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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. 23-cv-20964-SRC-MAH *Electronically Filed*

PLAINTIFFS' ANSWER TO DEFENDANTS' COUNTERCLAIMS

Plaintiffs Teva Branded Pharmaceutical Products R&D, Inc. ("Teva Branded"), Norton (Waterford) Ltd. ("Norton"), and Teva Pharmaceuticals USA, Inc. ("Teva USA") (collectively, "Plaintiffs" or "Teva"), by their undersigned attorneys, hereby answer the Counterclaims in Defendants Amneal Pharmaceuticals of New York, LLC; Amneal Ireland Limited; Amneal Pharmaceuticals LLC; and Amneal Pharmaceuticals Inc.'s (collectively, "Defendants" or "Amneal") Answer, Affirmative Defenses, and Counterclaims to Plaintiffs' First Amended

Complaint filed on December 1, 2023 (D.E. 12). Each of the paragraphs and headings below corresponds to the same-numbered paragraphs and headings in Defendants' Counterclaims. The headings are not allegations to which a response is necessary. To the extent a response is required, Teva denies any averments in the headings of the Counterclaims. To the extent not explicitly admitted, all allegations of the Counterclaims are denied.

NATURE OF THE ACTION[1]

1. Amneal repeats and incorporates by reference each of the foregoing paragraphs 1–206 of its Answer as well as its Affirmative Defenses to the First Amended Complaint, as if fully set forth herein.

ANSWER: Plaintiffs repeat and incorporate by reference each of the paragraphs of its First Amended Complaint as if fully set forth herein. As to Amneal's Affirmative Defenses, they state legal conclusions to which no response is required, and purport to characterize Amneal's affirmative defenses, which speak for themselves. To the extent a response is required, Plaintiffs deny them.

2. These counterclaims seek a declaratory judgment of non-infringement and invalidity of one or more claims of U.S. Patent Nos. 8,132,712 ("the '712 patent"), 9,463,289 ("the '289 patent"), 9,808,587 ("the '587 patent"), 10,561,808 ("the '808 patent"), and 11,395,889 ("the '889 patent") (collectively, the "Asserted Patents"); removal of the Asserted Patents from the Orange Book listing for ProAir® HFA, under 28 U.S.C. §§ 2201, 2202, and 21 U.S.C. § 355(j)(5)(C)(ii)(I); and relief from Counterclaim-Defendants' anticompetitive conduct to insulate, extend, and protect their monopoly in the market for ProAir® HFA and its generic equivalents, in violation of state and federal antitrust laws.

ANSWER: Paragraph 2 states legal conclusions to which no response is required, and purports to characterize Amneal's Counterclaims, which speak for themselves. To the extent a response is required, Plaintiffs admit that Amneal, through its Counterclaims, purports to seek

[1] As noted above, for the Court's convenience, Plaintiffs repeat the headings recited in Defendants' Counterclaims. In doing so, Plaintiffs make no admission regarding the accuracy of those headings. To the extent a response is required, Plaintiffs deny any averments in the headings of the Counterclaims and do not waive any right to challenge them.

relief under 28 U.S.C. §§ 2201, 2202, 21 U.S.C. § 355(j)(5)(C)(ii)(I), and state and federal antitrust laws. Plaintiffs admit that the identified patents in Paragraph 2 are the patents asserted in the First Amended Complaint (collectively, "the Asserted Patents"). To the extent there are remaining allegations in Paragraph 2, Plaintiffs deny them and deny that Amneal is entitled to any of the relief that it seeks.

3. Upon information and belief, a true and correct copy of the '712 patent was attached to Plaintiff's First Amended Complaint as Exhibit A, a true and correct copy of the '289 patent was attached to Plaintiff's First Amended Complaint as Exhibit B, a true and correct copy of the '587 patent was attached to Plaintiff's First Amended Complaint as Exhibit C, a true and correct copy of the '808 patent was attached to Plaintiff's First Amended Complaint as Exhibit D, and a true and correct copy of the '889 patent was attached to Plaintiff's First Amended Complaint as Exhibit E.

ANSWER: Admitted.

PARTIES

4. Amneal 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, Third Floor, Bridgewater, New Jersey 08807.

ANSWER: On information and belief, admitted.

5. Upon information and belief, Counterclaim-Defendant Teva Branded is a company organized under the laws of the State of Delaware with its principal place of business at 145 Brandywine Parkway, West Chester, Pennsylvania 19380. In addition, Teva Branded has a place of business at 400 Interpace Parkway #3, Parsippany, New Jersey 07054.

ANSWER: Admitted.

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

ANSWER: Admitted.

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

ANSWER: Admitted.

JURISDICTION AND VENUE

8. These counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*; the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and 21 U.S.C. § 355(j)(5)(C)(ii)(I). These counterclaims are also instituted under the Clayton Act, 15 U.S.C. §§ 15 and 26, to recover treble damages and the costs of suit, including a reasonable attorneys' fee, for the injuries sustained by Amneal resulting from violations by Counterclaim-Defendants, as hereinafter alleged, of Section 2 of the Sherman Act, 15 U.S.C. § 2.

ANSWER: Paragraph 8 states legal conclusions to which no response is required, and purports to characterize Amneal's Counterclaims, which speak for themselves. To the extent a response is required, Plaintiffs admit that Amneal purports to state counterclaims arising under the Patent Laws of the United States, the Declaratory Judgment Act, the Clayton Act, and the Sherman Act. To the extent there are remaining allegations in Paragraph 8, Plaintiffs deny them and deny that Amneal is entitled to any of the relief that it seeks.

9. This Court has subject matter jurisdiction to hear these counterclaims under 28 U.S.C. §§ 1331, 1337(a), and 1338(a); 15 U.S.C. §§ 15 and 26; and under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. The Court has jurisdiction over the state law claims under 28 U.S.C. § 1367(a).

ANSWER: Paragraph 9 states legal conclusions to which no response is required. To the extent a response is required, Plaintiffs do not contest subject matter jurisdiction for the federal counterclaims and supplemental jurisdiction for the state law counterclaims for purposes of this action only. Plaintiffs reserve the right to contest subject matter jurisdiction for the state law counterclaims in the event the Court dismisses the federal counterclaims. To the extent there are remaining allegations in Paragraph 9, denied.

10. This Court has personal jurisdiction over Counterclaim-Defendants because, among other reasons, they subjected themselves to the jurisdiction of this Court by filing their Complaint and First Amended Complaint here.

ANSWER: Paragraph 10 states legal conclusions to which no response is required. To the extent a response is required, Plaintiffs do not contest personal jurisdiction for purposes of this action only. To the extent there are remaining allegations in Paragraph 10, denied.

11. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), and because Counterclaim-Defendants commenced this lawsuit in this venue.

ANSWER: Paragraph 11 states legal conclusions to which no response is required. To the extent a response is required, Plaintiffs do not contest venue for purposes of this action only. To the extent there are remaining allegations in Paragraph 11, denied.

12. There is an actual and justiciable controversy between the parties that is of sufficient immediacy and reality to warrant the relief sought in these counterclaims.

ANSWER: Paragraph 12 states legal conclusions to which no response is required. To the extent a response is required, Plaintiffs admit that an actual controversy exists between Plaintiffs and Amneal regarding Amneal's infringement of and the validity of the asserted claims of U.S. Patent Nos. 8,132,712 ("the '712 patent"), 9,463,289 ("the '289 patent"), 9,808,587 ("the '587 patent"), 10,561,808 ("the '808 patent"), and 11,395,889 ("the '889 patent"). To the extent there are remaining allegations in Paragraph 12, denied.

BACKGROUND

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

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

ANSWER: Plaintiffs admit that 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. Otherwise denied.

14. On information and belief, Counterclaim-Defendants listed and maintained a listing for the Asserted Patents in the Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") in connection with NDA No. 021457.

ANSWER: Plaintiffs admit that in compliance with the governing statutes and regulations, Teva Branded submitted to FDA the required patent information for the Asserted

Patents in connection with ProAir® HFA (NDA No. 021457). Plaintiffs further admit that the Asserted Patents are listed in the Orange Book in connection with ProAir® HFA (NDA No. 021457) as of the date of this Answer (July 15, 2024). Otherwise denied.

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

ANSWER: Paragraph 15 purports to characterize the Asserted Patents, which speak for themselves, and states legal conclusions to which no response is required. To the extent a further response is required, denied.

16. Amneal Pharmaceuticals of NY, LLC ("Amneal NY") and Amneal Ireland Ltd. ("Amneal Ireland") submitted Abbreviated New Drug Application ("ANDA") No. 211600 ("Amneal's ANDA") to the United States Food and Drug Administration ("FDA") seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Albuterol Sulfate HFA Inhalation Aerosol, 90 mcg per actuation ("Amneal ANDA Products").

ANSWER: Plaintiffs admit that 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 Asserted Patents. To the extent there are remaining allegations in Paragraph 16, Plaintiffs lack knowledge and information sufficient to form a belief about the truth of these allegations and therefore deny them.

17. Amneal NY is a direct subsidiary of Amneal Pharmaceuticals LLC, and Amneal Ireland is an indirect subsidiary of Amneal Pharmaceuticals LLC.

ANSWER: Plaintiffs lack knowledge and information sufficient to form a belief about the truth of the allegations of paragraph 18 and therefore deny them.

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

ANSWER: Paragraph 18 states legal conclusions and Amneal's opinion and characterization of counterclaims to which no response is required. To the extent a response is required, Plaintiffs lack knowledge or information sufficient to form a belief about Amneal's past, present, and future submission of documents to the FDA and about Amneal's expectations. Otherwise denied.

19. In accordance with 21 U.S.C. §355 (j)(2)(B)(iv)(II), by letter dated August 24, 2023 ("Amneal Notice Letter"), Amneal NY notified Counterclaim-Defendants that Amneal NY and Amneal Ireland had submitted to the FDA Amneal's ANDA including Paragraph IV Certifications as to each of the Asserted Patents.

ANSWER: Plaintiffs admit that by the Amneal Notice Letter, dated August 24, 2023, Defendant Amneal NY notified Plaintiffs that Amneal had filed a Paragraph IV Certification with respect to each of the Asserted Patents. To the extent there are remaining allegations in Paragraph 19, denied.

20. On information and belief, Counterclaim-Defendants received the Amneal Notice Letter on August 28, 2023.

ANSWER: Admitted.

21. Counterclaim-Defendants filed this lawsuit on October 6, 2023, claiming that Amneal has infringed and will infringe the Asserted Patents by the filing of Amneal's ANDA with the FDA and/or by manufacturing, using, offering for sale, selling, marketing, distributing, and/or importing the products described in that ANDA.

ANSWER: Plaintiffs admit that they filed a complaint against Defendants on October 6, 2023 alleging infringement by Defendants of the Asserted Patents and U.S. Patent No. 10,695,512. Otherwise denied.

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

ANSWER: Paragraph 22 states legal conclusions and Amneal's opinion and characterization of counterclaims to which no response is required. To the extent a response is required, denied.

23. Counterclaim-Defendants filed this lawsuit within 45 days of receiving the Amneal Notice Letter. By doing so, Counterclaim-Defendants triggered a 30-month stay of final FDA approval of Amneal's ANDA pursuant to 21 U.S.C. § 355(j)(5)(B)(iii). The 30-month stay, which is imposed only where an NDA holder files a patent infringement suit within 45 days of receiving notice of a Paragraph IV certification, is not set to expire until February 28, 2026 – long after Amneal expects, based on FDA correspondence to Amneal, being otherwise able to launch the Amneal ANDA Products.

ANSWER: Paragraph 23 states legal conclusions to which no response is required. To the extent a response is required, Plaintiffs admit that this action was commenced within 45 days from the date of Plaintiffs' receipt of the Amneal Notice Letter. Plaintiffs further admit that the 30-month stay of final FDA approval of Amneal's ANDA expires on February 28, 2026. Plaintiffs lack knowledge or information sufficient to form a belief about Amneal's past, present, and future submission of documents to the FDA and about Amneal's expectations regarding FDA correspondence to Amneal. Plaintiffs deny that Amneal has received any FDA correspondence indicating or suggesting that they will be able to launch the Amneal ANDA Products before February 28, 2026. Otherwise denied.

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

ANSWER: Paragraph 24 states legal conclusions and Amneal's opinion and characterization of counterclaims to which no response is required. To the extent a response is required, denied.

25. During the time between the summer of 2024, when Amneal expects final approval, and February 28, 2026, Amneal will be deprived of the ability to launch its generic product, and consumers be deprived of the benefits of lower-priced generic competition from Amneal.

ANSWER: Plaintiffs lack knowledge or information sufficient to form a belief about Amneal's past, present, and future submission of documents to the FDA and about Amneal's expectations. Plaintiffs deny that Amneal has any basis to expect approval before February 28, 2026. To the extent there are remaining allegations in Paragraph 25, denied.

B. PATENT LISTING AND THE ORANGE BOOK

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

ANSWER: Paragraph 26 states legal conclusions to which no response is required. To the extent a response is required, Plaintiffs admit that 21 U.S.C. § 301 states "This chapter may be cited as the Federal Food, Drug, and Cosmetic Act." Otherwise denied.

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

ANSWER: Paragraph 27 states legal conclusions to which no response is required. To the extent a response is required, Plaintiffs admit that the quoted language "(I) claims the drug for which the applicant submitted the application and is a drug substance (active ingredient) patent or

a drug product (formulation or composition) patent; or (II) claims a method of using such drug for which approval is sought or has been granted in the application" appears in 21 U.S.C. § 355(b)(1)(A)(viii). Otherwise denied.

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

ANSWER: Paragraph 28 states legal conclusions to which no response is required. To the extent a response is required, Plaintiffs admit that the quoted language "Patent information that is not the type of patent information required by subsection (b)(1)(A)(viii) shall not be submitted under this paragraph" appears in 21 U.S.C. § 355(c)(2). Otherwise denied.

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

ANSWER: Paragraph 29 states legal conclusions to which no response is required. To the extent a response is required, Plaintiffs admit the FDA's website (https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book) states that "The publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the Orange Book) identifies drug products approved on the basis of safety and effectiveness by the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act (the Act) and related patent and exclusivity information" (bold type omitted). Otherwise denied.

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

responsibility of the NDA holder to determine whether a patent claims the drug or a method of using the drug that is the subject of the NDA for purposes of Orange Book listing"); *Jazz Pharmaceuticals, Inc.*, 60 F.4th at 1378.

ANSWER: Paragraph 30 states legal conclusions to which no response is required. To the extent a response is required, Plaintiffs admit that the quoted language "the FDA does not verify that submitted patents actually meet statutory listing criteria, nor does the FDA proactively remove improperly listed patents" appears in *Jazz Pharms. Inc. v. Avadel CNS Pharms.*, LLC, 60 F. 4th 1373, 1378 (Fed. Cir. 2023). Plaintiffs further admit that the quoted language "purely ministerial" appears in *Apotex, Inc. v. Thompson*, 347 F.3d 1335, 1347 (Fed. Cir. 2003). Otherwise denied.

31. The FDA has adopted a regulation, 21 C.F.R. § 314.53(f), codifying and implementing its position that its duties with respect to Orange Book listings are purely ministerial. *Apotex, Inc.*, 347 F.3d at 1347. Under this regulation, a third party may dispute an Orange Book listing, but the FDA will not modify the listing unless the NDA holder itself requests the modification. 21 C.F.R. § 314.53(f); *Apotex, Inc.*, 347 F.3d at 1347.

ANSWER: Paragraph 31 states legal conclusions to which no response is required. To the extent a response is required, denied.

C. APPROVAL OF GENERIC DRUGS

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

ANSWER: Paragraph 32 states legal conclusions to which no response is required. To the extent a response is required, Plaintiffs admit that the language "that such patent information has not been filed" appears in 21 U.S.C. § 355 (j)(2)(A)(vii)(I). Otherwise denied.

33. If, however, there are any patents listed in the Orange Book for the corresponding NDA, for each patent listed in the Orange Book for the relevant NDA product, the ANDA must include a certification for each patent stating (a) that the patent has expired (a "Paragraph II Certification"), (b) when the patent will expire (a "Paragraph III Certification"), or (c) that the

patent is invalid or will not be infringed by the manufacture, use or sale of the ANDA product (a "Paragraph IV Certification" or "PIV Certification"). 21 U.S.C. §355 (j)(2)(A)(vii)(II)-(IV).

ANSWER: Paragraph 33 states legal conclusions to which no response is required. To the extent a response is required, Plaintiffs admit that the language "that such patent has expired" appears in 21 U.S.C. § 355 (j)(2)(A)(vii)(II), the language "of the date on which such patent will expire" appears in 21 U.S.C. § 355 (j)(2)(A)(vii)(III), and the language "that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted" appears in 21 U.S.C. § 355 (j)(2)(A)(vii)(IV). Otherwise denied.

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

ANSWER: Paragraph 34 states legal conclusions to which no response is required. To the extent a response is required, denied.

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

ANSWER: Paragraph 35 states legal conclusions to which no response is required. To the extent a response is required, denied.

36. If an ANDA contains one or more PIV Certifications, the ANDA applicant must provide notice of same to the NDA holder and owner(s) of the corresponding patent(s) and provide a "detailed statement of the factual and legal basis for the opinion that the patent is invalid or will not be infringed." 21 U.S.C. §355 (j)(2)(B)(iv)(II).

ANSWER: Paragraph 36 states legal conclusions to which no response is required. To the extent a response is required, Plaintiffs admit that the language "a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed" appears in 21 U.S.C. § 355 (j)(2)(B)(iv)(II). Otherwise denied.

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

ANSWER: Paragraph 37 states legal conclusions to which no response is required. To the extent a response is required, denied.

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

ANSWER: Paragraph 38 states legal conclusions to which no response is required. To the extent a response is required, denied.

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

ANSWER: Paragraph 39 states legal conclusions to which no response is required. To the extent a response is required, Plaintiffs admit that the quoted language "the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder" appears in 21 U.S.C. § 355(j)(5)(C)(ii)(I). Otherwise denied.

D. THE PROAIR® HFA NDA AND PRODUCT

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

ANSWER: Plaintiffs admit that FDA approved the commercial marketing of ProAir® HFA (albuterol sulfate) Inhalation Aerosol on October 29, 2004 under NDA No. 021457. Otherwise denied.

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

ANSWER: Plaintiffs admit that Ivax Research, Inc. submitted NDA No. 021457 to FDA with a cover letter dated January 30, 2002. Plaintiffs lack knowledge and information sufficient

to form a belief about the truth of the remaining allegations of Paragraph 41 and therefore deny them.

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

ANSWER: Plaintiffs admit that FDA approved the commercial marketing of ProAir® HFA (albuterol sulfate) Inhalation Aerosol on October 29, 2004 under NDA No. 021457. Otherwise denied.

43. Attached as Exhibit A is a copy of the FDA approval letter reflecting the submission and approval dates for the ProAir® NDA.

ANSWER: Plaintiffs state that there was an Exhibit A attached to Amneal's Answer, Affirmative Defenses, and Counterclaims and that Paragraph 43 purports to characterize Exhibit A, which speaks for itself. To the extent a response is required, Plaintiffs respectfully refer the Court to Exhibit A for its actual language and complete content. Otherwise denied.

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

ANSWER: Plaintiffs admit that there was no approved tradename as of the October 29, 2004 date of approval for the product that was the subject of NDA No. 021457. Otherwise denied.

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

ANSWER: Plaintiffs admit that Volare® HFA (Albuterol Sulfate, USP) Inhalation Aerosol was the original trade name for the product that was the subject of NDA No. 021457 and that the name ultimately approved for the product that was the subject of NDA No. 021457 was ProAir® HFA (albuterol sulfate) Inhalation Aerosol. Otherwise denied.

46. Attached as Exhibit B is a copy of the collection of "Administrative Documents/Correspondence" for NDA No. 21-457 published by the FDA, reflecting the originally proposed trade name on the final page.

ANSWER: Plaintiffs state that there was an Exhibit B attached to Amneal's Answer, Affirmative Defenses, and Counterclaims and that Paragraph 46 purports to characterize Exhibit B, which speaks for itself. To the extent a response is required, Plaintiffs respectfully refer the Court to Exhibit B for its actual language and complete content. Otherwise denied.

47. Attached as Exhibit C is a copy of the labeling for NDA No. 21-457 approved on October 29, 2004.

ANSWER: Plaintiffs state that there was an Exhibit C attached to Amneal's Answer, Affirmative Defenses, and Counterclaims and that Paragraph 47 purports to characterize Exhibit C, which speaks for itself. To the extent a response is required, Plaintiffs respectfully refer the Court to Exhibit C for its actual language and complete content. Otherwise denied.

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

ANSWER: Plaintiffs admit that there was an Exhibit B attached to Amneal's Answer, Affirmative Defenses, and Counterclaims that includes a letter from Ivax Research, Inc. to FDA dated January 30, 2002 concerning NDA No. 021457, which states that "As discussed in our pre-NDA meetings of November 8 and 14, 2001, Proventil® HFA was used as the comparator in our clinical studies; and this submission is being presented as a 505(b)(2) application." To the extent a further response is required, Plaintiffs respectfully refer the Court to Exhibit B for its actual language and complete content. Otherwise denied.

49. Attached as Exhibit D is a copy of the Medical Review from the Approval Package for the ProAir® NDA. On at least page three, it reflects the 505(b)(2) status of the ProAir® NDA and identifies Proventil HFA Inhalation Aerosol as the comparator drug.

ANSWER: Plaintiffs state that there was an Exhibit D attached to Amneal's Answer, Affirmative Defenses, and Counterclaims and that Paragraph 49 purports to characterize Exhibit

D, which speaks for itself. To the extent a response is required, Plaintiffs respectfully refer the Court to Exhibit D for its actual language and complete content. Otherwise denied.

50. The ingredients in ProAir® HFA are albuterol sulfate, propellant HFA-134a, and ethanol. The active ingredient in ProAir® HFA is albuterol sulfate. Attached as Exhibit E is a copy of the current Prescribing Information and Patient Information for ProAir® HFA.

ANSWER: Plaintiffs state that there was an Exhibit E attached to Amneal's Answer, Affirmative Defenses, and Counterclaims and that Paragraph 50 purports to characterize Exhibit E, which speaks for itself. To the extent a response is required, Plaintiffs respectfully refer the Court to Exhibit E for its actual language and complete content. Otherwise denied.

51. As reflected in the ProAir® HFA label, albuterol sulfate was first approved by FDA more than forty years ago, in 1981. *See* Exhibit E (ProAir® HFA Prescribing Information at page 1).

ANSWER: Plaintiffs state that there was an Exhibit E attached to Amneal's Answer, Affirmative Defenses, and Counterclaims and that Paragraph 51 purports to characterize Exhibit E, which speaks for itself. To the extent a response is required, Plaintiffs respectfully refer the Court to Exhibit E for its actual language and complete content. Otherwise denied.

52. ProAir® HFA was initially approved without a dose counter. Attached as Exhibit D is a copy of the Medical Review from the ProAir® NDA Approval Package. Page three of this exhibit, which is internal page 2 of the Division Director's Memorandum of October 29, 2004, states: "A dose counter is not included in this drug product. This will be addressed by the applicant in future submissions."

ANSWER: Plaintiffs state that there was an Exhibit D attached to Amneal's Answer, Affirmative Defenses, and Counterclaims and that Paragraph 52 purports to characterize Exhibit D, which speaks for itself. To the extent a response is required, Plaintiffs respectfully refer the Court to Exhibit D for its actual language and complete content. Otherwise denied.

53. The Prescribing Information and Patient Information for ProAir® HFA has been amended several times since its initial approval in 2004. Attached as Exhibit F is a copy of the list published by the FDA of the Approval Dates and History, Letters, Labels, and Reviews for the ProAir® NDA.

ANSWER: Plaintiffs state that there was an Exhibit F attached to Amneal's Answer, Affirmative Defenses, and Counterclaims and that Paragraph 53 purports to characterize Exhibit F, which speaks for itself. To the extent a response is required, Plaintiffs respectfully refer the Court to Exhibit F for its actual language and complete content. Otherwise denied.

54. On August 17, 2010, in connection with a Supplemental New Drug Application to the ProAir® NDA, the FDA approved a revised package insert and patient instructions for use in support of an actuator approved on September 22, 2009. Attached as Exhibit G is a copy of the August 17, 2010 Supplement Approval letter from the FDA reflecting this approval.

ANSWER: Plaintiffs state that there was an Exhibit G attached to Amneal's Answer, Affirmative Defenses, and Counterclaims and that Paragraph 54 purports to characterize Exhibit G, which speaks for itself. To the extent a response is required, Plaintiffs respectfully refer the Court to Exhibit G for its actual language and complete content. Otherwise denied.

55. The earliest approved Prescribing Information and Patient Information for ProAir® HFA reflecting the presence of a dose counter attached to the actuator is the March 2012 revision. Attached as Exhibit H is a copy of the March 2012 revision of the Prescribing Information and Patient Information for ProAir® HFA.

ANSWER: Plaintiffs state that there was an Exhibit H attached to Amneal's Answer, Affirmative Defenses, and Counterclaims and that Paragraph 55 purports to characterize Exhibit H, which speaks for itself. To the extent a response is required, Plaintiffs respectfully refer the Court to Exhibit H for its actual language and complete content. Otherwise denied.

56. The March 2012 revision of the Prescribing Information and Patient Information for ProAir® HFA replaced the July 2010 revision. The July 2010 revision of the Prescribing Information and Patient Information for ProAir® HFA does not refer to a dose counter. Attached as Exhibit I is a copy of the July 2010 revision of the Prescribing Information and Patient Information for ProAir® HFA.

ANSWER: Plaintiffs state that there was an Exhibit I attached to Amneal's Answer, Affirmative Defenses, and Counterclaims and that Paragraph 56 purports to characterize Exhibit I, which speaks for itself. To the extent a response is required, Plaintiffs respectfully refer the Court to Exhibit I for its actual language and complete content. Otherwise denied.

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

ANSWER: Plaintiffs admit that 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. Otherwise denied.

58. On information and belief, Counterclaim-Defendants discontinued marketing ProAir® HFA in October 2022, but continue to sell an authorized generic version of the product.

ANSWER: Plaintiffs admit that the manufacturing of branded ProAir® HFA (albuterol sulfate) Inhalation Aerosol was discontinued on October 1, 2022. Plaintiffs further admit that Teva USA currently distributes an authorized generic of ProAir® HFA (albuterol sulfate) Inhalation Aerosol under NDA No. 021457 in the United States. Otherwise denied.

E. PRIOR ANDAS FOR GENERIC PROAIR® HFA

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

ANSWER: Paragraph 59 states legal conclusions and Amneal's opinion and characterization of counterclaims to which no response is required. To the extent a response is required, denied.

60. On September 5, 2012, Counterclaim-Defendants Teva Branded and Norton together with Teva Respiratory, LLC and Norton Healthcare Limited, filed a lawsuit captioned *Teva Branded Pharmaceutical Products R&D, Inc., Teva Respiratory, LLC, Norton (Waterford) Limited, and Norton Healthcare Limited v. Perrigo Pharmaceuticals Co., Perrigo Co., and Catalent Pharma Solutions, LLC*, U.S. District Court for the District of Delaware, Case 1:12-cv-01101 (defendants collectively "Perrigo"). Teva asserted U.S. Patent Nos. 7,105,152 ("the '152 patent") and 7,566,445 ("the '445 patent") in their complaint against Perrigo. The '445 patent is a device patent that Teva improperly listed in the Orange Book. On information and belief, Counterclaim-Defendants Teva Branded and Norton together with Teva Respiratory, LLC and

Norton Healthcare Limited filed a lawsuit against Perrigo within the 45-day period prescribed by 21 U.S.C. § 355(j)(5)(B)(iii), thereby triggering a 30-month stay of FDA approval of Perrigo's ANDA. The lawsuit was resolved by means of a stipulated dismissal on June 20, 2014.

ANSWER: Paragraph 60 states legal conclusions and Amneal's opinion and characterization of counterclaims to which no response is required. Paragraph 60 purports to characterize the '445 patent, which speaks for itself. To the extent a response is required, Plaintiffs admit that Teva Branded and Norton have filed other lawsuits relating to ProAir® HFA. Plaintiffs state that the lawsuits speak for themselves and deny any characterizations thereof. Otherwise denied.

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

ANSWER: Paragraph 61 states legal conclusions and Amneal's opinion and characterization of counterclaims to which no response is required. Paragraph 60 purports to characterize the '712 and '289 patents, which speak for themselves. To the extent a response is required, Plaintiffs admit that Teva Branded and Norton have filed other lawsuits relating to ProAir® HFA. Plaintiffs state that the lawsuits speak for themselves and deny any characterizations thereof. Otherwise denied.

62. These two prior lawsuits demonstrate that Counterclaim-Defendants Teva Branded and Norton, together with Teva Respiratory, LLC and Norton Healthcare Limited, have engaged in enforcement efforts relating to device patents listed improperly in the Orange Book for ProAir® HFA to try to delay or stop generic market entry.

ANSWER: Paragraph 62 states legal conclusions and Amneal's opinion and characterization of counterclaims to which no response is required. To the extent a response is required, denied.

63. According to the FDA, the date of first commercial marketing of a generic version of ProAir® HFA by the first-to-file ANDA applicant was February 26, 2020. Attached as Exhibit J is a copy of the Paragraph IV Patent Certifications published by the FDA and dated October 16, 2023. Page two of that document contains the entry for ProAir® HFA and reflects the February 26, 2020 launch date of the first-to-file generic version of ProAir® HFA.

ANSWER: Plaintiffs state that there was an Exhibit J attached to Amneal's Answer, Affirmative Defenses, and Counterclaims and that Paragraph 63 purports to characterize Exhibit J, which speaks for itself. To the extent a response is required, Plaintiffs respectfully refer the Court to Exhibit J for its actual language and complete content. Otherwise denied.

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

ANSWER: Plaintiffs admit that there have been more than 180 days between February 26, 2020 and the date of this Answer (July 15, 2024). Otherwise denied.

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

ANSWER: Paragraph 65 states legal conclusions and Amneal's opinion and characterization of counterclaims to which no response is required. To the extent a response is required, denied.

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

66. At the time Amneal NY and Amneal Ireland submitted Amneal's ANDA seeking FDA approval to market a generic version of ProAir® HFA, all five Asserted Patents were listed in the Orange Book for ProAir® HFA. Attached as Exhibit K is a copy of the Orange Book listing for ProAir® HFA.

ANSWER: Plaintiffs state that there was an Exhibit K attached to Amneal's Answer, Affirmative Defenses, and Counterclaims and that Paragraph 66 purports to characterize Exhibit K, which speaks for itself. To the extent a response is required, Plaintiffs respectfully refer the Court to Exhibit K for its actual language and complete content. Plaintiffs admit that the Patents-in-Suit were listed in FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") in connection with ProAir® HFA (NDA No. 021457) as of the filing of Amneal's Answer, Affirmative Defenses, and Counterclaims on December 1, 2023. Otherwise denied.

67. At the time of filing this Answer, Affirmative Defenses, and Counterclaims, all five Asserted Patents remained listed in the Orange Book for ProAir®.

ANSWER: Plaintiffs admit that the Asserted Patents were listed in the Orange Book in connection with ProAir® HFA (NDA No. 021457) as of the filing of Amneal's Answer, Affirmative Defenses, and Counterclaims on December 1, 2023. Otherwise denied.

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

ANSWER: Paragraph 68 purports to characterize the Asserted Patents, which speak for themselves, and states legal conclusions to which no response is required. To the extent a response is required, denied.

69. The United States Federal Trade Commission (the "FTC") has determined that the Asserted Patents are not properly listed in the Orange Book for ProAir® HFA. On or about November 7, 2023, the FTC sent a letter (the "FTC Delisting Letter") to Counterclaim-Defendant Teva Branded informing Teva Branded that the FTC believes that all of the Asserted Patents (plus others) are "improperly or inaccurately listed in the Orange Book" for ProAir® HFA. The FTC Delisting Letter indicates that the FTC has "submitted patent listing dispute communications to the FDA" regarding all five Asserted Patents. A copy of the FTC Delisting Letter is attached hereto as Exhibit L.

ANSWER: Plaintiffs state that there was an Exhibit L attached to Amneal's Answer, Affirmative Defenses, and Counterclaims and that Paragraph 69 purports to characterize Exhibit

L, which speaks for itself. Plaintiffs admit that in November 2023, Plaintiffs received a letter from the FTC related to the Asserted Patents, a copy of which is attached as Exhibit L to Amneal's Answer, Affirmative Defenses, and Counterclaims. Otherwise denied.

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

ANSWER: Plaintiffs state that Paragraph 70 purports to characterize Exhibit L, which speaks for itself. To the extent a response is required, Plaintiffs respectfully refer the Court to Exhibit L for its actual language and complete content. Otherwise denied.

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

> The Orange Book is only supposed to list patents covering active drug ingredients. So, we focused on device patents that have nothing to do with the active drug. Our staff analyzed several different types of these products and listings with an initial focus on products that were widely used and have been around for a while and we would have expected to see more generic competition. For example, asthma and COPD inhalers were a particular area of focus for us. Over 40 million Americans rely on inhalers and a lot of the drugs using these inhalers have been around for several decades. But we're still seeing people paying hundreds and hundreds of dollars for them.
>
> And we're not seeing a lot of lower cost generic use, even though the drugs have been around for several decades and have long expired drug substance patents. So that's what made inhalers like the asthma and COPD products a particular concern.
>
> * * * * *
>
> In the last few years, there's been a lot of discussion in this space on the Orange Book and how abusive listings can negatively affect competition and

> ultimately patients. So, we just thought more can be done here to help ensure that drug manufacturers don't abuse the Orange Book process.

ANSWER: Plaintiffs state that there was an Exhibit M attached to Amneal's Answer, Affirmative Defenses, and Counterclaims and that Paragraph 71 purports to characterize Exhibit M, which speaks for itself. To the extent a response is required, Plaintiffs respectfully refer the Court to Exhibit M for its actual language and complete content. Otherwise denied.

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

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

ANSWER: Plaintiffs state that Paragraph 72 purports to characterize Exhibit M, which speaks for itself. To the extent a response is required, Plaintiffs respectfully refer the Court to Exhibit M for its actual language and complete content. Otherwise denied.

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

> Q: …Does the FTC think that there are device patents that that can be listed or do you think that under the statute none of them can be listed?
>
> I don't think it's particularly controversial in terms of the statute, the regulations and the cases, and I think there have been FTC and FDA statements on this, that only patents that claim the active ingredient should be listed in the Orange Book. And drug-device patents that do not claim the active ingredient should not be listed.

ANSWER: Plaintiffs state that Paragraph 73 purports to characterize Exhibit M, which speaks for itself. To the extent a response is required, Plaintiffs respectfully refer the Court to Exhibit M for its actual language and complete content. Otherwise denied.

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

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

ANSWER: Plaintiffs state that Paragraph 74 purports to characterize Exhibit M, which speaks for itself. To the extent a response is required, Plaintiffs respectfully refer the Court to Exhibit M for its actual language and complete content. Otherwise denied.

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

ANSWER: Plaintiffs admit that the Asserted Patents are listed in the Orange Book in connection with ProAir® HFA (NDA No. 021457) as of the date of this Answer (July 15, 2024). Otherwise denied.

76. None of the Asserted Patents satisfies any of the statutory requirements for being properly listed in the Orange Book.

ANSWER: Paragraph 76 purports to characterize the Asserted Patents, which speak for themselves, and states legal conclusions to which no response is required. To the extent a response is required, denied.

77. None of the Asserted Patents claims a method of using a drug.

ANSWER: Paragraph 77 purports to characterize the Asserted Patents, which speak for themselves, and states legal conclusions to which no response is required. To the extent a response is required, Plaintiffs admit that for purposes of this case, Plaintiffs do not contend that the Asserted

Patents are properly listed in the Orange Book on the basis that they claim "an approved method of using ProAir® HFA." Otherwise denied.

78. None of the Asserted Patents claims an approved method of using ProAir® HFA.

ANSWER: Paragraph 78 purports to characterize the Asserted Patents, which speak for themselves, and states legal conclusions to which no response is required. To the extent a response is required, Plaintiffs admit that for purposes of this case, Plaintiffs do not contend that the Asserted Patents are properly listed in the Orange Book on the basis that they claim "an approved method of using ProAir® HFA." Otherwise denied.

79. None of the Asserted Patents claims "the drug for which the applicant submitted" the ProAir® NDA.

ANSWER: Paragraph 79 purports to characterize the Asserted Patents, which speak for themselves, and states legal conclusions to which no response is required. To the extent a response is required, denied.

80. None of the Asserted Patents is "a drug substance (active ingredient) patent" or claim a drug substance or active ingredient.

ANSWER: Paragraph 80 purports to characterize the Asserted Patents, which speak for themselves, and states legal conclusions to which no response is required. To the extent a response is required, Plaintiffs admit that for purposes of this case, Plaintiffs do not contend that the Asserted Patents are properly listed in the Orange Book on the basis that each is "a drug substance (active ingredient) patent." Otherwise denied.

81. None of the Asserted Patents is "a drug product (formulation or composition) patent" or claim a drug product or drug formulation, or drug composition.

ANSWER: Paragraph 81 purports to characterize the Asserted Patents, which speak for themselves, and states legal conclusions to which no response is required. To the extent a response is required, denied.

82. None of the Asserted Patents claims the active ingredient in ProAir® HFA.

ANSWER: Paragraph 82 purports to characterize the Asserted Patents, which speak for themselves, and states legal conclusions to which no response is required. To the extent a response is required, denied.

83. None of the Asserted Patents claims a drug.

ANSWER: Paragraph 83 purports to characterize the Asserted Patents, which speak for themselves, and states legal conclusions to which no response is required. To the extent a response is required, denied.

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

ANSWER: Paragraph 84 purports to characterize the Asserted Patents, which speak for themselves. To the extent a response is required, Plaintiffs respectfully refer the Court to the Asserted Patents for their actual language and complete content. Otherwise denied.

85. None of the Asserted Patents contains the word "albuterol."

ANSWER: Paragraph 85 purports to characterize the Asserted Patents, which speak for themselves. To the extent a response is required, Plaintiffs respectfully refer the Court to the Asserted Patents for their actual language and complete content. Otherwise denied.

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

ANSWER: Plaintiffs admit that the Asserted Patents are listed in the Orange Book in connection with ProAir® HFA (NDA No. 021457) and in connection with at least one other product as of the date of this Answer (July 15, 2024). Otherwise denied.

87. Attached as Exhibit N is a copy of the Orange Book listing for QVAR 40, which was approved under NDA No. 020911. The active ingredient in QVAR 40 is beclomethasone dipropionate.

ANSWER: Plaintiffs admit that QVAR® 40 was approved by FDA under NDA No. 020911. Plaintiffs state that there was an Exhibit N attached to Amneal's Answer, Affirmative Defenses, and Counterclaims and that Paragraph 87 purports to characterize Exhibit N, which speaks for itself. Plaintiffs admit that under "Product 002" in Exhibit N it states "BECLOMETHASONE DIPROPIONATE (QVAR 40) AEROSOL, METERED 0.04MG/INH." To the extent a further response is required, Plaintiffs respectfully refer the Court to Exhibit N for its actual language and complete content. Otherwise denied.

88. Attached as Exhibit O is a copy of the Orange Book listing for QVAR 80, which was approved under NDA No. 020911. The active ingredient in QVAR 80 is beclomethasone dipropionate.

ANSWER: Plaintiffs admit that QVAR® 80 was approved by FDA under NDA No. 020911. Plaintiffs state that there was an Exhibit O attached to Amneal's Answer, Affirmative Defenses, and Counterclaims and that Paragraph 88 purports to characterize Exhibit O, which speaks for itself. Plaintiffs admit that under "Product 001" in Exhibit O it states "BECLOMETHASONE DIPROPIONATE (QVAR 80) AEROSOL, METERED 0.08MG/INH." To the extent a further response is required, Plaintiffs respectfully refer the Court to Exhibit O for its actual language and complete content. Otherwise denied.

89. Attached as Exhibit P is a copy of the Orange Book listing for QVAR Redihaler, which was approved under NDA No 207921. The active ingredient in QVAR Redihaler is beclomethasone dipropionate.

ANSWER: Plaintiffs admit that QVAR RediHaler® was approved by FDA under NDA No. 207921. Plaintiffs state that there was an Exhibit P attached to Amneal's Answer, Affirmative Defenses, and Counterclaims and that Paragraph 89 purports to characterize Exhibit P, which speaks for itself. Plaintiffs admit that under "Product 002" in Exhibit P it states "BECLOMETHASONE DIPROPIONATE (QVAR REDIHALER) AEROSOL, METERED

0.08MG/INH." To the extent a further response is required, Plaintiffs respectfully refer the Court to Exhibit P for its actual language and complete content. Otherwise denied.

90. Beclomethasone dipropionate is a different active ingredient than albuterol sulfate.

ANSWER: Admitted.

91. Attached as Exhibit Q is a copy of the Orange Book listing for ProAir Digihaler, which was approved under NDA No. 205636. The active ingredient in ProAir Digihaler is albuterol sulfate.

ANSWER: Plaintiffs admit that ProAir® Digihaler® was approved by FDA under NDA No. 205636. Plaintiffs state that there was an Exhibit Q attached to Amneal's Answer, Affirmative Defenses, and Counterclaims and that Paragraph 91 purports to characterize Exhibit Q, which speaks for itself. Plaintiffs admit that under "Product 002" in Exhibit Q it states "ALBUTEROL SULFATE (PROAIR DIGIHALER) POWDER, METERED EQ 0.09MG BASE/INH." To the extent a further response is required, Plaintiffs respectfully refer the Court to Exhibit Q for its actual language and complete content. Otherwise denied.

92. Attached as Exhibit R is a copy of the Orange Book listing for ProAir Respiclick, which was approved under NDA No. 205636. The active ingredient in ProAir Respiclick is albuterol sulfate.

ANSWER: Plaintiffs admit that ProAir RespiClick® was approved by FDA under NDA No. 205636. Plaintiffs state that there was an Exhibit R attached to Amneal's Answer, Affirmative Defenses, and Counterclaims and that Paragraph 92 purports to characterize Exhibit R, which speaks for itself. Plaintiffs admit that under "Product 001" in Exhibit R it states "ALBUTEROL SULFATE (PROAIR RESPICLICK) POWDER, METERED EQ 0.09MG BASE/INH." To the extent a further response is required, Plaintiffs respectfully refer the Court to Exhibit R for its actual language and complete content. Otherwise denied.

93. Attached as Exhibit S is a copy of the Orange Book listing for ArmonAir Respiclick, which was approved under NDA No. 208798. The active ingredient in ArmonAir Respiclick is fluticasone propionate.

ANSWER: Plaintiffs admit that ArmonAir RespiClick® was approved by FDA under NDA No. 208798. Plaintiffs state that there was an Exhibit S attached to Amneal's Answer, Affirmative Defenses, and Counterclaims and that Paragraph 93 purports to characterize Exhibit S, which speaks for itself. Plaintiffs admit that under "Product 001" in Exhibit S it states "FLUTICASONE PROPIONATE (ARMONAIR RESPICLICK) POWDER 0.055MG/INH." To the extent a further response is required, Plaintiffs respectfully refer the Court to Exhibit S for its actual language and complete content. Otherwise denied.

94. Attached as Exhibit T is a copy of the Orange Book listing for ArmonAir Digihaler, which was approved under NDA No. 208798. The active ingredient in ArmonAir Digihaler is fluticasone propionate.

ANSWER: Plaintiffs admit that ArmonAir® Digihaler® was approved by FDA under NDA No. 208798. Plaintiffs state that there was an Exhibit T attached to Amneal's Answer, Affirmative Defenses, and Counterclaims and that Paragraph 94 purports to characterize Exhibit T, which speaks for itself. Plaintiffs admit that under "Product 004" in Exhibit T it states "FLUTICASONE PROPIONATE (ARMONAIR DIGIHALER) POWDER 0.055MG/INH." To the extent a further response is required, Plaintiffs respectfully refer the Court to Exhibit T for its actual language and complete content. Otherwise denied.

95. Fluticasone propionate is a different active ingredient than albuterol sulfate.

ANSWER: Admitted.

96. Attached as Exhibit U is a copy of the Orange Book listing for AirDuo Digihaler, which was approved under NDA No. 208799. The active ingredients in AirDuo Digihaler are fluticasone propionate and salmeterol xinafoate.

ANSWER: Plaintiffs admit that AirDuo® Digihaler® was approved by FDA under NDA No. 208799. Plaintiffs state that there was an Exhibit U attached to Amneal's Answer, Affirmative Defenses, and Counterclaims and that Paragraph 96 purports to characterize Exhibit U, which speaks for itself. Plaintiffs admit that under "Product 004" in Exhibit U it states "FLUTICASONE

PROPIONATE; SALMETEROL XINAFOATE (AIRDUO DIGIHALER) POWDER 0.055MG/INH; EQ 0.014MG BASE/INH." To the extent a further response is required, Plaintiffs respectfully refer the Court to Exhibit U for its actual language and complete content. Otherwise denied.

97. Attached as Exhibit V is a copy of the Orange Book listing for AirDuo Respiclick, which was approved under NDA No. 208799. The active ingredients in AirDuo Respiclick are fluticasone propionate and salmeterol xinafoate.

ANSWER: Plaintiffs admit that AirDuo RespiClick® was approved by FDA under NDA No. 208799. Plaintiffs state that there was an Exhibit V attached to Amneal's Answer, Affirmative Defenses, and Counterclaims and that Paragraph 97 purports to characterize Exhibit V, which speaks for itself. Plaintiffs admit that under "Product 001" in Exhibit V it states "FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE (AIRDUO RESPICLICK) POWDER 0.055MG/INH; EQ 0.014MG BASE/INH." To the extent a further response is required, Plaintiffs respectfully refer the Court to Exhibit V for its actual language and complete content. Otherwise denied.

98. Fluticasone propionate and salmeterol xinafoate are each a different active ingredient than albuterol sulfate.

ANSWER: Admitted.

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

ANSWER: Paragraph 99 states legal conclusions and Amneal's opinion and characterization of counterclaims to which no response is required. To the extent a response is required, denied.

100. Counterclaim-Defendants' enforcement efforts against, for example, Perrigo and Lupin regarding Orange Book patents listed for ProAir® HFA further shows that Counterclaim-

Defendants are using improperly-listed Orange Book patents to hinder and delay generic market entry.

ANSWER: Paragraph 100 states legal conclusions and Amneal's opinion and characterization of counterclaims to which no response is required. To the extent a response is required, denied.

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

101. Because Counterclaim-Defendants had improperly listed the Asserted Patents in the Orange Book, Amneal NY and Amneal Ireland were required to submit Paragraph IV Certifications as to each of the Asserted Patents (rather than a Paragraph I Certification) in order to seek approval from the FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Amneal ANDA Products prior to the expiration of the Asserted Patents. The Amneal Notice Letter, dated August 24, 2023, and, on information and belief, received by Counterclaim-Defendants on August 28, 2023, notified Counterclaim-Defendants that Amneal NY and Amneal Ireland had submitted to the FDA Amneal's ANDA including Paragraph IV Certifications as to each of the Asserted Patents.

ANSWER: Paragraph 101 states legal conclusions and Amneal's opinion and characterization of counterclaims to which no response is required. To the extent a response is required, Plaintiffs admit that the Amneal Notice Letter, dated August 24, 2023, notified Plaintiffs that Amneal had filed a Paragraph IV Certification with respect to each of the Asserted Patents. Plaintiffs further admit that they received the Amneal Notice Letter on August 28, 2023. Otherwise denied.

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

ANSWER: Paragraph 102 states legal conclusions, Amneal's opinion and characterization of counterclaims, and allegations subject to proof by expert testimony to which no response is required. To the extent a response is required, Plaintiffs admit that this action was commenced within 45 days from the date of Plaintiffs' receipt of the Amneal Notice Letter. Plaintiffs further admit that the 30-month stay of final FDA approval of Amneal's ANDA expires on February 28, 2026. Plaintiffs lack knowledge or information sufficient to form a belief about Amneal's past, present, and future submission of documents to the FDA. Otherwise denied.

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

ANSWER: Paragraph 103 states legal conclusions and Amneal's opinion and characterization of counterclaims to which no response is required. To the extent a response is required, denied.

104. Specifically, the Asserted Patents are directed to devices or portions of devices, and the device that Amneal seeks approval to use in Amneal's ANDA is itself prior art to the Asserted Patents. Thus, the Asserted Patents cannot cover the device used by Amneal under the doctrine of equivalents, because that would necessarily ensnare the prior art. And if the Amneal device is deemed to literally infringe the Asserted Patents, then axiomatically, the Asserted Patents would be invalid as anticipated.

ANSWER: Paragraph 104 purports to characterize the Asserted Patents, which speak for themselves, and states legal conclusions to which no response is required. To the extent a response is required, denied.

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

ANSWER: Paragraph 105 states legal conclusions and Amneal's opinion and characterization of counterclaims to which no response is required. To the extent a response is required, denied.

H. MARKET POWER AND MARKET DEFINITION

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

ANSWER: Paragraph 106 states legal conclusions, Amneal's opinion and characterization of counterclaims, and allegations subject to proof by expert testimony to which no response is required. To the extent a response is required, denied.

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

ANSWER: Paragraph 107 states legal conclusions, Amneal's opinion and characterization of counterclaims, and allegations subject to proof by expert testimony to which no response is required. To the extent a response is required, denied.

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

ANSWER: Paragraph 108 states legal conclusions, Amneal's opinion and characterization of counterclaims, and allegations subject to proof by expert testimony to which no response is required. To the extent a response is required, denied.

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

ANSWER: Paragraph 109 states legal conclusions, Amneal's opinion and characterization of counterclaims, and allegations subject to proof by expert testimony to which no response is required. To the extent a response is required, denied.

110. Counterclaim-Defendants have, and have exercised, the power to exclude competition to ProAir® HFA and its generic equivalents.

ANSWER: Paragraph 110 states legal conclusions, Amneal's opinion and characterization of counterclaims, and allegations subject to proof by expert testimony to which no response is required. To the extent a response is required, denied.

111. Counterclaim-Defendants enjoyed high barriers to entry with respect to the brand and generic versions of ProAir® HFA.

ANSWER: Paragraph 111 states legal conclusions, Amneal's opinion and characterization of counterclaims, and allegations subject to proof by expert testimony to which no response is required. To the extent a response is required, denied.

112. As set out above, Counterclaim-Defendants' anticompetitive conduct—including their improper listing of the Asserted Patents in the Orange Book and their filing of this sham litigation within 45 days of the receipt of Amneal's Notice Letter—is part of a pattern of conduct that began long before the instant litigation. Counterclaim-Defendants have, and have maintained, market power throughout the entirety of the course of their anticompetitive conduct.

ANSWER: Paragraph 112 states legal conclusions, Amneal's opinion and characterization of counterclaims, and allegations subject to proof by expert testimony to which no response is required. To the extent a response is required, Plaintiffs admit that this action was commenced within 45 days from the date of Plaintiffs' receipt of the Amneal Notice Letter. Otherwise denied.

113. There is direct evidence of market power and anticompetitive effects available in this case sufficient to show Counterclaim-Defendants' ability to control prices of its ProAir® HFA and ProAir® AG, and to exclude relevant competitors, without the need to show the relevant antitrust markets. The direct evidence consists of, among other things, (a) the fact that additional competing generic equivalents would have entered the market at substantial discounts to the brand version but for Counterclaim-Defendants' anticompetitive conduct; (b) Counterclaim-Defendants' history of improperly listing patents in the Orange Book and filing sham litigation with respect to

the same; and (c) Counterclaim-Defendants' supracompetitive pricing for ProAir® HFA and ProAir® AG.

ANSWER: Paragraph 113 states legal conclusions, Amneal's opinion and characterization of counterclaims, and allegations subject to proof by expert testimony to which no response is required. To the extent a response is required, denied.

114. To the extent proof of monopoly power by defining a relevant product market is required, Amneal alleges that the relevant antitrust market is the market for ProAir® HFA and its generic equivalents. ProAir® HFA and its generic equivalents are not reasonably interchangeable with other products due to the distinct qualities and characteristics of ProAir® HFA, which distinguish it from other albuterol sulfate inhalants. Indeed, researchers have recognized significant differences across the spectrum of albuterol sulfate HFA inhalation aerosol products. Johnson et al., *The effect of a holding chamber on albuterol metered-dose inhaler product differences*, ANNALS OF ALLERGY, ASTHMA, & IMMUNOLOGY 117(3):246-50 (2016). doi: 10.1016/j.anai.2016.07.016. PMID: 27613457 (attached as Exhibit W). Accordingly, ProAir® HFA and its generic equivalents are appropriately considered as a market of their own.

ANSWER: Paragraph 114 states legal conclusions, Amneal's opinion and characterization of counterclaims, and allegations subject to proof by expert testimony to which no response is required. To the extent a response is required, Plaintiffs state that Paragraph 114 purports to characterize Exhibit W, which speaks for itself. To the extent a further response is required, denied.

115. The United States, the District of Columbia, and the U.S. territories constitute the relevant geographic market.

ANSWER: Paragraph 115 states legal conclusions, Amneal's opinion and characterization of counterclaims, and allegations subject to proof by expert testimony to which no response is required. To the extent a response is required, denied.

116. Thus, for purposes of this lawsuit, the market for the sale of ProAir® HFA and its generic equivalents in the United States (the "Relevant Market") constitutes a relevant market. In the alternative, the relevant market encompasses all albuterol sulfate HFA inhaler aerosol products (the "Alternative Relevant Market").[2]

[2] Amneal maintains that the relevant product market for purposes of its Counterclaims is ProAir® HFA and its generic equivalents. However, to the extent the relevant product market is construed to encompass all albuterol sulfate HFA inhaler aerosol products (the Alternative Relevant Market),

ANSWER: Paragraph 116 and the accompanying footnote state legal conclusions, Amneal's opinion and characterization of counterclaims, and allegations subject to proof by expert testimony to which no response is required. To the extent a response is required, denied.

117. Upon information and belief, at all relevant times Counterclaim Defendants had a predominant share of the Relevant Market.

ANSWER: Paragraph 117 states legal conclusions, Amneal's opinion and characterization of counterclaims, and allegations subject to proof by expert testimony to which no response is required. To the extent a response is required, denied.

118. On information and belief, Counterclaim-Defendants were able to set prices of ProAir® HFA and the ProAir® AG above that which would be charged in a competitive market.

ANSWER: Paragraph 118 states legal conclusions, Amneal's opinion and characterization of counterclaims, and allegations subject to proof by expert testimony to which no response is required. To the extent a response is required, denied.

119. Counterclaim-Defendants possess monopoly power in the Relevant Market, as evidenced by, among other factors, their prior pricing actions and dominant market share.

ANSWER: Paragraph 119 states legal conclusions, Amneal's opinion and characterization of counterclaims, and allegations subject to proof by expert testimony to which no response is required. To the extent a response is required, denied.

I. ANTITRUST IMPACT AND IMPACT ON INTERSTATE COMMERCE

120. Amneal plans to launch the Amneal ANDA Products within days or weeks of receipt of final FDA approval.

ANSWER: Plaintiffs lack knowledge and information sufficient to form a belief about the truth of the allegations of paragraph 120 and therefore deny them.

121. Via a letter dated November 9, 2023, the FDA informed Amneal that it has set a goal date of June 25, 2024 for review of Amneal's ANDA if an inspection is not required, and a

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use of the term 'Relevant Market' herein encompasses both the Relevant Market and the Alternative Relevant Market.

goal date of August 25, 2024 for review of Amneal's ANDA if an inspection is required. Attached as Exhibit X is a copy of the November 9, 2023 FDA letter. Amneal reasonably expects to receive FDA approval in the summer of 2024. Because of Counterclaim-Defendants anticompetitive conduct, that approval will be tentative, meaning that Amneal will need to wait until expiration of the 30-month stay to receive final approval and launch the Amneal ANDA Products. The approval in the summer of 2024 would be final but for Counterclaim-Defendants' anticompetitive conduct.

ANSWER: Paragraph 121 states legal conclusions and Amneal's opinion and characterization of counterclaims to which no response is required. To the extent a response is required, Plaintiffs state that there was an Exhibit X attached to Amneal's Answer, Affirmative Defenses, and Counterclaims and that Paragraph 121 purports to characterize Exhibit X, which speaks for itself. To the extent a further response is required, Plaintiffs respectfully refer the Court to Exhibit X for its actual language and complete content. Otherwise, denied.

122. Amneal is making multi-million dollar investments to enable a successful launch as early as the summer of 2024. Specifically, in 2023 and early 2024, Amneal is making several million dollars in capital expenditures on new and expanded filling and packaging lines for the Amneal ANDA Products, as is spending several million dollars on device components, such as valves and actuators.

ANSWER: Plaintiffs lack knowledge and information sufficient to form a belief about the truth of the allegations of Paragraph 122 and therefore deny them.

123. On information and belief, some of the device components that Amneal is purchasing will expire before expiration of the 30-month stay.

ANSWER: Plaintiffs lack knowledge and information sufficient to form a belief about the truth of the allegations of Paragraph 123 and therefore deny them.

124. Counterclaim-Defendants' supracompetitive scheme to maintain its monopoly in the Relevant Market included delaying Amneal's entry through (1) Orange Book abuse and (2) engaging in sham litigation. Counterclaim-Defendants' anticompetitive scheme has had a direct, substantial, and adverse effect on Amneal and interstate competition in the Relevant Market by maintaining monopoly power, increasing prices, artificially creating barriers to entry, and delaying competition in the Relevant Market.

ANSWER: Paragraph 124 states legal conclusions, Amneal's opinion and characterization of counterclaims, and allegations subject to proof by expert testimony to which no response is required. To the extent a response is required, denied.

125. By impeding competition from generic equivalent products, including Amneal's, Counterclaim-Defendants' anticompetitive scheme has allowed (and, unless restrained by this Court, will continue to allow) Counterclaim-Defendants to maintain and extend their monopoly power in the Relevant Market and to sell ProAir® HFA and the ProAir® AG at artificially-inflated monopoly prices.

ANSWER: Paragraph 125 states legal conclusions, Amneal's opinion and characterization of counterclaims, and allegations subject to proof by expert testimony to which no response is required. To the extent a response is required, denied.

126. Counterclaim-Defendants' anticompetitive scheme has harmed the competitive process and has had a substantial effect on interstate commerce, as it has allowed Counterclaim Defendants to charge wholesalers, retailers, payors, and consumers nationwide supracompetitive prices. But for this anticompetitive conduct, consumers and payors would have enjoyed the benefits of lower-priced generic competition from Amneal earlier. Instead, as a result of Counterclaim-Defendants' strategies, which include improper listing of the Asserted Patents in the Orange Book and engaging in sham litigation, consumers and payors have been forced to pay monopoly prices for Counterclaim-Defendants' ProAir® HFA and the ProAir® AG. The impact of Counterclaim-Defendants' anticompetitive conduct, and the accompanying supracompetitive pricing, is felt throughout the health care industry, impacting pharmaceutical competitors, healthcare providers, insurers, and other direct purchasers, intermediaries, and consumers.

ANSWER: Paragraph 126 states legal conclusions, Amneal's opinion and characterization of counterclaims, and allegations subject to proof by expert testimony to which no response is required. To the extent a response is required, denied.

127. Amneal has suffered, and will continue to suffer, harm as a result of Counterclaim-Defendants' anticompetitive conduct. That harm includes:

a. Loss of future sales and profits due to being foreclosed from selling in the Relevant Market;
b. The large amount of time and expense associated with having to fight baseless, sham patent litigation based on patents that were improperly listed in the Orange Book;
c. A delay in Amneal's ability to recoup its investment in filling and packaging lines and device components for the Amneal ANDA Products; and

d. The loss of Amneal's investment in device components that will expire before expiration of the 30-month stay resultant from Counterclaim-Defendants' improper listing of patents in the Orange Book.

ANSWER: Paragraph 127 states legal conclusions, Amneal's opinion and characterization of counterclaims, and allegations subject to proof by expert testimony to which no response is required. To the extent a response is required, denied.

128. A claimant satisfies the injury-in-fact requirement of standing where, as here, "the threatened injury is real, immediate, and direct." *See Pfizer Inc. v. Apotex Inc.*, 726 F. Supp. 2d 921, 930 (N.D. Ill. 2010) (quoting *Davis v. Fed. Election Com'n*, 554 U.S. 724, 734 (2008)).

ANSWER: Paragraph 128 states legal conclusions to which no response is required. To the extent a response is required, Plaintiffs admit that the quoted language "the threatened injury is real, immediate, and direct" appears in *Pfizer Inc. v. Apotex Inc.*, 726 F. Supp. 2d 921, 930 (N.D. Ill. 2010). Otherwise denied.

129. "[T]he creation of 'an independent barrier to the drug market' by a brand drug company 'that deprives [the generic company] of an economic opportunity to compete' satisfies the injury-in-fact and causation requirements of Article III standing." *See Pfizer Inc.*, 726 F. Supp 2d at 930 (quoting *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1285 (Fed. Cir. 2008)).

ANSWER: Paragraph 129 states legal conclusions to which no response is required. To the extent a response is required, Plaintiffs admit that the quoted language "the creation of 'an independent barrier to the drug market' by a brand drug company 'that deprives [the generic company] of an economic opportunity to compete' satisfies the injury-in-fact and causation requirements of Article III standing" appears in *Pfizer Inc. v. Apotex Inc.*, 726 F. Supp. 2d 921, 930 (N.D. Ill. 2010) (alteration in original). Otherwise denied.

130. The injury to Amneal is immediate. Amneal is already spending time and money to litigate this baseless and sham patent litigation. Because Counterclaim-Defendants filed the instant patent suit, alleging infringement of patents improperly listed in the Orange Book, Amneal's final FDA approval is subject to the automatic 30-month stay. Based on the date which Counterclaim-Defendants filed the present lawsuit, Amneal's ANDA would not be eligible for final approval until February 28, 2026. Accordingly, from the date of Amneal's imminent tentative approval (in the summer of 2024) through February 28, 2026, 2026, Amneal's ANDA will be

ineligible for final approval, and Amneal therefore will be deprived of the ability to launch its generic product, as a result of the Counterclaim-Defendants' anticompetitive conduct.

ANSWER: Paragraph 130 states legal conclusions and Amneal's opinion and characterization of counterclaims to which no response is required. To the extent a response is required, Plaintiffs admit that they brough this action against Defendants alleging infringement by Defendants of the Asserted Patents. Plaintiffs further admit that the 30-month stay of final FDA approval of Amneal's ANDA expires on February 28, 2026. Otherwise denied.

131. As a result of Counterclaim-Defendants' improper listing of the Asserted Patents and sham litigation, Amneal has already suffered and will imminently suffer the injuries outlined above.

ANSWER: Paragraph 131 states legal conclusions and Amneal's opinion and characterization of counterclaims to which no response is required. To the extent a response is required, denied.

132. Counterclaim-Defendants' anticompetitive conduct, as alleged herein, is not entitled to any qualified *Noerr-Pennington* immunity, nor is it protected by the state action doctrine or any statute of limitations.

ANSWER: Paragraph 132 states legal conclusions and Amneal's opinion and characterization of counterclaims to which no response is required. To the extent a response is required, denied.

133. There is and was no legitimate, procompetitive justification for Counterclaim-Defendants' conduct. Even if there was some conceivable and cognizable justification, Counterclaim-Defendants' conduct was not necessary to achieve such a purpose, and, in any event, any procompetitive effects would be outweighed by the scheme's anticompetitive effects on Amneal, competition, and consumers.

ANSWER: Paragraph 133 states legal conclusions, Amneal's opinion and characterization of counterclaims, and allegations subject to proof by expert testimony to which no response is required. To the extent a response is required, denied.

COUNT 1:
DECLARATORY JUDGMENT
REQUIRING DELISTING OF U.S. PATENT NO. 8,132,712

134. Amneal incorporates and re-alleges each of the foregoing paragraphs 1–133 of its Counterclaims, as if fully set forth herein.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Plaintiffs incorporate by reference their responses to each of the foregoing paragraphs 1–133 of Amneal's Counterclaims as if fully set forth herein.

135. Amneal hereby seeks a declaration pursuant to 21 U.S.C. § 355(j)(5)(C)(ii) ordering Counterclaim-Defendants to delete or withdraw the '712 patent from the Orange Book.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Plaintiffs admit that Amneal purports to seek a declaration pursuant to 21 U.S.C. § 355(j)(5)(C)(ii) ordering Counterclaim-Defendants to delete or withdraw the '712 patent from the Orange Book. Otherwise denied.

136. An actual controversy exists between Counterclaim-Defendants and Amneal over the listing of the '712 patent in the Orange Book.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 136 states legal conclusions to which no response is required. To the extent a further response is required, denied.

137. The '712 patent is not properly listed in the Orange Book.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 137 states legal conclusions to which no response is required. To the extent a further response is required, denied.

138. The '712 patent does not satisfy any of the statutory requirements for being listed in the Orange Book.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32).

Accordingly, no further response is required. To the extent a response is required, Paragraph 138 purports to characterize the '712 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, denied.

139. The '712 patent does not claim a method of using a drug.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 139 purports to characterize the '712 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, Plaintiffs admit that for purposes of this case, Plaintiffs do not contend that the '712 patent is properly listed in the Orange Book on the basis that it claims "an approved method of using ProAir® HFA." Otherwise denied.

140. The '712 patent does not claim an approved method of using ProAir® HFA.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 140 purports to characterize the '712 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, Plaintiffs admit that

for purposes of this case, Plaintiffs do not contend that the '712 patent is properly listed in the Orange Book on the basis that it claims "an approved method of using ProAir® HFA." Otherwise denied.

141. The '712 patent does not claim "the drug for which the applicant submitted" the ProAir® NDA.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 141 purports to characterize the '712 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, denied.

142. The '712 patent is not "a drug substance (active ingredient) patent."

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 142 purports to characterize the '712 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, Plaintiffs admit that for purposes of this case, Plaintiffs do not contend that the '712 patent is properly listed in the Orange Book on the basis that it is "a drug substance (active ingredient) patent." Otherwise denied.

143. The '712 patent does not claim a drug substance.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 143 purports to characterize the '712 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, denied.

144. The '712 patent does not claim an active ingredient.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 144 purports to characterize the '712 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, denied.

145. The '712 patent is not "a drug product (formulation or composition) patent."

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32).

Accordingly, no further response is required. To the extent a response is required, Paragraph 145 purports to characterize the '712 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, denied.

146. The '712 patent does not claim a drug product.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 146 purports to characterize the '712 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, denied.

147. The '712 patent does not claim a drug formulation.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 147 purports to characterize the '712 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, denied.

148. The '712 patent does not claim a drug composition.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024

injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 148 purports to characterize the '712 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, denied.

149. The '712 patent does not claim a drug.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 149 purports to characterize the '712 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, denied.

150. The FTC has already determined that the '712 patent is not properly listed in the Orange Book for ProAir® HFA.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, denied.

151. On or about November 7, 2023, the FTC sent a letter to Teva Branded bearing that date and informing Teva Branded that the FTC believes that the '712 patent is "improperly or

inaccurately listed in the Orange Book" for ProAir® HFA. A copy of the FTC Delisting Letter to Teva Branded is attached to this Answer, Affirmative Defenses, and Counterclaims as Exhibit L.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Plaintiffs state that there was an Exhibit L attached to Amneal's Answer, Affirmative Defenses, and Counterclaims and that Paragraph 151 purports to characterize Exhibit L, which speaks for itself. Plaintiffs admit that in November 2023, Plaintiffs received a letter from the FTC related to the Asserted Patents, a copy of which is attached as Exhibit L to Amneal's Answer, Affirmative Defenses, and Counterclaims. To the extent a further response is required, denied.

152. The FTC Delisting Letter indicates that the FTC has "submitted patent listing dispute communications to the FDA" regarding all five Asserted Patents, including the '712 patent.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Plaintiffs state that Paragraph 152 purports to characterize Exhibit L, which speaks for itself. To the extent a further response is required, Plaintiffs lack knowledge and information sufficient to form a belief about the truth of the allegations of Paragraph 152 and therefore deny them.

153. The '712 patent contains 19 claims, of which only claims 1, 18, and 19 are independent. A copy of the '712 patent is attached as Exhibit A to the Complaint.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 153 purports to characterize the '712 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, Plaintiffs admit that the '712 patent contains 19 claims and that claims 1, 18, and 19 are independent. Plaintiffs further admit that a copy of the '712 patent is attached as Exhibit A to Plaintiffs' First Amended Complaint. Otherwise denied.

154. Claim 1 of the '712 patent is directed to "[a] dose counter for a metered-dose inhaler" having several recited structural features.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 154 purports to characterize the '712 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, Plaintiffs respectfully refer the Court to the '712 patent for its actual language and complete content. Otherwise denied.

155. Claim 1 of the '712 patent recites as follows:

> A dose counter for a metered-dose inhaler, the counter comprising:
>
> an actuator; a rotary gear; a driver for driving the rotary gear in a step-wise fashion in response to displacement of the actuator, the rotary gear comprising a wheel mounted on a spindle which wheel having a plurality of ratchet teeth around its periphery;
>
> a pawl to prevent reverse rotation of the rotary gear; and a display coupled to the rotary gear, the display having a visible array of incrementing integers on a surface thereof indexable by a single integer in response to each step of the step-wise rotary motion of the rotary gear;
>
> wherein the pawl comprises at least two ratchet teeth each for engaging with the ratchet teeth of the wheel to prevent reverse rotation of the rotary gear, the at least two ratchet teeth being radially spaced such that one of the at least two ratchet teeth of the pawl engages with the ratchet teeth of the wheel following each step of the step-wise rotary motion of the rotary gear.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 155 purports to characterize the '712 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, Plaintiffs admit that Paragraph 155 includes the language of claim 1 of the '712 patent. Otherwise denied.

156. Claim 18 of the '712 patent is directed to "[t]he use of a dose counter for preventing miscounting in a metered dose inhaler," in which the dose counter has several recited structural features.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district

court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 156 purports to characterize the '712 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, Plaintiffs respectfully refer the Court to the '712 patent for its actual language and complete content. Otherwise denied.

157. Claim 18 of the '712 patent recites as follows:

> The use of a dose counter for preventing miscounting in a metered dose inhaler, the dose counter comprising:
>
> an actuator; a rotary gear; a driver for driving the rotary gear in a step-wise fashion in response to displacement of the actuator, the rotary gear comprising a wheel mounted on a spindle which wheel having a plurality of ratchet teeth around its periphery;
>
> a pawl to prevent reverse rotation of the rotary gear; and a display coupled to the rotary gear, the display having a visible array of incrementing integers on a surface thereof indexable by a single integer in response to each step of the step-wise rotary motion of the rotary gear;
>
> wherein the pawl comprises at least two ratchet teeth each for engaging with the ratchet teeth of the wheel to prevent reverse rotation of the rotary gear, the at least two ratchet teeth being radially spaced such that one of the at least two ratchet teeth of the pawl engages with the ratchet teeth of the wheel following each step of the step-wise rotary motion of the rotary gear.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 157 purports to characterize the '712 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, Plaintiffs admit that Paragraph 157 includes the language of claim 18 of the '712 patent. Otherwise denied.

158. Claim 19 of the '712 patent is directed to "[t]he use of a dose counter for preventing undercounting in a metered dose inhaler," in which the dose counter has several recited structural features.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 158 purports to characterize the '712 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, Plaintiffs respectfully refer the Court to the '712 patent for its actual language and complete content. Otherwise denied.

159. Claim 19 of the '712 patent recites as follows:

> The use of a dose counter for preventing undercounting in a metered dose inhaler, the dose counter comprising:
>
> an actuator; a rotary gear; a driver for driving the rotary gear in a step-wise fashion in response to displacement of the actuator, the rotary gear comprising a wheel mounted on a spindle which wheel having a plurality of ratchet teeth around its periphery;
>
> a pawl to prevent reverse rotation of the rotary gear; and a display coupled to the rotary gear, the display having a visible array of incrementing integers on a surface thereof indexable by a single integer in response to each step of the step-wise rotary motion of the rotary gear;
>
> wherein the pawl comprises at least two ratchet teeth each for engaging with the ratchet teeth of the wheel to prevent reverse rotation of the rotary gear, the at least two ratchet teeth being radially spaced such that one of the at least two ratchet teeth of the pawl engages with the ratchet teeth of the wheel following each step of the step-wise rotary motion of the rotary gear.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024

injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 159 purports to characterize the '712 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, Plaintiffs admit that Paragraph 159 includes the language of claim 19 of the '712 patent. Otherwise denied.

160. None of the claims of the '712 patent recite a drug, a drug substance, an active ingredient, a drug product, a drug formulation, a drug composition, a method of using a drug, a method of using a drug product, a method of using a drug substance, a method of using an active pharmaceutical ingredient, a method of using a drug formulation, a method of using a drug composition, or a method of using a pharmaceutical formulation.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 160 purports to characterize the '712 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, Plaintiffs respectfully refer the Court to the '712 patent for its actual language and complete content. Otherwise denied.

161. None of the claims of the '712 patent recite "albuterol," "albuterol sulfate," "propellant HFA-134a," or "ethanol."

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit

for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 161 purports to characterize the '712 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, Plaintiffs respectfully refer the Court to the '712 patent for its actual language and complete content. Otherwise denied.

162. The '712 patent does not recite any of the following words or phrases: "albuterol," "albuterol sulfate," "HFA-134a," "ethanol," "ingredient," "formulation," or "bronchospasm."

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 162 purports to characterize the '712 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, Plaintiffs respectfully refer the Court to the '712 patent for its actual language and complete content. Otherwise denied.

163. Other than reciting the name of the assignee "Ivax Pharmaceuticals Ireland," the '712 patent does not recite the words "pharmaceutical," "pharmaceuticals," "pharmacological," "pharmacy," or "pharmaceutics."

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32).

Accordingly, no further response is required. To the extent a response is required, Paragraph 163 purports to characterize the '712 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, Plaintiffs respectfully refer the Court to the '712 patent for its actual language and complete content. Otherwise denied.

164. In addition to being listed in the Orange Book entry for ProAir® HFA, the '712 patent is listed in the Orange Book entry for QVAR Redihaler.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Plaintiffs admit that the '712 patent is listed in connection with ProAir® HFA (NDA No. 021457) and in connection with QVAR RediHaler® (NDA No. 207921) in the Orange Book. Otherwise denied.

COUNT 2:
DECLARATORY JUDGMENT
REQUIRING DELISTING OF U.S. PATENT NO. 9,463,289

165. Amneal incorporates and re-alleges each of the foregoing paragraphs 1–164 of its Counterclaims, as if fully set forth herein.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Plaintiffs

incorporate by reference their responses to each of the foregoing paragraphs 1–164 of Amneal's Counterclaims as if fully set forth herein.

166. Amneal hereby seeks a declaration pursuant to 21 U.S.C. § 355(j)(5)(C)(ii) ordering Counterclaim-Defendants to delete or withdraw the '289 patent from the Orange Book.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Plaintiffs admit that Amneal purports to seek a declaration pursuant to 21 U.S.C. § 355(j)(5)(C)(ii) ordering Counterclaim-Defendants to delete or withdraw the '289 patent from the Orange Book. Otherwise denied.

167. An actual controversy exists between Counterclaim-Defendants and Amneal over the listing of the '289 patent in the Orange Book.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 167 states legal conclusions to which no response is required. To the extent a further response is required, denied.

168. The '289 patent is not properly listed in the Orange Book.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 168 states legal conclusions to which no response is required. To the extent a further response is required, denied.

169. The '289 patent does not satisfy any of the statutory requirements for being listed in the Orange Book.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 169 purports to characterize the '289 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, denied.

170. The '289 patent does not claim a method of using a drug.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32).

Accordingly, no further response is required. To the extent a response is required, Paragraph 170 purports to characterize the '289 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, Plaintiffs admit that for purposes of this case, Plaintiffs do not contend that the '289 patent is properly listed in the Orange Book on the basis that it claims "an approved method of using ProAir® HFA." Otherwise denied.

171. The '289 patent does not claim an approved method of using ProAir® HFA.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 171 purports to characterize the '289 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, Plaintiffs admit that for purposes of this case, Plaintiffs do not contend that the '289 patent is properly listed in the Orange Book on the basis that it claims "an approved method of using ProAir® HFA." Otherwise denied.

172. The '289 patent does not claim "the drug for which the applicant submitted" the ProAir® NDA.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district

court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 172 purports to characterize the '289 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, denied.

173. The '289 patent is not "a drug substance (active ingredient) patent."

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 173 purports to characterize the '289 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, Plaintiffs admit that for purposes of this case, Plaintiffs do not contend that the '289 patent is properly listed in the Orange Book on the basis that it is "a drug substance (active ingredient) patent." Otherwise denied.

174. The '289 patent does not claim a drug substance.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 174 purports to characterize the '289 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, denied.

175. The ’289 patent does not claim an active ingredient.

ANSWER: On June 10, 2024, the district court granted Amneal’s Motion for Judgment on the Pleadings as to Amneal’s Counterclaim Counts 1–5 (D.E. 88). The Court’s June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that “the district court’s June 10, 2024 order is stayed until further notice of this court” (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 175 purports to characterize the ’289 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, denied.

176. The ’289 patent is not “a drug product (formulation or composition) patent.”

ANSWER: On June 10, 2024, the district court granted Amneal’s Motion for Judgment on the Pleadings as to Amneal’s Counterclaim Counts 1–5 (D.E. 88). The Court’s June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that “the district court’s June 10, 2024 order is stayed until further notice of this court” (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 176 purports to characterize the ’289 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, denied.

177. The ’289 patent does not claim a drug product.

ANSWER: On June 10, 2024, the district court granted Amneal’s Motion for Judgment on the Pleadings as to Amneal’s Counterclaim Counts 1–5 (D.E. 88). The Court’s June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that “the district court’s June 10, 2024 order is stayed until further notice of this court” (Fed. Cir., ECF No. 32).

Accordingly, no further response is required. To the extent a response is required, Paragraph 177 purports to characterize the '289 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, denied.

178. The '289 patent does not claim a drug formulation.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 178 purports to characterize the '289 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, denied.

179. The '289 patent does not claim a drug composition.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 179 purports to characterize the '289 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, denied.

180. The '289 patent does not claim a drug.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024

injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 180 purports to characterize the '289 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, denied.

181. The FTC has already determined that the '289 patent is not properly listed in the Orange Book for ProAir® HFA.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, denied.

182. On or about November 7, 2023, the FTC sent a letter to Teva Branded bearing that date and informing Teva Branded that the FTC believes that the '289 patent is "improperly or inaccurately listed in the Orange Book" for ProAir® HFA. A copy of the FTC Delisting Letter to Teva Branded is attached to this Answer, Affirmative Defenses, and Counterclaims as Exhibit L.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Plaintiffs state that there was an Exhibit L attached to Amneal's Answer, Affirmative Defenses, and Counterclaims and that Paragraph 182 purports to characterize Exhibit L, which speaks for itself.

Plaintiffs admit that in November 2023, Plaintiffs received a letter from the FTC related to the Asserted Patents, a copy of which is attached as Exhibit L to Amneal's Answer, Affirmative Defenses, and Counterclaims. To the extent a further response is required, denied.

183. The FTC Delisting Letter indicates that the FTC has "submitted patent listing dispute communications to the FDA" regarding all five Asserted Patents, including the '289 patent.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Plaintiffs state that Paragraph 183 purports to characterize Exhibit L, which speaks for itself. To the extent a further response is required, Plaintiffs lack knowledge and information sufficient to form a belief about the truth of the allegations of Paragraph 183 and therefore deny them.

184. The '289 patent contains 10 claims, of which only claim 1 is independent. A copy of the '289 patent is attached as Exhibit B to the Complaint.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 184 purports to characterize the '289 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, Plaintiffs admit that the '289 patent contains 10 claims and that claim 1 is independent. Plaintiffs further admit that a

copy of the '289 patent is attached as Exhibit B to Plaintiffs' First Amended Complaint. Otherwise denied.

185. Claim 1 of the '289 patent recites:

> An inhaler for metered dose inhalation, the inhaler comprising:
> a main body having a canister housing,
> a medicament canister, which is moveable relative to the canister housing and retained in a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister, and
> a dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister,
> wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall, and
> wherein the canister housing has a longitudinal axis X which passes through the center of the central outlet port,
> the inner wall canister support formation, the actuation member, and the central outlet port lying in a common plane coincident with the longitudinal axis X.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 185 purports to characterize the '289 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, Plaintiffs admit that Paragraph 185 includes the language of claim 1 of the '289 patent. Otherwise denied.

186. None of the claims of the '289 patent recite a drug, a drug substance, an active ingredient, a drug product, a drug formulation, a drug composition, a method of using a drug, a method of using a drug product, a method of using a drug substance, a method of using an active

pharmaceutical ingredient, a method of using a drug formulation, a method of using a drug composition, or a method of using a pharmaceutical formulation.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 186 purports to characterize the '289 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, Plaintiffs respectfully refer the Court to the '289 patent for its actual language and complete content. Otherwise denied.

187. None of the claims of the '289 patent recite "albuterol," "albuterol sulfate," "propellant HFA-134a," or "ethanol."

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 187 purports to characterize the '289 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, Plaintiffs respectfully refer the Court to the '289 patent for its actual language and complete content. Otherwise denied.

188. The '289 patent does not recite any of the following words or phrases: "albuterol," "albuterol sulfate," "HFA-134a," "ethanol," "ingredient," "formulation," or "bronchospasm."

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 188 purports to characterize the '289 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, Plaintiffs respectfully refer the Court to the '289 patent for its actual language and complete content. Otherwise denied.

189. Other than reciting the name of the assignees and applicants "Ivax Pharmaceuticals Ireland," and "Teva Pharmaceuticals Ireland," the '289 patent does not recite the words "pharmaceutical," "pharmaceuticals," "pharmacological," "pharmacy," or "pharmaceutics."

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 189 purports to characterize the '289 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, Plaintiffs respectfully refer the Court to the '289 patent for its actual language and complete content. Otherwise denied.

190. In addition to being listed in the Orange Book entry for ProAir® HFA, the '289 patent is listed in the Orange Book entries for (1) QVAR40 and (2) QVAR80.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024

injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Plaintiffs admit that the '289 patent is listed in connection with ProAir® HFA (NDA No. 021457), in connection with QVAR® 40 (NDA No. 020911), and in connection with QVAR® 80 (NDA No. 020911) in the Orange Book. Otherwise denied.

COUNT 3:
DECLARATORY JUDGMENT
REQUIRING DELISTING OF U.S. PATENT NO. 9,808,587

191. Amneal incorporates and re-alleges each of the foregoing paragraphs 1–190 of its Counterclaims, as if fully set forth herein.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Plaintiffs incorporate by reference their responses to each of the foregoing paragraphs 1–190 of Amneal's Counterclaims as if fully set forth herein.

192. Amneal hereby seeks a declaration pursuant to 21 U.S.C. § 355(j)(5)(C)(ii) ordering Counterclaim-Defendants to delete or withdraw the '587 patent from the Orange Book.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district

court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Plaintiffs admit that Amneal purports to seek a declaration pursuant to 21 U.S.C. § 355(j)(5)(C)(ii) ordering Counterclaim-Defendants to delete or withdraw the '587 patent from the Orange Book. Otherwise denied.

193. An actual controversy exists between Counterclaim-Defendants and Amneal over the listing of the '587 patent in the Orange Book.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 193 states legal conclusions to which no response is required. To the extent a further response is required, denied.

194. The '587 patent is not properly listed in the Orange Book.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 194 states legal conclusions to which no response is required. To the extent a further response is required, denied.

195. The ’587 patent does not satisfy any of the statutory requirements for being listed in the Orange Book.

ANSWER: On June 10, 2024, the district court granted Amneal’s Motion for Judgment on the Pleadings as to Amneal’s Counterclaim Counts 1–5 (D.E. 88). The Court’s June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that “the district court’s June 10, 2024 order is stayed until further notice of this court” (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 195 purports to characterize the ’587 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, denied.

196. The ’587 patent does not claim a method of using a drug.

ANSWER: On June 10, 2024, the district court granted Amneal’s Motion for Judgment on the Pleadings as to Amneal’s Counterclaim Counts 1–5 (D.E. 88). The Court’s June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that “the district court’s June 10, 2024 order is stayed until further notice of this court” (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 196 purports to characterize the ’587 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, Plaintiffs admit that for purposes of this case, Plaintiffs do not contend that the ’587 patent is properly listed in the Orange Book on the basis that it claims “an approved method of using ProAir® HFA.” Otherwise denied.

197. The ’587 patent does not claim an approved method of using ProAir® HFA.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 197 purports to characterize the '587 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, Plaintiffs admit that for purposes of this case, Plaintiffs do not contend that the '587 patent is properly listed in the Orange Book on the basis that it claims "an approved method of using ProAir® HFA." Otherwise denied.

198. The '587 patent does not claim "the drug for which the applicant submitted" the ProAir® NDA.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 198 purports to characterize the '587 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, denied.

199. The '587 patent is not "a drug substance (active ingredient) patent."

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024

injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 199 purports to characterize the '587 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, Plaintiffs admit that for purposes of this case, Plaintiffs do not contend that the '587 patent is properly listed in the Orange Book on the basis that it is "a drug substance (active ingredient) patent." Otherwise denied.

200. The '587 patent does not claim a drug substance.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 200 purports to characterize the '587 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, denied.

201. The '587 patent does not claim an active ingredient.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 201

purports to characterize the '587 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, denied.

202. The '587 patent is not "a drug product (formulation or composition) patent."

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 202 purports to characterize the '587 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, denied.

203. The '587 patent does not claim a drug product.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 203 purports to characterize the '587 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, denied.

204. The '587 patent does not claim a drug formulation.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit

for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 204 purports to characterize the '587 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, denied.

205. The '587 patent does not claim a drug composition.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 205 purports to characterize the '587 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, denied.

206. The '587 patent does not claim a drug.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 206 purports to characterize the '587 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, denied.

207. The FTC has already determined that the '587 patent is not properly listed in the Orange Book for ProAir® HFA.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, denied.

208. On or about November 7, 2023, the FTC sent a letter to Teva Branded bearing that date and informing Teva Branded that the FTC believes that the '587 patent is "improperly or inaccurately listed in the Orange Book" for ProAir® HFA. A copy of the FTC Delisting Letter to Teva Branded is attached to this Answer, Affirmative Defenses, and Counterclaims as Exhibit L.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Plaintiffs state that there was an Exhibit L attached to Amneal's Answer, Affirmative Defenses, and Counterclaims and that Paragraph 208 purports to characterize Exhibit L, which speaks for itself. Plaintiffs admit that in November 2023, Plaintiffs received a letter from the FTC related to the Asserted Patents, a copy of which is attached as Exhibit L to Amneal's Answer, Affirmative Defenses, and Counterclaims. To the extent a further response is required, denied.

209. The FTC Delisting Letter indicates that the FTC has "submitted patent listing dispute communications to the FDA" regarding all five Asserted Patents, including the '587 patent.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Plaintiffs state that Paragraph 209 purports to characterize Exhibit L, which speaks for itself. To the extent a further response is required, Plaintiffs lack knowledge and information sufficient to form a belief about the truth of the allegations of Paragraph 209 and therefore deny them.

210. The '587 patent contains 22 claims, of which only claims 1, 12, and 13 are independent. A copy of the '587 patent is attached as Exhibit C to the Complaint.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 210 purports to characterize the '587 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, Plaintiffs admit that the '587 patent contains 22 claims and that claims 1, 12, and 13 are independent. Plaintiffs further admit that a copy of the '587 patent is attached as Exhibit C to Plaintiffs' First Amended Complaint. Otherwise denied.

211. Claim 1 of the '587 patent recites:

> An inhaler for metered dose inhalation, the inhaler comprising:

> a main body having a canister housing,
> a medicament canister, which is moveable relative to the canister housing and retained in a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister, and
> a dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister,
> wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall,
> wherein the canister housing has a longitudinal axis X which passes through the center of the central outlet port, and
> wherein the first inner wall canister support formation, the actuation member, and the central outlet port lie in a common plane coincident with the longitudinal axis X such that the first inner wall canister support formation protects against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 211 purports to characterize the '587 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, Plaintiffs admit that Paragraph 211 includes the language of claim 1 of the '587 patent. Otherwise denied.

212. Claim 12 of the '587 patent recites:

> An inhaler for metered dose inhalation, the inhaler comprising:
> a main body having a canister housing,
> a medicament canister, which is moveable relative to the canister housing and retained in a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister, and

> a dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister,
>
> wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall,
>
> wherein the canister housing has a longitudinal axis X which passes through the center of the central outlet port, and
>
> wherein the first inner wall canister support formation, the actuation member, and the central outlet port lie in a common plane coincident with the longitudinal axis X such that the first inner wall canister support formation protects against dose count errors by reducing rocking of the medicament canister towards or away from the actuation member.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 212 purports to characterize the '587 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, Plaintiffs admit that Paragraph 212 includes the language of claim 12 of the '587 patent. Otherwise denied.

213. Claim 13 of the '587 patent recites:

> An inhaler for metered dose inhalation, the inhaler comprising:
>
> a main body having a canister housing,
>
> a medicament canister retained in the canister housing and movable relative thereto, and a dose counter, the dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister,
>
> wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall,
>
> wherein the canister housing has an aperture formed in the

inner wall through which the portion of the actuation member extends, and

wherein the first inner wall canister support formation extends from the main surface of the inner wall to the aperture.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 213 purports to characterize the '587 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, Plaintiffs admit that Paragraph 213 includes the language of claim 13 of the '587 patent. Otherwise denied.

214. None of the claims of the '587 patent recite a drug, a drug substance, an active ingredient, a drug product, a drug formulation, a drug composition, a method of using a drug, a method of using a drug product, a method of using a drug substance, a method of using an active pharmaceutical ingredient, a method of using a drug formulation, a method of using a drug composition, or a method of using a pharmaceutical formulation.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 214 purports to characterize the '587 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, Plaintiffs respectfully refer the Court to the '587 patent for its actual language and complete content. Otherwise denied.

215. None of the claims of the '587 patent recite "albuterol," "albuterol sulfate," "propellant HFA-134a," or "ethanol."

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 215 purports to characterize the '587 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, Plaintiffs respectfully refer the Court to the '587 patent for its actual language and complete content. Otherwise denied.

216. The '587 patent does not recite any of the following words or phrases: "albuterol," "albuterol sulfate," "HFA-134a," "ethanol," "ingredient," "formulation," or "bronchospasm."

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 216 purports to characterize the '587 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, Plaintiffs respectfully refer the Court to the '587 patent for its actual language and complete content. Otherwise denied.

217. Other than reciting the name of the assignees and applicants "Ivax Pharmaceuticals Ireland," and "Teva Pharmaceuticals Ireland," the '587 patent does not recite the words "pharmaceutical," "pharmaceuticals," "pharmacological," "pharmacy," or "pharmaceutics."

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 217 purports to characterize the '587 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, Plaintiffs respectfully refer the Court to the '587 patent for its actual language and complete content. Otherwise denied.

218. In addition to being listed in the Orange Book entry for ProAir® HFA, the '587 patent is listed in the Orange Book entries for (1) QVAR40 and (2) QVAR80.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Plaintiffs admit that the '587 patent is listed in connection with ProAir® HFA (NDA No. 021457), in connection with QVAR® 40 (NDA No. 020911), and in connection with QVAR® 80 (NDA No. 020911) in the Orange Book. Otherwise denied.

COUNT 4:
DECLARATORY JUDGMENT
REQUIRING DELISTING OF U.S. PATENT NO. 10,561,808

219. Amneal incorporates and re-alleges each of the foregoing paragraphs 1–218 of its Counterclaims, as if fully set forth herein.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Plaintiffs incorporate by reference their responses to each of the foregoing paragraphs 1–218 of Amneal's Counterclaims as if fully set forth herein.

220. Amneal hereby seeks a declaration pursuant to 21 U.S.C. § 355(j)(5)(C)(ii) ordering Counterclaim-Defendants to delete or withdraw the '808 patent from the Orange Book.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Plaintiffs admit that Amneal purports to seek a declaration pursuant to 21 U.S.C. § 355(j)(5)(C)(ii) ordering Counterclaim-Defendants to delete or withdraw the '808 patent from the Orange Book. Otherwise denied.

221. An actual controversy exists between Counterclaim-Defendants and Amneal over the listing of the '808 patent in the Orange Book.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district

court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 221 states legal conclusions to which no response is required. To the extent a further response is required, denied.

222. The '808 patent is not properly listed in the Orange Book.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 222 states legal conclusions to which no response is required. To the extent a further response is required, denied.

223. The '808 patent does not satisfy any of the statutory requirements for being listed in the Orange Book.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 223 purports to characterize the '808 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, denied.

224. The '808 patent does not claim a method of using a drug.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 224 purports to characterize the '808 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, Plaintiffs admit that for purposes of this case, Plaintiffs do not contend that the '808 patent is properly listed in the Orange Book on the basis that it claims "an approved method of using ProAir® HFA." Otherwise denied.

225. The '808 patent does not claim an approved method of using ProAir® HFA.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 225 purports to characterize the '808 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, Plaintiffs admit that for purposes of this case, Plaintiffs do not contend that the '808 patent is properly listed in the Orange Book on the basis that it claims "an approved method of using ProAir® HFA." Otherwise denied.

226. The ’808 patent does not claim “the drug for which the applicant submitted” the ProAir® NDA.

ANSWER: On June 10, 2024, the district court granted Amneal’s Motion for Judgment on the Pleadings as to Amneal’s Counterclaim Counts 1–5 (D.E. 88). The Court’s June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that “the district court’s June 10, 2024 order is stayed until further notice of this court” (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 226 purports to characterize the ’808 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, denied.

227. The ’808 patent is not “a drug substance (active ingredient) patent.”

ANSWER: On June 10, 2024, the district court granted Amneal’s Motion for Judgment on the Pleadings as to Amneal’s Counterclaim Counts 1–5 (D.E. 88). The Court’s June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that “the district court’s June 10, 2024 order is stayed until further notice of this court” (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 227 purports to characterize the ’808 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, Plaintiffs admit that for purposes of this case, Plaintiffs do not contend that the ’808 patent is properly listed in the Orange Book on the basis that it is “a drug substance (active ingredient) patent.” Otherwise denied.

228. The ’808 patent does not claim a drug substance.

ANSWER: On June 10, 2024, the district court granted Amneal’s Motion for Judgment on the Pleadings as to Amneal’s Counterclaim Counts 1–5 (D.E. 88). The Court’s June 10, 2024

injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 228 purports to characterize the '808 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, denied.

229. The '808 patent does not claim an active ingredient.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 229 purports to characterize the '808 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, denied.

230. The '808 patent is not "a drug product (formulation or composition) patent."

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 230 purports to characterize the '808 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, denied.

231. The ’808 patent does not claim a drug product.

ANSWER: On June 10, 2024, the district court granted Amneal’s Motion for Judgment on the Pleadings as to Amneal’s Counterclaim Counts 1–5 (D.E. 88). The Court’s June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that “the district court’s June 10, 2024 order is stayed until further notice of this court” (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 231 purports to characterize the ’808 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, denied.

232. The ’808 patent does not claim a drug formulation.

ANSWER: On June 10, 2024, the district court granted Amneal’s Motion for Judgment on the Pleadings as to Amneal’s Counterclaim Counts 1–5 (D.E. 88). The Court’s June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that “the district court’s June 10, 2024 order is stayed until further notice of this court” (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 232 purports to characterize the ’808 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, denied.

233. The ’808 patent does not claim a drug composition.

ANSWER: On June 10, 2024, the district court granted Amneal’s Motion for Judgment on the Pleadings as to Amneal’s Counterclaim Counts 1–5 (D.E. 88). The Court’s June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that “the district court’s June 10, 2024 order is stayed until further notice of this court” (Fed. Cir., ECF No. 32).

Accordingly, no further response is required. To the extent a response is required, Paragraph 233 purports to characterize the '808 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, denied.

234. The '808 patent does not claim a drug.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 234 purports to characterize the '808 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, denied.

235. The FTC has already determined that the '808 patent is not properly listed in the Orange Book for ProAir® HFA.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, denied.

236. On or about November 7, 2023, the FTC sent a letter to Teva Branded bearing that date and informing Teva Branded that the FTC believes that the '808 patent is "improperly or inaccurately listed in the Orange Book" for ProAir® HFA. A copy of the FTC Delisting Letter to Teva Branded is attached to this Answer, Affirmative Defenses, and Counterclaims as Exhibit L.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024

injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Plaintiffs state that there was an Exhibit L attached to Amneal's Answer, Affirmative Defenses, and Counterclaims and that Paragraph 236 purports to characterize Exhibit L, which speaks for itself. Plaintiffs admit that in November 2023, Plaintiffs received a letter from the FTC related to the Asserted Patents, a copy of which is attached as Exhibit L to Amneal's Answer, Affirmative Defenses, and Counterclaims. To the extent a further response is required, denied.

237. The FTC Delisting Letter indicates that the FTC has "submitted patent listing dispute communications to the FDA" regarding all five Asserted Patents, including the '808 patent.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Plaintiffs state that there was an Exhibit L attached to Amneal's Answer, Affirmative Defenses, and Counterclaims and that Paragraph 237 purports to characterize Exhibit L, which speaks for itself. To the extent a further response is required, Plaintiffs lack knowledge and information sufficient to form a belief about the truth of the allegations of Paragraph 237 and therefore deny them.

238. The '808 patent contains 29 claims, of which only claim 1 is independent. A copy of the '808 patent is attached as Exhibit D to the Complaint.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024

injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 238 purports to characterize the '808 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, Plaintiffs admit that the '808 patent contains 29 claims and that claim 1 is independent. Plaintiffs further admit that a copy of the '808 patent is attached as Exhibit D to Plaintiffs' First Amended Complaint. Otherwise denied.

239. Claim 1 of the '808 patent recites:

> A dose counter for an inhaler, the dose counter having
> a counter display arranged to indicate dosage information,
> a drive system arranged to move the counter display incrementally in a first direction from a first station to a second station in response to actuation input,
> wherein a regulator is provided which is arranged to act upon the counter display at the first station to regulate motion of the counter display at the first station to incremental movements.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 239 purports to characterize the '808 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, Plaintiffs admit that Paragraph 239 includes the language of claim 1 of the '808 patent. Otherwise denied.

240. None of the claims of the '808 patent recite a drug, a drug substance, an active ingredient, a drug product, a drug formulation, a drug composition, a method of using a drug, a method of using a drug product, a method of using a drug substance, a method of using an active pharmaceutical ingredient, a method of using a drug formulation, a method of using a drug composition, or a method of using a pharmaceutical formulation.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 240 purports to characterize the '808 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, Plaintiffs respectfully refer the Court to the '808 patent for its actual language and complete content. Otherwise denied.

241. None of the claims of the '808 patent recite "albuterol," "albuterol sulfate," "propellant HFA-134a," or "ethanol."

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 241 purports to characterize the '808 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, Plaintiffs respectfully refer the Court to the '808 patent for its actual language and complete content. Otherwise denied.

242. The '808 patent does not recite any of the following words or phrases: "albuterol," "albuterol sulfate," "HFA-134a," "ethanol," "ingredient," "formulation," or "bronchospasm."

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 242 purports to characterize the '808 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, Plaintiffs respectfully refer the Court to the '808 patent for its actual language and complete content. Otherwise denied.

243. Other than reciting the name of the assignees and applicants "Ivax Pharmaceuticals Ireland," and "Teva Pharmaceuticals Ireland," the '808 patent does not recite the words "pharmaceutical," "pharmaceuticals," "pharmacological," "pharmacy," or "pharmaceutics."

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 243 purports to characterize the '808 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, Plaintiffs respectfully refer the Court to the '808 patent for its actual language and complete content. Otherwise denied.

244. In addition to being listed in the Orange Book entry for ProAir® HFA, the '808 patent is listed in the Orange Book entries for (1) QVAR Redihaler, (2) AirDuo Digihaler, (3) AirDuo Respiclick, (4) ArmonAir Digihaler, (5) ArmonAir Respiclick, (6) ProAir Digihaler, (7) ProAir Respiclick, (8) QVAR40, and (9) QVAR80.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Plaintiffs admit that the '889 patent is listed (1) in connection with ProAir® HFA (NDA No. 021457), (2) in connection with QVAR RediHaler® (NDA No. 207921), (3) in connection with AirDuo® Digihaler® (NDA No. 208799), (4) in connection with AirDuo RespiClick® (NDA No. 208799), (5) in connection with ArmonAir® Digihaler® (NDA No. 208798), (6) in connection with ArmonAir RespiClick® (NDA No. 208798), (7) in connection with ProAir® Digihaler® (NDA No. 205636), (8) in connection with ProAir RespiClick® (NDA No. 205636), (9) in connection with QVAR® 40 (NDA No. 020911), and (10) in connection with QVAR® 80 (NDA No. 020911) in the Orange Book. Otherwise denied.

COUNT 5:
DECLARATORY JUDGMENT
REQUIRING DELISTING OF U.S. PATENT NO. 11,395,889

245. Amneal incorporates and re-alleges each of the foregoing paragraphs 1–244 of its Counterclaims, as if fully set forth herein.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Plaintiffs

incorporate by reference their responses to each of the foregoing paragraphs 1–244 of Amneal's Counterclaims as if fully set forth herein.

246. Amneal hereby seeks a declaration pursuant to 21 U.S.C. §355(j)(5)(C)(ii) ordering Counterclaim-Defendants to delete or withdraw the '889 patent from the Orange Book.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Plaintiffs admit that Amneal purports to seek a declaration pursuant to 21 U.S.C. § 355(j)(5)(C)(ii) ordering Counterclaim-Defendants to delete or withdraw the '889 patent from the Orange Book. Otherwise denied.

247. An actual controversy exists between Counterclaim-Defendants and Amneal over the listing of the '889 patent in the Orange Book.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 247 states legal conclusions to which no response is required. To the extent a further response is required, denied.

248. The '889 patent is not properly listed in the Orange Book.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 248 states legal conclusions to which no response is required. To the extent a further response is required, denied.

249. The '889 patent does not satisfy any of the statutory requirements for being listed in the Orange Book.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 249 purports to characterize the '889 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, denied.

250. The '889 patent does not claim a method of using a drug.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32).

Accordingly, no further response is required. To the extent a response is required, Paragraph 250 purports to characterize the '889 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, Plaintiffs admit that for purposes of this case, Plaintiffs do not contend that the '889 patent is properly listed in the Orange Book on the basis that it claims "an approved method of using ProAir® HFA." Otherwise denied.

251. The '889 patent does not claim an approved method of using ProAir® HFA.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 251 purports to characterize the '889 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, Plaintiffs admit that for purposes of this case, Plaintiffs do not contend that the '889 patent is properly listed in the Orange Book on the basis that it claims "an approved method of using ProAir® HFA." Otherwise denied.

252. The '889 patent does not claim "the drug for which the applicant submitted" the ProAir® NDA.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district

court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 252 purports to characterize the '889 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, denied.

253. The '889 patent is not "a drug substance (active ingredient) patent."

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 253 purports to characterize the '889 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, Plaintiffs admit that for purposes of this case, Plaintiffs do not contend that the '889 patent is properly listed in the Orange Book on the basis that it is "a drug substance (active ingredient) patent." Otherwise denied.

254. The '889 patent does not claim a drug substance.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 254 purports to characterize the '889 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, denied.

255. The ’889 patent does not claim an active ingredient.

ANSWER: On June 10, 2024, the district court granted Amneal’s Motion for Judgment on the Pleadings as to Amneal’s Counterclaim Counts 1–5 (D.E. 88). The Court’s June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that “the district court’s June 10, 2024 order is stayed until further notice of this court” (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 255 purports to characterize the ’889 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, denied.

256. The ’889 patent is not “a drug product (formulation or composition) patent.”

ANSWER: On June 10, 2024, the district court granted Amneal’s Motion for Judgment on the Pleadings as to Amneal’s Counterclaim Counts 1–5 (D.E. 88). The Court’s June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that “the district court’s June 10, 2024 order is stayed until further notice of this court” (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 256 purports to characterize the ’889 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, denied.

257. The ’889 patent does not claim a drug product.

ANSWER: On June 10, 2024, the district court granted Amneal’s Motion for Judgment on the Pleadings as to Amneal’s Counterclaim Counts 1–5 (D.E. 88). The Court’s June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that “the district court’s June 10, 2024 order is stayed until further notice of this court” (Fed. Cir., ECF No. 32).

Accordingly, no further response is required. To the extent a response is required, Paragraph 257 purports to characterize the '889 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, denied.

258. The '889 patent does not claim a drug formulation.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 258 purports to characterize the '889 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, denied.

259. The '889 patent does not claim a drug composition.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 259 purports to characterize the '889 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, denied.

260. The '889 patent does not claim a drug.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024

injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 260 purports to characterize the '889 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, denied.

261. The FTC has already determined that the '889 patent is not properly listed in the Orange Book for ProAir® HFA.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, denied.

262. On or about November 7, 2023, the FTC sent a letter to Teva Branded bearing that date and informing Teva Branded that the FTC believes that the '889 patent is "improperly or inaccurately listed in the Orange Book" for ProAir® HFA. A copy of the FTC Delisting Letter to Teva Branded is attached to this Answer, Affirmative Defenses, and Counterclaims as Exhibit L.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Plaintiffs state that there was an Exhibit L attached to Amneal's Answer, Affirmative Defenses, and Counterclaims and that Paragraph 262 purports to characterize Exhibit L, which speaks for itself.

Plaintiffs admit that in November 2023, Plaintiffs received a letter from the FTC related to the Asserted Patents, a copy of which is attached as Exhibit L to Amneal's Answer, Affirmative Defenses, and Counterclaims. To the extent a further response is required, denied.

263. The FTC Delisting Letter indicates that the FTC has "submitted patent listing dispute communications to the FDA" regarding all five Asserted Patents, including the '889 patent.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Plaintiffs state that Paragraph 263 purports to characterize Exhibit L, which speaks for itself. To the extent a further response is required, Plaintiffs lack knowledge and information sufficient to form a belief about the truth of the allegations of Paragraph 263 and therefore deny them.

264. The '889 patent contains 6 claims, of which only claim 1 is independent. A copy of the '889 patent is attached as Exhibit E to the Complaint.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 264 purports to characterize the '889 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, Plaintiffs admit that the '889 patent contains 6 claims and that claim 1 is independent. Plaintiffs further admit that a

copy of the ’889 patent is attached as Exhibit E to Plaintiffs’ First Amended Complaint. Otherwise denied.

265. Claim 1 of the ’889 patent recites:

> An incremental dose counter for a metered dose inhaler having a body arranged to retain a canister for movement of the canister relative thereto, the incremental dose counter having a main body,
>
> an actuator arranged to be driven and to drive an incremental output member in a count direction in response to canister motion, the actuator being configured to restrict motion of the output member in a direction opposite to the count direction, such that the actuator acts as an anti-back drive member when the actuator is in a non-depressed position, and
>
> wherein the incremental dose counter further comprises a second anti-back member configured to restrict motion of the output member in a direction opposite to the count direction when the actuator is disengaged from the output member by a bump surface.

ANSWER: On June 10, 2024, the district court granted Amneal’s Motion for Judgment on the Pleadings as to Amneal’s Counterclaim Counts 1–5 (D.E. 88). The Court’s June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that “the district court’s June 10, 2024 order is stayed until further notice of this court” (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 265 purports to characterize the ’889 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, Plaintiffs admit that Paragraph 265 includes the language of claim 1 of the ’889 patent. Otherwise denied.

266. None of the claims of the ’889 patent recite a drug, a drug substance, an active ingredient, a drug product, a drug formulation, a drug composition, a method of using a drug, a method of using a drug product, a method of using a drug substance, a method of using an active pharmaceutical ingredient, a method of using a drug formulation, a method of using a drug composition, or a method of using a pharmaceutical formulation.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 266 purports to characterize the '889 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, Plaintiffs respectfully refer the Court to the '889 patent for its actual language and complete content. Otherwise denied.

267. None of the claims of the '889 patent recite "albuterol," "albuterol sulfate," "propellant HFA-134a," or "ethanol."

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 267 purports to characterize the '889 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, Plaintiffs respectfully refer the Court to the '889 patent for its actual language and complete content. Otherwise denied.

268. The '889 patent does not recite any of the following words or phrases: "albuterol," "albuterol sulfate," "HFA-134a," "ethanol," "ingredient," "formulation," or "bronchospasm."

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit

for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 268 purports to characterize the '889 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, Plaintiffs respectfully refer the Court to the '889 patent for its actual language and complete content. Otherwise denied.

269. Other than reciting the name of the assignees and applicants "Ivax Pharmaceuticals Ireland," and "Teva Pharmaceuticals Ireland," the '889 patent does not recite the words "pharmaceutical," "pharmaceuticals," "pharmacological," "pharmacy," or "pharmaceutics."

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32). Accordingly, no further response is required. To the extent a response is required, Paragraph 269 purports to characterize the '889 patent, which speaks for itself, and states legal conclusions to which no response is required. To the extent a further response is required, Plaintiffs respectfully refer the Court to the '889 patent for its actual language and complete content. Otherwise denied.

270. In addition to being listed in the Orange Book entry for ProAir® HFA, the '889 patent is listed in the Orange Book entries for (1) QVAR Redihaler, (2) QVAR40, and (3) QVAR80.

ANSWER: On June 10, 2024, the district court granted Amneal's Motion for Judgment on the Pleadings as to Amneal's Counterclaim Counts 1–5 (D.E. 88). The Court's June 10, 2024 injunction Order (D.E. 88) was stayed to permit resolution of an application to the Federal Circuit for a stay pending appeal (D.E. 98). On July 10, 2024, the Federal Circuit ordered that "the district court's June 10, 2024 order is stayed until further notice of this court" (Fed. Cir., ECF No. 32).

Accordingly, no further response is required. To the extent a response is required, Plaintiffs admit that the '889 patent is listed in connection with ProAir® HFA (NDA No. 021457), in connection with QVAR RediHaler® (NDA No. 207921), in connection with QVAR® 40 (NDA No. 020911), and in connection with QVAR® 80 (NDA No. 020911) in the Orange Book. Otherwise denied.

COUNT 6:
UNLAWFUL MONOPOLIZATION – OVERALL SCHEME
IN VIOLATION OF THE SHERMAN ACT

271. Amneal incorporates and re-alleges each of the foregoing paragraphs 1–270 of its Counterclaims, as if fully set forth herein.

ANSWER: Plaintiffs incorporate by reference their responses to each of the foregoing paragraphs 1–270 of Amneal's Counterclaims as if fully set forth herein.

272. This claim arises under the Sherman Act, 15 U.S.C. § 2 and under the Clayton Act, 15 U.S.C. §§ 15 and 26.

ANSWER: Plaintiffs deny that they engaged in any anticompetitive or otherwise unlawful conduct. Paragraph 272 states legal conclusions and Amneal's opinion and characterization of counterclaims to which no response is required. To the extent a response is required, denied.

273. Counterclaim-Defendants are engaged in the development, commercialization, and marketing of prescription pharmaceutical products for the treatment of various disorders.

ANSWER: Plaintiffs admit that they develop, commercialize, and sell pharmaceutical products. To the extent there are remaining allegations in Paragraph 273, denied.

274. Amneal is a supplier of generic pharmaceutical products.

ANSWER: On information and belief, Defendants develop, manufacture, import, market, offer to sell, sell, and/or import generic drugs throughout the United States. Otherwise denied.

275. Amneal is a potential future direct competitor with Counterclaim-Defendants in the Relevant Market.

ANSWER: Paragraph 275 states legal conclusions, Amneal's opinion and characterization of counterclaims, and allegations subject to proof by expert testimony to which

no response is required. Plaintiffs state that, on information and belief, FDA has not approved the Amneal ANDA. Plaintiffs lack knowledge and information sufficient to form a belief regarding expected FDA approval of the Amneal ANDA and therefore deny any characterizations thereof. To the extent a response is required, denied.

276. On information and belief, Counterclaim-Defendants have a predominant share of the Relevant Market.

ANSWER: Paragraph 276 states legal conclusions, Amneal's opinion and characterization of counterclaims, and allegations subject to proof by expert testimony to which no response is required. To the extent a response is required, denied.

277. Counterclaim-Defendants have monopoly power in the Relevant Market.

ANSWER: Paragraph 277 states legal conclusions, Amneal's opinion and characterization of counterclaims, and allegations subject to proof by expert testimony to which no response is required. To the extent a response is required, denied.

278. Counterclaim-Defendants have exercised monopoly power in the Relevant Market.

ANSWER: Paragraph 278 states legal conclusions, Amneal's opinion and characterization of counterclaims, and allegations subject to proof by expert testimony to which no response is required. To the extent a response is required, denied.

279. Counterclaim-Defendants have the power to control prices and/or exclude competition in, or prevent entry into, the Relevant Market.

ANSWER: Paragraph 279 states legal conclusions, Amneal's opinion and characterization of counterclaims, and allegations subject to proof by expert testimony to which no response is required. To the extent a response is required, denied.

280. Substantial barriers to entry into the Relevant Market exist, including but not limited to, regulatory requirements and Counterclaim-Defendants' actions to delay and preclude entry into the Relevant Market, including but not limited to, improperly listing the Asserted Patents in the Orange Book and refusing to delist them, Counterclaim-Defendants' history of enforcement

efforts relating to patents listed in the Orange Book for ProAir® HFA, and Counterclaim-Defendants' present lawsuit for infringement of the Asserted Patents.

ANSWER: Paragraph 280 states legal conclusions, Amneal's opinion and characterization of counterclaims, and allegations subject to proof by expert testimony to which no response is required. To the extent a response is required, denied.

281. Counterclaim-Defendants knowingly and intentionally engaged in an anticompetitive and monopolistic scheme designed to injure or destroy competition in the Relevant Market by delaying market entry of the Amneal ANDA Products. Counterclaim-Defendants have baselessly and improperly wielded the Asserted Patents, including by improperly listing them in the Orange Book and asserting them in this case and others to trigger the automatic 30-month stay of FDA approval of ANDAs seeking approval to market generic versions of ProAir® HFA.

ANSWER: Plaintiffs deny that they engaged in any anticompetitive or otherwise unlawful conduct. Paragraph 281 states legal conclusions, Amneal's opinion and characterization of counterclaims, and allegations subject to proof by expert testimony to which no response is required. To the extent a response is required, denied.

282. These judicial proceedings are not a genuine effort by Counterclaim-Defendants to obtain an adjudication of a valid claim that is infringed, but rather were instituted to achieve an unlawful objective to the detriment of competition as a whole in the Relevant Market. The purpose of such action is to directly interfere with and harm Amneal's business and business relationships in the Relevant Market, and to forestall, frustrate, and prevent competition by Amneal.

ANSWER: Plaintiffs deny that they engaged in any anticompetitive or otherwise unlawful conduct. Paragraph 282 states legal conclusions, Amneal's opinion and characterization of counterclaims, and allegations subject to proof by expert testimony to which no response is required. To the extent a response is required, denied.

283. Counterclaim-Defendants engaged in this anticompetitive scheme and each lawsuit in order to consolidate, entrench, and enhance their monopolistic position in the Relevant Market and to stifle, delay, and eliminate competition and competitors with no economic, market, or competitive benefit.

ANSWER: Plaintiffs deny that they engaged in any anticompetitive or otherwise unlawful conduct. Paragraph 283 states legal conclusions, Amneal's opinion and characterization of

counterclaims, and allegations subject to proof by expert testimony to which no response is required. To the extent a response is required, denied.

284. Counterclaim-Defendants' scheme and actions have no procompetitive, business justification.

ANSWER: Paragraph 284 states legal conclusions, Amneal's opinion and characterization of counterclaims, and allegations subject to proof by expert testimony to which no response is required. To the extent a response is required, denied.

285. The patent infringement claims that Counterclaim-Defendants asserted in this lawsuit against Amneal are objectively baseless. No reasonable litigant could expect to secure favorable relief against Amneal on the merits because Amneal's ANDA Product does not infringe any of the claims of the Asserted Patents, and the Asserted Patents are invalid. The Asserted Patents are directed to devices or portions of devices, and the device that Amneal seeks approval to use in its ANDA is itself prior art to the Asserted Patents. Thus, the Asserted Patents cannot cover the device used by Amneal under the doctrine of equivalents, because that would necessarily ensnare the prior art. And if the Amneal device is deemed to literally infringe Asserted Patents, then axiomatically, the Asserted Patents would be invalid as anticipated.

ANSWER: Paragraph 285 states legal conclusions and Amneal's opinion and characterization of counterclaims to which no response is required. Paragraph 285 purports to characterize the Asserted Patents, which speak for themselves. To the extent a response is required, denied.

286. The patent infringement claims that Counterclaim-Defendants asserted in this lawsuit against Amneal are also objectively baseless because the Court does not properly have subject matter jurisdiction over this case.

ANSWER: Paragraph 286 states legal conclusions and Amneal's opinion and characterization of counterclaims to which no response is required. To the extent a response is required, denied.

287. Counterclaim-Defendants brought their patent infringement claims in bad faith, for an improper purpose, as a means of directly interfering with and harming Amneal's business, and to forestall, frustrate, and prevent competition by Amneal.

ANSWER: Plaintiffs deny that they engaged in any anticompetitive or otherwise unlawful conduct. Paragraph 287 states legal conclusions and Amneal's opinion and characterization of counterclaims to which no response is required. To the extent a response is required, denied.

288. Counterclaim-Defendants intentionally engaged in the exclusionary conduct alleged herein with the express purpose of achieving and maintaining monopoly power in the Relevant Market. Counterclaim-Defendants' lawsuit filed against Amneal alleging infringement of the Asserted Patents is both objectively and subjectively baseless, and constitutes sham litigation and bad faith enforcement of the Asserted Patents.

ANSWER: Plaintiffs deny that they engaged in any anticompetitive or otherwise unlawful conduct. Paragraph 288 states legal conclusions, Amneal's opinion and characterization of counterclaims, and allegations subject to proof by expert testimony to which no response is required. To the extent a response is required, denied.

289. Counterclaim-Defendants' anticompetitive activities are a direct, proximate, and reasonably foreseeable cause of Amneal's foreclosure from the Relevant Market and delay in entering the Relevant Market.

ANSWER: Plaintiffs deny that they engaged in any anticompetitive or otherwise unlawful conduct. Paragraph 289 states legal conclusions, Amneal's opinion and characterization of counterclaims, and allegations subject to proof by expert testimony to which no response is required. Plaintiffs state that, on information and belief, FDA has not approved the Amneal ANDA. Plaintiffs lack knowledge and information sufficient to form a belief regarding expected FDA approval of the Amneal ANDA and therefore deny any characterizations thereof. To the extent a response is required, denied.

290. But for Counterclaim-Defendants' actions alleged herein, Counterclaim-Defendants' market share in the Relevant Market would have decreased with the addition of Amneal in the Relevant Market, to the benefit of competition and consumers in the Relevant Market.

ANSWER: Plaintiffs deny that they engaged in any anticompetitive or otherwise unlawful conduct. Paragraph 290 states legal conclusions, Amneal's opinion and characterization of

counterclaims, and allegations subject to proof by expert testimony to which no response is required. Plaintiffs state that, on information and belief, FDA has not approved the Amneal ANDA. Plaintiffs lack knowledge and information sufficient to form a belief regarding expected FDA approval of the Amneal ANDA and therefore deny any characterizations thereof. To the extent a response is required, denied.

291. On information and belief, Counterclaim-Defendants have not acted to advance their position by competing on the merits in the Relevant Market, but solely to exclude potential competition from an alternate source in the Relevant Market.

ANSWER: Plaintiffs deny that they engaged in any anticompetitive or otherwise unlawful conduct. Paragraph 291 states legal conclusions, Amneal's opinion and characterization of counterclaims, and allegations subject to proof by expert testimony to which no response is required. To the extent a response is required, denied.

292. The effects of Counterclaim-Defendants' overall scheme, course of conduct and attempt to monopolize will be to unreasonably restrain trade and commerce in the Relevant Market, and permit Counterclaim-Defendants to monopolize the Relevant Market in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2, including the following effects, among others:

a. A delay of competition in the manufacture and sale of a generic equivalent of ProAir® HFA;

b. Purchasers of albuterol inhalants will be deprived of the benefits of free and open competition;

c. Payers and consumers will pay supracompetitive prices for albuterol inhalants;

d. Amneal will be deprived of revenues and profits it otherwise would have achieved but for Counterclaim-Defendants' illegal conduct.

ANSWER: Plaintiffs deny that they engaged in any anticompetitive or otherwise unlawful conduct. Paragraph 292 states legal conclusions, Amneal's opinion and characterization of counterclaims, and allegations subject to proof by expert testimony to which no response is required. Plaintiffs state that, on information and belief, FDA has not approved the Amneal ANDA. Plaintiffs lack knowledge and information sufficient to form a belief regarding expected

FDA approval of the Amneal ANDA and therefore deny any characterizations thereof. To the extent a response is required, denied.

293. Counterclaim-Defendants' exclusionary, anticompetitive, and unlawful activities threaten loss or damage to Amneal by forestalling, frustrating, and preventing Amneal's ability to compete in the Relevant Market.

ANSWER: Plaintiffs deny that they engaged in any anticompetitive or otherwise unlawful conduct. Paragraph 293 states legal conclusions, Amneal's opinion and characterization of counterclaims, and allegations subject to proof by expert testimony to which no response is required. Plaintiffs state that, on information and belief, FDA has not approved the Amneal ANDA. Plaintiffs lack knowledge and information sufficient to form a belief regarding expected FDA approval of the Amneal ANDA and therefore deny any characterizations thereof. To the extent a response is required, denied.

294. As a result of Counterclaim-Defendants' exclusionary, anticompetitive, and unlawful actions, Amneal has suffered, and will continue to suffer, injury to its business and property, including lost profits and business opportunities, and the costs and fees it has been forced to incur and that it continues to incur in connection with defending against this lawsuit.

ANSWER: Plaintiffs deny that they engaged in any anticompetitive or otherwise unlawful conduct. Paragraph 294 states legal conclusions, Amneal's opinion and characterization of counterclaims, and allegations subject to proof by expert testimony to which no response is required. Plaintiffs state that, on information and belief, FDA has not approved the Amneal ANDA. Plaintiffs lack knowledge and information sufficient to form a belief regarding expected FDA approval of the Amneal ANDA and therefore deny any characterizations thereof. To the extent a response is required, denied.

295. The threatened injury to Amneal results from the anticompetitive nature of Counterclaim-Defendants' conduct and constitutes antitrust injury.

ANSWER: Plaintiffs deny that they engaged in any anticompetitive or otherwise unlawful conduct. Paragraph 295 states legal conclusions, Amneal's opinion and characterization of

counterclaims, and allegations subject to proof by expert testimony to which no response is required. To the extent a response is required, denied.

296. Counterclaim-Defendants' conduct occurred in, and has had a substantial effect on, interstate commerce.

ANSWER: Plaintiffs deny that they engaged in any anticompetitive or otherwise unlawful conduct. Paragraph 296 states legal conclusions, Amneal's opinion and characterization of counterclaims, and allegations subject to proof by expert testimony to which no response is required. To the extent a response is required, denied.

297. Amneal is entitled to a judgment that Counterclaim-Defendants have violated Section 2 of the Sherman Act, 15 U.S.C. § 2; to the damages it suffered as a result of that violation, to be trebled in accordance with the Clayton Act, 15 U.S.C. § 15, plus interest; and to its costs and attorneys' fees.

ANSWER: Plaintiffs deny that they engaged in any anticompetitive or otherwise unlawful conduct. Paragraph 297 states legal conclusions and Amneal's opinion and characterization of counterclaims to which no response is required. To the extent a response is required, denied.

COUNT 7:
UNLAWFUL MONOPOLIZATION – SHAM LITIGATION
IN VIOLATION OF THE SHERMAN ACT

298. Amneal incorporates and re-alleges each of the foregoing paragraphs 1–297 of its Counterclaims, as if fully set forth herein.

ANSWER: Plaintiffs incorporate by reference their responses to each of the foregoing paragraphs 1–298 of Amneal's Counterclaims as if fully set forth herein.

299. Counterclaim-Defendants' have monopoly power in the Relevant Market.

ANSWER: Paragraph 299 states legal conclusions, Amneal's opinion and characterization of counterclaims, and allegations subject to proof by expert testimony to which no response is required. To the extent a response is required, denied.

300. Counterclaim-Defendants' knowingly and intentionally engaged in an anticompetitive and monopolistic scheme designed to injure or destroy competition in the Relevant

Market by delaying market entry of Amneal's generic equivalent of ProAir® HFA. Counterclaim-Defendants have engaged in a predatory scheme to monopolize the Relevant Market through, but not limited to, initiating objectively baseless and sham judicial proceedings designed to effectuate their monopoly over sales of albuterol inhalers in the United States.

ANSWER: Plaintiffs deny that they engaged in any anticompetitive or otherwise unlawful conduct. Paragraph 300 states legal conclusions, Amneal's opinion and characterization of counterclaims, and allegations subject to proof by expert testimony to which no response is required. Plaintiffs state that, on information and belief, FDA has not approved the Amneal ANDA. Plaintiffs lack knowledge and information sufficient to form a belief regarding expected FDA approval of the Amneal ANDA and therefore deny any characterizations thereof. To the extent a response is required, denied.

301. These judicial proceedings are not a genuine effort by Counterclaim-Defendants to obtain an adjudication of a valid claim that is infringed, but rather were instituted to achieve an unlawful objective to the detriment of competition as a whole in the Relevant Market. The purpose of such action is to directly interfere with and harm Amneal's business and business relationships in the Relevant Market, and to forestall, frustrate, and prevent competition by Amneal.

ANSWER: Plaintiffs deny that they engaged in any anticompetitive or otherwise unlawful conduct. Paragraph 301 states legal conclusions, Amneal's opinion and characterization of counterclaims, and allegations subject to proof by expert testimony to which no response is required. Plaintiffs state that, on information and belief, FDA has not approved the Amneal ANDA. Plaintiffs lack knowledge and information sufficient to form a belief regarding expected FDA approval of the Amneal ANDA and therefore deny any characterizations thereof. To the extent a response is required, denied.

302. Counterclaim-Defendants engaged in this conduct in order to consolidate, entrench, and enhance their monopolistic position in the Relevant Market and to stifle, delay, and eliminate competition and competitors with no economic, market, or competitive benefit.

ANSWER: Plaintiffs deny that they engaged in any anticompetitive or otherwise unlawful conduct. Paragraph 302 states legal conclusions, Amneal's opinion and characterization of

counterclaims, and allegations subject to proof by expert testimony to which no response is required. To the extent a response is required, denied.

303. Counterclaim-Defendants' anticompetitive activities are a direct, proximate, and reasonably foreseeable cause of Amneal's foreclosure from the Relevant Market and delay in entering the Relevant Market.

ANSWER: Plaintiffs deny that they engaged in any anticompetitive or otherwise unlawful conduct. Paragraph 303 states legal conclusions, Amneal's opinion and characterization of counterclaims, and allegations subject to proof by expert testimony to which no response is required. Plaintiffs state that, on information and belief, FDA has not approved the Amneal ANDA. Plaintiffs lack knowledge and information sufficient to form a belief regarding expected FDA approval of the Amneal ANDA and therefore deny any characterizations thereof. To the extent a response is required, denied.

304. As a result of Counterclaim-Defendants' exclusionary, anticompetitive, and unlawful actions, Amneal has suffered, and will continue to suffer, injury to their business and property, including lost profits and business opportunities, and the costs and fees it has been forced to incur and that it continues to incur in connection with defending against this lawsuit.

ANSWER: Plaintiffs deny that they engaged in any anticompetitive or otherwise unlawful conduct. Paragraph 304 states legal conclusions, Amneal's opinion and characterization of counterclaims, and allegations subject to proof by expert testimony to which no response is required. Plaintiffs state that, on information and belief, FDA has not approved the Amneal ANDA. Plaintiffs lack knowledge and information sufficient to form a belief regarding expected FDA approval of the Amneal ANDA and therefore deny any characterizations thereof. To the extent a response is required, denied.

305. The threatened injury to Amneal results from the anticompetitive nature of Counterclaim-Defendants' conduct and constitutes antitrust injury.

ANSWER: Plaintiffs deny that they engaged in any anticompetitive or otherwise unlawful conduct. Paragraph 305 states legal conclusions, Amneal's opinion and characterization of

counterclaims, and allegations subject to proof by expert testimony to which no response is required. To the extent a response is required, denied.

306. Counterclaim-Defendants' conduct occurred in, and has had a substantial effect on, interstate commerce.

ANSWER: Plaintiffs deny that they engaged in any anticompetitive or otherwise unlawful conduct. Paragraph 306 states legal conclusions, Amneal's opinion and characterization of counterclaims, and allegations subject to proof by expert testimony to which no response is required. To the extent a response is required, denied.

307. Amneal is entitled to a judgment that Counterclaim-Defendants have violated Section 2 of the Sherman Act, 15 U.S.C. § 2; to the damages it suffered as a result of that violation, to be trebled in accordance with the Clayton Act, 15 U.S.C. § 15, plus interest; and to its costs and attorneys' fees.

ANSWER: Plaintiffs deny that they engaged in any anticompetitive or otherwise unlawful conduct. Paragraph 307 states legal conclusions and Amneal's opinion and characterization of counterclaims to which no response is required. To the extent a response is required, denied.

COUNT 8:
UNLAWFUL MONOPOLIZATION – IMPROPER ORANGE BOOK LISTING IN VIOLATION OF THE SHERMAN ACT

308. Amneal incorporates and re-alleges each of the foregoing paragraphs 1–307 of its Counterclaims, as if fully set forth herein.

ANSWER: Plaintiffs incorporate by reference their responses to each of the foregoing paragraphs 1–307 of Amneal's Counterclaims as if fully set forth herein.

309. Counterclaim-Defendants' have monopoly power in the Relevant Market.

ANSWER: Paragraph 309 states legal conclusions, Amneal's opinion and characterization of counterclaims, and allegations subject to proof by expert testimony to which no response is required. To the extent a response is required, denied.

310. Counterclaim-Defendants' knowingly and intentionally engaged in an anticompetitive and monopolistic scheme designed to injure or destroy competition in the Relevant

Market by delaying market entry of Amneal's generic equivalent of ProAir® HFA. Counterclaim-Defendants have engaged in a predatory scheme to monopolize the Relevant Market through, but not limited to, improperly listing the Asserted Patents in the Orange Book.

ANSWER: Plaintiffs deny that they engaged in any anticompetitive or otherwise unlawful conduct. Paragraph 310 states legal conclusions, Amneal's opinion and characterization of counterclaims, and allegations subject to proof by expert testimony to which no response is required. Plaintiffs state that, on information and belief, FDA has not approved the Amneal ANDA. Plaintiffs lack knowledge and information sufficient to form a belief regarding expected FDA approval of the Amneal ANDA and therefore deny any characterizations thereof. To the extent a response is required, denied.

311. Counterclaim-Defendants engaged in this conduct in order to consolidate, entrench, and enhance their monopolistic position in the Relevant Market and to stifle, delay, and eliminate competition and competitors with no economic, market, or competitive benefit.

ANSWER: Plaintiffs deny that they engaged in any anticompetitive or otherwise unlawful conduct. Paragraph 311 states legal conclusions, Amneal's opinion and characterization of counterclaims, and allegations subject to proof by expert testimony to which no response is required. To the extent a response is required, denied.

312. Counterclaim-Defendants' anticompetitive activities are a direct, proximate, and reasonably foreseeable cause of Amneal's foreclosure from the Relevant Market and delay in entering the Relevant Market.

ANSWER: Plaintiffs deny that they engaged in any anticompetitive or otherwise unlawful conduct. Paragraph 312 states legal conclusions, Amneal's opinion and characterization of counterclaims, and allegations subject to proof by expert testimony to which no response is required. Plaintiffs state that, on information and belief, FDA has not approved the Amneal ANDA. Plaintiffs lack knowledge and information sufficient to form a belief regarding expected FDA approval of the Amneal ANDA and therefore deny any characterizations thereof. To the extent a response is required, denied.

313. As a result of Counterclaim-Defendants' exclusionary, anticompetitive, and unlawful actions, Amneal has suffered, and will continue to suffer, injury to their business and property, including lost profits and business opportunities, and the costs and fees it has been forced to incur and that it continues to incur in connection with defending against this lawsuit.

ANSWER: Plaintiffs deny that they engaged in any anticompetitive or otherwise unlawful conduct. Paragraph 313 states legal conclusions, Amneal's opinion and characterization of counterclaims, and allegations subject to proof by expert testimony to which no response is required. To the extent a response is required, denied.

314. The threatened injury to Amneal results from the anticompetitive nature of Counterclaim-Defendants' conduct and constitutes antitrust injury.

ANSWER: Plaintiffs deny that they engaged in any anticompetitive or otherwise unlawful conduct. Paragraph 314 states legal conclusions, Amneal's opinion and characterization of counterclaims, and allegations subject to proof by expert testimony to which no response is required. To the extent a response is required, denied.

315. Counterclaim-Defendants' conduct occurred in, and has had a substantial effect on, interstate commerce.

ANSWER: Plaintiffs deny that they engaged in any anticompetitive or otherwise unlawful conduct. Paragraph 315 states legal conclusions, Amneal's opinion and characterization of counterclaims, and allegations subject to proof by expert testimony to which no response is required. To the extent a response is required, denied.

316. Amneal is entitled to a judgment that Counterclaim-Defendants have violated Section 2 of the Sherman Act, 15 U.S.C. § 2; to the damages it suffered as a result of that violation, to be trebled in accordance with the Clayton Act, 15 U.S.C. § 15, plus interest; and to its costs and attorneys' fees.

ANSWER: Plaintiffs deny that they engaged in any anticompetitive or otherwise unlawful conduct. Paragraph 316 states legal conclusions and Amneal's opinion and characterization of counterclaims to which no response is required. To the extent a response is required, denied.

COUNT 9:
ATTEMPTED UNLAWFUL MONOPOLIZATION
IN VIOLATION OF THE SHERMAN ACT

317. Amneal incorporates and re-alleges each of the foregoing paragraphs 1–316 of its Counterclaim, as if fully set forth herein.

ANSWER: Plaintiffs incorporate by reference their responses to each of the foregoing paragraphs 1–316 of Amneal's Counterclaims as if fully set forth herein.

318. Counterclaim-Defendants' scheme constitutes anticompetitive conduct taken with the specific intent to monopolize the market for albuterol sulfate inhalants in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2. On information and belief, Counterclaim-Defendants purposefully and knowingly improperly listed the Asserted Patents, and others, in the Orange Book, and refused to delist them, even after receiving a letter from the FTC stating that they should be delisted. Counterclaim-Defendants then commenced sham patent litigation against Amneal under 35 U.S.C. § 271(e), despite fully knowing the Asserted Patents were improperly listed in the Orange Book, thereby unlawfully procuring an automatic 30-month stay of FDA approval.

ANSWER: Plaintiffs deny that they engaged in any anticompetitive or otherwise unlawful conduct. Paragraph 318 states legal conclusions and Amneal's opinion and characterization of counterclaims to which no response is required. To the extent a response is required, denied.

319. Counterclaim-Defendants have created a dangerous probability that they will achieve their goal of monopolizing the Relevant Market. Counterclaim-Defendants' market share in the Relevant Market, coupled with other market structure and conduct evidence, including but not limited to, the lack of competition in the Relevant Market, the likely effect of competitive entry, the nature of the anticompetitive conduct alleged herein, and the related economic and market factors, constitute a dangerous probability that Counterclaim-Defendants will succeed in their efforts to maintain a monopoly in the Relevant Market.

ANSWER: Plaintiffs deny that they engaged in any anticompetitive or otherwise unlawful conduct. Paragraph 319 states legal conclusions and Amneal's opinion and characterization of counterclaims to which no response is required. To the extent a response is required, denied.

COUNT 10:
SHAM LITIGATION – MONOPOLIZATION
N.J. STAT, ANN. §§ 56:9-1 ET SEQ.

320. Amneal incorporates and re-alleges each of the foregoing paragraphs 1–319 of its Counterclaims, as if fully set forth herein.

ANSWER: Plaintiffs incorporate by reference their responses to each of the foregoing paragraphs 1–320 of Amneal's Counterclaims as if fully set forth herein.

321. This claim arises under the New Jersey Antitrust Act, N.J. Stat. Ann. 56:9 et seq., and seeks a judgment that Counterclaim Defendants' conduct as alleged herein has violated New Jersey Antitrust, N.J. Stat. Ann. 56:9-4. Counterclaim-Defendants' conduct as alleged herein constitutes monopolization, attempted monopolization, and maintenance of monopoly in violation of N.J. Stat. Ann. 56:9-4.

ANSWER: Plaintiffs deny that they engaged in any anticompetitive or otherwise unlawful conduct. Paragraph 321 states legal conclusions and Amneal's opinion and characterization of counterclaims to which no response is required. To the extent a response is required, denied.

322. Specifically, Counterclaim-Defendants' anticompetitive scheme, including abuse of the regulatory processes and court filings and improperly listing the Asserted Patents in the Orange Book and refusing to delist them were calculated to maintain monopoly power in the Relevant Market, in violation of N.J. Stat. Ann. 56:9-4.

ANSWER: Plaintiffs deny that they engaged in any anticompetitive or otherwise unlawful conduct. Paragraph 322 states legal conclusions and Amneal's opinion and characterization of counterclaims to which no response is required. To the extent a response is required, denied.

323. Counterclaim-Defendants' anticompetitive and exclusionary conduct has directly and proximately caused injury to Amneal's business and property, as set forth above. Amneal's injury is of the type the antitrust laws are intended to prohibit and thus constitutes antitrust injury.

ANSWER: Plaintiffs deny that they engaged in any anticompetitive or otherwise unlawful conduct. Paragraph 323 states legal conclusions and Amneal's opinion and characterization of counterclaims to which no response is required. To the extent a response is required, denied.

COUNT 11:
DECLARATORY JUDGMENT OF NON-INFRINGEMENT

324. Amneal incorporates and re-alleges each of the foregoing paragraphs 1–323 of its Counterclaims, as if fully set forth herein.

ANSWER: Plaintiffs incorporate by reference their responses to each of the foregoing paragraphs 1–323 of Amneal's Counterclaims as if fully set forth herein.

325. Amneal does not, has not, and would not, if the products described in ANDA No. 211600 are marketed, directly or indirectly infringe any valid and enforceable claims of the '712, '289, '587, '808, and '889 patents, either literally or under the doctrine of equivalents.

ANSWER: Denied.

326. Amneal's manufacture, use, offer for sale, sale in the United States, and/or importation into the United States of the Amneal ANDA Products will not infringe, directly or indirectly, any valid and enforceable claims of the '712, '289, '587, '808, and '889 patents, either literally or under the doctrine of equivalents.

ANSWER: Denied.

327. Because Amneal has not infringed and will not infringe any valid and enforceable claim of the '712, '289, '587, '808, and '889 patents, Amneal is entitled to a declaratory judgment of non-infringement.

ANSWER: Denied.

COUNT 12:
DECLARATORY JUDGMENT OF INVALIDITY

328. Amneal incorporates and re-alleges each of the foregoing paragraphs 1–327 of its Counterclaims, as if fully set forth herein.

ANSWER: Plaintiffs incorporate by reference their responses to each of the foregoing paragraphs 1–327 of Amneal's Counterclaims as if fully set forth herein.

329. The claims of the '712, '289, '587, '808, and '889 patents are invalid and/or unenforceable for failure to comply with one or more of the requirements of Title 35, United States Code, including, without limitation, §§ 101, 102, 103, and/or 112.

ANSWER: Denied.

330. Because the claims of the '712, '289, '587, '808, and '889 patents are invalid and/or unenforceable for failure to comply with one or more of the requirements of Title 35, United States Code, including, without limitation, §§ 101, 102, 103, and/or 112, Amneal is entitled to a declaratory judgment of invalidity.

ANSWER: Denied.

RESPONSE TO JURY DEMAND

Amneal's jury demand is a legal conclusion to which no response is required. To the extent a response is required, denied.

RESPONSE TO AMNEAL'S PRAYER FOR RELIEF

The "WHEREFORE" paragraph and subparagraphs A-L on pages 108-109 of Amneal's Answer, Affirmative Defenses, and Counterclaims state a prayer for relief to which no response is required. To the extent a response is required, Plaintiffs deny the allegations of the "WHEREFORE" paragraph and subparagraphs A-L. Plaintiffs further deny that Amneal is entitled to any requested relief or to any relief whatsoever.

* * *

TEVA'S SEPARATE DEFENSES

Without prejudice to the responses and denials set forth in Plaintiffs' Answer, and without admitting any of the allegations in the Counterclaims not otherwise admitted, Plaintiffs assert the following separate defenses in response to Amneal's Counterclaims without assuming the burden of proof on any such defense that would otherwise rest with Amneal. Plaintiffs reserve the right to amend this Answer to seek and allege any and all defenses not presently known or that are revealed during the course of discovery or otherwise.

FIRST SEPARATE DEFENSE

Amneal's counterclaims, and each and every purported cause of action alleged therein, fail to state facts sufficient to constitute a cause of action upon which relief may be granted.

SECOND SEPARATE DEFENSE

The claims of the Asserted Patents are valid and comply with the statutory provisions of Title 35 of the United States Code, including, without limitation, sections 101, 102, 103, 112, *et seq.*, and other judicially-created doctrines.

THIRD SEPARATE DEFENSE

Amneal is not entitled to attorneys' fees against Teva because Amneal has not sufficiently alleged and cannot prove that this is an exceptional case under 35 U.S.C. § 285.

FOURTH SEPARATE DEFENSE

Amneal's counterclaims are barred, in whole or in part, because Amneal failed to mitigate damages, if any, allegedly suffered as a result of the conduct Amneal alleges.

FIFTH SEPARATE DEFENSE

Any and all of Teva's actions alleged by Amneal were lawful, justified, explained, procompetitive, carried out in furtherance of Teva's legitimate business interests, and constitute *bona fide* business competition.

SIXTH SEPARATE DEFENSE

Amneal's counterclaims are barred, in whole or in part, because, even assuming that the alleged conduct had any potential anticompetitive effect, the procompetitive benefits outweigh any alleged anticompetitive effect.

SEVENTH SEPARATE DEFENSE

Amneal's counterclaims are barred, in whole or in part, by the United States patent laws and/or are preempted by federal patent law.

EIGHTH SEPARATE DEFENSE

Amneal's counterclaims are barred, in whole or in part, because they are based on petitioning activities protected under the *Noerr-Pennington* doctrine and the First Amendment to the United States Constitution.

NINETH SEPARATE DEFENSE

Amneal's counterclaims are barred, in whole or in part, because Teva reasonably and in good faith attempted to comply with the regulatory demands of the Hatch-Waxman Act and the Hatch-Waxman scheme.

TENTH SEPARATE DEFENSE

Amneal's counterclaims are barred, in whole or in part, because Teva's submission of patent information to FDA for the Asserted Patents in connection with ProAir® HFA (NDA No. 021457) was not objectively unreasonable under the FDA's listing requirements and regulations.

ELEVENTH SEPARATE DEFENSE

Amneal's counterclaims are barred, in whole or in part, by the doctrine set out in *Verizon Communications. Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398 (2004).

TWELFTH SEPARATE DEFENSE

Amneal's counterclaims are barred, in whole or in part, by the implied immunity doctrine.

THIRTEENTH SEPARATE DEFENSE

Amneal's counterclaims are barred, in whole or in part, because any harm to competition stems from the intricate, multi-tiered regulatory regime that governs the approval, production, sale, and manufacture of pharmaceutical products, including the Federal Food, Drug, and Cosmetic Act, the Drug Price Competition and Patent Term Restoration Act of 1984, and related amendments.

FOURTEENTH SEPARATE DEFENSE

Any additional defenses that discovery may reveal.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment dismissing with prejudice Amneal's Counterclaims and denying all relief sought by Amneal;

B. An award to Teva of its costs and expenses in this action;

C. The entry of Judgment declaring that Amneal's acts render this an exceptional case and awarding Teva attorneys' fees pursuant to 35 U.S.C. §§ 271(e)(4) and 285;

D. An award to Teva of the relief requested in its First Amended Complaint; and

E. Such further and other relief as this Court deems just and proper.

Dated: July 15, 2024

Respectfully submitted,

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