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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. AMNEAL PHARMACEUTICALS OF NEW YORK, LLC, AMNEAL IRELAND LIMITED, AMNEAL PHARMACEUTICALS LLC, and AMNEAL PHARMACEUTICALS INC. Defendants.	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 Defendants Amneal Pharmaceuticals of New York, LLC ("Amneal NY"), Amneal Ireland Limited ("Amneal

Ireland"), Amneal Pharmaceuticals LLC ("Amneal Pharma"), and Amneal Pharmaceuticals Inc. ("Amneal Inc.") (collectively, "Amneal" or "Defendants"), 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 Amneal's submission of Abbreviated New Drug Application ("ANDA") No. 211600 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"), 10,561,808 ("the '808 patent"), 10,695,512 ("the '512 patent"), and 11,395,889 ("the '889 patent"). Collectively, the '712 patent, the '289 patent, the '587 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.

Defendants

5. On information and belief, Defendant Amneal NY is a limited liability company organized and existing under the laws of the State of Delaware, having a principal place of business at 400 Crossing Boulevard, 3rd Floor, Bridgewater, New Jersey 08807. On information and belief, Amneal NY is a wholly-owned subsidiary of Amneal Pharma. On further information and belief, Amneal NY is the U.S. agent for Amneal Ireland.

6. On information and belief, Defendant Amneal Ireland is a company organized and existing under the laws of Ireland, having a place of business at Cahir Road, Cashel, Co. Tipperary, Ireland E25 XD5l.

7. On information and belief, Defendant Amneal Pharma is a limited liability company organized and existing under the laws of Delaware, having a principal place of business at 400 Crossing Boulevard, 3rd Floor, Bridgewater, New Jersey 08807. On information and belief, Amneal Pharma is a wholly-owned subsidiary of Amneal Inc.

8. On information and belief, Defendant Amneal Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 400 Crossing Boulevard, 3rd Floor, Bridgewater, New Jersey 08807.

9. On information and belief, Defendants operate as a single vertically-integrated business with respect to the regulatory approval, manufacturing, marketing, sale and distribution of pharmaceutical products throughout the United States, including in this District. *See* Amneal

Pharmaceuticals, Inc., Form 10-K for 2022 Fiscal Year, at 6-8 https://s22.q4cdn.com/186279204/files/doc_financials/2023/07/Amneal-2022-Form-10-K-as-filed.pdf (last visited October 6, 2023).

10. By a letter dated August 24, 2023 ("Amneal Notice Letter"), Defendant Amneal NY notified Plaintiffs that Amneal NY and Amneal Ireland had submitted to FDA ANDA No. 211600 ("Amneal's ANDA") for a purported generic version of ProAir® HFA (albuterol sulfate) Inhalation Aerosol, 90 mcg per actuation ("Amneal ANDA Products"), seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Amneal ANDA Products in and/or into the United States, including New Jersey, prior to the expiration of the Patents-in-Suit.

11. On information and belief, Defendants acted in concert to prepare and submit Amneal's ANDA and the Amneal Notice Letter.

JURISDICTION AND VENUE

Subject Matter Jurisdiction

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

13. 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.

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

Personal Jurisdiction

15. Plaintiffs incorporate each of the preceding paragraphs 1–14 as if fully set forth herein.

16. 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 Defendants.

17. This Court has personal jurisdiction over Defendants because, among other things, Defendants have purposefully availed themselves of the benefits and protections of New Jersey's laws such that they should reasonably anticipate being haled into court here. On information and belief, Defendants develop, manufacture, import, market, offer to sell, sell, and/or import generic drugs throughout the United States, including in New Jersey, and therefore transact business within New Jersey, and/or have engaged in systematic and continuous business contacts within New Jersey.

18. In addition, this Court has personal jurisdiction over Defendants because, among other things, on information and belief: (1) Defendants filed Amneal's ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Amneal ANDA Products in the United States, including in New Jersey; and (2) upon approval of Amneal's ANDA, Defendants, individually and/or in concert, will market, distribute, offer for sale, sell, and/or import the Amneal ANDA Products in the United States, including in New Jersey, and will derive substantial revenue from the use or consumption of the Amneal ANDA Products in New Jersey. *See Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755, 763 (Fed. Cir. 2016). On information and belief, upon approval of Amneal's ANDA, the Amneal ANDA Products will, among other things, be marketed, distributed, offered for sale, sold, and/or imported in New Jersey; prescribed by physicians practicing in New Jersey; dispensed by pharmacies located within New Jersey; and/or used by patients in New Jersey, all of which would have a substantial effect on New Jersey.

19. On information and belief, this Court also has personal jurisdiction over Defendant Amneal Inc. because it has its principal place of business in New Jersey.

20. On information and belief, this Court also has personal jurisdiction over Defendant Amneal Pharma because it has its principal place of business in New Jersey.

21. On information and belief, this Court also has personal jurisdiction over Defendant Amneal NY because it has its principal place of business in New Jersey.

22. On information and belief, this Court also has personal jurisdiction over Defendant Amneal Ireland because its U.S. agent, Amneal NY, has its principal place of business in New Jersey. On information and belief, Amneal Ireland acts through its U.S. agent Amneal NY.

23. The Amneal Notice Letter was sent by Bryan Sommese, Esq., Senior Patent Litigation Counsel – IP, for Amneal Pharma in Bridgewater, New Jersey, on behalf of Amneal NY and Amneal Ireland.

24. On information and belief, one or more acts related to Amneal's preparation of Amneal's ANDA were conducted in this District and/or will be conducted in the District.

25. On information and belief, Defendant Amneal Inc.'s corporate headquarters is located in Bridgewater, New Jersey.

26. On information and belief, Defendant Amneal NY is registered as "Manufacturer and Wholesale" with the State of New Jersey's Department of Health under Registration No. 5003663, originally issued on October 7, 2008.

27. On information and belief, Defendant Amneal Pharma is registered as "Manufacturer and Wholesale" with the State of New Jersey's Department of Health under Registration No. 5002991, originally issued on April 3, 2003. The Registered Addresses include

131 Chambers Brook Rd., Branchburg, NJ 08876; 1 New England Ave, Piscataway, NJ 08854; 1 Murray Rd, East Hanover, NJ 07936; 19 Readington Rd., Branchburg, NJ 08876; 47 Colonial Dr., Piscataway, NJ 08854; 21 Colonial Dr., Piscataway, NJ 08854; 400 Crossing Blvd., 3rd Fl., Bridgewater, NJ 08807; and 65 Readington Rd., Branchburg, NJ 08876.

28. On information and belief, Defendant Amneal Pharma is registered with the State of New Jersey's Department of the Treasury, Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 0600211542.

29. On information and belief, Defendant Amneal Pharma leases at least ten (10) significant properties in New Jersey for the purposes of its executive offices, R&D, manufacturing, packaging, and warehousing, including in Bridgewater, Piscataway, Branchburg, and East Hanover. *See* Amneal Pharmaceuticals, Inc., Form 10-K for 2022 Fiscal Year, at 46 https://s22.q4cdn.com/186279204/files/doc_financials/2023/07/Amneal-2022-Form-10-K-as-filed.pdf (last visited October 6, 2023).

30. In addition, this Court has personal jurisdiction over Defendants Amneal Ireland and Amneal NY because, on information and belief, Amneal NY, the U.S. agent of Amneal Ireland, regularly (1) engages in patent litigation concerning its ANDA Products in this District; (2) does not contest personal jurisdiction in this District; and (3) purposefully avails itself of the rights and benefits of this Court by asserting claims and/or counterclaims in this District. *See, e.g.,* Answer (Dkt. 11) ¶¶ 23-39, Counterclaims, *Therapeutics MD, Inc. v. Amneal Pharms., Inc. et al.*, Civil Action No. 3:20-cv-05256-FLW-TJB (D.N.J. filed July 7, 2020) (not contesting personal jurisdiction in this District and asserting counterclaims); Answer (Dkt. 14) ¶¶ 20, 26, *Janssen Products, LP et al. v. Amneal Pharmaceuticals LLC et al.*, No. 2:18-cv-17585-WHW-CLW (D.N.J. filed March 4, 2019) ("Amneal admits that Amneal NY has not contested personal

jurisdiction in this District in several previous matters, solely for the purposes of those prior litigations and their specific subject matter."); Answer (Dkt. 87) ¶ 164, *BTG international Limited et al. v. Actavis Laboratories FL, Inc. et al.*, Case No. 2:15-cv-05909-KM-JBC (D.N.J. filed Oct. 15, 2015) ("Amneal does not object to this Court's personal jurisdiction over Amneal Pharmaceuticals and Amneal New York for the purposes of this action only.").

31. In addition, this Court has personal jurisdiction over Defendant Amneal Pharma because, on information and belief, Amneal Pharma regularly (1) engages in patent litigation concerning its ANDA Products in this District; (2) does not contest personal jurisdiction in this District; and (3) purposefully avails itself of the rights and benefits of this Court by asserting claims and/or counterclaims in this District. *See, e.g.,* Answer (Dkt. 11) ¶¶ 23-39, Counterclaims, *Therapeutics MD, Inc. v. Amneal Pharms., Inc. et al.*, No. 3:20-cv-05256-FLW-TJB (D.N.J. filed July 7, 2020) (not contesting personal jurisdiction in this District and asserting counterclaims); Answer (Dkt. 14) ¶ 16, *Janssen Products, LP et al. v. Amneal Pharmaceuticals LLC et al.*, No. 2:18-cv-17585-WHW-CLW (D.N.J. filed March 4, 2019) ("Amneal LLC admits that it has not contested personal jurisdiction in this District in several previous matters solely for the purposes of those prior litigations and their specific subject matter."); Answer (Dkt. 87) ¶ 164, *BTG international Limited et al. v. Actavis Laboratories FL, Inc. et al.*, Case No. 2:15-cv-05909-KM-JBC (D.N.J. filed Oct. 15, 2015) ("Amneal does not object to this Court's personal jurisdiction over Amneal Pharmaceuticals and Amneal New York for the purposes of this action only.").

32. In addition, this Court has personal jurisdiction over Defendant Amneal Inc. because, on information and belief, Amneal Inc., directly or indirectly through its subsidiaries including Amneal Pharma and Amneal NY, regularly (1) engages in patent litigation concerning

its ANDA Products in this District; (2) does not contest personal jurisdiction in this District; and (3) purposefully avails itself of the rights and benefits of this Court by asserting claims and/or counterclaims in this District. *See* Answer (Dkt. 11) ¶¶ 23-39, Counterclaims, *Therapeutics MD, Inc. v. Amneal Pharms., Inc. et al.*, No. 3:20-cv-05256-FLW-TJB (D.N.J. filed July 7, 2020) (Amneal Inc. not contesting personal jurisdiction in this District and asserting counterclaims); *see also, e.g.*, Answer (Dkt. 14) ¶ 16, *Janssen Products, LP et al. v. Amneal Pharmaceuticals LLC et al.*, No. 2:18-cv-17585-WHW-CLW (D.N.J. filed March 4, 2019) ("Amneal LLC admits that it has not contested personal jurisdiction in this District in several previous matters solely for the purposes of those prior litigations and their specific subject matter."); Answer (Dkt. 87) ¶ 164, *BTG international Limited et al. v. Actavis Laboratories FL, Inc. et al.*, Case No. 2:15-cv-05909-KM-JBC (D.N.J. filed Oct. 15, 2015) ("Amneal does not object to this Court's personal jurisdiction over Amneal Pharmaceuticals and Amneal New York for the purposes of this action only.").

33. For the above reasons, it would not be unfair or unreasonable for Defendants to litigate this action in this District, and the Court has personal jurisdiction over Defendants here.

34. In the alternative, Defendant Amneal Ireland is subject to personal jurisdiction in this forum because the requirements of Federal Rule of Civil Procedure 4(k)(2) are met as (a) Plaintiffs' claims arise under federal law; (b) Amneal Ireland is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Amneal Ireland has sufficient contacts in the United States as a whole, including, but not limited to, by participating in the preparation and submission of Amneal's ANDA, and/or manufacturing, importing, offering to sell, or selling pharmaceutical products that are distributed throughout the United States,

including in this District, such that this Court's exercise of jurisdiction over Amneal Ireland satisfies due process.

Venue

35. Plaintiffs incorporate each of the preceding paragraphs 1–34 as if fully set forth herein.

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

37. On information and belief, Defendants have a regular and established place of business in this District and have committed and/or will commit acts of infringement in this District. *See* 28 U.S.C. § 1400(b).

38. On information and belief, Defendants have committed or aided, abetted, contributed to, and/or participated in the commission of, acts of infringement of the Patents-in-Suit by, among other things, preparing or assisting in preparing Amneal's ANDA in New Jersey and/or seeking to market the Amneal ANDA Products throughout the United States, including within New Jersey.

39. On information and belief, Defendants (1) engage in patent litigation concerning their ANDA Products in this District, and (2) do not contest venue in this District. *See, e.g.*, Answer (Dkt. 11) ¶ 39, *Therapeutics MD, Inc. v. Amneal Pharms., Inc. et al.*, No. 3:20-cv-05256-FLW-TJB (D.N.J. filed July 7, 2020) (Amneal Inc., Amneal Pharma, and Amneal NY, the U.S. agent of Amneal Ireland, not contesting that venue is proper in this District); Answer (Dkt. 14) ¶¶ 59, 60, *Janssen Products, LP et al. v. Amneal Pharmaceuticals LLC et al.*, No. 2:18-cv-17585-WHW-CLW (D.N.J. filed March 4, 2019) (Amneal Pharma and Amneal NY, the U.S. agent of Amneal Ireland, not contesting venue in this District); Answer (Dkt. 87) ¶ 143, *BTG international Limited et al. v. Actavis Laboratories FL, Inc. et al.*, Case No. 2:15-cv-05909-KM-JBC (D.N.J. filed Oct. 15, 2015) (same).

40. On information and belief, Defendant Amneal Inc. has a regular and established place of business in this District at least because it: (1) has a principal place of business in the State of New Jersey; (2) has acted in concert with Amneal NY, Amneal Ireland, and Amneal Pharma to seek approval from FDA to market and sell the Amneal ANDA Products in this District; (3) has engaged in regular and established business contacts with the State of New Jersey by, among other things, contracting and engaging in related commercial activities related to the marketing, making, shipping, using, offering to sell or selling Defendants' products in this District, and deriving substantial revenue from such activities; and (4) has made agreements with retailers, wholesalers or distributors providing for the distribution of Defendants' products in the State of New Jersey.

41. On information and belief, Defendant Amneal Pharma has a regular and established place of business in this District at least because it: (1) has a principal place of business in the State of New Jersey; (2) has acted in concert with Amneal NY, Amneal Ireland, and Amneal Inc. to seek approval from FDA to market and sell the Amneal ANDA Products in this District; (3) has engaged in regular and established business contacts with the State of New Jersey by, among other things, contracting and engaging in related commercial activities related to the marketing, making, shipping, using, offering to sell or selling Defendants' products in this District, and deriving substantial revenue from such activities; and (4) has made agreements with retailers, wholesalers or distributors providing for the distribution of Defendants' products in the State of New Jersey.

42. On information and belief, Defendant Amneal NY has a regular and established place of business in this District at least because it: (1) has a principal place of business in the State of New Jersey; (2) has acted in concert with Amneal Ireland, Amneal Pharma, and Amneal

Inc. to seek approval from FDA to market and sell the Amneal ANDA Products in this District; (3) has engaged in regular and established business contacts with the State of New Jersey by, among other things, contracting and engaging in related commercial activities related to the marketing, making, shipping, using, offering to sell or selling Defendants' products in this District, and deriving substantial revenue from such activities; and (4) has made agreements with retailers, wholesalers or distributors providing for the distribution of Defendants' products in the State of New Jersey.

43. On information and belief, Defendant Amneal Ireland has a regular and established place of business in this District at least because it: (1) has acted in concert with Amneal NY, Amneal Pharma, and Amneal Inc. to seek approval from FDA to market and sell the Amneal ANDA Products in this District; (2) conducts business, individually and/or in concert with its U.S. agent, Amneal NY that is located in the State of New Jersey, in this District; and (3) has engaged in regular and established business contacts with the State of New Jersey by, among other things, marketing, making, shipping, using, offering to sell or selling Defendants' products in this District, and deriving substantial revenue from such activities.

44. Venue is also proper in this District for Amneal Ireland at least because, among other things, Amneal Ireland is a foreign corporation organized and existing under the laws of Ireland and may be sued in any judicial district in which it is subject to personal jurisdiction, including in the State of New Jersey. *See* 28 U.S.C. § 1391(c)(3); *see also* 28 U.S.C. § 1400(b).

BACKGROUND

NDA No. 021457

45. 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.

46. 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.

The '712 Patent

47. 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.

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

49. 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").

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

The '289 Patent

51. 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.

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

53. The '289 patent is listed in connection with ProAir® HFA (NDA No. 021457) in the Orange Book.

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

The '587 Patent

55. 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.

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

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

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

The '808 Patent

59. 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 D.

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

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

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

The '512 Patent

63. 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 E.

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

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

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

The ’ 889 Patent

67. 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 F.

68. Norton is the owner and assignee of the ’889 patent.

69. The ’889 patent is listed in connection with ProAir® HFA (NDA No. 021457) in the Orange Book.

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

Defendants’ ANDA and Notice of Paragraph IV Certification

71. On information and belief, Defendants have submitted or caused the submission of Amneal’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 Amneal ANDA Products prior to the expiration of the Patents-in-Suit.

72. On information and belief, FDA has not yet approved Amneal’s ANDA.

73. In the Amneal Notice Letter, Defendant Amneal NY notified Plaintiffs of the submission of Amneal’s ANDA to FDA.

74. In the Amneal Notice Letter, Defendant Amneal NY notified Plaintiffs that Amneal 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 Amneal ANDA Products prior to the expiration of the Patents-in-Suit.

75. The purpose of Defendants' submission of Amneal'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 Amneal ANDA Products prior to the expiration of the Patents-in-Suit.

76. On information and belief, Defendants, through their own actions and through the actions of their agents, affiliates, and subsidiaries, prepared and submitted Amneal's ANDA, and intend to further prosecute Amneal's ANDA. On information and belief, if FDA approves Amneal's ANDA, Defendants will manufacture, offer for sale, or sell the Amneal ANDA Products within the United States, or will import the Amneal ANDA Products into the United States. On information and belief, if FDA approves Amneal's ANDA, Defendants, through their own actions and through the actions of their agents, affiliates, and subsidiaries, will actively induce or contribute to the manufacture, use, offer for sale, sale, or importation of the Amneal ANDA Products in or into the United States.

77. In the Amneal Notice Letter, Defendant Amneal NY stated that the subject of Amneal's ANDA is "Albuterol Sulfate Inhalation Aerosol, 90 mcg per actuation."

78. In the Amneal Notice Letter, Defendant Amneal NY stated that the active ingredient of the Amneal ANDA Products is albuterol sulfate.

79. In the Amneal Notice Letter, Defendant Amneal NY stated that the dosage form of the Amneal ANDA Products is "inhalation aerosol."

80. In the Amneal Notice Letter, Defendant Amneal NY stated that the strength of the Amneal ANDA Products is 90 mcg per actuation.

81. On information and belief, Amneal'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 Amneal ANDA Products ("Amneal's Paragraph IV Certification"). Defendants notified Plaintiffs of Amneal's Paragraph IV Certification in the Amneal Notice Letter, dated August 24, 2023, sent by United Parcel Service.

82. In the Amneal Notice Letter, Defendants offered Plaintiffs confidential access to ANDA No. 211600 on terms and conditions set forth in an attached "Offer of Confidential Access" ("OCA"). The OCA provided by Defendants contained various terms and conditions, several of which went above and beyond protections typically afforded in a protective order.

83. By correspondence, counsel for Plaintiffs and counsel for Defendants discussed the terms of Defendants' OCA.

84. On September 16, 2023, Plaintiffs' counsel sent Defendants' counsel an email identifying various unreasonably restrictive terms in Defendants' OCA. Plaintiffs' counsel also included a revised draft of the OCA in this correspondence.

85. On September 25, 2023, Defendants' counsel sent Plaintiffs' counsel a revised OCA. That offer addressed some of Plaintiffs' concerns but remained unreasonably restrictive.

86. On September 27, 2023, Plaintiffs' counsel sent another email reiterating its concerns regarding the restrictions in Defendants' OCA, and attaching a revised draft of the OCA.

87. On September 28, 2023, the parties reached agreement on the terms of the OCA, which was finalized on October 2, 2023. Amneal did not produce any portion of its ANDA until

October 3, 2023 and did not produce the requested samples until October 4, 2023, shortly before the 45-day statutory deadline to file suit.

88. The Amneal Notice Letter appends a document titled "Detailed Factual and Legal Basis of Non-Infringement, Unenforceability, and/or Invalidity" asserting that the commercial manufacture, use, offer for sale, or sale of the Amneal ANDA Products will not infringe any of the Patents-in-Suit ("Detailed Statement"). However, the Amneal Notice Letter and "Detailed Statement" do not provide information regarding the Amneal ANDA Products sufficient to evaluate Defendants' assertions of noninfringement.

89. Given the 45-day statutory deadline to file suit set forth in 21 U.S.C. § 355(j)(5)(B)(iii), the timing of the production of Amneal's ANDA and samples, and the limited information provided by Defendants 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 Amneal ANDA Products fall within the scope of one or more claims of the Patents-in-Suit.

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

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

91. Plaintiffs incorporate each of the preceding paragraphs 1–90 as if fully set forth herein.

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

93. If approved by FDA, Amneal's commercial manufacture, use, importation, sale, and/or offer for sale of the Amneal ANDA Products 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).

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

95. In the Amneal Notice Letter, Amneal did not contest, or otherwise assert, any grounds challenging, the validity or enforceability of any claim of the '712 patent.

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

97. On information and belief, the use of the Amneal ANDA Products in accordance with and as directed by Amneal'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, Amneal plans and intends to, and will, actively induce infringement of the '712 patent when Amneal's ANDA is approved, and plans and intends to, and will, do so after approval.

99. On information and belief, Amneal knows that the Amneal ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '712 patent and that the Amneal ANDA Products and their proposed labeling are not suitable for substantial non-

infringing use. On information and belief, Amneal plans and intends to, and will, contribute to infringement of the '712 patent after approval of Amneal's ANDA.

100. The foregoing actions by Amneal 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, Amneal 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. Unless Amneal 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 II – DECLARATORY JUDGMENT OF INFRINGEMENT BY AMNEAL OF U.S. PATENT NO. 8,132,712

103. Plaintiffs incorporate each of the preceding paragraphs 1–102 as if fully set forth herein.

104. Amneal has knowledge of the '712 patent.

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

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

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

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

109. On information and belief, Amneal knows that the Amneal ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '712 patent and that the Amneal ANDA Products and their proposed labeling are not suitable for substantial non-infringing use. On information and belief, Amneal plans and intends to, and will, contribute to infringement of the '712 patent after approval of Amneal's ANDA.

110. The foregoing actions by Amneal 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.

111. On information and belief, Amneal 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.

112. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Amneal regarding whether Amneal's manufacture, use, sale, offer for sale, or importation into the United States of the Amneal ANDA Products with their proposed labeling according to Amneal'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.

113. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of the Amneal ANDA Products with their 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.

114. Amneal 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 III – INFRINGEMENT BY AMNEAL OF U.S. PATENT NO. 9,463,289 UNDER 35 U.S.C. § 271(e)(2)

115. Plaintiffs incorporate each of the preceding paragraphs 1–114 as if fully set forth herein.

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

117. If approved by FDA, Amneal's commercial manufacture, use, importation, sale, and/or offer for sale of the Amneal ANDA Products 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).

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

119. In the Amneal Notice Letter, Amneal did not contest, or otherwise assert, any grounds challenging, the validity or enforceability of any claim of the ’289 patent.

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

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

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

123. On information and belief, Amneal knows that the Amneal ANDA Products and their proposed labeling are especially made or adapted for use in infringing the ’289 patent and that the Amneal ANDA Products and their proposed labeling are not suitable for substantial non-infringing use. On information and belief, Amneal plans and intends to, and will, contribute to infringement of the ’289 patent after approval of Amneal’s ANDA.

124. The foregoing actions by Amneal 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.

125. On information and belief, Amneal 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.

126. Unless Amneal 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 IV – DECLARATORY JUDGMENT OF INFRINGEMENT BY AMNEAL OF U.S. PATENT NO. 9,463,289

127. Plaintiffs incorporate each of the preceding paragraphs 1–126 as if fully set forth herein.

128. Amneal has knowledge of the '289 patent.

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

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

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

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

133. On information and belief, Amneal knows that the Amneal ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '289 patent and that the Amneal ANDA Products and their proposed labeling are not suitable for substantial non-

infringing use. On information and belief, Amneal plans and intends to, and will, contribute to infringement of the '289 patent after approval of Amneal's ANDA.

134. The foregoing actions by Amneal 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.

135. On information and belief, Amneal 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.

136. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Amneal regarding whether Amneal's manufacture, use, sale, offer for sale, or importation into the United States of the Amneal ANDA Products with their proposed labeling according to Amneal'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.

137. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of the Amneal ANDA Products with their 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.

138. Amneal 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 V – INFRINGEMENT BY AMNEAL OF U.S. PATENT NO. 9,808,587 UNDER 35 U.S.C. § 271(e)(2)

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

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

141. If approved by FDA, Amneal's commercial manufacture, use, importation, sale, and/or offer for sale of the Amneal ANDA Products 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).

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

143. In the Amneal Notice Letter, Amneal did not contest, or otherwise assert, any grounds challenging, the validity or enforceability of any claim of the '587 patent.

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

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

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

147. On information and belief, Amneal knows that the Amneal ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '587 patent and that the Amneal ANDA Products and their proposed labeling are not suitable for substantial non-infringing use. On information and belief, Amneal plans and intends to, and will, contribute to infringement of the '587 patent after approval of Amneal's ANDA.

148. The foregoing actions by Amneal 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.

149. On information and belief, Amneal 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.

150. Unless Amneal 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 VI – DECLARATORY JUDGMENT OF INFRINGEMENT BY AMNEAL OF U.S. PATENT NO. 9,808,587

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

152. Amneal has knowledge of the '587 patent.

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

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

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

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

157. On information and belief, Amneal knows that the Amneal ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '587 patent and that the Amneal ANDA Products and their proposed labeling are not suitable for substantial non-infringing use. On information and belief, Amneal plans and intends to, and will, contribute to infringement of the '587 patent after approval of Amneal's ANDA.

158. The foregoing actions by Amneal 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.

159. On information and belief, Amneal 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.

160. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Amneal regarding whether Amneal's manufacture, use, sale, offer for sale, or importation into the United States of the Amneal ANDA Products with their proposed labeling according to Amneal'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.

161. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of the Amneal ANDA Products with their 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.

162. Amneal 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 VII – INFRINGEMENT BY AMNEAL OF U.S. PATENT NO. 10,561,808 UNDER 35 U.S.C. § 271(e)(2)

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

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

165. If approved by FDA, Amneal's commercial manufacture, use, importation, sale, and/or offer for sale of the Amneal ANDA Products 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).

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

167. In the Amneal Notice Letter, Amneal did not contest, or otherwise assert, any grounds challenging, the validity or enforceability of any claim of the '808 patent.

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

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

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

171. On information and belief, Amneal knows that the Amneal ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '808 patent and that the Amneal ANDA Products and their proposed labeling are not suitable for substantial non-

infringing use. On information and belief, Amneal plans and intends to, and will, contribute to infringement of the '808 patent after approval of Amneal's ANDA.

172. The foregoing actions by Amneal 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.

173. On information and belief, Amneal 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.

174. Unless Amneal 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 VIII – DECLARATORY JUDGMENT OF INFRINGEMENT BY AMNEAL OF U.S. PATENT NO. 10,561,808

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

176. Amneal has knowledge of the '808 patent.

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

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

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

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

181. On information and belief, Amneal knows that the Amneal ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '808 patent and that the Amneal ANDA Products and their proposed labeling are not suitable for substantial non-infringing use. On information and belief, Amneal plans and intends to, and will, contribute to infringement of the '808 patent after approval of Amneal's ANDA.

182. The foregoing actions by Amneal 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.

183. On information and belief, Amneal 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.

184. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Amneal regarding whether Amneal's manufacture, use, sale, offer for sale, or importation into the United States of the Amneal ANDA Products with their proposed labeling according to Amneal'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.

185. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of the Amneal ANDA Products with their 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.

186. Amneal 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 IX – INFRINGEMENT BY AMNEAL OF U.S. PATENT NO. 10,695,512 UNDER 35 U.S.C. § 271(e)(2)

187. Plaintiffs incorporate each of the preceding paragraphs 1–186 as if fully set forth herein.

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

189. If approved by FDA, Amneal's commercial manufacture, use, importation, sale, and/or offer for sale of the Amneal ANDA Products 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).

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

191. In the Amneal Notice Letter, Amneal did not contest, or otherwise assert, any grounds challenging, the validity or enforceability of any claim of the '512 patent.

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

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

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

195. On information and belief, Amneal knows that the Amneal ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '512 patent and that the Amneal ANDA Products and their proposed labeling are not suitable for substantial non-infringing use. On information and belief, Amneal plans and intends to, and will, contribute to infringement of the '512 patent after approval of Amneal's ANDA.

196. The foregoing actions by Amneal 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.

197. On information and belief, Amneal 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.

198. Unless Amneal 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 X – DECLARATORY JUDGMENT OF INFRINGEMENT BY AMNEAL OF U.S. PATENT NO. 10,695,512

199. Plaintiffs incorporate each of the preceding paragraphs 1–198 as if fully set forth herein.

200. Amneal has knowledge of the '512 patent.

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

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

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

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

205. On information and belief, Amneal knows that the Amneal ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '512 patent and that the Amneal ANDA Products and their proposed labeling are not suitable for substantial non-

infringing use. On information and belief, Amneal plans and intends to, and will, contribute to infringement of the '512 patent after approval of Amneal's ANDA.

206. The foregoing actions by Amneal 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.

207. On information and belief, Amneal 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 '712 patent, actively inducing infringement of the '512 patent, and contributing to the infringement by others of the '512 patent.

208. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Amneal regarding whether Amneal's manufacture, use, sale, offer for sale, or importation into the United States of the Amneal ANDA Products with their proposed labeling according to Amneal'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.

209. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of the Amneal ANDA Products with their 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.

210. Amneal 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 XI – INFRINGEMENT BY AMNEAL OF U.S. PATENT NO. 11,395,889 UNDER 35 U.S.C. § 271(e)(2)

211. Plaintiffs incorporate each of the preceding paragraphs 1–210 as if fully set forth herein.

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

213. If approved by FDA, Amneal's commercial manufacture, use, importation, sale, and/or offer for sale of the Amneal ANDA Products 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).

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

215. In the Amneal Notice Letter, Amneal did not contest, or otherwise assert, any grounds challenging, the validity or enforceability of any claim of the '889 patent.

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

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

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

219. On information and belief, Amneal knows that the Amneal ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '889 patent and that the Amneal ANDA Products and their proposed labeling are not suitable for substantial non-infringing use. On information and belief, Amneal plans and intends to, and will, contribute to infringement of the '889 patent after approval of Amneal's ANDA.

220. The foregoing actions by Amneal 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.

221. On information and belief, Amneal 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.

222. Unless Amneal 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 XII – DECLARATORY JUDGMENT OF INFRINGEMENT BY AMNEAL OF U.S. PATENT NO. 11,395,889

223. Plaintiffs incorporate each of the preceding paragraphs 1–222 as if fully set forth herein.

224. Amneal has knowledge of the '889 patent.

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

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

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

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

229. On information and belief, Amneal knows that the Amneal ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '889 patent and that the Amneal ANDA Products and their proposed labeling are not suitable for substantial non-infringing use. On information and belief, Amneal plans and intends to, and will, contribute to infringement of the '889 patent after approval of Amneal's ANDA.

230. The foregoing actions by Amneal 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.

231. On information and belief, Amneal 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.

232. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Amneal regarding whether Amneal's manufacture, use, sale, offer for sale, or importation into the United States of the Amneal ANDA Products with their proposed labeling according to Amneal'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.

233. Plaintiffs should be granted a declaratory judgment that the making, using, sale, offer for sale, and importation into the United States of the Amneal ANDA Products with their 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.

234. Amneal 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 Defendants' submission to FDA of Amneal'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 Defendants to make, use, offer for sale, sell, market, distribute, or import the Amneal ANDA Products, 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 Defendants, their 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 Amneal ANDA Products, 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 Amneal ANDA Products, 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 any Defendant, their 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 Amneal ANDA Products, 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 Defendants 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: October 6, 2023

Respectfully submitted,

/s/ Liza M. Walsh

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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 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 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: October 6, 2023

/s/ Liza M. Walsh

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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: October 6, 2023

/s/ Liza M. Walsh

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