed Statement"). However, the Deva Notice Letter and "Detailed Statement" do not provide information regarding the Deva ANDA Product sufficient to evaluate Deva's assertions of noninfringement.

ANSWER: Deva directs Plaintiffs to the Deva Notice Letter for the best description of the "Detailed Factual and Legal Bases for Deva's Paragraph IV Certification." Otherwise, denied.

80. Given the 45-day statutory deadline to file suit set forth in 21 U.S.C. § 355(j)(5)(B)(iii), Deva's revocation of its OCA and refusal to provide Plaintiffs with any

documentation from Deva's ANDA, and the limited information provided by Deva to date, Plaintiffs turn to the judicial process and the aid of discovery to obtain, under appropriate judicial safeguards, such information as is required to further confirm their allegations of infringement and to present to the Court evidence that the Deva ANDA Product falls within the scope of one or more claims of the Patents-in-Suit.

ANSWER: Paragraph 80 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 80.

81. This action is being commenced within 45 days from the date of Plaintiffs' receipt of the Deva Notice Letter.

ANSWER: Deva admits that this action is being commenced within 45 days from the date of Plaintiffs' receipt of the Deva Notice Letter.

COUNT I- INFRINGEMENT BY DEVA OF U.S. PATENT NO. 8,132,712 UNDER 35 U.S.C. § 271(e)(2)

82. Plaintiffs incorporate each of the preceding paragraphs 1–81 as if fully set forth herein.

ANSWER: Defendant repeats, reiterates and re-alleges the responses to paragraphs 1 through and including 81 of the Complaint with the same force and effect as if hereinafter set forth at length.

83. Deva's submission of Deva's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Deva ANDA Product prior to the expiration of the '712 patent was an act of infringement of the '712 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Paragraph 83 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 83.

84. If approved by FDA, Deva's commercial manufacture, use, offer for sale, sale, and/or importation of the Deva ANDA Product in or into the United States will directly infringe, contribute to the infringement of, and/or actively induce the infringement of one or more claims of the '712 patent under 35 U.S.C. § 271(a)-(c).

ANSWER: Deva cannot respond as to its actions should the FDA approve its ANDA, as intervening events, including but not limited to competition by others, changes in the marketplace, and FDA actions with respect to the brand product, can affect the actions Deva ultimately undertakes. To the extent an answer is required, Deva denies the allegations of Paragraph 84.

85. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Deva ANDA Product would infringe one or more claims of the '712 patent, including at least claim 1, either literally or under the doctrine of equivalents.

ANSWER: Paragraph 85 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 85.

86. On information and belief, Deva will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Deva ANDA Product immediately and imminently upon FDA approval of Deva's ANDA.

ANSWER: Deva cannot respond as to its actions should the FDA approve its ANDA, as intervening events, including but not limited to competition by others, changes in the marketplace,

and FDA actions with respect to the brand product, can affect the actions Deva ultimately undertakes. To the extent an answer is required, Deva denies the allegations of Paragraph 86.

87. On information and belief, the use of the Deva ANDA Product in accordance with and as directed by Deva's proposed labeling for those products would infringe one or more claims of the '712 patent, including at least claim 1.

ANSWER: Paragraph 87 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 87.

88. On information and belief, Deva plans and intends to, and will, actively induce infringement of the '712 patent when Deva's ANDA is approved, and plans and intends to, and will, do so after approval.

ANSWER: Deva cannot respond as to its actions should the FDA approve its ANDA, as intervening events, including but not limited to competition by others, changes in the marketplace, and FDA actions with respect to the brand product, can affect the actions Deva ultimately undertakes. To the extent an answer is required, Deva denies the allegations of Paragraph 88.

89. On information and belief, Deva knows that the Deva ANDA Product and its proposed labeling are specially made or adapted for use in infringing the '712 patent and that the Deva ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Deva plans and intends to, and will, contribute to infringement of the '712 patent after approval of Deva's ANDA.

ANSWER: Paragraph 89 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of

Paragraph 89.

90. The foregoing actions by Deva constitute and/or will constitute infringement of the '712 patent, active inducement of infringement of the '712 patent, and contribution to the infringement by others of the '712 patent.

ANSWER: Paragraph 90 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 90.

91. On information and belief, Deva has acted with full knowledge of the '712 patent and without a reasonable basis for believing that it would not be liable for infringing the '712 patent, actively inducing infringement of the '712 patent, and contributing to the infringement by others of the '712 patent.

ANSWER: Paragraph 91 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 91.

92. Unless Deva is enjoined from infringing the '712 patent, actively inducing infringement of the '712 patent, and contributing to the infringement by others of the '712 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 92 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 92.

COUNT 2 – DECLARATORY JUDGMENT OF INFRINGEMENT BY DEVA OF U.S. PATENT NO. 8,132,712

93. Plaintiffs incorporate each of the preceding paragraphs 1–92 as if fully set forth herein.

ANSWER: Defendant repeats, reiterates and re-alleges the responses to paragraphs 1 through and including 92 of the Complaint with the same force and effect as if hereinafter set forth at length.

94. Deva has knowledge of the ’712 patent.

ANSWER: Paragraph 94 sets forth legal conclusions to which no response is required. To the extent an answer is required, Deva admits that it has knowledge of the ’712 patent

95. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Deva ANDA Product would infringe one or more claims of the ’712 patent, including at least claim 1, either literally or under the doctrine of equivalents.

ANSWER: Paragraph 95 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 95.

96. On information and belief, Deva will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Deva ANDA Product immediately and imminently upon FDA approval of Deva’s ANDA.

ANSWER: Deva cannot respond as to its actions should the FDA approve its ANDA, as intervening events, including but not limited to competition by others, changes in the marketplace, and FDA actions with respect to the brand product, can affect the actions Deva ultimately undertakes. To the extent an answer is required, Deva denies the allegations of Paragraph 96.

97. On information and belief, the use of the Deva ANDA Product in accordance with and as directed by Deva's proposed labeling for those products would infringe one or more claims of the '712 patent, including at least claim 1.

ANSWER: Paragraph 97 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 97.

98. On information and belief, Deva plans and intends to, and will, actively induce infringement of the '712 patent when Deva's ANDA is approved, and plans and intends to, and will, do so after approval.

ANSWER: Deva cannot respond as to its actions should the FDA approve its ANDA, as intervening events, including but not limited to competition by others, changes in the marketplace, and FDA actions with respect to the brand product, can affect the actions Deva ultimately undertakes. To the extent an answer is required, Deva denies the allegations of Paragraph 98.

99. On information and belief, Deva knows that the Deva ANDA Product and its proposed labeling are specially made or adapted for use in infringing the '712 patent and that the Deva ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Deva plans and intends to, and will, contribute to infringement of the '712 patent after approval of Deva's ANDA.

ANSWER: Paragraph 99 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 99.

100. The foregoing actions by Deva constitute and/or will constitute infringement of the

'712 patent, active inducement of infringement of the '712 patent, and contribution to the infringement by others of the '712 patent.

ANSWER: Paragraph 100 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 100.

101. On information and belief, Deva has acted with full knowledge of the '712 patent and without a reasonable basis for believing that it would not be liable for infringing the '712 patent, actively inducing infringement of the '712 patent, and contributing to the infringement by others of the '712 patent.

ANSWER: Paragraph 101 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 101.

102. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Deva regarding whether Deva's manufacture, use, sale, offer for sale, or importation into the United States of the Deva ANDA Product with its proposed labeling according to Deva's ANDA will infringe one or more claims of the '712 patent, including at least claim 1, and whether said claims of the '712 patent are valid.

ANSWER: Paragraph 102 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 102.

103. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of the Deva ANDA Product with its proposed

labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '712 patent and that the claims of the '712 patent are valid.

ANSWER: Paragraph 103 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 103.

104. Deva should be enjoined from infringing the '712 patent, actively inducing infringement of the '712 patent, and contributing to the infringement by others of the '712 patent; otherwise, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 104 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 104.

COUNT 3 – INFRINGEMENT BY DEVA OF
U.S. PATENT NO. 9,463,289 UNDER 35 U.S.C. § 271(e)(2)

105. Plaintiffs incorporate each of the preceding paragraphs 1–104 as if fully set forth herein.

ANSWER: Defendant repeats, reiterates and re-alleges the responses to paragraphs 1 through and including 104 of the Complaint with the same force and effect as if hereinafter set forth at length.

106. Deva's submission of Deva's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Deva ANDA Product prior to the expiration of the '289 patent was an act of infringement of the '289 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Paragraph 106 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 106.

107. If approved by FDA, Deva's commercial manufacture, use, offer for sale, sale, and/or importation of the Deva ANDA Product in or into the United States will directly infringe, contribute to the infringement of, and/or actively induce the infringement of one or more claims of the '289 patent under 35 U.S.C. § 271(a)-(c).

ANSWER: Deva cannot respond as to its actions should the FDA approve its ANDA, as intervening events, including but not limited to competition by others, changes in the marketplace, and FDA actions with respect to the brand product, can affect the actions Deva ultimately undertakes. To the extent an answer is required, Deva denies the allegations of Paragraph 107.

108. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Deva ANDA Product would infringe one or more claims of the '289 patent, including at least claim 1, either literally or under the doctrine of equivalents.

ANSWER: Paragraph 108 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 108.

109. On information and belief, Deva will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Deva ANDA Product immediately and imminently upon FDA approval of Deva's ANDA.

ANSWER: Deva cannot respond as to its actions should the FDA approve its ANDA, as intervening events, including but not limited to competition by others, changes in the marketplace,

and FDA actions with respect to the brand product, can affect the actions Deva ultimately undertakes. To the extent an answer is required, Deva denies the allegations of Paragraph 109.

110. On information and belief, the use of the Deva ANDA Product in accordance with and as directed by Deva's proposed labeling for those products would infringe one or more claims of the '289 patent, including at least claim 1.

ANSWER: Paragraph 110 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 110.

111. On information and belief, Deva plans and intends to, and will, actively induce infringement of the '289 patent when Deva's ANDA is approved, and plans and intends to, and will, do so after approval.

ANSWER: Deva cannot respond as to its actions should the FDA approve its ANDA, as intervening events, including but not limited to competition by others, changes in the marketplace, and FDA actions with respect to the brand product, can affect the actions Deva ultimately undertakes. To the extent an answer is required, Deva denies the allegations of Paragraph 111.

112. On information and belief, Deva knows that the Deva ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '289 patent and that the Deva ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Deva plans and intends to, and will, contribute to infringement of the '289 patent after approval of Deva's ANDA.

ANSWER: Paragraph 112 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of

Paragraph 112.

113. The foregoing actions by Deva constitute and/or will constitute infringement of the '289 patent, active inducement of infringement of the '289 patent, and contribution to the infringement by others of the '289 patent.

ANSWER: Paragraph 113 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 113.

114. On information and belief, Deva has acted with full knowledge of the '289 patent and without a reasonable basis for believing that it would not be liable for infringing the '289 patent, actively inducing infringement of the '289 patent, and contributing to the infringement by others of the '289 patent.

ANSWER: Paragraph 114 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 114.

115. Unless Deva is enjoined from infringing the '289 patent, actively inducing infringement of the '289 patent, and contributing to the infringement by others of the '289 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 115 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 115.

COUNT 4 – DECLARATORY JUDGMENT OF INFRINGEMENT BY DEVA OF U.S. PATENT NO. 9,463,289

116. Plaintiffs incorporate each of the preceding paragraphs 1–115 as if fully set forth herein.

ANSWER: Defendant repeats, reiterates and re-alleges the responses to paragraphs 1 through and including 115 of the Complaint with the same force and effect as if hereinafter set forth at length.

117. Deva has knowledge of the ’289 patent.

ANSWER: Paragraph 117 sets forth legal conclusions to which no response is required. To the extent an answer is required, Deva admits that it has knowledge of the ’289 patent.

118. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Deva ANDA Product would infringe one or more claims of the ’289 patent, including at least claim 1, either literally or under the doctrine of equivalents.

ANSWER: Paragraph 118 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 118.

119. On information and belief, Deva will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Deva ANDA Product immediately and imminently upon FDA approval of Deva’s ANDA.

ANSWER: Deva cannot respond as to its actions should the FDA approve its ANDA, as intervening events, including but not limited to competition by others, changes in the marketplace, and FDA actions with respect to the brand product, can affect the actions Deva ultimately undertakes. To the extent an answer is required, Deva denies the allegations of Paragraph 119.

120. On information and belief, the use of the Deva ANDA Product in accordance with and as directed by Deva's proposed labeling for those products would infringe one or more claims of the '289 patent, including at least claim 1.

ANSWER: Paragraph 120 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 120.

121. On information and belief, Deva plans and intends to, and will, actively induce infringement of the '289 patent when Deva's ANDA is approved, and plans and intends to, and will, do so after approval.

ANSWER: Deva cannot respond as to its actions should the FDA approve its ANDA, as intervening events, including but not limited to competition by others, changes in the marketplace, and FDA actions with respect to the brand product, can affect the actions Deva ultimately undertakes. To the extent an answer is required, Deva denies the allegations of Paragraph 121.

122. On information and belief, Deva knows that the Deva ANDA Product and its proposed labeling are specially made or adapted for use in infringing the '289 patent and that the Deva ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Deva plans and intends to, and will, contribute to infringement of the '289 patent after approval of Deva's ANDA.

ANSWER: Paragraph 122 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 122.

123. The foregoing actions by Deva constitute and/or will constitute infringement of the

'289 patent, active inducement of infringement of the '289 patent, and contribution to the infringement by others of the '289 patent.

ANSWER: Paragraph 123 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 123.

124. On information and belief, Deva has acted with full knowledge of the '289 patent and without a reasonable basis for believing that it would not be liable for infringing the '289 patent, actively inducing infringement of the '289 patent, and contributing to the infringement by others of the '289 patent.

ANSWER: Paragraph 124 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 124.

125. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Deva regarding whether Deva's manufacture, use, sale, offer for sale, or importation into the United States of the Deva ANDA Product with its proposed labeling according to Deva's ANDA will infringe one or more claims of the '289 patent, including at least claim 1, and whether said claims of the '289 patent are valid.

ANSWER: Paragraph 125 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 125.

126. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of the Deva ANDA Product with its proposed

labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '289 patent and that the claims of the '289 patent are valid.

ANSWER: Paragraph 126 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 126.

127. Deva should be enjoined from infringing the '289 patent, actively inducing infringement of the '289 patent, and contributing to the infringement by others of the '289 patent; otherwise, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 127 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 127.

COUNT 5 – INFRINGEMENT BY DEVA OF
U.S. PATENT NO. 9,808,587 UNDER 35 U.S.C. § 271(e)(2)

128. Plaintiffs incorporate each of the preceding paragraphs 1–127 as if fully set forth herein.

ANSWER: Defendant repeats, reiterates and re-alleges the responses to paragraphs 1 through and including 127 of the Complaint with the same force and effect as if hereinafter set forth at length.

129. Deva's submission of Deva's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Deva ANDA Product prior to the expiration of the '587 patent was an act of infringement of the '587 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Paragraph 129 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 129.

130. If approved by FDA, Deva's commercial manufacture, use, offer for sale, sale, and/or importation of the Deva ANDA Product in or into the United States will directly infringe, contribute to the infringement of, and/or actively induce the infringement of one or more claims of the '587 patent under 35 U.S.C. § 271(a)-(c).

ANSWER: Deva cannot respond as to its actions should the FDA approve its ANDA, as intervening events, including but not limited to competition by others, changes in the marketplace, and FDA actions with respect to the brand product, can affect the actions Deva ultimately undertakes. To the extent an answer is required, Deva denies the allegations of Paragraph 130.

131. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Deva ANDA Product would infringe one or more claims of the '587 patent, including at least claim 1, either literally or under the doctrine of equivalents.

ANSWER: Paragraph 131 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 131.

132. On information and belief, Deva will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Deva ANDA Product immediately and imminently upon FDA approval of Deva's ANDA.

ANSWER: Deva cannot respond as to its actions should the FDA approve its ANDA, as intervening events, including but not limited to competition by others, changes in the marketplace,

and FDA actions with respect to the brand product, can affect the actions Deva ultimately undertakes. To the extent an answer is required, Deva denies the allegations of Paragraph 132.

133. On information and belief, the use of the Deva ANDA Product in accordance with and as directed by Deva's proposed labeling for those products would infringe one or more claims of the '587 patent, including at least claim 1.

ANSWER: Paragraph 133 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 133.

134. On information and belief, Deva plans and intends to, and will, actively induce infringement of the '587 patent when Deva's ANDA is approved, and plans and intends to, and will, do so after approval.

ANSWER: Deva cannot respond as to its actions should the FDA approve its ANDA, as intervening events, including but not limited to competition by others, changes in the marketplace, and FDA actions with respect to the brand product, can affect the actions Deva ultimately undertakes. To the extent an answer is required, Deva denies the allegations of Paragraph 134.

135. On information and belief, Deva knows that the Deva ANDA Product and its proposed labeling are specially made or adapted for use in infringing the '587 patent and that the Deva ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Deva plans and intends to, and will, contribute to infringement of the '587 patent after approval of Deva's ANDA.

ANSWER: Paragraph 135 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of

Paragraph 135.

136. The foregoing actions by Deva constitute and/or will constitute infringement of the '587 patent, active inducement of infringement of the '587 patent, and contribution to the infringement by others of the '587 patent.

ANSWER: Paragraph 136 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 136.

137. On information and belief, Deva has acted with full knowledge of the '587 patent and without a reasonable basis for believing that it would not be liable for infringing the '587 patent, actively inducing infringement of the '587 patent, and contributing to the infringement by others of the '587 patent.

ANSWER: Paragraph 137 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 137.

138. Unless Deva is enjoined from infringing the '587 patent, actively inducing infringement of the '587 patent, and contributing to the infringement by others of the '587 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 138 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 138.

COUNT 6 – DECLARATORY JUDGMENT OF INFRINGEMENT BY DEVA OF U.S. PATENT NO. 9,808,587

139. Plaintiffs incorporate each of the preceding paragraphs 1–138 as if fully set forth herein.

ANSWER: Defendant repeats, reiterates and re-alleges the responses to paragraphs 1 through and including 138 of the Complaint with the same force and effect as if hereinafter set forth at length.

140. Deva has knowledge of the '587 patent.

ANSWER: Paragraph 140 sets forth legal conclusions to which no response is required. To the extent an answer is required, Deva admits that it has knowledge of the '587 patent.

141. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Deva ANDA Product would infringe one or more claims of the '587 patent, including at least claim 1, either literally or under the doctrine of equivalents.

ANSWER: Paragraph 141 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 141.

142. On information and belief, Deva will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Deva ANDA Product immediately and imminently upon FDA approval of Deva's ANDA.

ANSWER: Deva cannot respond as to its actions should the FDA approve its ANDA, as intervening events, including but not limited to competition by others, changes in the marketplace, and FDA actions with respect to the brand product, can affect the actions Deva ultimately undertakes. To the extent an answer is required, Deva denies the allegations of Paragraph 142.

143. On information and belief, the use of the Deva ANDA Product in accordance with and as directed by Deva's proposed labeling for those products would infringe one or more claims of the '587 patent, including at least claim 1.

ANSWER: Paragraph 143 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 143.

144. On information and belief, Deva plans and intends to, and will, actively induce infringement of the '587 patent when Deva's ANDA is approved, and plans and intends to, and will, do so after approval.

ANSWER: Deva cannot respond as to its actions should the FDA approve its ANDA, as intervening events, including but not limited to competition by others, changes in the marketplace, and FDA actions with respect to the brand product, can affect the actions Deva ultimately undertakes. To the extent an answer is required, Deva denies the allegations of Paragraph 144.

145. On information and belief, Deva knows that the Deva ANDA Product and its proposed labeling are specially made or adapted for use in infringing the '587 patent and that the Deva ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Deva plans and intends to, and will, contribute to infringement of the '587 patent after approval of Deva's ANDA.

ANSWER: Paragraph 145 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 145.

146. The foregoing actions by Deva constitute and/or will constitute infringement of the

'587 patent, active inducement of infringement of the '587 patent, and contribution to the infringement by others of the '587 patent.

ANSWER: Paragraph 146 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 146.

147. On information and belief, Deva has acted with full knowledge of the '587 patent and without a reasonable basis for believing that it would not be liable for infringing the '587 patent, actively inducing infringement of the '587 patent, and contributing to the infringement by others of the '587 patent.

ANSWER: Paragraph 147 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 147.

148. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Deva regarding whether Deva's manufacture, use, sale, offer for sale, or importation into the United States of the Deva ANDA Product with its proposed labeling according to Deva's ANDA will infringe one or more claims of the '587 patent, including at least claim 1, and whether said claims of the '587 patent are valid.

ANSWER: Paragraph 148 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 148.

149. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of the Deva ANDA Product with its proposed

labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '587 patent and that the claims of the '587 patent are valid.

ANSWER: Paragraph 149 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 149.

150. Deva should be enjoined from infringing the '587 patent, actively inducing infringement of the '587 patent, and contributing to the infringement by others of the '587 patent; otherwise, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 150 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 150.

COUNT 7 – INFRINGEMENT BY DEVA OF
U.S. PATENT NO. 10,022,509 UNDER 35 U.S.C. § 271(e)(2)

151. Plaintiffs incorporate each of the preceding paragraphs 1–150 as if fully set forth herein.

ANSWER: Defendant repeats, reiterates and re-alleges the responses to paragraphs 1 through and including 150 of the Complaint with the same force and effect as if hereinafter set forth at length.

152. Deva's submission of Deva's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Deva ANDA Product prior to the expiration of the '509 patent was an act of infringement of the '509

patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Paragraph 152 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 152.

153. If approved by FDA, Deva's commercial manufacture, use, offer for sale, sale, and/or importation of the Deva ANDA Product in or into the United States will directly infringe, contribute to the infringement of, and/or actively induce the infringement of one or more claims of the '509 patent under 35 U.S.C. § 271(a)-(c).

ANSWER: Deva cannot respond as to its actions should the FDA approve its ANDA, as intervening events, including but not limited to competition by others, changes in the marketplace, and FDA actions with respect to the brand product, can affect the actions Deva ultimately undertakes. To the extent an answer is required, Deva denies the allegations of Paragraph 153.

154. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Deva ANDA Product would infringe one or more claims of the '509 patent, including at least claim 1, either literally or under the doctrine of equivalents.

ANSWER: Paragraph 154 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 154.

155. On information and belief, Deva will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Deva ANDA Product immediately and imminently upon FDA approval of Deva's ANDA.

ANSWER: Deva cannot respond as to its actions should the FDA approve its ANDA, as

intervening events, including but not limited to competition by others, changes in the marketplace, and FDA actions with respect to the brand product, can affect the actions Deva ultimately undertakes. To the extent an answer is required, Deva denies the allegations of Paragraph 155.

156. On information and belief, the use of the Deva ANDA Product in accordance with and as directed by Deva's proposed labeling for those products would infringe one or more claims of the '509 patent, including at least claim 1.

ANSWER: Paragraph 156 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 156.

157. On information and belief, Deva plans and intends to, and will, actively induce infringement of the '509 patent when Deva's ANDA is approved, and plans and intends to, and will, do so after approval.

ANSWER: Deva cannot respond as to its actions should the FDA approve its ANDA, as intervening events, including but not limited to competition by others, changes in the marketplace, and FDA actions with respect to the brand product, can affect the actions Deva ultimately undertakes. To the extent an answer is required, Deva denies the allegations of Paragraph 157.

158. On information and belief, Deva knows that the Deva ANDA Product and its proposed labeling are specially made or adapted for use in infringing the '509 patent and that the Deva ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Deva plans and intends to, and will, contribute to infringement of the '509 patent after approval of Deva's ANDA.

ANSWER: Paragraph 158 sets forth legal conclusions based on alleged activities to which

no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 158.

159. The foregoing actions by Deva constitute and/or will constitute infringement of the '509 patent, active inducement of infringement of the '509 patent, and contribution to the infringement by others of the '509 patent.

ANSWER: Paragraph 159 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 159.

160. On information and belief, Deva has acted with full knowledge of the '509 patent and without a reasonable basis for believing that it would not be liable for infringing the '509 patent, actively inducing infringement of the '509 patent, and contributing to the infringement by others of the '509 patent.

ANSWER: Paragraph 160 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 160.

161. Unless Deva is enjoined from infringing the '509 patent, actively inducing infringement of the '509 patent, and contributing to the infringement by others of the '509 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 161 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 161.

COUNT 8 – DECLARATORY JUDGMENT OF INFRINGEMENT BY DEVA OF

U.S. PATENT NO. 10,022,509

162. Plaintiffs incorporate each of the preceding paragraphs 1–161 as if fully set forth herein.

ANSWER: Defendant repeats, reiterates and re-alleges the responses to paragraphs 1 through and including 161 of the Complaint with the same force and effect as if hereinafter set forth at length.

163. Deva has knowledge of the '509 patent.

ANSWER: Paragraph 163 sets forth legal conclusions to which no response is required. To the extent an answer is required, Deva admits that it has knowledge of the '509 patent

164. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Deva ANDA Product would infringe one or more claims of the '509 patent, including at least claim 1, either literally or under the doctrine of equivalents.

ANSWER: Paragraph 164 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 164.

165. On information and belief, Deva will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Deva ANDA Product immediately and imminently upon FDA approval of Deva's ANDA.

ANSWER: Deva cannot respond as to its actions should the FDA approve its ANDA, as intervening events, including but not limited to competition by others, changes in the marketplace, and FDA actions with respect to the brand product, can affect the actions Deva ultimately

undertakes. To the extent an answer is required, Deva denies the allegations of Paragraph 165.

166. On information and belief, the use of the Deva ANDA Product in accordance with and as directed by Deva's proposed labeling for those products would infringe one or more claims of the '509 patent, including at least claim 1.

ANSWER: Paragraph 166 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 166.

167. On information and belief, Deva plans and intends to, and will, actively induce infringement of the '509 patent when Deva's ANDA is approved, and plans and intends to, and will, do so after approval.

ANSWER: Deva cannot respond as to its actions should the FDA approve its ANDA, as intervening events, including but not limited to competition by others, changes in the marketplace, and FDA actions with respect to the brand product, can affect the actions Deva ultimately undertakes. To the extent an answer is required, Deva denies the allegations of Paragraph 167.

168. On information and belief, Deva knows that the Deva ANDA Product and its proposed labeling are specially made or adapted for use in infringing the '509 patent and that the Deva ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Deva plans and intends to, and will, contribute to infringement of the '509 patent after approval of Deva's ANDA.

ANSWER: Paragraph 168 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 168.

169. The foregoing actions by Deva constitute and/or will constitute infringement of the '509 patent, active inducement of infringement of the '509 patent, and contribution to the infringement by others of the '509 patent.

ANSWER: Paragraph 169 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 169.

170. On information and belief, Deva has acted with full knowledge of the '509 patent and without a reasonable basis for believing that it would not be liable for infringing the '509 patent, actively inducing infringement of the '509 patent, and contributing to the infringement by others of the '509 patent.

ANSWER: Paragraph 170 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 170.

171. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Deva regarding whether Deva's manufacture, use, sale, offer for sale, or importation into the United States of the Deva ANDA Product with its proposed labeling according to Deva's ANDA will infringe one or more claims of the '509 patent, including at least claim 1, and whether said claims of the '509 patent are valid.

ANSWER: Paragraph 171 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 171.

172. Plaintiffs should be granted a declaratory judgment that the making, using, sale,

offer for sale, and importation into the United States of the Deva ANDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '509 patent and that the claims of the '509 patent are valid.

ANSWER: Paragraph 172 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 172.

173. Deva should be enjoined from infringing the '509 patent, actively inducing infringement of the '509 patent, and contributing to the infringement by others of the '509 patent; otherwise, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 173 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 173.

COUNT 9 – INFRINGEMENT BY DEVA OF
U.S. PATENT NO. 10,022,510 UNDER 35 U.S.C. § 271(e)(2)

174. Plaintiffs incorporate each of the preceding paragraphs 1–173 as if fully set forth herein.

ANSWER: Defendant repeats, reiterates and re-alleges the responses to paragraphs 1 through and including 173 of the Complaint with the same force and effect as if hereinafter set forth at length.

175. Deva's submission of Deva's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Deva

ANDA Product prior to the expiration of the '510 patent was an act of infringement of the '510 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Paragraph 175 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 175.

176. If approved by FDA, Deva's commercial manufacture, use, offer for sale, sale, and/or importation of the Deva ANDA Product in or into the United States will directly infringe, contribute to the infringement of, and/or actively induce the infringement of one or more claims of the '510 patent under 35 U.S.C. § 271(a)-(c).

ANSWER: Deva cannot respond as to its actions should the FDA approve its ANDA, as intervening events, including but not limited to competition by others, changes in the marketplace, and FDA actions with respect to the brand product, can affect the actions Deva ultimately undertakes. To the extent an answer is required, Deva denies the allegations of Paragraph 176.

177. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Deva ANDA Product would infringe one or more claims of the '510 patent, including at least claim 1, either literally or under the doctrine of equivalents.

ANSWER: Paragraph 177 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 177.

178. On information and belief, Deva will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Deva ANDA Product immediately and imminently upon FDA approval of Deva's ANDA.

ANSWER: Deva cannot respond as to its actions should the FDA approve its ANDA, as intervening events, including but not limited to competition by others, changes in the marketplace, and FDA actions with respect to the brand product, can affect the actions Deva ultimately undertakes. To the extent an answer is required, Deva denies the allegations of Paragraph 178.

179. On information and belief, the use of the Deva ANDA Product in accordance with and as directed by Deva's proposed labeling for those products would infringe one or more claims of the '510 patent, including at least claim 1.

ANSWER: Paragraph 179 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 179.

180. On information and belief, Deva plans and intends to, and will, actively induce infringement of the '510 patent when Deva's ANDA is approved, and plans and intends to, and will, do so after approval.

ANSWER: Deva cannot respond as to its actions should the FDA approve its ANDA, as intervening events, including but not limited to competition by others, changes in the marketplace, and FDA actions with respect to the brand product, can affect the actions Deva ultimately undertakes. To the extent an answer is required, Deva denies the allegations of Paragraph 180.

181. On information and belief, Deva knows that the Deva ANDA Product and its proposed labeling are specially made or adapted for use in infringing the '510 patent and that the Deva ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Deva plans and intends to, and will, contribute to infringement of the '510 patent after approval of Deva's ANDA.

ANSWER: Paragraph 181 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 181.

182. The foregoing actions by Deva constitute and/or will constitute infringement of the '510 patent, active inducement of infringement of the '510 patent, and contribution to the infringement by others of the '510 patent.

ANSWER: Paragraph 182 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 182.

183. On information and belief, Deva has acted with full knowledge of the '510 patent and without a reasonable basis for believing that it would not be liable for infringing the '510 patent, actively inducing infringement of the '510 patent, and contributing to the infringement by others of the '510 patent.

ANSWER: Paragraph 183 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 183.

184. Unless Deva is enjoined from infringing the '510 patent, actively inducing infringement of the '510 patent, and contributing to the infringement by others of the '510 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 184 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 184.

COUNT 10 – DECLARATORY JUDGMENT OF INFRINGEMENT BY DEVA OF U.S. PATENT NO. 10,022,510

185. Plaintiffs incorporate each of the preceding paragraphs 1–184 as if fully set forth herein.

ANSWER: Defendant repeats, reiterates and re-alleges the responses to paragraphs 1 through and including 184 of the Complaint with the same force and effect as if hereinafter set forth at length.

186. Deva has knowledge of the '510 patent.

ANSWER: Paragraph 186 sets forth legal conclusions to which no response is required. To the extent an answer is required, Deva admits that it has knowledge of the '510 patent.

187. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Deva ANDA Product would infringe one or more claims of the '510 patent, including at least claim 1, either literally or under the doctrine of equivalents.

ANSWER: Paragraph 187 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 187.

188. On information and belief, Deva will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Deva ANDA Product immediately and imminently upon FDA approval of Deva's ANDA.

ANSWER: Deva cannot respond as to its actions should the FDA approve its ANDA, as intervening events, including but not limited to competition by others, changes in the marketplace, and FDA actions with respect to the brand product, can affect the actions Deva ultimately

undertakes. To the extent an answer is required, Deva denies the allegations of Paragraph 188.

189. On information and belief, the use of the Deva ANDA Product in accordance with and as directed by Deva's proposed labeling for those products would infringe one or more claims of the '510 patent, including at least claim 1.

ANSWER: Paragraph 189 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 189.

190. On information and belief, Deva plans and intends to, and will, actively induce infringement of the '510 patent when Deva's ANDA is approved, and plans and intends to, and will, do so after approval.

ANSWER: Deva cannot respond as to its actions should the FDA approve its ANDA, as intervening events, including but not limited to competition by others, changes in the marketplace, and FDA actions with respect to the brand product, can affect the actions Deva ultimately undertakes. To the extent an answer is required, Deva denies the allegations of Paragraph 190.

191. On information and belief, Deva knows that the Deva ANDA Product and its proposed labeling are specially made or adapted for use in infringing the '510 patent and that the Deva ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Deva plans and intends to, and will, contribute to infringement of the '510 patent after approval of Deva's ANDA.

ANSWER: Paragraph 191 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 191.

192. The foregoing actions by Deva constitute and/or will constitute infringement of the '510 patent, active inducement of infringement of the '510 patent, and contribution to the infringement by others of the '510 patent.

ANSWER: Paragraph 192 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 192.

193. On information and belief, Deva has acted with full knowledge of the '510 patent and without a reasonable basis for believing that it would not be liable for infringing the '510 patent, actively inducing infringement of the '510 patent, and contributing to the infringement by others of the '510 patent.

ANSWER: Paragraph 193 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 193.

194. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Deva regarding whether Deva's manufacture, use, sale, offer for sale, or importation into the United States of the Deva ANDA Product with its proposed labeling according to Deva's ANDA will infringe one or more claims of the '510 patent, including at least claim 1, and whether said claims of the '510 patent are valid.

ANSWER: Paragraph 194 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 194.

195. Plaintiffs should be granted a declaratory judgment that the making, using, sale,

offer for sale, and importation into the United States of the Deva ANDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '510 patent and that the claims of the '510 patent are valid.

ANSWER: Paragraph 195 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 195.

196. Deva should be enjoined from infringing the '510 patent, actively inducing infringement of the '510 patent, and contributing to the infringement by others of the '510 patent; otherwise, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 196 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 196.

COUNT 11 – INFRINGEMENT BY DEVA OF
U.S. PATENT NO. 10,086,156 UNDER 35 U.S.C. § 271(e)(2)

197. Plaintiffs incorporate each of the preceding paragraphs 1–196 as if fully set forth herein.

ANSWER: Defendant repeats, reiterates and re-alleges the responses to paragraphs 1 through and including 196 of the Complaint with the same force and effect as if hereinafter set forth at length.

198. Deva's submission of Deva's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Deva

ANDA Product prior to the expiration of the '156 patent was an act of infringement of the '156 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Paragraph 198 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 198.

199. If approved by FDA, Deva's commercial manufacture, use, offer for sale, sale, and/or importation of the Deva ANDA Product in or into the United States will directly infringe, contribute to the infringement of, and/or actively induce the infringement of one or more claims of the '156 patent under 35 U.S.C. § 271(a)-(c).

ANSWER: Deva cannot respond as to its actions should the FDA approve its ANDA, as intervening events, including but not limited to competition by others, changes in the marketplace, and FDA actions with respect to the brand product, can affect the actions Deva ultimately undertakes. To the extent an answer is required, Deva denies the allegations of Paragraph 199.

200. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Deva ANDA Product would infringe one or more claims of the '156 patent, including at least claim 1, either literally or under the doctrine of equivalents.

ANSWER: Paragraph 200 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 200.

201. On information and belief, Deva will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Deva ANDA Product immediately and imminently upon FDA approval of Deva's ANDA.

ANSWER: Deva cannot respond as to its actions should the FDA approve its ANDA, as intervening events, including but not limited to competition by others, changes in the marketplace, and FDA actions with respect to the brand product, can affect the actions Deva ultimately undertakes. To the extent an answer is required, Deva denies the allegations of Paragraph 201.

202. On information and belief, the use of the Deva ANDA Product in accordance with and as directed by Deva's proposed labeling for those products would infringe one or more claims of the '156 patent, including at least claim 1.

ANSWER: Paragraph 202 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 202.

203. On information and belief, Deva plans and intends to, and will, actively induce infringement of the '156 patent when Deva's ANDA is approved, and plans and intends to, and will, do so after approval.

ANSWER: Deva cannot respond as to its actions should the FDA approve its ANDA, as intervening events, including but not limited to competition by others, changes in the marketplace, and FDA actions with respect to the brand product, can affect the actions Deva ultimately undertakes. To the extent an answer is required, Deva denies the allegations of Paragraph 203.

204. On information and belief, Deva knows that the Deva ANDA Product and its proposed labeling are specially made or adapted for use in infringing the '156 patent and that the Deva ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Deva plans and intends to, and will, contribute to infringement of the '156 patent after approval of Deva's ANDA.

ANSWER: Paragraph 204 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 204.

205. The foregoing actions by Deva constitute and/or will constitute infringement of the '156 patent, active inducement of infringement of the '156 patent, and contribution to the infringement by others of the '156 patent.

ANSWER: Paragraph 205 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 205.

206. On information and belief, Deva has acted with full knowledge of the '156 patent and without a reasonable basis for believing that it would not be liable for infringing the '156 patent, actively inducing infringement of the '156 patent, and contributing to the infringement by others of the '156 patent.

ANSWER: Paragraph 206 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 206.

207. Unless Deva is enjoined from infringing the '156 patent, actively inducing infringement of the '156 patent, and contributing to the infringement by others of the '156 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 207 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 207.

COUNT 12 – DECLARATORY JUDGMENT OF INFRINGEMENT BY DEVA OF U.S. PATENT NO. 10,086,156

208. Plaintiffs incorporate each of the preceding paragraphs 1–207 as if fully set forth herein.

ANSWER: Defendant repeats, reiterates and re-alleges the responses to paragraphs 1 through and including 207 of the Complaint with the same force and effect as if hereinafter set forth at length.

209. Deva has knowledge of the '156 patent.

ANSWER: Paragraph 209 sets forth legal conclusions to which no response is required. To the extent an answer is required, Deva admits that it has knowledge of the '156 patent.

210. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Deva ANDA Product would infringe one or more claims of the '156 patent, including at least claim 1, either literally or under the doctrine of equivalents.

ANSWER: Paragraph 210 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 210.

211. On information and belief, Deva will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Deva ANDA Product immediately and imminently upon FDA approval of Deva's ANDA.

ANSWER: Deva cannot respond as to its actions should the FDA approve its ANDA, as intervening events, including but not limited to competition by others, changes in the marketplace, and FDA actions with respect to the brand product, can affect the actions Deva ultimately

undertakes. To the extent an answer is required, Deva denies the allegations of Paragraph 211.

212. On information and belief, the use of the Deva ANDA Product in accordance with and as directed by Deva's proposed labeling for those products would infringe one or more claims of the '156 patent, including at least claim 1.

ANSWER: Paragraph 212 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 212.

213. On information and belief, Deva plans and intends to, and will, actively induce infringement of the '156 patent when Deva's ANDA is approved, and plans and intends to, and will, do so after approval.

ANSWER: Deva cannot respond as to its actions should the FDA approve its ANDA, as intervening events, including but not limited to competition by others, changes in the marketplace, and FDA actions with respect to the brand product, can affect the actions Deva ultimately undertakes. To the extent an answer is required, Deva denies the allegations of Paragraph 213.

214. On information and belief, Deva knows that the Deva ANDA Product and its proposed labeling are specially made or adapted for use in infringing the '156 patent and that the Deva ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Deva plans and intends to, and will, contribute to infringement of the '156 patent after approval of Deva's ANDA.

ANSWER: Paragraph 214 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 214.

215. The foregoing actions by Deva constitute and/or will constitute infringement of the '156 patent, active inducement of infringement of the '156 patent, and contribution to the infringement by others of the '156 patent.

ANSWER: Paragraph 215 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 215.

216. On information and belief, Deva has acted with full knowledge of the '156 patent and without a reasonable basis for believing that it would not be liable for infringing the '156 patent, actively inducing infringement of the '156 patent, and contributing to the infringement by others of the '156 patent.

ANSWER: Paragraph 216 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 216.

217. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Deva regarding whether Deva's manufacture, use, sale, offer for sale, or importation into the United States of the Deva ANDA Product with its proposed labeling according to Deva's ANDA will infringe one or more claims of the '156 patent, including at least claim 1, and whether said claims of the '156 patent are valid.

ANSWER: Paragraph 217 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 217.

218. Plaintiffs should be granted a declaratory judgment that the making, using, sale,

offer for sale, and importation into the United States of the Deva ANDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '156 patent and that the claims of the '156 patent are valid.

ANSWER: Paragraph 218 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 218.

219. Deva should be enjoined from infringing the '156 patent, actively inducing infringement of the '156 patent, and contributing to the infringement by others of the '156 patent; otherwise, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 219 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 219.

COUNT 13 – INFRINGEMENT BY DEVA OF
U.S. PATENT NO. 10,561,808 UNDER 35 U.S.C. § 271(e)(2)

220. Plaintiffs incorporate each of the preceding paragraphs 1–219 as if fully set forth herein.

ANSWER: Defendant repeats, reiterates and re-alleges the responses to paragraphs 1 through and including 219 of the Complaint with the same force and effect as if hereinafter set forth at length.

221. Deva's submission of Deva's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Deva ANDA Product prior to the expiration of the '808 patent was an act of infringement of the '808

patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Paragraph 221 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 221.

222. If approved by FDA, Deva's commercial manufacture, use, offer for sale, sale, and/or importation of the Deva ANDA Product in or into the United States will directly infringe, contribute to the infringement of, and/or actively induce the infringement of one or more claims of the '808 patent under 35 U.S.C. § 271(a)-(c).

ANSWER: Deva cannot respond as to its actions should the FDA approve its ANDA, as intervening events, including but not limited to competition by others, changes in the marketplace, and FDA actions with respect to the brand product, can affect the actions Deva ultimately undertakes. To the extent an answer is required, Deva denies the allegations of Paragraph 222.

223. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Deva ANDA Product would infringe one or more claims of the '808 patent, including at least claim 1, either literally or under the doctrine of equivalents.

ANSWER: Paragraph 223 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 223.

224. On information and belief, Deva will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Deva ANDA Product immediately and imminently upon FDA approval of Deva's ANDA.

ANSWER: Deva cannot respond as to its actions should the FDA approve its ANDA, as

intervening events, including but not limited to competition by others, changes in the marketplace, and FDA actions with respect to the brand product, can affect the actions Deva ultimately undertakes. To the extent an answer is required, Deva denies the allegations of Paragraph 224.

225. On information and belief, the use of the Deva ANDA Product in accordance with and as directed by Deva's proposed labeling for those products would infringe one or more claims of the '808 patent, including at least claim 1.

ANSWER: Paragraph 225 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 225.

226. On information and belief, Deva plans and intends to, and will, actively induce infringement of the '808 patent when Deva's ANDA is approved, and plans and intends to, and will, do so after approval.

ANSWER: Deva cannot respond as to its actions should the FDA approve its ANDA, as intervening events, including but not limited to competition by others, changes in the marketplace, and FDA actions with respect to the brand product, can affect the actions Deva ultimately undertakes. To the extent an answer is required, Deva denies the allegations of Paragraph 226.

227. On information and belief, Deva knows that the Deva ANDA Product and its proposed labeling are specially made or adapted for use in infringing the '808 patent and that the Deva ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Deva plans and intends to, and will, contribute to infringement of the '808 patent after approval of Deva's ANDA.

ANSWER: Paragraph 227 sets forth legal conclusions based on alleged activities to which

no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 227.

228. The foregoing actions by Deva constitute and/or will constitute infringement of the '808 patent, active inducement of infringement of the '808 patent, and contribution to the infringement by others of the '808 patent.

ANSWER: Paragraph 228 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 228.

229. On information and belief, Deva has acted with full knowledge of the '808 patent and without a reasonable basis for believing that it would not be liable for infringing the '808 patent, actively inducing infringement of the '808 patent, and contributing to the infringement by others of the '808 patent.

ANSWER: Paragraph 229 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 229.

230. Unless Deva is enjoined from infringing the '808 patent, actively inducing infringement of the '808 patent, and contributing to the infringement by others of the '808 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 230 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 230.

COUNT 14 – DECLARATORY JUDGMENT OF INFRINGEMENT BY DEVA OF

U.S. PATENT NO. 10,561,808

231. Plaintiffs incorporate each of the preceding paragraphs 1–230 as if fully set forth herein.

ANSWER: Defendant repeats, reiterates and re-alleges the responses to paragraphs 1 through and including 230 of the Complaint with the same force and effect as if hereinafter set forth at length.

232. Deva has knowledge of the '808 patent.

ANSWER: Paragraph 246 sets forth legal conclusions to which no response is required. To the extent an answer is required, Deva admits that it has knowledge of the '808 patent.

233. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Deva ANDA Product would infringe one or more claims of the '808 patent, including at least claim 1, either literally or under the doctrine of equivalents.

ANSWER: Paragraph 233 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 233.

234. On information and belief, Deva will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Deva ANDA Product immediately and imminently upon FDA approval of Deva's ANDA.

ANSWER: Deva cannot respond as to its actions should the FDA approve its ANDA, as intervening events, including but not limited to competition by others, changes in the marketplace, and FDA actions with respect to the brand product, can affect the actions Deva ultimately

undertakes. To the extent an answer is required, Deva denies the allegations of Paragraph 234.

235. On information and belief, the use of the Deva ANDA Product in accordance with and as directed by Deva's proposed labeling for those products would infringe one or more claims of the '808 patent, including at least claim 1.

ANSWER: Paragraph 235 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 235.

236. On information and belief, Deva plans and intends to, and will, actively induce infringement of the '808 patent when Deva's ANDA is approved, and plans and intends to, and will, do so after approval.

ANSWER: Deva cannot respond as to its actions should the FDA approve its ANDA, as intervening events, including but not limited to competition by others, changes in the marketplace, and FDA actions with respect to the brand product, can affect the actions Deva ultimately undertakes. To the extent an answer is required, Deva denies the allegations of Paragraph 236.

237. On information and belief, Deva knows that the Deva ANDA Product and its proposed labeling are specially made or adapted for use in infringing the '808 patent and that the Deva ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Deva plans and intends to, and will, contribute to infringement of the '808 patent after approval of Deva's ANDA.

ANSWER: Paragraph 237 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 237.

238. The foregoing actions by Deva constitute and/or will constitute infringement of the '808 patent, active inducement of infringement of the '808 patent, and contribution to the infringement by others of the '808 patent.

ANSWER: Paragraph 238 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 238.

239. On information and belief, Deva has acted with full knowledge of the '808 patent and without a reasonable basis for believing that it would not be liable for infringing the '808 patent, actively inducing infringement of the '808 patent, and contributing to the infringement by others of the '808 patent.

ANSWER: Paragraph 239 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 239.

240. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Deva regarding whether Deva's manufacture, use, sale, offer for sale, or importation into the United States of the Deva ANDA Product with its proposed labeling according to Deva's ANDA will infringe one or more claims of the '808 patent, including at least claim 1, and whether said claims of the '808 patent are valid.

ANSWER: Paragraph 240 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 240.

241. Plaintiffs should be granted a declaratory judgment that the making, using, sale,

offer for sale, and importation into the United States of the Deva ANDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '808 patent and that the claims of the '808 patent are valid.

ANSWER: Paragraph 241 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 241.

242. Deva should be enjoined from infringing the '808 patent, actively inducing infringement of the '808 patent, and contributing to the infringement by others of the '808 patent; otherwise, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 242 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 242.

COUNT 15 – INFRINGEMENT BY DEVA OF
U.S. PATENT NO. 10,695,512 UNDER 35 U.S.C. § 271(e)(2)

243. Plaintiffs incorporate each of the preceding paragraphs 1–242 as if fully set forth herein.

ANSWER: Defendant repeats, reiterates and re-alleges the responses to paragraphs 1 through and including 242 of the Complaint with the same force and effect as if hereinafter set forth at length.:

244. Deva's submission of Deva's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Deva ANDA Product prior to the expiration of the '512 patent was an act of infringement of the '512

patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Paragraph 244 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 244.

245. If approved by FDA, Deva's commercial manufacture, use, offer for sale, sale, and/or importation of the Deva ANDA Product in or into the United States will directly infringe, contribute to the infringement of, and/or actively induce the infringement of one or more claims of the '512 patent under 35 U.S.C. § 271(a)-(c).

ANSWER: Deva cannot respond as to its actions should the FDA approve its ANDA, as intervening events, including but not limited to competition by others, changes in the marketplace, and FDA actions with respect to the brand product, can affect the actions Deva ultimately undertakes. To the extent an answer is required, Deva denies the allegations of Paragraph 245.

246. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Deva ANDA Product would infringe one or more claims of the '512 patent, including at least claim 1, either literally or under the doctrine of equivalents.

ANSWER: Paragraph 246 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 246.

247. On information and belief, Deva will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Deva ANDA Product immediately and imminently upon FDA approval of Deva's ANDA.

ANSWER: Deva cannot respond as to its actions should the FDA approve its ANDA, as

intervening events, including but not limited to competition by others, changes in the marketplace, and FDA actions with respect to the brand product, can affect the actions Deva ultimately undertakes. To the extent an answer is required, Deva denies the allegations of Paragraph 247.

248. On information and belief, the use of the Deva ANDA Product in accordance with and as directed by Deva's proposed labeling for those products would infringe one or more claims of the '512 patent, including at least claim 1.

ANSWER: Paragraph 248 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 248.

249. On information and belief, Deva plans and intends to, and will, actively induce infringement of the '512 patent when Deva's ANDA is approved, and plans and intends to, and will, do so after approval.

ANSWER: Deva cannot respond as to its actions should the FDA approve its ANDA, as intervening events, including but not limited to competition by others, changes in the marketplace, and FDA actions with respect to the brand product, can affect the actions Deva ultimately undertakes. To the extent an answer is required, Deva denies the allegations of Paragraph 249.

250. On information and belief, Deva knows that the Deva ANDA Product and its proposed labeling are specially made or adapted for use in infringing the '512 patent and that the Deva ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Deva plans and intends to, and will, contribute to infringement of the '512 patent after approval of Deva's ANDA.

ANSWER: Paragraph 250 sets forth legal conclusions based on alleged activities to which

no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 250.

251. The foregoing actions by Deva constitute and/or will constitute infringement of the '512 patent, active inducement of infringement of the '512 patent, and contribution to the infringement by others of the '512 patent.

ANSWER: Paragraph 251 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 251.

252. On information and belief, Deva has acted with full knowledge of the '512 patent and without a reasonable basis for believing that it would not be liable for infringing the '512 patent, actively inducing infringement of the '512 patent, and contributing to the infringement by others of the '512 patent.

ANSWER: Paragraph 252 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 252.

253. Unless Deva is enjoined from infringing the '512 patent, actively inducing infringement of the '512 patent, and contributing to the infringement by others of the '512 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 253 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 253.

COUNT 16 – DECLARATORY JUDGMENT OF INFRINGEMENT BY DEVA OF U.S. PATENT NO. 10,695,512

254. Plaintiffs incorporate each of the preceding paragraphs 1–253 as if fully set forth herein.

ANSWER: Defendant repeats, reiterates and re-alleges the responses to paragraphs 1 through and including 253 of the Complaint with the same force and effect as if hereinafter set forth at length.

255. Deva has knowledge of the '512 patent.

ANSWER: Paragraph 255 sets forth legal conclusions to which no response is required. To the extent an answer is required, Deva admits that it has knowledge of the '512 patent.

256. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Deva ANDA Product would infringe one or more claims of the '512 patent, including at least claim 1, either literally or under the doctrine of equivalents.

ANSWER: Paragraph 256 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 256.

257. On information and belief, Deva will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Deva ANDA Product immediately and imminently upon FDA approval of Deva's ANDA.

ANSWER: Deva cannot respond as to its actions should the FDA approve its ANDA, as intervening events, including but not limited to competition by others, changes in the marketplace, and FDA actions with respect to the brand product, can affect the actions Deva ultimately

undertakes. To the extent an answer is required, Deva denies the allegations of Paragraph 257.

258. On information and belief, the use of the Deva ANDA Product in accordance with and as directed by Deva's proposed labeling for those products would infringe one or more claims of the '512 patent, including at least claim 1.

ANSWER: Paragraph 258 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 258.

259. On information and belief, Deva plans and intends to, and will, actively induce infringement of the '512 patent when Deva's ANDA is approved, and plans and intends to, and will, do so after approval.

ANSWER: Deva cannot respond as to its actions should the FDA approve its ANDA, as intervening events, including but not limited to competition by others, changes in the marketplace, and FDA actions with respect to the brand product, can affect the actions Deva ultimately undertakes. To the extent an answer is required, Deva denies the allegations of Paragraph 259.

260. On information and belief, Deva knows that the Deva ANDA Product and its proposed labeling are specially made or adapted for use in infringing the '512 patent and that the Deva ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Deva plans and intends to, and will, contribute to infringement of the '512 patent after approval of Deva's ANDA.

ANSWER: Paragraph 260 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 260.

261. The foregoing actions by Deva constitute and/or will constitute infringement of the '512 patent, active inducement of infringement of the '512 patent, and contribution to the infringement by others of the '512 patent.

ANSWER: Paragraph 261 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 261.

262. On information and belief, Deva has acted with full knowledge of the '512 patent and without a reasonable basis for believing that it would not be liable for infringing the '512 patent, actively inducing infringement of the '512 patent, and contributing to the infringement by others of the '512 patent.

ANSWER: Paragraph 262 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 262.

263. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Deva regarding whether Deva's manufacture, use, sale, offer for sale, or importation into the United States of the Deva ANDA Product with its proposed labeling according to Deva's ANDA will infringe one or more claims of the '512 patent, including at least claim 1, and whether said claims of the '512 patent are valid.

ANSWER: Paragraph 263 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 263.

264. Plaintiffs should be granted a declaratory judgment that the making, using, sale,

offer for sale, and importation into the United States of the Deva ANDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '512 patent and that the claims of the '512 patent are valid.

ANSWER: Paragraph 264 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 264.

265. Deva should be enjoined from infringing the '512 patent, actively inducing infringement of the '512 patent, and contributing to the infringement by others of the '512 patent; otherwise, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 265 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 265.

COUNT 17 – INFRINGEMENT BY DEVA OF
U.S. PATENT NO. 11,395,889 UNDER 35 U.S.C. § 271(e)(2)

266. Plaintiffs incorporate each of the preceding paragraphs 1–265 as if fully set forth herein.

ANSWER: Defendant repeats, reiterates and re-alleges the responses to paragraphs 1 through and including 265 of the Complaint with the same force and effect as if hereinafter set forth at length.

267. Deva's submission of Deva's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Deva ANDA Product prior to the expiration of the '889 patent was an act of infringement of the '889

patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Paragraph 267 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 267.

268. If approved by FDA, Deva's commercial manufacture, use, offer for sale, sale, and/or importation of the Deva ANDA Product in or into the United States will directly infringe, contribute to the infringement of, and/or actively induce the infringement of one or more claims of the '889 patent under 35 U.S.C. § 271(a)-(c).

ANSWER: Deva cannot respond as to its actions should the FDA approve its ANDA, as intervening events, including but not limited to competition by others, changes in the marketplace, and FDA actions with respect to the brand product, can affect the actions Deva ultimately undertakes. To the extent an answer is required, Deva denies the allegations of Paragraph 268.

269. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Deva ANDA Product would infringe one or more claims of the '889 patent, including at least claim 1, either literally or under the doctrine of equivalents.

ANSWER: Paragraph 269 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 269.

270. On information and belief, Deva will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Deva ANDA Product immediately and imminently upon FDA approval of Deva's ANDA.

ANSWER: Deva cannot respond as to its actions should the FDA approve its ANDA, as

intervening events, including but not limited to competition by others, changes in the marketplace, and FDA actions with respect to the brand product, can affect the actions Deva ultimately undertakes. To the extent an answer is required, Deva denies the allegations of Paragraph 270.

271. On information and belief, the use of the Deva ANDA Product in accordance with and as directed by Deva's proposed labeling for those products would infringe one or more claims of the '889 patent, including at least claim 1.

ANSWER: Paragraph 271 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 271.

272. On information and belief, Deva plans and intends to, and will, actively induce infringement of the '889 patent when Deva's ANDA is approved, and plans and intends to, and will, do so after approval.

ANSWER: Deva cannot respond as to its actions should the FDA approve its ANDA, as intervening events, including but not limited to competition by others, changes in the marketplace, and FDA actions with respect to the brand product, can affect the actions Deva ultimately undertakes. To the extent an answer is required, Deva denies the allegations of Paragraph 272.

273. On information and belief, Deva knows that the Deva ANDA Product and its proposed labeling are specially made or adapted for use in infringing the '889 patent and that the Deva ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Deva plans and intends to, and will, contribute to infringement of the '889 patent after approval of Deva's ANDA.

ANSWER: Paragraph 273 sets forth legal conclusions based on alleged activities to which

no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 273.

274. The foregoing actions by Deva constitute and/or will constitute infringement of the '889 patent, active inducement of infringement of the '889 patent, and contribution to the infringement by others of the '889 patent.

ANSWER: Paragraph 274 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 274.

275. On information and belief, Deva has acted with full knowledge of the '889 patent and without a reasonable basis for believing that it would not be liable for infringing the '889 patent, actively inducing infringement of the '889 patent, and contributing to the infringement by others of the '889 patent.

ANSWER: Paragraph 275 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 275.

276. Unless Deva is enjoined from infringing the '889 patent, actively inducing infringement of the '889 patent, and contributing to the infringement by others of the '889 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 276 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 276.

COUNT 18 – DECLARATORY JUDGMENT OF INFRINGEMENT BY DEVA OF U.S. PATENT NO. 11,395,889

277. Plaintiffs incorporate each of the preceding paragraphs 1–276 as if fully set forth herein.

ANSWER: Defendant repeats, reiterates and re-alleges the responses to paragraphs 1 through and including 276 of the Complaint with the same force and effect as if hereinafter set forth at length.

278. Deva has knowledge of the '889 patent.

ANSWER: Paragraph 278 sets forth legal conclusions to which no response is required. To the extent an answer is required, Deva admits that it has knowledge of the '889 patent.

279. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Deva ANDA Product would infringe one or more claims of the '889 patent, including at least claim 1, either literally or under the doctrine of equivalents.

ANSWER: Paragraph 279 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 279.

280. On information and belief, Deva will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the Deva ANDA Product immediately and imminently upon FDA approval of Deva's ANDA.

ANSWER: Deva cannot respond as to its actions should the FDA approve its ANDA, as intervening events, including but not limited to competition by others, changes in the marketplace, and FDA actions with respect to the brand product, can affect the actions Deva ultimately

undertakes. To the extent an answer is required, Deva denies the allegations of Paragraph 280.

281. On information and belief, the use of the Deva ANDA Product in accordance with and as directed by Deva's proposed labeling for those products would infringe one or more claims of the '889 patent, including at least claim 1.

ANSWER: Paragraph 281 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 281.

282. On information and belief, Deva plans and intends to, and will, actively induce infringement of the '889 patent when Deva's ANDA is approved, and plans and intends to, and will, do so after approval.

ANSWER: Deva cannot respond as to its actions should the FDA approve its ANDA, as intervening events, including but not limited to competition by others, changes in the marketplace, and FDA actions with respect to the brand product, can affect the actions Deva ultimately undertakes. To the extent an answer is required, Deva denies the allegations of Paragraph 282.

283. On information and belief, Deva knows that the Deva ANDA Product and its proposed labeling are specially made or adapted for use in infringing the '889 patent and that the Deva ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Deva plans and intends to, and will, contribute to infringement of the '889 patent after approval of Deva's ANDA.

ANSWER: Paragraph 283 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 283.

284. The foregoing actions by Deva constitute and/or will constitute infringement of the '889 patent, active inducement of infringement of the '889 patent, and contribution to the infringement by others of the '889 patent.

ANSWER: Paragraph 284 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 284.

285. On information and belief, Deva has acted with full knowledge of the '889 patent and without a reasonable basis for believing that it would not be liable for infringing the '889 patent, actively inducing infringement of the '889 patent, and contributing to the infringement by others of the '889 patent.

ANSWER: Paragraph 285 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 285.

286. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Deva regarding whether Deva's manufacture, use, sale, offer for sale, or importation into the United States of the Deva ANDA Product with its proposed labeling according to Deva's ANDA will infringe one or more claims of the '889 patent, including at least claim 1, and whether said claims of the '889 patent are valid.

ANSWER: Paragraph 286 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 286.

287. Plaintiffs should be granted a declaratory judgment that the making, using, sale,

offer for sale, and importation into the United States of the Deva ANDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '889 patent and that the claims of the '889 patent are valid.

ANSWER: Paragraph 287 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 287.

288. Deva should be enjoined from infringing the '889 patent, actively inducing infringement of the '889 patent, and contributing to the infringement by others of the '889 patent; otherwise, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 288 sets forth legal conclusions based on alleged activities to which no response is required. To the extent an answer is required, Deva denies the allegations of Paragraph 288.

RESPONSE TO PLAINTIFFS' PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

(a) A judgment that each of the Patents-in-Suit has been infringed under 35 U.S.C. § 271(e)(2) by Deva's submission to FDA of Deva's ANDA;

ANSWER: Deva denies that Plaintiffs are entitled to any of its requests for relief.

(b) A judgment that the Patents-in-Suit are valid and enforceable;

ANSWER: Deva denies that Plaintiffs are entitled to any of its requests for relief.

(c) A judgment pursuant to, among other things, 35 U.S.C. § 271(e)(4)(A) ordering that the effective date of any FDA approval for Deva to make, use, offer for sale, sell, market, distribute,

or import the Deva ANDA Product, or any other product, the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the Patents-in-Suit, shall not be earlier than the latest of the expiration dates of the Patents-in-Suit, inclusive of any extension(s) and additional period(s) of exclusivity;

ANSWER: Deva denies that Plaintiffs are entitled to any of its requests for relief.

(d) A preliminary and permanent injunction pursuant to, among other things, 35 U.S.C. §§ 271(e)(4)(B) and 283 enjoining Deva, its officers, agents, servants, employees and attorneys, and all persons acting in concert with them, from making, using, selling, offering for sale, marketing, distributing, or importing the Deva ANDA Product, or any other product, the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the Patents-in-Suit, or the inducement of or the contribution to any of the foregoing, prior to the latest of the expiration dates of the Patents-in- Suit, inclusive of any extension(s) and additional period(s) of exclusivity;

ANSWER: Deva denies that Plaintiffs are entitled to any of its requests for relief.

(e) A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing the Deva ANDA Product, or any other product, the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the Patents-in- Suit, prior to the expiration date of the Patents-in-Suit, respectively, will infringe, actively induce infringement of, and/or contribute to the infringement by others of the Patents-in-Suit under 35 U.S.C. §§ 271(a)-(c);89

ANSWER: Deva denies that Plaintiffs are entitled to any of its requests for relief.

(f) An award of Plaintiffs' damages or other monetary relief to compensate Plaintiffs if Deva, its officers, agents, servants, employees and attorneys, or any person acting in concert with

them, engages in the manufacture, use, offer for sale, sale, marketing, distribution, or importation of the Deva ANDA Product, or any other product, the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the Patents-in-Suit, or the inducement of or the contribution to any of the foregoing, prior to the latest of the expiration dates of the Patents-in-Suit, inclusive of any extension(s) and additional period(s) of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(C);

ANSWER: Deva denies that Plaintiffs are entitled to any of its requests for relief.

(g) A judgment that Deva willfully and deliberately infringed the Patents-in-Suit;

ANSWER: Deva denies that Plaintiffs are entitled to any of its requests for relief.

(h) A declaration that this case is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. §§ 285 and 271(e)(4);

ANSWER: Deva denies that Plaintiffs are entitled to any of its requests for relief.

(i) An award of Plaintiffs' costs and expenses in this action; and

ANSWER: Deva denies that Plaintiffs are entitled to any of its requests for relief.

(j) Such further and other relief as this Court may deem just and proper.

ANSWER: Deva denies that Plaintiffs are entitled to any of its requests for relief.

SEPARATE DEFENSES

Deva Holding A.S. a/k/a Deva Holdings A.S. ("Deva" or "Defendant") asserts the following defenses without prejudice to the denials in this Answer, without admitting any allegations of this Complaint not otherwise admitted.

FIRST SEPARATE DEFENSE
FAILURE TO STATE A CLAIM

Plaintiffs' Complaint, in whole or in part, fails to state claims upon which relief may be granted.

SECOND SEPARATE DEFENSE
INVALIDITY AND UNENFORCEABILITY

U.S. Patent Nos. 8,132,712 ("the '712 patent"), 9,463,289 ("the '289 patent"), 9,808,587 ("the '587 patent"), 10,022,509 ("the '509 patent"), 10,022,510 ("the '510 patent"), 10,086,156 ("the '156 patent"), 10,561,808 ("the '808 patent"), 10,695,512 ("the '512 patent"), 11,395,889 ("the '889 patent") (collectively, the '712 patent, the '289 patent, the '587 patent, the '509 patent, the '510 patent, the '156 patent, the '808 patent, the '512 patent, and the '889 patent are referred to herein as the "Patents-in-Suit."), and each of the claims thereof, are invalid and/or unenforceable for failure to comply with one or more conditions for patentability and/or enforceability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidity and/or unenforceability, and as set forth in the February 19, 2024 Notice Letter ("Deva Notice Letter"), sent in respect to Deva Paragraph IV Certification.

THIRD SEPARATE DEFENSE
NO DIRECT INFRINGEMENT

As set forth in the Detailed Statement in the Deva Notice Letter, Defendant does not infringe literally any valid and enforceable claim of the Patents-in-Suit and thus cannot be said to literally infringe the same. As no equivalent can be found in the Deva ANDA Product for the missing elements of any of the claims of the Patents-in-Suit, there can be no infringement under the doctrine of equivalents.

FOURTH SEPARATE DEFENSE
NO INDIRECT INFRINGEMENT

Defendant has not, does not, and will not induce the infringement of, or contribute to the infringement of, any valid and enforceable claim of the Patents-in-Suit, and the manufacturing, marketing, sale, offer for sale, importation, and/or distribution of the Deva ANDA Product do not induce the infringement of, or contribute to the infringement of, any valid and enforceable claim of the Patents-in-Suit.

FIFTH SEPARATE DEFENSE
NO COSTS

Plaintiffs are barred by 35 U.S.C. § 288 from recovering any costs associated with this suit.

SIXTH SEPARATE DEFENSE
FAILURE TO STATE CLAIM OF WILFULNESS

Plaintiff fails to state a proper claim for willful infringement or exceptional case under 35 U.S.C. §§ 271(e)(4) and 285, or otherwise.

SEVENTH SEPARATE DEFENSE
UNCLEAN HANDS

Plaintiffs are barred from obtaining the relief they seek because Plaintiffs have unclean hands.

EIGHTH SEPARATE DEFENSE
PATENT MISUSE

The Patents-in-Suit are unenforceable because Plaintiffs have engaged in misuse of the Patents-in-Suit by seeking to impermissibly broaden the scope of the patent grant with respect to the Patents-in-Suit, with anticompetitive effect.

NINETH SEPARATE DEFENSE
IMPROPER LISTING OF PATENTS

The Patents-in-Suit are improperly listed on the FDA's "Orange Book," and, therefore, cannot serve as a basis for Plaintiffs' lawsuit against Deva.

TENTH SEPARATE DEFENSE
LACK OF SUBJECT MATTER

The Court lacks subject matter jurisdiction over this lawsuit.

ELEVENTH SEPARATE DEFENSE
FAILURE TO PROSECUTE

Plaintiffs failed to timely disclose and assert any claims of the '712, '509, '510, '512, or '889 patents against Deva.

TWELVTH SEPARATE DEFENSE
RESERVATION OF RIGHTS

Defendant reserves the right to assert additional defenses or counterclaims that discovery may reveal.

COUNTERCLAIMS OF DEFENDANT

Pursuant to Rule 13 of the Federal Rules of Civil Procedure, Deva Holding A.S. a/k/a Deva Holdings A.S. ("Deva" or "Defendant" or "Counterclaim-Plaintiff") by and through its counsel, for its Counterclaims against Plaintiffs Teva Branded Pharmaceutical Products R&D, Inc. ("Teva Branded"), Norton (Waterford) Ltd. ("Norton"), and Teva Pharmaceuticals USA, Inc. ("Teva USA") (collectively, "Plaintiffs" or "Counterclaim-Defendants") hereby state the following:

1. Counterclaim-Plaintiff repeats and incorporates by reference each of the foregoing paragraphs of Defendant's Answer and Additional Defenses to the Complaint.

2. This is an action for a declaratory judgment of non-infringement and invalidity and/or unenforceability of the claims of U.S. Patent Nos. 8,132,712 ("the '712 patent"), 9,463,289 ("the '289 patent"), 9,808,587 ("the '587 patent"), 10,022,509 ("the '509 patent"), 10,022,510 ("the '510 patent"), 10,086,156 ("the '156 patent"), 10,561,808 ("the '808 patent"), 10,695,512 ("the '512 patent"), 11,395,889 ("the '889 patent") (collectively, the '712 patent, the '289 patent, the '587 patent, the '509 patent, the '510 patent, the '156 patent, the '808 patent, the '512 patent, and the '889 patent are referred to herein as the "Patents-in-Suit").

THE PARTIES

3. Counterclaim-Plaintiff Deva Holding A.S. (a/k/a Deva Holdings A.S.) is a corporation organized and existing under the laws of Turkey, having a principal place of business at Halkalı Merkez Mah. Basın Ekspres Cad. No: 1 34303 Küçükçekmece - Istanbul Sicil No: 70061.

4. On information and belief, and based upon the Complaint filed, Counterclaim-Defendant Teva Branded is a company organized under the laws of the State of Delaware with its principal place of business at 145 Brandywine Parkway, West Chester, Pennsylvania 19380. In

addition, Teva Branded has a place of business at 400 Interpace Parkway #3, Parsippany, New Jersey 07054.

5. On information and belief, Counterclaim Defendant Norton is a private limited company organized under the laws of the Republic of Ireland and having its registered office at Unit 301, IDA Industrial Park, Waterford X91 WK68, Republic of Ireland. Norton trades, i.e., does business, as Ivax Pharmaceuticals Ireland and as Teva Pharmaceuticals Ireland.

6. On information and belief, Counterclaim-Defendant Teva USA is a company organized and existing under the laws of the State of Delaware, with a principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054.

JURISDICTION

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

8. This Court has personal jurisdiction over Counterclaim-Defendants based, inter alia, on the filing by Counterclaim-Defendants of this lawsuit in this jurisdiction and because Counterclaim-Defendants are doing business in this jurisdiction.

9. Venue is proper in this district over Counterclaim-Defendants based, inter alia, on the filing by Counterclaim-Defendants of this lawsuit in this jurisdiction and because Counterclaim-Defendants are doing business in this jurisdiction.

ORANGE BOOK PATENT LISTING

10. The Hatch-Waxman Amendments to the Food, Drug and Cosmetic Act require NDA holders to disclose to the FDA the patent numbers and expiration dates of those patents that the holder believes claim the "drug" for which their NDA is submitted, or patents covering a "method of using such drug." 21 U.S.C. §§ 355(b)(1) and (c)(2).

11. On information and belief, a true and correct copy of the ’712 patent is attached to the Complaint as Exhibit A.

12. On information and belief, a true and correct copy of the ’289 patent is attached hereto as Exhibit B.

13. On information and belief, a true and correct copy of the ’587 patent is attached to the Complaint as Exhibit C.

14. On information and belief, a true and correct copy of the ’509 patent is attached to the Complaint as Exhibit D.

15. On information and belief, a true and correct copy of the ’510 patent is attached to the Complaint as Exhibit E.

16. On information and belief, a true and correct copy of the ’156 patent is attached to the Complaint as Exhibit F.

17. On information and belief, a true and correct copy of the ’808 patent is attached to the Complaint as Exhibit G.

18. On information and belief, a true and correct copy of the ’512 patent is attached to the Complaint as Exhibit H.

19. On information and belief, a true and correct copy of the '889 patent is attached to the Complaint as Exhibit I.

20. On information and belief, pursuant to 21 U.S.C. §§ 355(b)(l), Counterclaim-Defendants caused the FDA to list the Patents-in-Suit in the Orange Book in connection with New Drug Application ("NDA") No. 021457, under which FDA approved the commercial marketing of ProAir® HFA (albuterol sulfate) Inhalation Aerosol on October 29, 2004.

21. Counterclaim-Defendants represented to the world that the Patents-in-Suit could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale (21 U.S.C. § 355(b)(l)) of the respective brand name product before the expiration of the Patents-in-Suit.

ABBREVIATED NEW DRUG APPLICATION

22. Deva filed ANDA No. 21-3818 ("Deva's ANDA") with the FDA seeking approval to market use, or sale of generic versions of a generic version of ProAir® HFA (albuterol sulfate) Inhalation Aerosol, 90 mcg (EQ 0.09 mg base) per actuation ("Deva ANDA Product"), The ANDA included a Paragraph IV Certification, certifying that to the best of its knowledge that all the claims of the Patents-in-Suit is invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale, offer to sell, and/or importation of the Deva ANDA Product.

THE PRESENCE OF A CASE OR CONTROVERSY

23. By maintaining the Orange Book listing of the Patents-in-Suit in connection with the NDA, Counterclaim-Defendants represented that the Patents-in-Suit could reasonably be asserted against anyone making, using, or selling the Deva ANDA Product, without a license from Counterclaim-Defendants prior to the expiration of the Patents-in-Suit.

24. Counterclaim-Defendants have filed an infringement action under Title 35, United States Code, Sections 100 et seq., asserting the Patents-in-Suit against Counterclaim-Plaintiff and seeking a declaration of infringement regarding the Patents-in-Suit. There has been, and is now, an actual and justiciable controversy between Counterclaim-Plaintiff on the one hand, and Counterclaim-Defendants, on the other hand, as to whether the Deva ANDA Product infringes the Patents-in-Suit, and whether any valid, enforceable claim in the Patents-in-Suit exists.

25. Counterclaim-Plaintiff seeks to market the Deva ANDA Product in the United States prior to the expiration of the Patents-in-Suit.

26. If Counterclaim-Plaintiff succeeds in proving that the Deva ANDA Product does not infringe the Patents-in-Suit or all asserted claims are invalid or unenforceable, and thus non-infringing, such a judgment will remove any uncertainty that may exist by virtue of Counterclaim-Defendants' maintenance of the Patents-in-Suit in the Orange Book in connection with the NDA.

27. Considering all the circumstances, an actual substantial and continuing justiciable controversy having sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Counterclaim-Defendants and Counterclaim-Plaintiff as to whether the claims of the Patents-in-Suit are invalid and/or not infringed by Counterclaim-Plaintiff.

BACKGROUND

A. DEVA's ANDA AND THE 30-MONTH STAY OF FDA APPROVAL OF DEVA's ANDA THAT COUNTERCLAIM-DEFENDANTS TRIGGERED BY BRINGING THEIR BASELESS PATENT LITIGATION

28. On information and belief, Counterclaim-Defendant Teva Branded is the holder of New Drug Application ("NDA") No. 21-457 ("ProAir® NDA"), under which FDA approved the commercial marketing of ProAir® HFA (albuterol sulfate) Inhalation Aerosol.

29. On information and belief, Counterclaim-Defendants listed and maintained a listing for the Patents-in-Suit in the Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") in connection with NDA No. 21-457.

30. The Patents-in-Suit do not meet the statutory requirements to be listed in the Orange Book, as they do not claim a drug, drug substance (active ingredient), drug product (formulation or composition), or a method of using a drug. See 21 U.S.C. § 355(b)(1)(A)(viii).

31. On information and belief, Deva has submitted or caused the submission of Deva's ANDA to FDA under 21 U.S.C. § 355(j) to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of the Deva ANDA Product prior to the expiration of the Patents-in-Suit.

32. Because Counterclaim-Defendants had improperly listed the Patents-in-Suit in the Orange Book, and because Deva sought approval from the FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of a generic version of ProAir® HFA prior to the expiration of the Patents-in-Suit, Deva was required to file a Paragraph IV Certification with respect to each of the Patents-in-Suit. A Paragraph IV Certification certifies that a patent listed in the Orange Book is invalid or will not be infringed by the manufacture, use or sale of the Deva ANDA Product.

33. In accordance with 21 U.S.C. §355 (j)(2)(B)(iv)(II), by a letter dated February 19, 2024 ("Deva Notice Letter"), Defendant notified Plaintiffs that Deva had submitted to FDA

ANDA No. 21-3818 ("Deva's ANDA") for a purported generic version of ProAir® HFA (albuterol sulfate) Inhalation Aerosol, 90 mcg (EQ 0.09 mg base) per actuation ("Deva ANDA Product"), seeking FDA approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Deva ANDA Product in and/or into the United States prior to the expiration of the Patents-in-Suit.

34. On information and belief, Counterclaim-Defendants received the Deva Notice Letter by February 22, 2024.

35. Counterclaim-Defendants filed this lawsuit on March 29, 2024, claiming that Deva has infringed and will infringe the Patents-in-Suit by the filing of Deva's ANDA with the FDA and/or by manufacturing, using, offering for sale, selling, marketing, distributing, and/or importing the products described in that ANDA.

36. The patent infringement claims that Counterclaim-Defendants asserted in this lawsuit against Deva are objectively baseless. As described below, no reasonable litigant could expect to secure favorable relief against Deva on the merits because the Deva ANDA Product does not infringe any of the claims of the Patents-in-Suit, and the Patents-in-Suit are invalid.

37. Counterclaim-Defendants filed this lawsuit within 45 days of receiving the Deva Notice Letter. By doing so, Counterclaim-Defendants triggered a 30-month stay of final FDA approval of Deva's ANDA pursuant to 21 U.S.C. § 355(j)(5)(B)(iii). The 30-month stay, which is imposed only where an NDA holder files a patent infringement suit under 35 U.S.C. § 271(e)(2) within 45 days of receiving notice of a Paragraph IV certification, is not set to expire until August 22, 2026 – long after Deva expects, based on FDA correspondence to Deva, being otherwise able to launch the Deva ANDA Product.

38. But for Counterclaim-Defendants' improper listing of the Patents-in-Suit in the Orange Book and Counterclaim-Defendants' choice to bring baseless litigation within 45 days of receipt of the Deva Notice Letter, there would be no 30-month stay imposed under 21 U.S.C. § 355(j)(5)(B)(iii).

39. Upon receiving tentative approval from the FDA, due to Teva's actions including listing patents on the Orange Book and asserting them against Deva, Deva will be deprived of the benefits of lower-priced generic competition from Deva.

B. PATENT LISTING AND THE ORANGE BOOK

40. The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 et seq. ("FDCA" or "Act"), governs the manufacture, sale, and marketing of prescription pharmaceuticals in the United States.

41. Pursuant to the FDCA, any company that wishes to sell a new drug in the United States must seek FDA approval by filing an NDA with the FDA. As part of that application, the submitter of the NDA must provide the FDA with information identifying each patent "for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug" that is the subject of the NDA, and that either (I) "claims the drug for which the applicant submitted the application and is a drug substance (active ingredient) patent or a drug product (formulation or composition) patent;" or (II) "claims a method of using such drug for which approval is sought or has been granted in the application." 21 U.S.C. § 355(b)(1)(A)(viii); Jazz Pharms., Inc. v. Avadel CNS Pharms., LLC., 60 F.4th 1373, 1377 (Fed. Cir. 2023).

42. Submission of information on patents that do not meet these criteria is prohibited by law. 21 U.S.C. § 355(c)(2) ("Patent information that is not the type of patent information required by subsection (b)(1)(A)(viii) shall not be submitted under this paragraph.").

43. Upon approval of an NDA, the patent information submitted to the FDA by the NDA holder under 21 U.S.C. § 355(b)(1)(A)(viii) is published by the FDA in a publicly- available online database entitled "Approved Drug Products with Therapeutic Equivalence Evaluations | Orange Book" (the "Orange Book"). *Jazz Pharms., Inc.*, 60 F.4th at 1377. The Orange Book is located at the following web address: https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book.

44. "[T]he FDA does not verify that submitted patents actually meet the statutory listing criteria, nor does the FDA proactively remove improperly listed patents" from the Orange Book. *Jazz Pharms., Inc.*, 60 F.4th at 1378. Rather, the FDA's role with respect to Orange Book patent listings is "purely ministerial." *Apotex, Inc. v. Thompson*, 347 F.3d 1335, 1347 (Fed. Cir.2003) (noting FDA arguments that (i) FDA does not have a duty to determine "whether the patent claims the drug," (ii) "FDA has a only a ministerial role in the listing process," and (iii) "it is the responsibility of the NDA holder to determine whether a patent claims the drug or a method of using the drug that is the subject of the NDA for purposes of Orange Book listing"); *Jazz Pharmaceuticals, Inc.*, 60 F.4th at 1378.

45. The FDA has adopted a regulation, 21 C.F.R. § 314.53(f), codifying and implementing its position that its duties with respect to Orange Book listings are purely ministerial. *Apotex, Inc.*, 347 F.3d at 1347. Under this regulation, a third party may dispute an Orange Book

listing, but the FDA will not modify the listing unless the NDA holder itself requests the modification. 21 C.F.R. § 314.53(f); *Apotex, Inc.*, 347 F.3d at 1347.

C. APPROVAL OF GENERIC DRUGS

46. When an ANDA is submitted to the FDA seeking permission to market a generic version of an approved NDA product, if there are no patents listed in the Orange Book for the corresponding NDA product, the ANDA must include a certification that no such patent information has been filed. 21 U.S.C. § 355 (j)(2)(A)(vii)(I). This is known as a "Paragraph I Certification."

47. If, however, there are any patents listed in the Orange Book for the corresponding NDA, for each patent listed in the Orange Book for the relevant NDA product, the ANDA must include a certification for each patent stating (a) that the patent has expired (a "Paragraph II Certification"), (b) when the patent will expire (a "Paragraph III Certification"), or (c) that the patent is invalid or will not be infringed by the manufacture, use or sale of the Deva ANDA Product (a "Paragraph IV Certification" or "PIV Certification"). 21 U.S.C. §355 (j)(2)(A)(vii)(II)-(IV).

48. If the ANDA contains only Paragraph I Certification(s) and/or Paragraph II certification(s), the FDA may approve the ANDA immediately. 21 U.S.C. § 355 (j)(5)(B)(i).

49. If the ANDA contains Paragraph III Certifications and no PIV Certification, the FDA may approve the ANDA on the patent expiration date certified in the Paragraph III certification. 21 U.S.C. §355 (j)(5)(B)(ii).

50. If an ANDA contains one or more PIV Certifications, the ANDA applicant must provide notice of same to the NDA holder and owner(s) of the corresponding patent(s) and provide

a "detailed statement of the factual and legal basis for the opinion that the patent is invalid or will not be infringed." 21 U.S.C. §355 (j)(2)(B)(iv)(II).

51. If an ANDA containing a PIV Certification is the first such ANDA submitted, then, subject to other requirements, it can qualify for 180 days of generic exclusivity, during which the FDA will not make effective its approval of another ANDA product that is a generic version of the same NDA product as the first-to-file ANDA. 21 U.S.C. §355 (j)(5)(B)(iv).

52. The filing of a PIV Certification is treated under the patent law as an act of technical infringement that provides the brand company an opportunity to sue. See 35 U.S.C. § 271(e)(2)(A). If the NDA holder brings a patent infringement suit within 45 days after it receives the notice of the PIV filing, the FDA's approval of the corresponding ANDA will automatically be stayed for 30 months, unless the patent litigation is resolved sooner. 21 U.S.C. §355 (j)(5)(B)(iii).

53. If an infringement action is brought against an ANDA applicant in response to receiving notice of a PIV Certification, the ANDA applicant may "assert a counterclaim seeking an order requiring the [NDA] holder to correct or delete the patent information submitted by the [NDA] holder." 21 U.S.C. § 355(j)(5)(C)(ii)(I).

D. THE PROAIR® HFA NDA AND PRODUCT

54. ProAir® HFA was approved under the ProAir® NDA.

55. The ProAir® NDA was submitted by Ivax Research, Inc. ("Ivax") to the FDA on January 31, 2003.

56. The ProAir® NDA was approved by FDA on October 29, 2004.

57. At the time of its approval on October 29, 2004, there was no approved trade name for the product that was the subject of NDA No. 21-457.

58. The trade name originally proposed for the product that was the subject of NDA No. 21-457 was Volare HFA (Albuterol Sulfate, USP) Inhalation Aerosol. The FDA did not approve of that trade name for the product that was the subject of NDA No. 21-457.

59. The ProAir® NDA was submitted under Section 505(b)(2) of the Drug Price Competition and Patent Term Restoration Act of 1984 and relied on Proventil HFA Inhalation Aerosol as the comparator drug.

60. The ingredients in ProAir® HFA are albuterol sulfate, propellant HFA-134a, and ethanol. The active ingredient in ProAir® HFA is albuterol sulfate.

61. Albuterol sulfate was first approved by FDA more than forty years ago, in 1981.

62. ProAir® HFA was initially approved without a dose counter.

63. The Prescribing Information and Patient Information for ProAir® HFA has been amended several times since its initial approval in 2004.

64. On August 17, 2010, in connection with a Supplemental New Drug Application to the ProAir® NDA, the FDA approved a revised package insert and patient instructions for use in support of an actuator approved on September 22, 2009.

65. ProAir® HFA reflecting the presence of a dose counter attached to the actuator is the March 2012 revision.

66. The March 2012 revision of the Prescribing Information and Patient Information for ProAir® HFA replaced the July 2010 revision.

67. The July 2010 revision of the Prescribing Information and Patient Information for ProAir® HFA does not refer to a dose counter.

68. ProAir® HFA is approved for treatment or prevention of bronchospasm in patients 4 years of age and older with reversible obstructive airway disease, and for prevention of exercise-induced bronchospasm in patients 4 years of age and older.

69. On information and belief, Counterclaim-Defendants discontinued marketing

70. ProAir® HFA in October 2022 but continue to sell an authorized generic version of the product.

E. PRIOR ANDAS FOR GENERIC PROAIR® HFA

71. Counterclaim-Defendants Teva Branded and Norton, together with Teva Respiratory, LLC and Norton Healthcare Limited, have established a pattern and practice of improperly listing device patents in the Orange Book and subsequently asserting those device patents against ANDA filers seeking to market generic versions of ProAir® HFA within 45 days of the filing of any Paragraph IV Certification thereto, thereby ensuring the ANDA applicant's approval is subject to the automatic 30-month stay.

72. On September 5, 2012, Counterclaim-Defendants Teva Branded and Norton together with Teva Respiratory, LLC and Norton Healthcare Limited, filed a lawsuit captioned Teva Branded Pharmaceutical Products R&D, Inc., Teva Respiratory, LLC, Norton (Waterford) Limited, and Norton Healthcare Limited v. Perrigo Pharmaceuticals Co., Perrigo Co., and Catalent Pharma Solutions, LLC, U.S. District Court for the District of Delaware, Case 1:12-cv- 01101 (defendants collectively "Perrigo"). Teva asserted U.S. Patent Nos. 7,105,152 ("the '152 patent")

and 7,566,445 ("the '445 patent") in their complaint against Perrigo. The '445 patent is a device patent that Teva improperly listed in the Orange Book. On information and belief, Counterclaim-Defendants Teva Branded and Norton together with Teva Respiratory, LLC and Norton Healthcare Limited filed a lawsuit against Perrigo within the 45-day period prescribed by 21 U.S.C. § 355(j)(5)(B)(iii), thereby triggering a 30-month stay of FDA approval of Perrigo's ANDA. The lawsuit was resolved by means of a stipulated dismissal on June 20, 2014.

73. On March 21, 2017, Counterclaim-Defendants Teva Branded and Norton together with Teva Respiratory, LLC and Norton Healthcare Limited, filed a lawsuit captioned Teva Branded Pharmaceutical Products R&D, Inc., Teva Respiratory, LLC, Norton (Waterford) Limited, and Norton Healthcare Limited v. Lupin Atlantis Holdings SA, Lupin Pharmaceuticals, Inc., and Lupin Ltd., U.S. District Court for the District of Delaware, Case 1:17-cv-00307 (defendants collectively "Lupin"). Teva asserted U.S. Patent Nos. 7,105,152 ("the '152 patent"), 8,132,712 ("the '712 patent"), and 9,463,289 ("the '289 patent") in the complaint against Lupin. The '712 and '289 patents are device patents that Teva improperly listed in the Orange Book, and that Counterclaim-Defendants asserted in the Complaint against Deva in the present case. On information and belief, Counterclaim-Defendants Teva Branded and Norton together with Teva Respiratory, LLC and Norton Healthcare Limited filed their lawsuit within the 45-day period prescribed by 21 U.S.C. § 355(j)(5)(B)(iii), thereby triggering a 30-month stay of FDA approval of Lupin's ANDA. This lawsuit against Lupin was resolved by means of a stipulated dismissal on November 2, 2017.

74. These two prior lawsuits demonstrate that Counterclaim-Defendants Teva Branded and Norton, together with Teva Respiratory, LLC and Norton Healthcare Limited, have engaged in

enforcement efforts relating to device patents listed improperly in the Orange Book for ProAir® HFA to try to delay or stop generic market entry.

75. According to the FDA, the date of first commercial marketing of a generic version of ProAir® HFA by the first-to-file ANDA applicant was February 26, 2020.

76. More than 180 days have elapsed since February 26, 2020.

77. Currently, there is no ANDA applicant eligible for 180-day generic exclusivity, and any such exclusivity that may once have existed has expired or has been extinguished. Accordingly, there is no barrier to removal of the Patents-in-Suit from the Orange Book pursuant to 21 C.F.R. § 314.53(f)(2)(i).

F. THE ORANGE BOOK LISTING FOR PROAIR® HFA AND COUNTERCLAIM-DEFENDANTS ' REFUSAL TO COMPLY WITH THE FEDERAL TRADE COMMISS ION'S DELISTING REQUEST

78. At the time Deva submitted Deva's ANDA seeking FDA approval to market a generic version of ProAir® HFA, all nine Patents-in-Suit were listed in the Orange Book for ProAir® HFA.

79. At the time of filing this Answer, SeparateDefenses, and Counterclaims, all nine Patents-in-Suit remainlisted in the Orange Book for ProAir® HFA.

80. None of the Patents-in-Suit is properly listed in the Orange Book because all of the Patents-in-Suit claim devices, and none of the Patents-in-Suit claims a drug, drug substance (active ingredient), drug product (formulation or composition), or a method of using a drug, as required under 21 U.S.C. § 355(b)(1)(A)(viii).

81. The United States Federal Trade Commission (the "FTC") has determined that the Patents-in-Suit are not properly listed in the Orange Book for ProAir® HFA.

82. On or about November 7, 2023, the FTC sent a letter (the "FTC Delisting Letter") to Counterclaim-Defendant Teva Branded informing Teva Branded that the FTC believes that all of the Patents-in-Suit (plus others) are "improperly or inaccurately listed in the Orange Book" for ProAir® HFA.

83. The FTC Delisting Letter indicates that the FTC has "submitted patent listing dispute communications to the FDA" regarding all nine Patents-in-Suit.

84. The FTC Delisting Letter cites the FTC's September 14, 2023 statement concerning brand drug manufacturers' improper listing of patents in the Orange Book, which explains the FTC's position that patents, including the Patents-in-Suit, are not properly listed in the Orange Book, and that the improper listing of patents in the Orange Book "undermines the competitive process" and "may also constitute illegal monopolization.

85. In an interview published on November 12, 2023, in Citeline Regulatory's "Pink Sheet," Rahul Rao, the Deputy Director of the FTC's Bureau of Competition, explained why the FTC sent the FTC Delisting Letter to Teva Branded (among others):

> The Orange Book is only supposed to list patents covering active drug ingredients. So, we focused on device patents that have nothing to do with the active drug. Our staff analyzed several different types of these products and listings with an initial focus on products that were widely used and have been around for a while and we would have expected to see more generic competition. For example, asthma and COPD inhalers were a particular area of focus for us. Over 40 million Americans rely on inhalers and a lot of the drugs using these inhalers have been

> around for several decades. But we're still seeing people paying hundreds and hundreds of dollars for them.
>
> And we're not seeing a lot of lower cost generic use, even though the drugs have been around for several decades and have long expired drug substance patents. So that's what made inhalers like the asthma and COPD products a particular concern.
>
> * * * * *
>
> In the last few years, there's been a lot of discussion in this space on the Orange Book and how abusive listings can negatively affect competition and ultimately patients. So, we just thought more can be done here to help ensure that drug manufacturers don't abuse the Orange Book process.

86. The FTC further explained in that interview that the FTC wants Teva Branded to delist the Patents-in-Suit (among others):

> Q: What's your goal with the letters? Do you want companies to delist the patents? Is FTC looking to take enforcement action if they don't?
>
> Yes, we would like the companies to delist patents. We've just identified patents that we think are improperly listed and we have opted in these instances to go through the FDA process on how to address improper Orange Book listings, which involves delisting.

87. The FTC further explained in that interview that drug-device patents that do not claim the active ingredient should not be listed in the Orange Book:

> Q: …Does the FTC think that there are device patents that that can be listed or do you think that under the statute none of them can be listed?
>
> I don't think it's particularly controversial in terms of the statute, the regulations and the cases, and I

> think there have been FTC and FDA statements on this, that only patents that claim the active ingredient should be listed in the Orange Book. And drug-device patents that do not claim the active ingredient should not be listed.

88. The publication of that interview concludes with the following statement from the FTC:

> And ultimately, we think the law is actually relatively clear. There's not a lot of ambiguity here in terms of what should and should not be listed.

89. On information and belief, despite receiving the FTC's Delisting Letter and despite receiving notification from the FDA regarding the FTC's listing dispute regarding ProAir® HFA, none of the Counterclaim-Defendants has agreed to request that the FDA delist the Patents-in-Suit or requested the FDA delist the Patents-in-Suit.

90. None of the Patents-in-Suit satisfies any of the statutory requirements for being properly listed in the Orange Book.

91. None of the Patents-in-Suit claims a method of using a drug.

92. None of the Patents-in-Suit claims an approved method of using ProAir® HFA.

93. None of the Patents-in-Suit claims "the drug for which the applicant submitted" the ProAir® NDA.

94. None of the Patents-in-Suit is "a drug substance (active ingredient) patent" or claim a drug substance or active ingredient.

95. None of the Patents-in-Suit is "a drug product (formulation or composition) patent" or claim a drug product or drug formulation, or drug composition.

96. None of the Patents-in-Suit claims the active ingredient in ProAir® HFA.

97. None of the Patents-in-Suit claims a drug.

98. None of the Patents-in-Suit contains the phrase "albuterol sulfate," which is the name of the active ingredient in ProAir® HFA.

99. None of the Patents-in-Suit contains the word "albuterol."

100. In addition to being listed in the Orange Book for ProAir® HFA, each Asserted Patent is also concurrently listed in the Orange Book for at least one other product. Those other products include QVAR 40, QVAR 80, QVAR Redihaler, ProAir Digihaler, ProAir Respiclick, ArmonAir Digihaler, ArmonAir Respiclick, AirDuo Digihaler, and/or AirDuo Respiclick.

101. The Orange Book listing of the Patents-in-Suit for other products shows a pattern and practice by Counterclaim-Defendants of improperly listing the Patents-in-Suit in the Orange Book for multiple products including ProAir® HFA to, among other things, deter generic market entry.

102. Counterclaim-Defendants' enforcement efforts against, for example, Perrigo and Lupin regarding Orange Book patents listed for ProAir® HFA further shows that Counterclaim-Defendants are using improperly listed Orange Book patents to hinder and delay generic market entry.

G. COUNTERCLAIM-DEFENDANTS ABUSE ORANGE BOOK AND REGULATORY PROCESS BY PURSUING BASELESS PATENT LITIGATION

103. Because Counterclaim-Defendants had improperly listed the Patents-in-Suit in the Orange Book, Deva was required to submit Paragraph IV Certifications as to each of the Patents-

in-Suit (rather than a Paragraph I Certification) in order to seek approval from the FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Deva ANDA Product prior to the expiration of the Patents-in-Suit.

104. The Deva Notice Letter dated February 19, 2024, and, on information and belief, received by Counterclaim-Defendants by February 22, 2024, notified Counterclaim-Defendants that Deva had submitted to the FDA Deva's ANDA including Paragraph IV Certifications as to each of the Patents-in-Suit.

105. In response, Counterclaim-Defendants filed this lawsuit under 35 U.S.C. § 271(e), alleging Deva infringed the Patents-in-Suit. The lawsuit triggered the Hatch-Waxman Act's 30-month stay of final approval of Deva's ANDA, which occurs only when an NDA holder files suit under 35 U.S.C. § 271(e) within 45 days of receiving notice of an ANDA with a Paragraph IV Certification. *See* 21 U.S.C. § 355(j)(5)(B)(iii). But for Counterclaim-Defendants' improper Orange Book listing, Deva would not have submitted Paragraph IV Certifications (but instead a Paragraph I Certification), and no 30-month stay would be imposed. Similarly, but for Counterclaim-Defendants' decision to file this baseless lawsuit within 45 days of receipt of the Deva Notice Letter, no 30-month stay would be imposed.

106. Counterclaim-Defendants' patent infringement claims asserted in this lawsuit against Deva are objectively baseless and were brought in bad faith. No reasonable litigant could expect to secure favorable relief against Deva on the merits because the Deva ANDA Product does not infringe any of the claims of the Patents-in-Suit, and the Patents-in-Suit are invalid.

107. Specifically, the Patents-in-Suit are directed to devices or portions of devices, and the device that Deva seeks approval to use in Deva's ANDA is itself prior art to the Patents-in-Suit.

Thus, the Patents-in-Suit cannot cover the device used by Deva under the doctrine of equivalents, because that would necessarily ensnare the prior art. And if the Deva device is deemed to literally infringe the Patents-in-Suit, then axiomatically, the Patents-in-Suit would be invalid as anticipated.

108. Counterclaim-Defendants' patent litigation against Deva as to the Patents-in-Suit constitutes sham litigation because the litigation was brought without any reasonable chance of prevailing and, on information and belief, for the specific and purpose of restricting competition by Deva by delaying approval of Deva's generic equivalent of ProAir® HFA.

109. On September 6, 2024, Counterclaim-Defendants served upon Deva "Plaintiffs' Disclosure of Asserted Claims Pursuant to L. Pat. R. 3.6(b)" in this lawsuit ("Plaintiffs' Asserted Claims").

110. In Plaintiffs' Asserted Claims, Plaintiffs asserted claims from only four of the nine Patents-in-Suit.

111. Plaintiffs/Counterclaim-Defendants are still maintaining this lawsuit and asserting all nine Patents-in-Suit against Deva.

112. In Plaintiffs' Asserted Claims, Plaintiffs state, "Teva further reserves the right to supplement and/or amend this disclosure in light of this late production."

H. MARKET POWER AND MARKET DEFINITION

113. At all relevant times, Counterclaim-Defendants had monopoly power in the market for ProAir® HFA and its generic equivalents because it had the power to raise or maintain the price of ProAir® HFA and/or an authorized generic version of ProAir® HFA ("ProAir® AG"), which Counterclaim-Defendants also marketed, at supracompetitive levels without losing enough sales to make supracompetitive prices unprofitable, as well as the power to exclude competitors.

114. At all times during Counterclaim-Defendants' monopoly, a small but significant, non-transitory increase to the price of ProAir® HFA and its generic equivalents would not have caused Counterclaim-Defendants to suffer a significant loss of sales.

115. On information and belief, ProAir® HFA and its generic equivalents do not exhibit significant, positive cross-elasticity of demand with respect to price with any other albuterol sulfate inhalant products. Notwithstanding the commercialization of other albuterol sulfate inhalant products, Counterclaim-Defendants continued to charge supracompetitive prices and exclude competitors.

116. On information and belief, Counterclaim-Defendants sold ProAir® HFA and the ProAir® AG at prices well in excess of marginal costs, and in excess of the competitive price, and enjoyed high profit margins.

117. Counterclaim-Defendants have, and have exercised, the power to exclude competition to ProAir® HFA and its generic equivalents.

118. Counterclaim-Defendants enjoyed high barriers to entry with respect to the brand and generic versions of ProAir® HFA.

119. As set out above, Counterclaim-Defendants' anticompetitive conduct—including their improper listing of the Patents-in-Suit in the Orange Book and their filing of this sham litigation within 45 days of the receipt of Deva's Notice Letter—is part of a pattern of conduct that began long before the instant litigation. Counterclaim-Defendants have, and have maintained, market power throughout the entirety of the course of their anticompetitive conduct.

120. There is direct evidence of market power and anticompetitive effects available in this case sufficient to show Counterclaim-Defendants' ability to control prices of its ProAir® HFA

and ProAir® AG, and to exclude relevant competitors, without the need to show the relevant antitrust markets. The direct evidence consists of, among other things, (a) the fact that additional competing generic equivalents would have entered the market at substantial discounts to the brand version but for Counterclaim-Defendants' anticompetitive conduct; (b) Counterclaim-Defendants' history of improperly listing patents in the Orange Book and filing sham litigation with respect to the same; and (c) Counterclaim-Defendants' supracompetitive pricing for ProAir® HFA and ProAir® AG.

121. To the extent proof of monopoly power by defining a relevant product market is required, Deva alleges that the relevant antitrust market is the market for ProAir® HFA and its generic equivalents. ProAir® HFA and its generic equivalents are not reasonably interchangeable with other products due to the distinct qualities and characteristics of ProAir® HFA, which distinguish it from other albuterol sulfate inhalants. Indeed, researchers have recognized significant differences across the spectrum of albuterol sulfate HFA inhalation aerosol products.

122. Accordingly, ProAir® HFA and its generic equivalents are appropriately considered as a market of their own.

123. The United States, the District of Columbia, and the U.S. territories constitute the relevant geographic market.

124. Thus, for purposes of this lawsuit, the market for the sale of ProAir® HFA and its generic equivalents in the United States (the "Relevant Market") constitutes a relevant market. In the alternative, the relevant market encompasses all albuterol sulfate HFA inhaler aerosol products (the "Alternative Relevant Market")[2].

[2] Deva maintains that the relevant product market for purposes of its Counterclaims is ProAir®

125. Upon information and belief, at all relevant times Counterclaim Defendants had a predominant share of the Relevant Market.

126. On information and belief, Counterclaim-Defendants were able to set prices of ProAir® HFA and the ProAir® AG above that which would be charged in a competitive market.

127. Counterclaim-Defendants possess monopoly power in the Relevant Market, as evidenced by, among other factors, their prior pricing actions and dominant market share.

I. ANTITRUST IMPACT AND IMPACT ON INTERSTATE COMMERCE

128. Deva plans to launch the Deva ANDA Product within days or weeks of receipt of final FDA approval.

129. Under the Generic Drug User Fee Amendments (GDUFA) reauthorization for fiscal years (FYs) 2023-2027, known as GDUFA III, FDA has established a target action date (a goal date for approval) in 10 months.

130. Deva reasonably expects to receive FDA approval in 10 months from the filing of its ANDA filing date.

131. Because of Counterclaim-Defendants anticompetitive conduct, that approval will be tentative, meaning that Deva will need to wait until expiration of the 30-month stay to receive final approval and launch Deva' ANDA Product. The approval in the summer of 2024 would be final but for Counterclaim-Defendants' anticompetitive conduct.

HFA and its generic equivalents. However, to the extent the relevant product market is construed to encompass all albuterol sulfate HFA inhaler aerosol products (the Alternative Relevant Market), use of the term 'Relevant Market' herein encompasses both the Relevant Market and the Alternative Relevant Market.

132. Deva is making several million dollars in capital expenditures on new and expanded filling and packaging lines for the Deva ANDA Product, as is spending several million dollars on device components, such as valves and actuators.

133. On information and belief, some of the device components that Deva is purchasing will expire before expiration of the 30-month stay.

134. Counterclaim-Defendants' supracompetitive scheme to maintain its monopoly in the Relevant Market included delaying Deva's entry through (1) Orange Book abuse and (2) engaging in sham litigation. Counterclaim-Defendants' anticompetitive scheme has had a direct, substantial, and adverse effect on Deva and interstate competition in the Relevant Market by maintaining monopoly power, increasing prices, artificially creating barriers to entry, and delaying competition in the Relevant Market.

135. By impeding competition from generic equivalent products, including Deva's, Counterclaim-Defendants' anticompetitive scheme has allowed (and, unless restrained by this Court, will continue to allow) Counterclaim-Defendants to maintain and extend their monopoly power in the Relevant Market and to sell ProAir® HFA and the ProAir® AG at artificially- inflated monopoly prices.

136. Counterclaim-Defendants' anticompetitive scheme has harmed the competitive process and has had a substantial effect on interstate commerce, as it has allowed Counterclaim Defendants to charge wholesalers, retailers, payors, and consumers nationwide supracompetitive prices.

137. But for this anticompetitive conduct, consumers and payors would have enjoyed the benefits of lower-priced generic competition from Deva earlier.

138. Instead, as a result of Counterclaim-Defendants' strategies, which include improper listing of the Patents-in-Suit in the Orange Book and engaging in sham litigation, consumers and payors have been forced to pay monopoly prices for Counterclaim-Defendants' ProAir® HFA and the ProAir® AG.

139. The impact of Counterclaim-Defendants' anticompetitive conduct, and the accompanying supracompetitive pricing, is felt throughout the health care industry, impacting pharmaceutical competitors, healthcare providers, insurers, and other direct purchasers, intermediaries, and consumers.

140. Deva has suffered, and will continue to suffer, harm as a result of

141. Counterclaim-Defendants' anticompetitive conduct. That harm includes:

a. Loss of future sales and profits due to being foreclosed from selling in the Relevant Market;

b. The large amount of time and expense associated with having to fight baseless, sham patent litigation based on patents that were improperly listed in the Orange Book;

c. A delay in Deva's ability to recoup its investment in filling and packaging lines and device components for the Deva ANDA Product; and

d. The loss of Deva's investment in device components that will expire before expiration of the 30-month stay resultant from Counterclaim-Defendants' improper listing of patents in the Orange Book.

142. A claimant satisfies the injury-in-fact requirement of standing where, as here, "the threatened injury is real, immediate, and direct." *See Pfizer Inc. v. Apotex Inc.*, 726 F. Supp. 2d 921, 930 (N.D. Ill. 2010) (quoting *Davis v. Fed. Election Com'n*, 554 U.S. 724, 734 (2008)).

143. "[T]he creation of 'an independent barrier to the drug market' by a brand drug company 'that deprives [the generic company] of an economic opportunity to compete' satisfies the injury-in-fact and causation requirements of Article III standing." *See Pfizer Inc.*, 726 F. Supp

2d at 930 (quoting *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1285 (Fed. Cir. 2008)).

144. The injury to Deva is immediate. Deva is already spending time and money to litigate this baseless and sham patent litigation. Because Counterclaim-Defendants filed the instant patent suit, alleging infringement of patents improperly listed in the Orange Book, Deva's final FDA approval is subject to the automatic 30-month stay. Based on the date which Counterclaim-Defendants filed the present lawsuit, Deva's ANDA would not be eligible for final approval until August 22, 2026. Accordingly, from the date of Deva's imminent tentative approval, Deva's ANDA will be ineligible for final approval, and Deva therefore will be deprived of the ability to launch its generic product, as a result of the Counterclaim-Defendants' anticompetitive conduct.

145. As a result of Counterclaim-Defendants' improper listing of the Patents-in-Suit and sham litigation, Deva has already suffered and will imminently suffer the injuries outlined above.

146. Counterclaim-Defendants' anticompetitive conduct, as alleged herein, is not entitled to any qualified *Noerr-Pennington* immunity, nor is it protected by the state action doctrine or any statute of limitations.

147. There is and was no legitimate, procompetitive justification for Counterclaim-Defendants' conduct. Even if there was some conceivable and cognizable justification, Counterclaim-Defendants' conduct was not necessary to achieve such a purpose, and, in any event, any procompetitive effects would be outweighed by the scheme's anticompetitive effects on Deva, competition, and consumers.

COUNT 1: DECLARATORY JUDGMENT REQUIRING DELISTING OF U.S. PATENT NO. 8,132,712

148. Deva incorporates and re-alleges each of the foregoing paragraphs 1–148 of its Counterclaims, as if fully set forth herein.

149. Deva hereby seeks a declaration pursuant to 21 U.S.C. § 355(j)(5)(C)(ii) ordering Counterclaim-Defendants to delete or withdraw the ’712 patent from the Orange Book.

150. An actual controversy exists between Counterclaim-Defendants and Deva over the listing of the ’712 patent in the Orange Book.

151. The ’712 patent is not properly listed in the Orange Book.

152. The ’712 patent does not satisfy any of the statutory requirements for being listed in the Orange Book.

153. The ’712 patent does not claim a method of using a drug.

154. The ’712 patent does not claim an approved method of using ProAir® HFA.

155. The ’712 patent does not claim “the drug for which the applicant submitted” the ProAir® NDA.

156. The ’712 patent is not “a drug substance (active ingredient) patent.”

157. The ’712 patent does not claim a drug substance.

158. The ’712 patent does not claim an active ingredient.

159. The ’712 patent is not “a drug product (formulation or composition) patent.”

160. The ’712 patent does not claim a drug product.

161. The ’712 patent does not claim a drug formulation.

162. The ’712 patent does not claim a drug composition.

163. The ’712 patent does not claim a drug.

164. The FTC has already determined that the ’712 patent is not properly listed in the Orange Book for ProAir® HFA.

165. On or about November 7, 2023, the FTC sent a letter to Teva Branded bearing that date and informing Teva Branded that the FTC believes that the ’712 patent is “improperly or inaccurately listed in the Orange Book” for ProAir® HFA.

166. The FTC Delisting Letter indicates that the FTC has “submitted patent listing dispute communications to the FDA” regarding all nine Patents-in-Suit, including the ’712 patent.

167. The ’712 patent contains 19 claims, of which only claims 1, 18, and 19 are independent. A copy of the ’712 patent is attached as Exhibit A to the Complaint.

168. Claim 1 of the ’712 patent is directed to “[a] dose counter for a metered-dose inhaler” having several recited structural features.

169. Claim 1 of the ’712 patent recites as follows:

> A dose counter for a metered-dose inhaler, the counter comprising:
> an actuator; a rotary gear; a driver for driving the rotary gear in a step-wise fashion in response to displacement of the actuator, the rotary gear comprising a wheel mounted on a spindle which wheel having a plurality of ratchet teeth around its periphery;
> a pawl to prevent reverse rotation of the rotary gear; and a display coupled to the rotary gear, the display having a visible array of incrementing integers on a surface thereof indexable by a single integer in response to each step of the step-wise rotary motion of the rotary gear; wherein the pawl comprises at least two ratchet teeth each for engaging with the ratchet teeth of the wheel to prevent reverse rotation of the rotary gear, the at least two ratchet teeth being radially spaced such that one of the at least two ratchet teeth of the pawl engages with the ratchet teeth of the wheel following each step of the step-wise rotary motion of the rotary gear.

170. Claim 18 of the ’712 patent is directed to “[t]he use of a dose counter for preventing miscounting in a metered dose inhaler,” in which the dose counter has several recited structural features.

171. Claim 18 of the ’712 patent recites as follows:

> The use of a dose counter for preventing miscounting in a metered dose inhaler, the dose counter comprising:
> an actuator; a rotary gear; a driver for driving the rotary gear in a step-wise fashion in response to displacement of the actuator, the rotary gear comprising a wheel mounted on a spindle which wheel having a plurality of ratchet teeth around its periphery;
> a pawl to prevent reverse rotation of the rotary gear; and a display coupled to the rotary gear, the display having a visible array of incrementing integers on a surface thereof indexable by a single
> integer in response to each step of the step-wise rotary motion of the rotary gear;
> wherein the pawl comprises at least two ratchet teeth each for engaging with the ratchet teeth of the wheel to prevent reverse rotation of the rotary gear, the at least two ratchet teeth being radially spaced such that one of the at least two ratchet teeth of the pawl engages with the ratchet teeth of the wheel following each step of the step-wise rotary motion of the rotary gear.

172. Claim 19 of the ’712 patent is directed to “[t]he use of a dose counter for preventing undercounting in a metered dose inhaler,” in which the dose counter has several recited structural features.

173. Claim 19 of the ’712 patent recites as follows:

> The use of a dose counter for preventing undercounting in a metered dose inhaler, the dose counter comprising:
> an actuator; a rotary gear; a driver for driving the rotary gear in a step-wise fashion in response to displacement of the actuator, the rotary gear comprising a wheel mounted on a spindle which wheel having a plurality of ratchet teeth around its periphery;
> a pawl to prevent reverse rotation of the rotary gear; and a display coupled to the rotary gear, the display having a visible array of incrementing integers on a surface thereof indexable by a single

> integer in response to each step of the step-wise rotary motion of the rotary gear;
> wherein the pawl comprises at least two ratchet teeth each for engaging with the ratchet teeth of the wheel to prevent reverse rotation of the rotary gear, the at least two ratchet teeth being radially spaced such that one of the at least two ratchet teeth of the pawl engages with the ratchet teeth of the wheel following each step of the step-wise rotary motion of the rotary gear.

174. None of the claims of the '712 patent recite a drug, a drug substance, an active ingredient, a drug product, a drug formulation, a drug composition, a method of using a drug, a method of using a drug product, a method of using a drug substance, a method of using an active pharmaceutical ingredient, a method of using a drug formulation, a method of using a drug composition, or a method of using a pharmaceutical formulation.

175. None of the claims of the '712 patent recite "albuterol," "albuterol sulfate," "propellant HFA-134a," or "ethanol."

176. The '712 patent does not recite any of the following words or phrases: "albuterol," "albuterol sulfate," "HFA-134a," "ethanol," "ingredient," "formulation," or "bronchospasm."

177. Other than reciting the name of the assignee "Ivax Pharmaceuticals Ireland," the '712 patent does not recite the words "pharmaceutical," "pharmaceuticals," "pharmacological," "pharmacy," or "pharmaceutics."

178. In addition to being listed in the Orange Book entry for ProAir® HFA, the '712 patent is listed in the Orange Book entry for QVAR Redihaler.

COUNT 2: DECLARATORY JUDGMENT REQUIRING DELISTING OF U.S. PATENT NO. 9,463,289

179. Deva incorporates and re-alleges each of the foregoing paragraphs 1–178 of its Counterclaims, as if fully set forth herein.

180. Deva hereby seeks a declaration pursuant to 21 U.S.C. § 355(j)(5)(C)(ii) ordering Counterclaim-Defendants to delete or withdraw the '289 patent from the Orange Book.

181. An actual controversy exists between Counterclaim-Defendants and Deva over the listing of the '289 patent in the Orange Book.

182. The '289 patent is not properly listed in the Orange Book.

183. The '289 patent does not satisfy any of the statutory requirements for being listed in the Orange Book.

184. The '289 patent does not claim a method of using a drug.

185. The '289 patent does not claim an approved method of using ProAir® HFA.

186. The '289 patent does not claim "the drug for which the applicant submitted" the ProAir® NDA.

187. The '289 patent is not "a drug substance (active ingredient) patent."

188. The '289 patent does not claim a drug substance.

189. The '289 patent does not claim an active ingredient.

190. The '289 patent is not "a drug product (formulation or composition) patent."

191. The '289 patent does not claim a drug product.

192. The '289 patent does not claim a drug formulation.

193. The '289 patent does not claim a drug composition.

194. The '289 patent does not claim a drug.

195. The FTC has already determined that the ’289 patent is not properly listed in the Orange Book for ProAir® HFA.

196. On or about November 7, 2023, the FTC sent a letter to Teva Branded bearing that date and informing Teva Branded that the FTC believes that the ’289 patent is “improperly or inaccurately listed in the Orange Book” for ProAir® HFA. A copy of the FTC Delisting Letter to Teva Branded is attached to this Answer, Affirmative Defenses, and Counterclaims as Exhibit L.

197. The FTC Delisting Letter indicates that the FTC has “submitted patent listing dispute communications to the FDA” regarding all nine Patents-in-Suit, including the ’289 patent.

198. The ’289 patent contains 10 claims, of which only claim 1 is independent. A copy of the ’289 patent is attached as Exhibit B to the Complaint.

199. Claim 1 of the ’289 patent recites:

> An inhaler for metered dose inhalation, the inhaler comprising:
> a main body having a canister housing,
> a medicament canister, which is moveable relative to the canister housing and retained in a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister, and
> a dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister,
> wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall, and
> wherein the canister housing has a longitudinal axis X which passes through the center of the central outlet port,
> the inner wall canister support formation, the actuation member, and the central outlet port lying in a common plane coincident with the longitudinal axis X.

200. None of the claims of the ’289 patent recite a drug, a drug substance, an active ingredient, a drug product, a drug formulation, a drug composition, a method of using a drug, a

method of using a drug product, a method of using a drug substance, a method of using an active pharmaceutical ingredient, a method of using a drug formulation, a method of using a drug composition, or a method of using a pharmaceutical formulation. None of the claims of the '289 patent recite "albuterol," "albuterol sulfate," "propellant HFA-134a," or "ethanol."

201. The '289 patent does not recite any of the following words or phrases: "albuterol," "albuterol sulfate," "HFA-134a," "ethanol," "ingredient," "formulation," or "bronchospasm."

202. Other than reciting the name of the assignees and applicants "Ivax Pharmaceuticals Ireland," and "Teva Pharmaceuticals Ireland," the '289 patent does not recite the words "pharmaceutical," "pharmaceuticals," "pharmacological," "pharmacy," or "pharmaceutics."

203. In addition to being listed in the Orange Book entry for ProAir® HFA, the '289 patent is listed in the Orange Book entries for (1) QVAR40 and (2) QVAR80.

COUNT 3: DECLARATORY JUDGMENT REQUIRING DELISTING OF U.S. PATENT NO. 9,808,587

204. Deva incorporates and re-alleges each of the foregoing paragraphs 1–203 of its Counterclaims, as if fully set forth herein.

205. Deva hereby seeks a declaration pursuant to 21 U.S.C. § 355(j)(5)(C)(ii) ordering Counterclaim-Defendants to delete or withdraw the '587 patent from the Orange Book.

206. An actual controversy exists between Counterclaim-Defendants and Deva over the listing of the '587 patent in the Orange Book.

207. The '587 patent is not properly listed in the Orange Book.

208. The ’587 patent does not satisfy any of the statutory requirements for being listed in the Orange Book.

209. The ’587 patent does not claim a method of using a drug.

210. The ’587 patent does not claim an approved method of using ProAir® HFA.

211. The ’587 patent does not claim “the drug for which the applicant submitted” the ProAir® NDA.

212. The ’587 patent is not “a drug substance (active ingredient) patent.”

213. The ’587 patent does not claim a drug substance.

214. The ’587 patent does not claim an active ingredient.

215. The ’587 patent is not “a drug product (formulation or composition) patent.”

216. The ’587 patent does not claim a drug product.

217. The ’587 patent does not claim a drug formulation.

218. The ’587 patent does not claim a drug composition.

219. The ’587 patent does not claim a drug.

220. The FTC has already determined that the ’587 patent is not properly listed in the Orange Book for ProAir® HFA.

221. On or about November 7, 2023, the FTC sent a letter to Teva Branded bearing that date and informing Teva Branded that the FTC believes that the ’587 patent is “improperly or inaccurately listed in the Orange Book” for ProAir® HFA.

222. The FTC Delisting Letter indicates that the FTC has "submitted patent listing dispute communications to the FDA" regarding all nine Patents-in-Suit, including the '587 patent.

223. The '587 patent contains 22 claims, of which only claims 1, 12, and 13 are independent. A copy of the '587 patent is attached as Exhibit C to the Complaint.

224. Claim 1 of the '587 patent recites:

> An inhaler for metered dose inhalation, the inhaler comprising:
> a main body having a canister housing,
> a medicament canister, which is moveable relative to the canister housing and retained in a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister, and
> a dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister,
> wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall,
> wherein the canister housing has a longitudinal axis X which passes through the center of the central outlet port, and
> wherein the first inner wall canister support formation, the actuation member, and the central outlet port lie in a common plane coincident with the longitudinal axis X such that the first inner wall canister support formation protects against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler.

225. Claim 12 of the '587 patent recites:

> An inhaler for metered dose inhalation, the inhaler comprising:
> a main body having a canister housing,
> a medicament canister, which is moveable relative to the canister housing and retained in a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister, and
> a dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister,
> wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall,
> wherein the canister housing has a longitudinal axis X which passes

through the center of the central outlet port, and
wherein the first inner wall canister support formation, the actuation member, and the central outlet port lie in a common plane coincident with the longitudinal axis X such that the first inner wall canister support formation protects against dose count errors by reducing rocking of the medicament canister towards or away from the actuation member.

226. Claim 13 of the ’587 patent recites:

An inhaler for metered dose inhalation, the inhaler comprising:
a main body having a canister housing,
a medicament canister retained in the canister housing and movable relative thereto, and a dose counter, the dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister,
wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall,
wherein the canister housing has an aperture formed in the inner wall through which the portion of the actuation member extends, and
wherein the first inner wall canister support formation extends from the main surface of the inner wall to the aperture.

227. None of the claims of the ’587 patent recite a drug, a drug substance, an active ingredient, a drug product, a drug formulation, a drug composition, a method of using a drug, a method of using a drug product, a method of using a drug substance, a method of using an active pharmaceutical ingredient, a method of using a drug formulation, a method of using a drug composition, or a method of using a pharmaceutical formulation.

228. None of the claims of the ’587 patent recite “albuterol,” “albuterol sulfate,” “propellant HFA-134a,” or “ethanol.”

229. The ’587 patent does not recite any of the following words or phrases: “albuterol,” “albuterol sulfate,” “HFA-134a,” “ethanol,” “ingredient,” “formulation,” or “bronchospasm.”

230. Other than reciting the name of the assignees and applicants "Ivax Pharmaceuticals Ireland," and "Teva Pharmaceuticals Ireland," the '587 patent does not recite the words "pharmaceutical," "pharmaceuticals," "pharmacological," "pharmacy," or "pharmaceutics."

231. In addition to being listed in the Orange Book entry for ProAir® HFA, the '587 patent is listed in the Orange Book entries for (1) QVAR40 and (2) QVAR80.

COUNT 4: DECLARATORY JUDGMENT REQUIRING DELISTING OF U.S. PATENT NO. 10,022,509

232. Deva incorporates and re-alleges each of the foregoing paragraphs 1–231 of its Counterclaims, as if fully set forth herein.

233. Deva hereby seeks a declaration pursuant to 21 U.S.C. §355(j)(5)(C)(ii) ordering Counterclaim-Defendants to delete or withdraw the '509 patent from the Orange Book.

234. An actual controversy exists between Counterclaim-Defendants and Deva over the listing of the '509 patent in the Orange Book.

235. The '509 patent is not properly listed in the Orange Book.

236. The '509 patent does not satisfy any of the statutory requirements for being listed in the Orange Book.

237. The '509 patent does not claim a method of using a drug.

238. The '509 patent does not claim an approved method of using ProAir® HFA.

239. The '509 patent does not claim "the drug for which the applicant submitted" the ProAir® NDA.

240. The '509 patent is not "a drug substance (active ingredient) patent."

241. The ’509 patent does not claim a drug substance.

242. The ’509 patent does not claim an active ingredient.

243. The ’509 patent is not “a drug product (formulation or composition) patent.”

244. The ’509 patent does not claim a drug product.

245. The ’509 patent does not claim a drug formulation.

246. The ’509 patent does not claim a drug composition.

247. The ’509 patent does not claim a drug.

248. The FTC has already determined that the ’509 patent is not properly listed in the Orange Book for ProAir® HFA.

249. On or about November 7, 2023, the FTC sent a letter to Teva Branded bearing that date and informing Teva Branded that the FTC believes that the ’889 patent is “improperly or inaccurately listed in the Orange Book” for ProAir® HFA.

250. The FTC Delisting Letter indicates that the FTC has “submitted patent listing dispute communications to the FDA” regarding all nine Patents-in-Suit, including the ’509 patent.

251. The ’509 patent contains 16 claims, of which only claim 1 is independent. A copy of the ’509 patent is attached as Exhibit D to the Complaint.

252. Claim 1 of the ’509 patent recites:

> A dose counter for an inhaler, the dose counter having a display tape arranged to be incrementally driven from a tape stock bobbin onto an incremental tape take-up drive shaft, the bobbin having an internal bore supported by and for rotation about a support shaft, at least one of the bore and the support shaft having a radially extending protrusion having a leading portion edge, a trailing portion edge,

> wherein at least one of the leading portion edge and the trailing portion edge are tapered, and a friction edge between the leading portion edge and the trailing portion edge, wherein the friction edge is substantially parallel to a longitudinal axis of the support shaft and the leading portion edge and trailing portion edge are not parallel to the longitudinal axis of the support shaft, and the friction edge is resiliently biased into frictional engagement with the other of the bore and support shaft with longitudinally extending mutual frictional interaction and wherein the friction edge extends further in a longitudinal direction than the protrusion extends radially.

253. None of the claims of the '509 patent recite a drug, a drug substance, an active ingredient, a drug product, a drug formulation, a drug composition, a method of using a drug, a method of using a drug product, a method of using a drug substance, a method of using an active pharmaceutical ingredient, a method of using a drug formulation, a method of using a drug composition, or a method of using a pharmaceutical formulation.

254. None of the claims of the '509 patent recite "albuterol," "albuterol sulfate," "propellant HFA-134a," or "ethanol."

255. The '509 patent does not recite any of the following words or phrases: "albuterol," "albuterol sulfate," "HFA-134a," "ethanol," "ingredient," "formulation," or "bronchospasm."

256. Other than reciting the name of the assignees and applicants "Ivax Pharmaceuticals Ireland," and "Teva Pharmaceuticals Ireland," the '509 patent does not recite the words "pharmaceutical," "pharmaceuticals," "pharmacological," "pharmacy," or "pharmaceutics."

257. In addition to being listed in the Orange Book entry for ProAir® HFA, the '509 patent is listed in the Orange Book entries for (1) QVAR Redihaler, (2) QVAR40, and (3) QVAR80.

COUNT 5: DECLARATORY JUDGMENT REQUIRING DELISTING OF U.S. PATENT NO. 10,022,510

258. Deva incorporates and re-alleges each of the foregoing paragraphs 1–257 of its Counterclaims, as if fully set forth herein.

259. Deva l hereby seeks a declaration pursuant to 21 U.S.C. §355(j)(5)(C)(ii) ordering Counterclaim-Defendants to delete or withdraw the ’510 patent from the Orange Book.

260. An actual controversy exists between Counterclaim-Defendants and Deva over the listing of the ’510 patent in the Orange Book. The ’510 patent is not properly listed in the Orange Book.

261. The ’510 patent does not satisfy any of the statutory requirements for being listed in the Orange Book.

262. The ’510 patent does not claim a method of using a drug.

263. The ’510 patent does not claim an approved method of using ProAir® HFA.

264. The ’510 patent does not claim “the drug for which the applicant submitted” the ProAir® NDA.

265. The ’510 patent is not “a drug substance (active ingredient) patent.”

266. The ’510 patent does not claim a drug substance.

267. The ’510 patent does not claim an active ingredient.

268. The ’510 patent is not “a drug product (formulation or composition) patent.”

269. The ’510 patent does not claim a drug product.

270. The ’510 patent does not claim a drug formulation.

271. The ’510 patent does not claim a drug composition.

272. The ’510 patent does not claim a drug.

273. The FTC has already determined that the ’510 patent is not properly listed in the Orange Book for ProAir® HFA.

274. On or about November 7, 2023, the FTC sent a letter to Teva Branded bearing that date and informing Teva Branded that the FTC believes that the ’510 patent is “improperly or inaccurately listed in the Orange Book” for ProAir® HFA.

275. The FTC Delisting Letter indicates that the FTC has “submitted patent listing dispute communications to the FDA” regarding all nine Patents-in-Suit, including the ’510 patent.

276. The ’510 patent contains 23 claims, of which claim 1, claim 10 and claim 20 are independent. A copy of the ’510 patent is attached as Exhibit E to the Complaint.

277. Claim 1 of the ’510 patent recites:

> An inhaler comprising a dose count
> er and dose counter viewing window, the inhaler being configured to be readied by priming before first use and the dose counter comprising:
> a tape system having a main elongate tape structure, dosing indicia located on the main elongate tape structure, tape positioning indicia located on the main elongate tape structure, a tape size marker located on the main elongate tape structure indicating a number of dosing indicia on the main elongate tape structure, and priming indicia located on the main elongate tape structure, the priming indicia being located between the dosing indicia and a first end of the main elongate tape structure and visible in the dose counter viewing window before priming before first use, and
> wherein the first end of the main elongate tape structure is fixed to a tape reel shaft and a second end of the main elongate tape structure is attached to a stock bobbin, and wherein the main elongate tape structure is around both the stock bobbin and tape reel shaft when the priming indicia is visible in the dose counter viewing window before priming before first use.

278. Claim 10 of the ‘510 patent recites:

> An inhaler comprising a dose counter and dose counter viewing window,

> the inhaler being configured to be readied by priming before first use and the dose counter comprising:
> a tape system having a main elongate tape structure, dosing indicia located on the main elongate tape structure, tape positioning indicia located on the main elongate tape structure, and a tape size marker located on the main elongate tape structure indicating a number of dosing indicia on the main elongate tape structure, wherein the tape size marker is positioned between a first end of the main elongate tape structure and the tape positioning indicia,
> wherein the first end of the main elongate tape structure is fixed to a tape reel shaft and a second end of the main elongate tape structure is attached to a stock bobbin, and wherein the tape is around both the stock bobbin and tape reel shaft and a portion of the main elongate tape structure between the tape positioning indicia and the dosing indicia is visible in the dose counter viewing window before priming before first use.

279. Claim 20 of the ‘510 patent recites:

> An inhaler comprising a dose counter and dose counter viewing window, the inhaler being configured to be readied by priming before first use and the dose counter comprising:
> a tape system having a main elongate tape structure, dosing indicia located on the main elongate tape structure, tape positioning indicia located on the main elongate tape structure so as to be visible in the dose counter viewing window before priming before first use, and priming indicia located on the main elongate tape structure, the priming indicia being located between the tape positioning indicia and the dosing indicia,
> wherein a first end of the main elongate tape structure is attached to a stock bobbin and a second end of the main elongate tape structure is fixed to a tape reel shaft, and wherein the main elongate tape structure is around both the stock bobbin and tape reel shaft when the priming indicia is visible in the dose counter viewing window before priming before first use.

280. None of the claims of the ’510 patent recite a drug, a drug substance, an active ingredient, a drug product, a drug formulation, a drug composition, a method of using a drug, a method of using a drug product, a method of using a drug substance, a method of using an active pharmaceutical ingredient, a method of using a drug formulation, a method of using a drug composition, or a method of using a pharmaceutical formulation.

281. None of the claims of the '510 patent recite "albuterol," "albuterol sulfate," "propellant HFA-134a," or "ethanol."

282. The '510 patent does not recite any of the following words or phrases: "albuterol," "albuterol sulfate," "HFA-134a," "ethanol," "ingredient," "formulation," or "bronchospasm."

283. Other than reciting the name of the assignees and applicants "Ivax Pharmaceuticals Ireland," and "Teva Pharmaceuticals Ireland," the '510 patent does not recite the words "pharmaceutical," "pharmaceuticals," "pharmacological," "pharmacy," or "pharmaceutics."

284. In addition to being listed in the Orange Book entry for ProAir® HFA, the '510 patent is listed in the Orange Book entries for (1) QVAR Redihaler, (2) QVAR40, and (3) QVAR80.

COUNT 6: DECLARATORY JUDGMENT REQUIRING DELISTING OF U.S. PATENT NO. 10,086,156

285. Deva incorporates and re-alleges each of the foregoing paragraphs 1–284 of its Counterclaims, as if fully set forth herein.

286. Deva hereby seeks a declaration pursuant to 21 U.S.C. §355(j)(5)(C)(ii) ordering Counterclaim-Defendants to delete or withdraw the '156 patent from the Orange Book.

287. An actual controversy exists between Counterclaim-Defendants and Deva over the listing of the '156 patent in the Orange Book. The '156 patent is not properly listed in the Orange Book.

288. The '156 patent does not satisfy any of the statutory requirements for being listed in the Orange Book.

289. The '156 patent does not claim a method of using a drug.

290. The '156 patent does not claim an approved method of using ProAir® HFA.

291. The ’156 patent does not claim “the drug for which the applicant submitted” the ProAir® NDA.

292. The ’156 patent is not “a drug substance (active ingredient) patent.”

293. The ’156 patent does not claim a drug substance.

294. The ’156 patent does not claim an active ingredient.

295. The ’156 patent is not “a drug product (formulation or composition) patent.”

296. The ’156 patent does not claim a drug product.

297. The ’156 patent does not claim a drug formulation.

298. The ’156 patent does not claim a drug composition.

299. The ’156 patent does not claim a drug.

300. The FTC has already determined that the ’156 patent is not properly listed in the Orange Book for ProAir® HFA.

301. On or about November 7, 2023, the FTC sent a letter to Teva Branded bearing that date and informing Teva Branded that the FTC believes that the ’156 patent is “improperly or inaccurately listed in the Orange Book” for ProAir® HFA.

302. The FTC Delisting Letter indicates that the FTC has “submitted patent listing dispute communications to the FDA” regarding all nine Patents-in-Suit, including the ’156 patent.

303. The ’156 patent contains 13 claims, of which only claim 1 is independent. A copy of the ’156 patent is attached as Exhibit F to the Complaint.

304. Claim 1 of the ’156 patent recites:

> A dose counter for a metered dose inhaler having a body arranged to retain a medicament canister of predetermined configuration for movement of the medicament canister relative thereto, the medicament canister containing an active drug; the dose counter comprising:
> a ratchet wheel having a plurality of circumferentially spaced teeth,
> an actuator comprising an actuator pawl arranged to engage with a first tooth of the ratchet wheel, wherein the actuator can be driven in response to canister motion to drive the ratchet wheel to rotate,
> a count pawl arranged to engage with a second tooth of the ratchet wheel, wherein as the ratchet wheel is driven by the actuator to rotate, the count pawl rides along a forward surface of the second tooth and resiliently jumps over the second tooth, and
> a dosage indicator associated with the count pawl,
> wherein the actuator is arranged to define a first reset position in which the actuator pawl is brought into engagement with the first tooth,
> wherein the actuator is further arranged such that, during a canister fire sequence, when the actuator is in a second position, which is after the first reset position and at a canister fire configuration, the medicament canister fires medicament before the dose counter reaches a count configuration, and when the actuator is in a third position after the second position, the count pawl resiliently jumps over the second tooth and the dose counter reaches the count configuration, whereby the dosage indicator has indicated a count,
> wherein, in the canister fire configuration, the actuator pawl is below a datum plane which passes through a shoulder of a valve stem block configured to receive the medicament canister.

305. None of the claims of the ’156 patent recite a drug, a drug substance, an active ingredient, a drug product, a drug formulation, a drug composition, a method of using a drug, a method of using a drug product, a method of using a drug substance, a method of using an active pharmaceutical ingredient, a method of using a drug formulation, a method of using a drug composition, or a method of using a pharmaceutical formulation.

306. None of the claims of the ’156 patent recite “albuterol,” “albuterol sulfate,” “propellant HFA-134a,” or “ethanol.”

307. The ’156 patent does not recite any of the following words or phrases: “albuterol,” “albuterol sulfate,” “HFA-134a,” “ethanol,” “ingredient,” “formulation,” or “bronchospasm.”

308. Other than reciting the name of the assignees and applicants "Ivax Pharmaceuticals Ireland," and "Teva Pharmaceuticals Ireland," the '156 patent does not recite the words "pharmaceutical," "pharmaceuticals," "pharmacological," "pharmacy," or "pharmaceutics."

309. In addition to being listed in the Orange Book entry for ProAir® HFA, the '156 patent is listed in the Orange Book entries for (1) QVAR Redihaler, (2) QVAR40, and (3) QVAR80.

COUNT 7: DECLARATORY JUDGMENT REQUIRING DELISTING OF U.S. PATENT NO. 10,561,808

310. Deva incorporates and re-alleges each of the foregoing paragraphs 1–309 of its Counterclaims, as if fully set forth herein.

311. Deva hereby seeks a declaration pursuant to 21 U.S.C. § 355(j)(5)(C)(ii) ordering Counterclaim-Defendants to delete or withdraw the '808 patent from the Orange Book.

312. An actual controversy exists between Counterclaim-Defendants and Deva over the listing of the '808 patent in the Orange Book.

313. The '808 patent is not properly listed in the Orange Book.

314. The '808 patent does not satisfy any of the statutory requirements for being listed in the Orange Book.

315. The '808 patent does not claim a method of using a drug.

316. The '808 patent does not claim an approved method of using ProAir® HFA.

317. The '808 patent does not claim "the drug for which the applicant submitted" the ProAir® NDA.

318. The '808 patent is not "a drug substance (active ingredient) patent."

319. The ’808 patent does not claim a drug substance.

320. The ’808 patent does not claim an active ingredient.

321. The ’808 patent is not “a drug product (formulation or composition) patent.”

322. The ’808 patent does not claim a drug product.

323. The ’808 patent does not claim a drug formulation. The ’808 patent does not claim a drug composition.

324. The ’808 patent does not claim a drug.

325. The FTC has already determined that the ’808 patent is not properly listed in the Orange Book for ProAir® HFA.

326. On or about November 7, 2023, the FTC sent a letter to Teva Branded bearing that date and informing Teva Branded that the FTC believes that the ’808 patent is “improperly or inaccurately listed in the Orange Book” for ProAir® HFA.

327. The FTC Delisting Letter indicates that the FTC has “submitted patent listing dispute communications to the FDA” regarding all nine Patents-in-Suit, including the ’808 patent.

328. The ’808 patent contains 29 claims, of which only claim 1 is independent. A copy of the ’808 patent is attached as Exhibit G to the Complaint.

329. Claim 1 of the ’808 patent recites:

> A dose counter for an inhaler, the dose counter having
> a counter display arranged to indicate dosage information,
> a drive system arranged to move the counter display incrementally in a first direction from a first station to a second station in response to actuation input,
> wherein a regulator is provided which is arranged to act upon the counter display at the first station to regulate motion of the counter display at the first station to incremental movements.

330. None of the claims of the ’808 patent recite a drug, a drug substance, an active ingredient, a drug product, a drug formulation, a drug composition, a method of using a drug, a method of using a drug product, a method of using a drug substance, a method of using an active pharmaceutical ingredient, a method of using a drug formulation, a method of using a drug composition, or a method of using a pharmaceutical formulation.

331. None of the claims of the ’808 patent recite “albuterol,” “albuterol sulfate,” “propellant HFA-134a,” or “ethanol.”

332. The ’808 patent does not recite any of the following words or phrases: “albuterol,” “albuterol sulfate,” “HFA-134a,” “ethanol,” “ingredient,” “formulation,” or “bronchospasm.”

333. Other than reciting the name of the assignees and applicants “Ivax Pharmaceuticals Ireland,” and “Teva Pharmaceuticals Ireland,” the ’808 patent does not recite the words “pharmaceutical,” “pharmaceuticals,” “pharmacological,” “pharmacy,” or “pharmaceutics.”

334. In addition to being listed in the Orange Book entry for ProAir® HFA, the ’808 patent is listed in the Orange Book entries for (1) QVAR Redihaler, (2) AirDuo Digihaler, (3) AirDuo Respiclick, (4) ArmonAir Digihaler, (5) ArmonAir Respiclick, (6) ProAir Digihaler, (7) ProAir Respiclick, (8) QVAR40, and (9) QVAR80.

COUNT 8: DECLARATORY JUDGMENT REQUIRING DELISTING OF U.S. PATENT NO. 10,695,512

335. Deva incorporates and re-alleges each of the foregoing paragraphs 1–334 of its Counterclaims, as if fully set forth herein.

336. Deva hereby seeks a declaration pursuant to 21 U.S.C. §355(j)(5)(C)(ii) ordering Counterclaim-Defendants to delete or withdraw the ’512 patent from the Orange Book.

337. An actual controversy exists between Counterclaim-Defendants and Deva over the listing of the ’512 patent in the Orange Book.

338. The ’512 patent is not properly listed in the Orange Book.

339. The ’512 patent does not satisfy any of the statutory requirements for being listed in the Orange Book.

340. The ’512 patent does not claim a method of using a drug.

341. The ’512 patent does not claim an approved method of using ProAir® HFA.

342. The ’512 patent does not claim “the drug for which the applicant submitted” the ProAir® NDA.

343. The ’512 patent is not “a drug substance (active ingredient) patent.”

344. The ’512 patent does not claim a drug substance.

345. The ’512 patent does not claim an active ingredient.

346. The ’512 patent is not “a drug product (formulation or composition) patent.”

347. The ’512 patent does not claim a drug product.

348. The ’512 patent does not claim a drug formulation.

349. The ’512 patent does not claim a drug composition.

350. The ’512 patent does not claim a drug.

351. The FTC has already determined that the ’512 patent is not properly listed in the Orange Book for ProAir® HFA.

352. On or about November 7, 2023, the FTC sent a letter to Teva Branded bearing that date and informing Teva Branded that the FTC believes that the '512 patent is "improperly or inaccurately listed in the Orange Book" for ProAir® HFA.

353. The FTC Delisting Letter indicates that the FTC has "submitted patent listing dispute communications to the FDA" regarding all nine Patents-in-Suit, including the '512 patent.

354. The '512 patent contains 6 claims, of which only claim 1 is independent. A copy of the '512 patent is attached as Exhibit H to the Complaint.

355. Claim 1 of the '512 patent recites:

> An inhaler for inhaling medicament, the inhaler having:
> A body for retaining a medicament canister; and
> a dose counter, the dose counter having a moveable actuator and a chassis mounted on the body;
> wherein one of the body and the chassis includes a plurality of apertures for receiving one or more pins on the other of the body and the chassis,
> wherein either the pins or the apertures on the chassis are positioned on different sides of the chassis for stabilizing the chassis on the body, and
> wherein the chassis comprises at least one of a pin or aperture heat staked to a respective aperture or pin of the body to mount the chassis to the body.

356. None of the claims of the '512 patent recite a drug, a drug substance, an active ingredient, a drug product, a drug formulation, a drug composition, a method of using a drug, a method of using a drug product, a method of using a drug substance, a method of using an active pharmaceutical ingredient, a method of using a drug formulation, a method of using a drug composition, or a method of using a pharmaceutical formulation.

357. None of the claims of the '512 patent recite "albuterol," "albuterol sulfate," "propellant HFA-134a," or "ethanol."

358. The ’512 patent does not recite any of the following words or phrases: “albuterol,” “albuterol sulfate,” “HFA-134a,” “ethanol,” “ingredient,” “formulation,” or “bronchospasm.”

359. Other than reciting the name of the assignees and applicants “Ivax Pharmaceuticals Ireland,” and “Teva Pharmaceuticals Ireland,” the ’512 patent does not recite the words “pharmaceutical,” “pharmaceuticals,” “pharmacological,” “pharmacy,” or “pharmaceutics.”

360. In addition to being listed in the Orange Book entry for ProAir® HFA, the ’512 patent is listed in the Orange Book entries for (1) QVAR Redihaler, (2) QVAR40, and (3) QVAR80.

COUNT 9: DECLARATORY JUDGMENT REQUIRING DELISTING OF U.S. PATENT NO. 11,395,889

361. Deva incorporates and re-alleges each of the foregoing paragraphs 1–360 of its Counterclaims, as if fully set forth herein.

362. Deva hereby seeks a declaration pursuant to 21 U.S.C. §355(j)(5)(C)(ii) ordering Counterclaim-Defendants to delete or withdraw the ’889 patent from the Orange Book.

363. An actual controversy exists between Counterclaim-Defendants and Deva over the listing of the ’889 patent in the Orange Book.

364. The ’889 patent is not properly listed in the Orange Book.

365. The ’889 patent does not satisfy any of the statutory requirements for being listed in the Orange Book.

366. The ’889 patent does not claim a method of using a drug.

367. The ’889 patent does not claim an approved method of using ProAir® HFA.

368. The ’889 patent does not claim “the drug for which the applicant submitted” the ProAir® NDA.

369. The ’889 patent is not “a drug substance (active ingredient) patent.”

370. The ’889 patent does not claim a drug substance.

371. The ’889 patent does not claim an active ingredient.

372. The ’889 patent is not “a drug product (formulation or composition) patent.”

373. The ’889 patent does not claim a drug product.

374. The ’889 patent does not claim a drug formulation.

375. The ’889 patent does not claim a drug composition.

376. The ’889 patent does not claim a drug.

377. The FTC has already determined that the ’889 patent is not properly listed in the Orange Book for ProAir® HFA.

378. On or about November 7, 2023, the FTC sent a letter to Teva Branded bearing that date and informing Teva Branded that the FTC believes that the ’889 patent is “improperly or inaccurately listed in the Orange Book” for ProAir® HFA.

379. The FTC Delisting Letter indicates that the FTC has “submitted patent listing dispute communications to the FDA” regarding all nine Patents-in-Suit, including the ’889 patent.

380. The ’889 patent contains 6 claims, of which only claim 1 is independent. A copy of the ’889 patent is attached as Exhibit I to the Complaint.

381. Claim 1 of the ’889 patent recites:

> An incremental dose counter for a metered dose inhaler having a body arranged to retain a canister for movement of the canister relative thereto, the incremental dose counter having a main body, an actuator arranged to be driven and to drive an incremental output member in a count direction in response to canister motion, the actuator being configured to restrict motion of the output member in a direction opposite to the count direction, such that the actuator acts as an anti-back drive member when the actuator is in a non-depressed position, and wherein the incremental dose counter further comprises a second anti-back member configured to restrict motion of the output member in a direction opposite to the count direction when the actuator is disengaged from the output member by a bump surface.

382. None of the claims of the ’889 patent recite a drug, a drug substance, an active ingredient, a drug product, a drug formulation, a drug composition, a method of using a drug, a method of using a drug product, a method of using a drug substance, a method of using an active pharmaceutical ingredient, a method of using a drug formulation, a method of using a drug composition, or a method of using a pharmaceutical formulation.

383. None of the claims of the ’889 patent recite “albuterol,” “albuterol sulfate,” “propellant HFA-134a,” or “ethanol.”

384. The ’889 patent does not recite any of the following words or phrases: “albuterol,” “albuterol sulfate,” “HFA-134a,” “ethanol,” “ingredient,” “formulation,” or “bronchospasm.”

385. Other than reciting the name of the assignees and applicants “Ivax Pharmaceuticals Ireland,” and “Teva Pharmaceuticals Ireland,” the ’889 patent does not recite the words “pharmaceutical,” “pharmaceuticals,” “pharmacological,” “pharmacy,” or “pharmaceutics.”

386. In addition to being listed in the Orange Book entry for ProAir® HFA, the ’889 patent is listed in the Orange Book entries for (1) QVAR Redihaler, (2) QVAR40, and (3) QVAR80.

COUNT 10: UNLAWFUL MONOPOLIZATION OVERALL SCHEME IN VIOLATION OF THE SHERMAN ACT

387. Deva incorporates and re-alleges each of the foregoing paragraphs 1–386 of its Counterclaims, as if fully set forth herein.

388. This claim arises under the Sherman Act, 15 U.S.C. § 2 and under the Clayton Act, 15 U.S.C. §§ 15 and 26.

389. Counterclaim-Defendants are engaged in the development, commercialization, and marketing of prescription pharmaceutical products for the treatment of various disorders. Deva is a supplier of generic pharmaceutical products.

390. Deva is a potential future direct competitor with Counterclaim-Defendants in the Relevant Market.

391. On information and belief, Counterclaim-Defendants have a predominant share of the Relevant Market.

392. Counterclaim-Defendants have monopoly power in the Relevant Market.

393. Counterclaim-Defendants have exercised monopoly power in the Relevant Market.

394. Counterclaim-Defendants have the power to control prices and/or exclude competition in, or prevent entry into, the Relevant Market.

395. Substantial barriers to entry into the Relevant Market exist, including but not limited to, regulatory requirements and Counterclaim-Defendants' actions to delay and preclude entry into the Relevant Market, including but not limited to, improperly listing the Patents-in-Suit in the Orange Book and refusing to delist them, Counterclaim-Defendants' history of enforcement efforts relating to patents listed in the Orange Book for ProAir® HFA, and Counterclaim-Defendants' present lawsuit for infringement of the Patents-in-Suit.

396. Counterclaim-Defendants knowingly and intentionally engaged in an anticompetitive and monopolistic scheme designed to injure or destroy competition in the Relevant Market by delaying market entry of the Deva ANDA Product.

397. Counterclaim-Defendants have baselessly and improperly wielded the Patents-in-Suit, including by improperly listing them in the Orange Book and asserting them in this case and others to trigger the automatic 30-month stay of FDA approval of ANDAs seeking approval to market generic versions of ProAir® HFA.

398. These judicial proceedings are not a genuine effort by Counterclaim-Defendants to obtain an adjudication of a valid claim that is infringed, but rather were instituted to achieve an unlawful objective to the detriment of competition as a whole in the Relevant Market. The purpose of such action is to directly interfere with and harm Deva's business and business relationships in the Relevant Market, and to forestall, frustrate, and prevent competition by Deva.

399. Counterclaim-Defendants engaged in this anticompetitive scheme and each lawsuit in order to consolidate, entrench, and enhance their monopolistic position in the Relevant Market and to stifle, delay, and eliminate competition and competitors with no economic, market, or competitive benefit.

400. Counterclaim-Defendants' scheme and actions have no procompetitive, business justification.

401. The patent infringement claims that Counterclaim-Defendants asserted in this lawsuit against Deva are objectively baseless. No reasonable litigant could expect to secure favorable relief against Deva on the merits because the Deva ANDA Product does not infringe any of the claims of the Patents-in-Suit, and the Patents-in-Suit are invalid.

402. The Patents-in-Suit are directed to devices or portions of devices, and the device that Deva seeks approval to use in its ANDA is itself prior art to the Patents-in-Suit. Thus, the Patents-in-Suit cannot cover the device used by Deva under the doctrine of equivalents, because that would necessarily ensnare the prior art.

403. And if the Deva device is deemed to literally infringe Patents-in-Suit, then axiomatically, the Patents-in-Suit would be invalid as anticipated.

404. The 30-month-stay-conferring 35 U.S.C. § 271(e) patent infringement claims that Counterclaim-Defendants asserted in this lawsuit against Deva are also objectively baseless because the Court does not properly have subject matter jurisdiction over this case.

405. Counterclaim-Defendants brought their patent infringement claims in bad faith, for an improper purpose, as a means of directly interfering with and harming Deva's business, and to forestall, frustrate, and prevent competition by Deva.

406. Counterclaim-Defendants intentionally engaged in the exclusionary conduct alleged herein with the express purpose of achieving and maintaining monopoly power in the Relevant Market. Counterclaim-Defendants' lawsuit filed against Deva alleging infringement of the Patents-in-Suit is both objectively and subjectively baseless and constitutes sham litigation and bad faith enforcement of the Patents-in-Suit.

407. Counterclaim-Defendants' anticompetitive activities are a direct, proximate, and reasonably foreseeable cause of Deva's foreclosure from the Relevant Market and delay in entering the Relevant Market.

408. But for Counterclaim-Defendants' actions alleged herein, Counterclaim-Defendants' market share in the Relevant Market would have decreased with the addition of Deva in the Relevant Market, to the benefit of competition and consumers in the Relevant Market.

409. On information and belief, Counterclaim-Defendants have not acted to advance their position by competing on the merits in the Relevant Market, but solely to exclude potential competition from an alternate source in the Relevant Market.

410. The effects of Counterclaim-Defendants' overall scheme, course of conduct and attempt to monopolize will be to unreasonably restrain trade and commerce in the Relevant Market, and permit Counterclaim-Defendants to monopolize the Relevant Market in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2, including the following effects, among others:

a. A delay of competition in the manufacture and sale of a generic equivalent of ProAir® HFA;

b. Purchasers of albuterol inhalants will be deprived of the benefits of free and open competition;

c. Payers and consumers will pay supracompetitive prices for albuterol inhalants;

d. Deva will be deprived of revenues and profits it otherwise would have achieved but for Counterclaim-Defendants' illegal conduct.

411. Counterclaim-Defendants' exclusionary, anticompetitive, and unlawful activities threaten loss or damage to Deva by forestalling, frustrating, and preventing Deva's ability to compete in the Relevant Market.

412. As a result of Counterclaim-Defendants' exclusionary, anticompetitive, and unlawful actions, Deva has suffered, and will continue to suffer, injury to its business and property, including lost profits and business opportunities, and the costs and fees it has been forced to incur and that it continues to incur in connection with defending against this lawsuit.

413. The threatened injury to Deva results from the anticompetitive nature of Counterclaim-Defendants' conduct and constitutes antitrust injury.

414. Counterclaim-Defendants' conduct occurred in, and has had a substantial effect on, interstate commerce.

415. Deva is entitled to a judgment that Counterclaim-Defendants have violated Section 2 of the Sherman Act, 15 U.S.C. § 2; to the damages it suffered as a result of that violation, to be trebled in accordance with the Clayton Act, 15 U.S.C. § 15, plus interest; and to its costs and attorneys' fees.

COUNT 11: UNLAWFUL MONOPOLIZATION
SHAM LITIGATION IN VIOLATION OF THE SHERMAN ACT

416. Deva incorporates and re-alleges each of the foregoing paragraphs 1–415 of its Counterclaims, as if fully set forth herein.

417. Counterclaim-Defendants' have monopoly power in the Relevant Market.

418. Counterclaim-Defendants' knowingly and intentionally engaged in an anticompetitive and monopolistic scheme designed to injure or destroy competition in the Relevant Market by delaying market entry of Deva's generic equivalent of ProAir® HFA. Counterclaim-Defendants have engaged in a predatory scheme to monopolize the Relevant Market through, but not limited to, initiating objectively baseless and sham judicial proceedings designed to effectuate their monopoly over sales of albuterol inhalers in the United States.

419. These judicial proceedings are not a genuine effort by Counterclaim-Defendants to obtain an adjudication of a valid claim that is infringed, but rather were instituted to achieve an unlawful objective to the detriment of competition as a whole in the Relevant Market. The purpose

of such action is to directly interfere with and harm Deva's business and business relationships in the Relevant Market, and to forestall, frustrate, and prevent competition by Deva.

420. Counterclaim-Defendants engaged in this conduct in order to consolidate, entrench, and enhance their monopolistic position in the Relevant Market and to stifle, delay, and eliminate competition and competitors with no economic, market, or competitive benefit.

421. Counterclaim-Defendants' anticompetitive activities are a direct, proximate, and reasonably foreseeable cause of Deva's foreclosure from the Relevant Market and delay in entering the Relevant Market.

422. As a result of Counterclaim-Defendants' exclusionary, anticompetitive, and unlawful actions, Deva has suffered, and will continue to suffer, injury to their business and property, including lost profits and business opportunities, and the costs and fees it has been forced to incur and that it continues to incur in connection with defending against this lawsuit.

423. The threatened injury to Deva results from the anticompetitive nature of Counterclaim-Defendants' conduct and constitutes antitrust injury.

424. Counterclaim-Defendants' conduct occurred in, and has had a substantial effect on, interstate commerce.

425. Deva is entitled to a judgment that Counterclaim-Defendants have violated Section 2 of the Sherman Act, 15 U.S.C. § 2; to the damages it suffered as a result of that violation, to be trebled in accordance with the Clayton Act, 15 U.S.C. § 15, plus interest; and to its costs and attorneys' fees.

COUNT 12: UNLAWFUL MONOPOLIZATION
IMPROPER ORANGE BOOK LISTING IN VIOLATION OF THE SHERMAN ACT

426. Deva incorporates and re-alleges each of the foregoing paragraphs 1–425 of its Counterclaims, as if fully set forth herein.

427. Counterclaim-Defendants have monopoly power in the Relevant Market.

428. Counterclaim-Defendants knowingly and intentionally engaged in an anticompetitive and monopolistic scheme designed to injure or destroy competition in the Relevant Market by delaying market entry of Deva's generic equivalent of ProAir® HFA. Counterclaim-Defendants have engaged in a predatory scheme to monopolize the Relevant Market through, but not limited to, improperly listing the Patents-in-Suit in the Orange Book.

429. Counterclaim-Defendants engaged in this conduct in order to consolidate, entrench, and enhance their monopolistic position in the Relevant Market and to stifle, delay, and eliminate competition and competitors with no economic, market, or competitive benefit.

430. Counterclaim-Defendants anticompetitive activities are a direct, proximate, and reasonably foreseeable cause of Deva's foreclosure from the Relevant Market and delay in entering the Relevant Market.

431. As a result of Counterclaim-Defendants exclusionary, anticompetitive, and unlawful actions, Deva has suffered, and will continue to suffer, injury to their business and property, including lost profits and business opportunities, and the costs and fees it has been forced to incur and that it continues to incur in connection with defending against this lawsuit.

432. The threatened injury to Deva results from the anticompetitive nature of Counterclaim-Defendants' conduct and constitutes antitrust injury.

433. Counterclaim-Defendants' conduct occurred in, and has had a substantial effect on, interstate commerce.

434. Deva is entitled to a judgment that Counterclaim-Defendants have violated Section 2 of the Sherman Act, 15 U.S.C. § 2; to the damages it suffered as a result of that violation, to be trebled in accordance with the Clayton Act, 15 U.S.C. § 15, plus interest; and to its costs and attorneys' fees.

COUNT 13: ATTEMPTED UNLAWFUL MONOPOLIZATION IN VIOLATION OF THE SHERMAN ACT

435. Deva incorporates and re-alleges each of the foregoing paragraphs 1–434 of its Counterclaim, as if fully set forth herein.

436. Counterclaim-Defendants' scheme constitutes anticompetitive conduct taken with the specific intent to monopolize the market for albuterol sulfate inhalants in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2. On information and belief, Counterclaim-Defendants purposefully and knowingly improperly listed the Patents-in-Suit, and others, in the Orange Book, and refused to delist them, even after receiving a letter from the FTC stating that they should be delisted. Counterclaim-Defendants then commenced sham patent litigation against Deva under 35 U.S.C. § 271(e), despite fully knowing the Patents-in-Suit were improperly listed in the Orange Book, thereby unlawfully procuring an automatic 30-month stay of FDA approval.

437. Counterclaim-Defendants have created a dangerous probability that they will achieve their goal of monopolizing the Relevant Market. Counterclaim-Defendants' market share in the Relevant Market, coupled with other market structure and conduct evidence, including but not limited to, the lack of competition in the Relevant Market, the likely effect of competitive entry, the nature of the anticompetitive conduct alleged herein, and the related economic and market factors, constitute a dangerous probability that Counterclaim-Defendants will succeed in their efforts to maintain a monopoly in the Relevant Market.

COUNT 14: SHAM LITIGATION MONOPOLIZATION N.J. STAT, ANN. §§ 56:9-1 ET SEQ.

438. Deva incorporates and re-alleges each of the foregoing paragraphs 1–437 of its Counterclaims, as if fully set forth herein.

439. This claim arises under the New Jersey Antitrust Act, N.J. Stat. Ann. 56:9 et seq., and seeks a judgment that Counterclaim Defendants' conduct as alleged herein has violated New Jersey Antitrust, N.J. Stat. Ann. 56:9-4. Counterclaim-Defendants' conduct as alleged herein constitutes monopolization, attempted monopolization, and maintenance of monopoly in violation of N.J. Stat. Ann. 56:9-4.

440. Specifically, Counterclaim-Defendants' anticompetitive scheme, including abuse of the regulatory processes and court filings and improperly listing the Patents-in-Suit in the Orange Book and refusing to delist them were calculated to maintain monopoly power in the Relevant Market, in violation of N.J. Stat. Ann. 56:9-4.

441. Counterclaim-Defendants' anticompetitive and exclusionary conduct has directly and proximately caused injury to Deva's business and property, as set forth above. Deva's injury is of the type, the antitrust laws are intended to prohibit and thus constitutes antitrust injury.

COUNT 15: DECLARATORY JUDGMENT OF NON-INFRINGEMENT U.S. PATENT NOS. 9,463,289, 9,808,587, 10,086,156, AND 10,561,808

442. Deva incorporates and re-alleges each of the foregoing paragraphs 1–441 of its Counterclaims, as if fully set forth herein.

443. Deva does not, has not, and would not, if the products described in ANDA No. 21-3818 are marketed, directly or indirectly infringe any valid and enforceable claims of the '289, '587, '156, '808 patents, either literally or under the doctrine of equivalents.

444. Deva's manufacture, use, offer for sale, sale in the United States, and/or importation into the United States of the Deva ANDA Product will not infringe, directly or indirectly, any valid and enforceable claims of the '289, '587, '156, '808 patents, either literally or under the doctrine of equivalents.

445. Because Deva has not infringed and will not infringe any valid and enforceable claim of the '289, '587, '156, '808 patents. Deva is entitled to a declaratory judgment of non-infringement.

COUNT 16: DECLARATORY JUDGMENT OF NON-INFRINGEMENT U.S. PATENT NOS. 8,132,712, 10,022,509, 10,022,510, 10,695,512 AND 11,395,889

446. Deva incorporates and re-alleges each of the foregoing paragraphs 1–445 of its Counterclaims, as if fully set forth herein.

447. Deva does not, has not, and would not, if the products described in ANDA No. 21-3818 are marketed, directly or indirectly infringe any valid and enforceable claims of the '712, '509, '510, '512, and '889 patents, either literally or under the doctrine of equivalents.

448. Deva's manufacture, use, offer for sale, sale in the United States, and/or importation into the United States of the Deva ANDA Product will not infringe, directly or indirectly, any valid and enforceable claims of the '712, '509, '510, '512, and '889 patents, either literally or under the doctrine of equivalents.

449. Because Deva has not infringed and will not infringe any valid and enforceable claim of the '712, '509, '510, '512, and '889 patents, Deva is entitled to a declaratory judgment of non-infringement.

COUNT 17: DECLARATORY JUDGMENT OF INVALIDITY U.S. PATENT NOS. 9,463,289, 9,808,587, 10,086,156, AND 10,561,808

450. Deva incorporates and re-alleges each of the foregoing paragraphs 1–449 of its Counterclaims, as if fully set forth herein.

451. The claims of the ’289, ’587, ‘156, ’808 patents are invalid and/or unenforceable for failure to comply with one or more of the requirements of Title 35, United States Code, including, without limitation, §§ 101, 102, 103, and/or 112, or under any judicially-created doctrines.

452. Because the claims of the ’289, ’587, ‘156, ’808 patents are invalid and/or unenforceable for failure to comply with one or more of the requirements of Title 35, United States Code, including, without limitation, §§ 101, 102, 103, and/or 112, or under any judicially-created doctrines, Deva is entitled to a declaratory judgment of invalidity.

COUNT 18: DECLARATORY JUDGMENT OF INVALIDITY
U.S. PATENT NOS. 8,132,712, 10,022,509, 10,022,510, 10,695,512 AND 11,395,889

453. Deva incorporates and re-alleges each of the foregoing paragraphs 1–452 of its Counterclaims, as if fully set forth herein.

454. The claims of the ’712, ‘509, ‘510, ‘512, and ’889 patents are invalid and/or unenforceable for failure to comply with one or more of the requirements of Title 35, United States Code, including, without limitation, §§ 101, 102, 103, and/or 112, or under any judicially-created doctrines.

455. Because the claims of the ’712, ‘509, ‘510, ‘512, and ’889 patents are invalid and/or unenforceable for failure to comply with one or more of the requirements of Title 35, United States Code, including, without limitation, §§ 101, 102, 103, and/or 112, or under any judicially-created doctrines, Deva is entitled to a declaratory judgment of invalidity.

PRAYER FOR RELIEF OF DEFENDANT

WHEREFORE, Deva respectfully requests that the Court enter judgment in its favor and grant the following relief:

A. Declare that each of the Patents-in-Suit were not and are not properly listed in the Orange Book for ProAir® HFA;

B. Enter an Order requiring the holder of the ProAir® NDA to withdraw all of the Patents-in-Suit from the Orange Book listing for the ProAir® NDA, and to submit to the FDA an amendment to that effect to the ProAir® NDA, in compliance with 21 C.F.R. § 314.53(f)(2)(i);

C. Declare and enter judgment that Counterclaim-Defendants have violated Section 2 of the Sherman Act, 15 U.S.C. § 2;

D. Enter judgment awarding treble damages to Deva under Section 4 of the Clayton Act, 15 U.S.C. § 15, for the damages sustained by Deva as a result of Counterclaim-Defendants' unlawful conduct;

E. Enter an order permanently enjoining Counterclaim-Defendants from continuing the unlawful conduct alleged, and from engaging in related conduct in the future, including from monopolizing or attempting to monopolize the relevant product and geographic markets, as provided by 15 U.S.C. § 26;

F. Declare and enter judgment that Counterclaim-Defendants have violated N.J. Stat. Ann. §§ 56:9-1 Et Seq., and award Deva damages, including costs and reasonable attorneys' fees, sustained by Deva as a result of Counterclaim-Defendants' unlawful conduct;

G. Enter judgment dismissing Counterclaim-Defendants' Complaint and denying each and every prayer for relief contained therein, with prejudice;

H. Declare and enter judgment that Deva has not infringed any valid and

enforceable claim of the Patents-in-Suit;

I. Declare and enter judgment that the Deva ANDA Product and the submission of ANDA No. 21- 3818 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Deva ANDA Product prior to the expiration of the Patents-in-Suit do not and will not infringe, directly or indirectly, either literally or under the doctrine of equivalents, any valid and enforceable claims of the Patents-in-Suit;

J. Declare and enter judgment that the claims of the Patents-in-Suit are invalid and/or unenforceable for failure to comply with one or more of the requirements of Title 35, United States Code, including, without limitation, §§ 101, 102, 103, 112, and/or under any judicially-created doctrines;

K. Declare and enter judgment that this is an exceptional case under 35 U.S.C. § 285 and award Deva its costs, expenses, and reasonable attorneys' fees under 35 U.S.C. § 285 and all other applicable statutes and rules in common law that would be appropriate, with pre- and post-judgment interest thereon; and

L. Award Deva such other and further relief as the Court deems just and proper.

Dated: September 11, 2024

By:

s/ Gregory D. Miller

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