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R&D, Inc., Norton (Waterford) Ltd., and Teva Pharmaceuticals USA, Inc.*

**UNITED STATES DISTRICT COURT  
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.

Civil Action No. \_\_\_\_\_

**COMPLAINT**

Plaintiffs Teva Branded Pharmaceutical Products R&D, Inc. (“Teva Branded”), Norton (Waterford) Ltd. (“Norton”), and Teva Pharmaceuticals USA, Inc. (“Teva USA”) (collectively, “Plaintiffs”), by their undersigned attorneys, bring this action against Defendant Deva Holding A.S. a/k/a Deva Holdings A.S. (“Deva” or “Defendant”), and allege as follows:

**NATURE OF THE 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<sup>®</sup> 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.”

## **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.

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.

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.

**Defendant**

5. On information and belief, Defendant Deva Holding A.S. (a/k/a Deva Holdings A.S.)<sup>1</sup> 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<sup>®</sup> 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.

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.

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<sup>1</sup> 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](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.

## **JURISDICTION AND VENUE**

### **Subject Matter Jurisdiction**

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

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.

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

### **Personal Jurisdiction**

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

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.

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.

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

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 . . .”).

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.

### **Venue**

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

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

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).

### **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<sup>®</sup> HFA (albuterol sulfate) Inhalation Aerosol on October 29, 2004. ProAir<sup>®</sup> 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.

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

**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.

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

25. The '712 patent is listed in connection with ProAir<sup>®</sup> 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.

**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.

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

29. The '289 patent is listed in connection with ProAir<sup>®</sup> HFA (NDA No. 021457) in the Orange Book.

30. 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.

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

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

34. 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.

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

37. The '509 patent is listed in connection with ProAir<sup>®</sup> HFA (NDA No. 021457) in the Orange Book.

38. 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.

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

41. The '510 patent is listed in connection with ProAir<sup>®</sup> HFA (NDA No. 021457) in the Orange Book.

42. 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.

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

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

46. 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.

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

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

50. 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.

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

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

54. 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.

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

57. The '889 patent is listed in connection with ProAir<sup>®</sup> HFA (NDA No. 021457) in the Orange Book.

58. 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.

60. On information and belief, 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.

62. 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.

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.

65. On information and belief, Deva 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.

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.

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."

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

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

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

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.

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”).

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.

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.

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.

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.

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.

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.

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.

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

**COUNT 1 – 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.

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).

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).

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.

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.

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.

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.

89. 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 '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.

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.

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.

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.

**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.

94. Deva 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.

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.

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.

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.

99. 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 '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.

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.

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.

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.

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.

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.

**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.



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).

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).

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.

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.

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.

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.

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.

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.

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.

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.

**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.

117. Deva 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.

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.

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.

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.

122. 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.

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.

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.

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.

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.

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.

**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.

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).

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).

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.

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.

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.

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.

135. 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 '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.

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.

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.

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.

**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.

140. Deva 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.

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.

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.

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.

145. 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 '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.

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.

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.

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.

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.

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.

**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.

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).

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).

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.

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.

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.

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.



158. 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 '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.

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.

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.

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.

**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.

163. Deva 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.

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.

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.

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.

168. 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 '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.

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.

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.

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.

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.

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.

**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.

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).

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).

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.

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.

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.

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.

181. 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 '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.

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.

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.

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.

**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.

186. Deva 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.

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.

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.

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.

191. 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 '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.

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.

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.

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.

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.

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.

**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.

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).

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).

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.

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.

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.

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.

204. 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 '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.

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.

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.

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.

**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.

209. Deva 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.



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.

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.

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.

214. 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 '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.

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.

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.

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.

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.

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.

**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.

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).

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).

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.

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.

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.

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.

227. 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 '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.

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.

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.

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.

**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.

232. Deva 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.

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.

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.

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.

237. 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 '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.

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.

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.

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.

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.

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.

**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.

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).

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).

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.

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.

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.

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.

250. 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 '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.

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.

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.

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.

**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.

255. Deva 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.

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.

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.

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.

260. 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 '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.

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.

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.

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.

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.

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.

**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.

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).

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).

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.

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.

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.

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.

273. 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 '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.

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.

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.

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.

**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.

278. Deva 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.

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.

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.

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.

283. 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 '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.

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.

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.

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.

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.

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.

**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;

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

(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;

(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;

(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);

(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);

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

(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);

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

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

Dated: March 29, 2024

Respectfully submitted,

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**LOCAL CIVIL RULES 11.2 AND 40.1(C) CERTIFICATIONS**

Pursuant to Local Civil Rule 11.2, I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of any action pending in any court or of any arbitration or administrative proceeding.

Pursuant to Local Civil Rule 40.1(c), I hereby certify that this matter is related to the following three actions:

(i) the matter captioned *Teva Branded Pharmaceutical Products R&D, Inc., et al. v. Amneal Pharmaceuticals Of New York, LLC, et al.*, Civil Action No. 23-20964 (SRC) (MAH) is a related case currently pending before the Honorable Stanley R. Chesler in this Court because it involves (i) the same plaintiffs, (ii) the same NDA, and (iii) the validity and infringement of five (5) of the same patents as the matter in controversy;

(ii) the matter captioned *Teva Branded Pharmaceutical Products R&D, Inc., et al. v. Cipla USA, Inc., et al.*, Civil Action No. 24-00909 (SRC) (MAH) is a related case currently pending before the Honorable Stanley R. Chesler in this Court because it involves (i) two (2) of the same plaintiffs and (ii) the validity and infringement of seven (7) of the same patents as the matter in controversy; and

(iii) the matter captioned *Teva Branded Pharmaceutical Products R&D, Inc., et al. v. Cipla Ltd., et al.*, Civil Action No. 20-10172 (JXN) (MAH) (Consolidated with Civil Action Nos. 20-14833 and 20-14890) was a related case before the Honorable Julien Xavier Neals in this Court because it involved (i) two of the same plaintiffs and (ii) the validity and infringement of three (3) of the same patents as the matter in controversy.



Dated: March 29, 2024

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**LOCAL CIVIL RULE 201.1 CERTIFICATION**

Pursuant to Local Civil Rule 201.1, I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that Plaintiffs seek, *inter alia*, injunctive relief.

Dated: March 29, 2024

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