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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.	**FILED UNDER SEAL** Civil Action No. 23-cv-20964-SRC-MAH **Oral Argument Requested** *Electronically Filed*

BRIEF IN SUPPORT OF PLAINTIFFS' MOTION TO DISMISS DEFENDANTS' COUNTERCLAIM COUNTS 1–10

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INTRODUCTION

Defendants' "improper listing" based counterclaims should be dismissed with prejudice. Defendants have alleged two legal theories based on the contention that the five patents asserted in this Hatch-Waxman case are improperly listed in FDA's Orange Book: (1) in Counts 1 to 5, Defendants seek a declaration pursuant to 21 U.S.C. § 355(j)(5)(C)(ii) that each asserted patent is improperly listed and requires delisting; and (2) in Counts 6 to 10, Defendants assert antitrust violations under both federal and state law, based upon improper listing and "sham litigation." However, Defendants' factual allegations, even taken as true, fail to state a claim for relief.

Defendants' delisting counterclaims are predicated on an incorrect interpretation of the controlling statute. Defendants contend that a patent can only be listed in the Orange Book if it explicitly recites the active ingredient of the drug product in the claims of the patent. But the statute is not nearly so narrow. To the contrary, the statute requires an NDA holder to list any patent that "claims the drug" approved in the NDA. "Drug" is explicitly defined not to be limited to the active ingredient, but to include all components of a drug product. And courts, including the Federal Circuit, have consistently interpreted the word "claims" as used here to include all products covered by the claims of a patent. As there can be little question that the metered-dose inhaler of ProAir® HFA is a "drug product", and Defendants do not allege that the patents do not cover ProAir® HFA, the patents are properly

listed. Defendants' delisting counterclaims should be dismissed with prejudice.

The antitrust claims fare no better. Whether or not the patents are properly listed (they are), the sole remedy to address such a claim is the delisting counterclaim adopted by Congress. Defendants' attempt to bootstrap an antitrust claim to conduct for which Congress adopted a specific process and a limited remedy is improper as a matter of law. And Defendants' unsupported claims of "sham" litigation lack the necessary supporting allegations—merely using the word "sham" in the counterclaim is insufficient to render such claims plausible. Defendants' antitrust counterclaims should similarly be dismissed with prejudice.

BACKGROUND

I. Regulatory Background

A. New Drug Applications (NDAs) & the Orange Book

The U.S. Food and Drug Administration ("FDA") regulates the manufacture, sale, and labeling of prescription drugs under a complex statutory scheme. *See* Federal Food, Drug, and Cosmetic Act ("FDCA") (codified at Title 21 Chapter 9 of the United States Code). To market a new drug in the United States, a company must submit a New Drug Application ("NDA") to FDA for approval. *See* 21 U.S.C. §§ 355(a)–(b). The NDA must include, *inter alia*, the composition of the drug, a list of the components of the drug, scientific data demonstrating the drug is safe and effective, and proposed labeling describing the uses for which the drug will be marketed. *Id.* §§ 355(b)(1) & (d); *see also Caraco Pharm. Lab'ys, Ltd. v. Novo*

Nordisk A/S, 566 U.S. 399, 404–05 (2012) (summarizing regulatory scheme).

As part of the NDA, the applicant must submit certain patent information to FDA. Specifically, the applicant "shall submit" the following:

> the patent number and expiration date of 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, and that--
>
> (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) (the "Listing Statute"). When submitting this patent information to FDA, the NDA applicant must identify whether the patent claims one or more of the following three categories: "[1] the drug substance (active ingredient), [2] drug product (formulation and composition), [and/]or [3] approved method of use." 21 C.F.R. § 314.53(c)(2); *see id.* § 314.53(b)(1). FDA publishes the patent information submitted for approved NDAs—including the patent number, expiration date, and patent category—in *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as "the Orange Book"). *See* 21 C.F.R. § 314.53(e); *Caraco*, 566 U.S. at 405–06.

B. Abbreviated New Drug Applications (ANDAs)

After an NDA has been approved, another company may seek permission to market a generic version of an approved drug under the Hatch-Waxman Act. *See*

Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (21 U.S.C. § 355(j)). The Hatch-Waxman Act allows "a generic competitor to file an abbreviated new drug application (ANDA) piggy-backing on the brand's NDA." *Caraco*, 566 U.S. at 404–05. "[T]his process is designed to speed the introduction of low-cost generic drugs to market." *Id.* at 405.

As part of its ANDA, an applicant must submit a certification with respect to each patent listed in the Orange Book for the corresponding NDA. *See* 21 U.S.C. § 355(j)(2)(A)(vii). If the applicant wishes to seek FDA approval of its ANDA ***before*** a listed patent has expired, the applicant must submit a Paragraph IV Certification to FDA "that such patent is invalid or will not be infringed by the manufacture, use, or sale of the" ANDA product. *Id.* § 355(j)(2)(A)(vii)(IV).

The ANDA applicant must provide the NDA holder and each patent owner with notice of its Paragraph IV Certification, including "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." 21 U.S.C. § 355 (j)(2)(B)(iv)(II) ("Detailed Statement"). If the NDA holder or patent owner brings an infringement suit against the ANDA applicant within 45 days of receipt of this notice, FDA's approval of the ANDA will be stayed for 30 months from the date of receipt of the notice, unless the patent litigation resolves the patent infringement and validity issues sooner. *Id.* § 355(j)(5)(B)(iii).

C. Statutory Counterclaim for Delisting

Under 21 U.S.C. § 355(j)(5)(C)(ii) (the "Delisting Statute"), an ANDA applicant sued for patent infringement "may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the [NDA] holder . . . on the ground that the patent does not claim . . . the drug for which the application was approved." 21 U.S.C. § 355(j)(5)(C)(ii)(I); *see Caraco*, 566 U.S. at 404–05, 408–09 (construing this statutory provision). The statute is clear that delisting must be asserted as a counterclaim and cannot be asserted as an independent cause of action. *See* 21 U.S.C. § 355(j)(5)(C)(ii)(II). An ANDA holder asserting such a statutory counterclaim must plausibly allege that each asserted patent "does not claim . . . the drug" for which the NDA was approved. *Id*. § 355(j)(5)(C)(ii)(I). Damages are not available as a remedy; the only remedy for improper listing of a patent is to have it delisted or the listing amended. *Id.* §§ 355(j)(5)(C)(ii) & (iii).

II. ProAir® HFA & its Orange Book Listing

Teva Branded Pharmaceutical Products R&D, Inc. ("Teva Branded") is the holder of NDA No. 021457, under which FDA approved the commercial marketing of ProAir® HFA (albuterol sulfate) Inhalation Aerosol. *See* CC Ex. A (ECF No. 12-1, Approval Letter for NDA No. 021457).[1] ProAir® HFA "is a pressurized metered-dose aerosol unit with a dose counter." CC Ex. E (ECF No. 12-5 at 9, Prescribing Information Rev. 03/12). The active ingredient of ProAir® HFA is albuterol sulfate.

[1] "CC" refers to Amneal's Counterclaims (ECF No. 12 at 57–112) and exhibits.

Id.[2] ProAir® HFA 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. *Id.* at 1–3. There are nine unexpired patents listed in the Orange Book for ProAir® HFA, each listed as a drug product patent. *See* CC Ex. K (ECF No. 12-11).

III. Nature of the Proceedings

By a letter dated August 24, 2023 ("Notice Letter"), Amneal[3] notified Teva[4] that it 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 Product") with Paragraph IV Certifications, seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Amneal ANDA Product in and/or into the United States prior to the expiration of the nine unexpired Orange Book patents listed for ProAir® HFA. In its Notice Letter, Amneal asserted only that it did not infringe any of the patents listed for ProAir® HFA, but did not assert that any of the listed patents were invalid. *See* Ex. 1, Amneal's Detailed Statement at 1–32. Teva brought this

[2] "HFA" refers to the propellant used in the metered dose inhaler.

[3] The terms "Amneal" and "Defendants" refer to Defendants Amneal Pharmaceuticals of New York, LLC, Amneal Ireland Limited, Amneal Pharmaceuticals LLC, and Amneal Pharmaceuticals Inc., collectively.

[4] The terms "Teva" and "Plaintiffs" refer to Plaintiffs Teva Branded, Norton (Waterford) Ltd., and Teva Pharmaceuticals USA, Inc., collectively.

action for patent infringement against Amneal on October 6, 2023 asserting infringement of six of the patents for which Amneal submitted a Paragraph IV Certification. *See* ECF No. 1 (Complaint). Since this action was brought within 45 days of Teva's receipt of Amneal's Notice Letter, there is a 30-month stay of final FDA approval of Amneal's ANDA. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

On October 27, 2023, Teva filed its First Amended Complaint narrowing the asserted patents to 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"). *See* ECF No. 7. On December 1, 2023, Amneal filed its Answer, Affirmative Defenses, and Counterclaims to Plaintiffs' First Amended Complaint. *See* ECF No. 12. Each of Amneal's Counterclaim Counts 1–5 (collectively, "Delisting Counterclaims") "seeks a declaration pursuant to 21 U.S.C. § 355(j)(5)(C)(ii) ordering [Teva] to delete or withdraw the [asserted] patent from the Orange Book." CC ¶¶ 135, 166, 192, 220, 246. Amneal's Counterclaim Counts 6–10 assert a number of antitrust counterclaims (collectively, "Antitrust Counterclaims"). *Id.* ¶¶ 271–323. Amneal's Counterclaim Counts 1–10 should be dismissed with prejudice.

LEGAL STANDARDS

A counterclaim must be dismissed if the counterclaim does not contain sufficient factual allegations to conclude that it is at least plausible that the

counterclaim states a claim to relief. "Courts use the same standard in ruling on a motion to dismiss a counterclaim under Federal Rule of Civil Procedure 12(b)(6) as they do for a motion to dismiss a complaint." *RBC Bank (USA) v. Petrozzini*, 2012 WL 1965370, at *2 (D.N.J. May 31, 2012). To survive a Rule 12(b)(6) motion, a counterclaim "must contain sufficient factual matter . . . to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)).

The Court need not credit legal conclusions or formulaic recitations of the elements of a claim. "In evaluating the sufficiency of a counterclaim, district courts must separate the factual and legal elements." *2109971 Ontario Inc. v. Best Deals Discount Furniture LLC*, 2023 WL 3072756, at *2 (D.N.J. April 25, 2023). "A court must accept all of the [counterclaim's] well-pleaded facts as true," but should not "credit labels, conclusions, or a formulaic recitation of the elements of a cause of action." *Id.* (citation omitted); *Interlink Prods. Int'l, Inc. v. HDS Trading Corp., Inc.*, 2015 WL 12840378, at *2 (D.N.J. Oct. 14, 2015) ("[A] court . . . will not accept bald assertions, unsupported conclusions, unwarranted inferences, or sweeping legal conclusions cast in the form of factual allegations.").

ARGUMENT

I. Amneal Fails to State a Claim for Delisting of Any Asserted Patent

Amneal fails to state a claim that the Asserted Patents should be delisted from

the Orange Book for ProAir® HFA. Indeed, Amneal cannot state such a claim because the Asserted Patents are properly listed under the governing statutes. Under the Delisting Statute, Amneal must allege that each Asserted Patent "does not claim . . . the drug for which the [NDA] was approved." 21 U.S.C. § 355(j)(5)(C)(ii)(I). While the Listing Statute requires that the NDA holder submit each patent that, *inter alia*, "***claims the drug*** for which the applicant submitted the application" (emphasis added), Amneal tries to rewrite the statute to allow only listing patents that ***explicitly recite*** the ***active ingredient.***[5] In doing so, Amneal attempts to narrow what patents are required to be listed in the Orange Book. Because Amneal's Delisting Counterclaims are based on re-writing and misconstruing the Listing Statute, they have not, and cannot, allege that the Asserted Patents do not "claim the drug" under § 355, and should be delisted. Amneal fails to allege facts that would support the conclusion that the Asserted Patents do not claim the drug product ProAir® HFA or a component thereof, and its Delisting Counterclaims should be dismissed.

A. The Listing Statute Broadly Requires Listing All Patents that "Claim the Drug" in the NDA

Amneal's counterclaims are predicated on a misinterpretation of the relevant statutes. Amneal alleges that delisting is proper because "only patents that claim the

[5] Amneal uses "recites" and "contains the word/phrase" interchangeably in asserting that the Asserted Patents do not explicitly recite (or contain the exact name) of the active ingredient. *See, e.g.*, CC ¶¶ 84, 161, 187, 215, 241, 268. Neither of these phrases appear in the statute.

active ingredient should be listed in the Orange Book. And drug-device patents that do not claim the active ingredient should not be listed." CC ¶ 73; *see also, e.g.*, CC ¶ 161 (alleging that "[n]one of the claims of the '712 patent recite" by name the active ingredient or other elements of the formulation). But the Listing Statute ***requires*** an NDA applicant to list any patent that "claims the drug." 21 U.S.C. § 355(b)(1)(A)(viii). Under patent law and the relevant statutes, "claims the drug" is a broad phrase—(1) "drug" is explicitly, and broadly, defined in the statute; and (2) a patent "claims" something in patent law when it reads on the product. Thus, the Asserted Patents do "claim the drug" approved by Teva Branded's ProAir® HFA NDA as required under the statute, and are properly listed.

1. The term "drug" should be interpreted as defined under the statute, not redefined to mean only "active ingredient"

Section 355 requires that listed patents "claim the ***drug***," but, contrary to Amneal's allegations, does not require that the patents claim the "active ingredient." The relevant statute contains an explicit, and broad, definition of the term "drug":

> The term "drug" means (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C).

21 U.S.C. § 321(g)(1). Clauses (A)–(C) include reference to both the active

ingredient and the complete drug product. *Id.* For example, the official United States Pharmacopoeia ("USP"), as referenced in clause (A), recognizes a long list of articles that are complete drug products, including inhalation aerosols like ProAir® HFA.[6] Clause (B) references "articles intended for use in the . . . mitigation [or] treatment" of disease, which by definition include the entire drug product and not just the active ingredient. Clause (C) targets articles intended to improve body functions, such as breathing. Clause (D) is explicit that the term "drug" also includes "a component of any article specified in clause (A), (B), or (C)." The term "drug" must be given its unambiguous definition provided under the statute. *Stenberg v. Carhart*, 530 U.S. 914, 942 (2000) ("When a statute includes an explicit definition, we must follow [it], even if it varies from that term's ordinary meaning.").

While the text of § 355 is unambiguous and the Court need not consider other evidence, the legislative history is informative. Previously, the definition of "drug" specified that it "does not include devices or their components, parts, or accessories." 21 U.S.C. § 321(g) (1938)*; see also United States v. Article of Drug, Bacto-Unidisk*,

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[6] *See* Ex. 2, USP ⟨5⟩ Inhalation and Nasal Drug Products at 1 (Official Date: Aug. 1, 2023) (defining "Inhalation Aerosol" as "[a] drug product for oral inhalation that is packaged under pressure, aerosolizes, and delivers a specified amount of active ingredient(s) upon activation of an accurate metering valve system in association with an actuator mechanism. Inhalation aerosol drug products are more commonly known as metered-dose inhalers or MDIs."). The Court may consider the USP as Amneal incorporated the "statutory requirements" for listing in its Counterclaims (*see, e.g.*, CC ¶ 15) and it is a matter of which the Court may take judicial notice. *See Nasyrova v. Immunomedics, Inc.*, 2015 WL 382846, at *5 (D.N.J. Jan. 28, 2015).

394 U.S. 784, 789 (1969) ("a 'device' expressly cannot be a 'drug' under the last phrase of the drug definition"). But Congress amended the statute in 1990 to remove the exclusion of devices and their components. Safe Medical Device Act of 1990, Pub. L. No. 101–629, 104 Stat. 4511, 4526 ("[i]n paragraph (g)(1), by striking out '; but does not include devices or their components, parts or accessories'"); *see Genus Med. Techs., LLC v. FDA*, 427 F. Supp. 3d 74, 84 (D.D.C. 2019) (summarizing legislative history), *aff'd*, 994 F.3d 631 (D.C. Cir. 2021). The amendments highlight that "components" of a drug product—including components of devices that are part of the approved drug—are included in the definition of "drug" today.

The surrounding statutory text further demonstrates that the term "drug" includes components of the drug product. *See United States v. Cleveland Indians Baseball Co.*, 532 U.S. 200, 217 (2001) ("[S]tatutory construction 'is a holistic endeavor' and that the meaning of a provision is 'clarified by the remainder of the statutory scheme . . . .'"). For example, the subsections preceding where "claims the drug" appears also refer to a "drug" that is made of "components". *See* 21 U.S.C. § 355(b)(1)(A)(ii) ("a full list of the articles used as ***components*** of such drug" (emphasis added); *id.* § 355(b)(1)(A)(v) ("such samples of such drug and of the articles used as ***components*** thereof as the Secretary may require . . ." (emphasis added))); *id.* § 355(b)(1)(A)(iii) (mandating the NDA holder to submit a "full statement of the composition of such drug"). A holistic review of the statute

confirms that a "drug" includes its components, and not just the active ingredient.

Furthermore, subsection (viii) itself specifies in a parenthetical that "drug product" patents refer to "formulation or composition" patents. *See id.* § 355(b)(1)(A)(viii) ("[C]laims 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 . . . ." (emphasis added)). The statute uses different language when specifying the active ingredient, referring explicitly to "drug substance (active ingredient)." *Id.* "Drug" therefore must be read to include ***both*** the active ingredient ***and*** the formulation or composition of the drug product. To interpret "drug" in the statute to only refer to the active ingredient (as Amneal's counterclaims require) would impermissibly render the reference to the phrase "drug product (formulation or composition) patent" superfluous. *See Duncan v. Walker*, 533 U.S. 167, 174 (2001). The Court should reject such a reading.

To the extent that Amneal's argument that "drug" requires explicit recital of the "active ingredient" is based on the decision in *In re Lantus Direct Purchaser Antitrust Litig.*, 950 F.3d 1 (1st Cir. 2020), Amneal is wrong. The statutory provisions cursorily addressed by the First Circuit in *In re Lantus* were significantly amended by the enactment of the Orange Book Transparency Act of 2020 ("OBTA"), which came into effect almost eleven months after *In re Lantus* was decided. *See* Orange Book Transparency Act of 2020, Pub. L. No. 116-290, 134

Stat. 4889 (Jan. 5, 2021). And Section 355 has been amended additionally since. *See, e.g.*, Pub. L. No. 117-9, 135 Stat. 256 (Apr. 23, 2021). The OBTA changed the structure and order of §§ 355(b) and (c) and added new language to both sections. For example, the Court in *In re Lantus* relied, in part, on the fact that the statute at the time did not use the term "component" in the recited provisions. 950 F.3d at 9. The amended statute explicitly uses the terms "component" and "composition." *See* 21 U.S.C. §§ 355(b)(1)(A)(ii), (iii), (v), & (viii).

The statute is clear that "drug" includes the drug product and its components, such as inhalers with dose counters.

2. The term "claims" should be given its meaning under patent law, which does not require explicit recitation

Section 355 requires an NDA applicant to list any patent that "***claims*** the drug," but does not require that the patent explicitly "recites" the drug. While the term "claims" is not explicitly defined by the statute, "[i]t is a settled principle of interpretation that, absent other indication, 'Congress intends to incorporate the well-settled meaning of the common-law terms it uses.'" *United States v. Castleman*, 572 U.S. 157, 162 (2014) (citation omitted). The Federal Circuit has held that the term "claims" in this statute should be construed to be given its ordinary meaning in patent law. *See Jazz Pharms., Inc. v. Avadel CNS Pharms., LLC*, 60 F.4th 1373, 1379 (Fed. Cir. 2023). "An inquiry into whether a patent may be properly listed or delisted from the Orange Book [] clearly requires a determination of what that patent claims." *Id.*

Under patent law, a patent "claims" a product when any claim of the patent "reads on, or in other words is found in" the product even if an element of the product is not explicitly recited in the claim. *See United Food & Com. Workers Loc. 1776 & Participating Emps. Health & Welfare Fund v. Takeda Pharm. Co. Ltd.*, 11 F.4th 118, 132–33 (2d Cir. 2021) (internal quotation marks omitted) (quoting *Allen Eng'g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1345 (Fed. Cir. 2002)). In other words, a patent "claims" a product if the patent would be infringed by the product, even if the product has elements that are not explicitly recited by the claim. Thus, under the provision "claims the drug for which the applicant submitted the [NDA]" in § 355, "a patent must be listed if it *contains a product claim that reads on the drug that is the subject of the NDA*." *Id.* at 132–33 & n.2 (emphasis in original). Section 355 does not require that a patent explicitly "recites" the drug.

This interpretation is further confirmed by earlier language in the same clause, which requires the listing of "each patent for which ***a claim of patent infringement could reasonably be asserted*** . . . ." 21 U.S.C. § 355(b)(1)(A)(viii) (emphasis added). A bedrock canon of statutory construction is that identical words used in a statute should be read to have the same meaning. *See Nat'l Credit Union Admin. v. First Nat'l. Bank & Tr. Co.*, 522 U.S. 479, 501 (1998). "Claim(s)" should be interpreted under its meaning in patent law each time it is used in the statute. Therefore, properly interpreted, the statute does not require the patent explicitly

"recite" the drug, but rather the patent must "claim," or "read on" the drug.

3. Regulations further confirm patents claiming drug products or their components must be listed in the Orange Book

Regulations adopted by FDA further confirm that patents claiming drug products or their components must be listed in the Orange Book. These regulations require that an NDA holder submit the same three categories of patents as required under the Listing Statute: (i) "drug substance (active ingredient) patents," (ii) "drug product (formulation and composition) patents," and (iii) "method-of-use patents." 21 C.F.R. § 314.53(b). "For patents that claim a drug product, the applicant must submit information only on those patents that claim the drug product, as is defined in § 314.3, that is described in the pending or approved NDA." *Id.*

Section 314.3 defines the term "drug product" as "a finished dosage form, e.g., tablet, capsule, or solution, that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients." 21 C.F.R. § 314.3. The term "dosage form" is also defined:

> Dosage form is the physical manifestation containing the active and inactive ingredients that delivers a dose of the drug product. This includes such factors as:
> (1) The physical appearance of the drug product;
> (2) The physical form of the drug product prior to dispensing to the patient;
> (3) The way the product is administered; and
> (4) The design features that affect frequency of dosing.

Id. The Orange Book lists "metered aerosol" as a "dosage form". *See* Ex. 3,

Appendix C, Orange Book (44th Ed. 2024) at C-1.[7] FDA guidance also discusses metered aerosols as a "dosage form[]." *See* 68 Fed. Reg. 36,676, 36,680 (June 18, 2003). Thus, FDA regulations require listing patents covering any of the components of the drug product that contribute to the drug product's "finished dosage form," including components relating to "[t]he way the product is administered" and "design features that affect frequency of dosing," such as a "metered aerosol."

Additionally, the regulation governing submission of patent information—§ 314.53—is explicit about categories of patents that should ***not*** be listed. The last sentence of § 314.53(b)(1) reads: "Process patents, patents claiming packaging, patents claiming metabolites, and patents claiming intermediates ***are not covered by this section, and*** information on these patents ***must not be submitted to FDA***." 21 C.F.R. § 314.53(b)(1) (emphasis added). By specifying types of patents which should ***not*** be listed, other types of patents not specifically enumerated are, in contrast, covered by the section. *See Bates v. United States*, 522 U.S. 23, 29–30 (1997) ("Where Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion."). But FDA did not exclude the patents listed here, further supporting the propriety of the listing.

[7] The Court may consider this edition of the Orange Book as Amneal incorporated the web address for the Orange Book in its Counterclaims (CC ¶ 29) and it is a matter of which the Court may take judicial notice. *See Nasyrova*, 2015 WL 382846, at *5.

4. Plaintiffs' interpretation of the Delisting Statute is consistent with the policy of the Hatch-Waxman Act

Teva's interpretation of the provisions concerning what patents must be listed in the Orange Book is consistent with the policy behind the Hatch-Waxman Act. "The purpose of listing a patent in the Orange Book is to put potential generic manufacturers on notice that the brand considers the patent to cover its drug." *In re Restasis (Cyclosporine Ophthalmic Emulsion) Antitrust Litig.*, 333 F. Supp. 3d 135, 149 (E.D.N.Y. 2018). The process is "designed to speed the introduction of low-cost generic drugs to market." *Caraco*, 566 U.S. at 405. Moreover, Hatch-Waxman provided NDA holders and their prospective competitors pre-launch certainty about their respective rights. *See Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 677–78 (1990). Under Amneal's interpretation, the patents would not go away; rather, potential generic manufacturers would no longer receive notice of which patents the brand considers to cover its drug. The lack of notice might actually slow the introduction of low-cost generic drugs to market as a patent holder could still assert an infringement claim. Instead of taking place in the orderly Hatch-Waxman context, the litigation would happen later, potentially in a truncated emergency court proceeding. Moreover, such later litigation risks substantial damages liability for infringement, and increases the likelihood of an injunction taking a generic off the market after launch, results the balanced and orderly procedures set forth in the Hatch-Waxman Act were designed to prevent.

B. Amneal Fails to Allege Facts to Support Delisting Under the Proper Interpretation of the Governing Statute

1. Amneal's conclusory statements, formulaic recitations, and legal conclusions cannot support its counterclaims

Amneal's counterclaims are riddled with conclusory statements, formulaic recitations, and legal conclusions that cannot form the basis for adequately pleading a delisting counterclaim. For example, Amneal alleges that the Asserted Patents do not meet the "statutory requirements" to be listed in the Orange Book (*see* CC ¶¶ 15, 76, 138, 169, 195, 223, 249); are "improperly listed" or "not properly listed" in the Orange Book (*see id.* ¶¶ 18, 61, 101, 127, 130, 137, 168, 194, 222, 248); and "do not claim a drug, drug substance (active ingredient), drug product (formulation or composition), or a method of using a drug" (*id.* ¶ 15; *see id.* ¶¶ 68, 77–83, 139–149, 160, 170–180, 186, 196–206, 214, 224–234, 240, 250–260, 266 (variations of the same)) without any factual assertions to support them. These variations all suffer from the same defect—even under a generous reading, they are only legal conclusions and recitals of the elements of a cause of action supported by mere conclusory statements that must be disregarded. *Interlink Prods.*, 2015 WL 12840378, at *2 ("[A] court . . . will not accept bald assertions, unsupported conclusions, unwarranted inferences, or sweeping legal conclusions cast in the form of factual allegations." (citation omitted)); *Malleus v. George*, 641 F.3d 560, 563 (3d Cir. 2011) (allegations that are "no more than conclusions[] are not entitled to

the assumption of truth." (quoting *Iqbal*, 556 U.S. at 679)). This Court should not credit Amneal's "labels, conclusions, or [] formulaic recitation[s] of the elements." *Best Deals*, 2023 WL 3072756, at *2 (citing *Twombly*, 550 U.S. at 555).

Amneal also parrots conclusory statements and legal conclusions made by the Federal Trade Commission ("FTC"), but again, these statements cannot form the basis of an adequately plead claim. Amneal alleges that the FTC "has determined that the Asserted Patents are not properly listed in the Orange Book for ProAir® HFA." CC ¶ 69; *see also id.* ¶¶ 70–74, 150–152, 181–183, 207–209, 235–237, 261–263. As Amneal's references to FTC statements are legal assertions and not factual allegations, they should not be credited. *See Best Deals*, 2023 WL 3072756, at *3.[8]

2. The few remaining factual allegations in the Delisting Counterclaims fail to state a claim

After striking Amneal's legal and conclusory allegations, the remaining well-pleaded components of the counterclaims fail to state a claim for delisting. Specifically, Amneal fails to allege any ***facts*** to support the conclusion that the Asserted Patents do not "claim the drug" approved in the ProAir® HFA NDA. *See*

[8] Furthermore, any deference to agency interpretation of the Orange Book Listing Statute requires that the agency interpretation in question be by the agency charged with administering that statute. *See Epic Systems Corp. v. Lewis*, 138 S. Ct. 1612, 1618 (2018) (finding no *Chevron* deference because its "essential premises are missing," including that the agency sought to interpret a statute "which the agency does not administer"). Accordingly, FDA's guidance would control here, not FTC's, rendering FTC's purported "determination" irrelevant. Moreover, the FTC appears to have relied on *In re Lantus* and ignored the subsequent statutory amendment.

Apotex, Inc. v. Thompson, 347 F.3d 1335, 1343–44 (Fed. Cir. 2003) ("The listing decision thus requires what amounts to a finding of patent infringement, except that the 'accused product' is the drug that is the subject of the NDA.").

First, Amneal has not asserted any facts to support that the Asserted Patents do not claim the "drug." While Amneal alleges they do not claim "a drug substance," "an active ingredient," "a drug product," "a drug formulation," "a drug composition," or "a drug," (*see, e.g.*, CC ¶¶ 143–149), Amneal does not provide any factual support for such conclusory statements. Amneal has not asserted, for example, that ProAir® HFA is not an inhalation aerosol; not an article for use in the treatment or prevention of bronchospasm; not an article used to improve the function of breathing; or not a component of such articles. Amneal thus has not properly alleged the Asserted Patents listed for ProAir® HFA do not claim the "drug" as defined under 21 U.S.C. § 321(g)(1)(A), (B), (C) & (D).

Second, Amneal has not asserted facts to support its allegation that the Asserted Patents do not "claim" the drug. Amneal alleges none of the claims of the Asserted Patents "recite" a list of words or phrases, including for example "albuterol" and "albuterol sulfate" (*see, e.g.*, CC ¶¶ 160–163), but the Listing Statute does not require that the listed patents "recite" anything, let alone the active ingredient. *See* 21 U.S.C. § 355(b)(1)(A)(viii). Amneal thus has failed to plausibly allege that the Asserted Patents do not "claim" the drug product ProAir® HFA or the

components thereof (such as the dose counter) as required under § 355. Accordingly, Amneal fails to adequately allege any delisting counterclaim.

The unremarkable fact that one or more of the Asserted Patents is listed in the Orange Book for other branded drugs (*see* CC ¶¶ 86–99, 164, 190, 218, 244, 270) does not mean that the Asserted Patents do not "claim" ProAir® HFA. The Listing Statute requires NDA holders to list all patents that claim a drug product with respect to "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." 21 U.S.C. § 355(b)(1)(A)(viii). Therefore, even if other drug products may infringe on the Asserted Patents, Teva still was required to list the Asserted Patents for ProAir® HFA in order to comply with the statute.

C. Amneal Cannot State a Claim for a Delisting Counterclaim Because the Asserted Patents Are Properly Listed in the Orange Book

The Asserted Patents are properly listed as they "claim the drug" ProAir® HFA, so Amneal's Delisting Counterclaims should be dismissed with prejudice.

The Asserted Patents listed for ProAir® HFA claim "the drug" as defined under 21 U.S.C. § 321(g)(1). ProAir® HFA is an inhalation aerosol (*see* CC ¶ 13 & Ex. E at 2), which, as discussed above,[9] is considered a "drug product" by the USP and thus a "drug" under clause (A) of the definition. *See* 21 U.S.C. § 321(g)(1)(A).

[9] *See supra* note 6; *see also* Ex. 2 at 1 ("Inhalation aerosol drug products are more commonly known as metered-dose inhalers or MDIs.").

ProAir® HFA is also an article for use in the treatment or prevention of bronchospasm and an article used to improve the function of breathing (*see* CC Ex. E at 2–4), and thus is a "drug" under clauses (B) and (C) of the definition. *See id.* § 321(g)(1)(B) & (C). Furthermore, components of ProAir® HFA constitute "a component of any article specified in clause[s] (A), (B), or (C)" and thus are a "drug" under clause (D) of the definition. *Id.* § 321(g)(1)(D). The Asserted Patents claim the drug product ProAir® HFA[10] as well as components thereof (such as the dose counter).[11] Under a plain reading of the statute, they are properly listed in the Orange Book for ProAir® HFA.

The regulatory regime further supports that the Asserted Patents are properly listed. As discussed above, the Orange Book lists "metered aerosol" as a "dosage form" as well as the dosage form for ProAir® HFA. *See* Ex. 3, Orange Book at 3-11, C-1; *see also* CC Ex. E at 9 ("PROAIR HFA Inhalation Aerosol is a pressurized metered-dose aerosol unit with a dose counter.")). As the Asserted Patents claim a "metered aerosol" and components thereof, they claim a drug product as defined under the applicable regulations. *See* 21 C.F.R. § 314.3.

* * *

In sum, Amneal's Delisting Counterclaims are devoid of allegations sufficient

[10] *See, e.g.*, '712 patent at claims 16, 17; '289 patent at claims 1–10; '587 patent at claims 1–22.

[11] *See, e.g.*, '712 patent at claim 1; '808 patent at claim 1; '889 patent at claim 1.

to state an actionable counterclaim that the Asserted Patents should be delisted under 21 U.S.C. § 355, and should be dismissed with prejudice.

II. Amneal's Antitrust Counterclaims (Counts 6–10) Must Be Dismissed

Amneal's Antitrust Counterclaims should be dismissed in their entirety.[12] The monopolization-based claims that Amneal asserts require that the antitrust defendant both: (a) has monopoly power, and (b) engaged in anticompetitive conduct to improperly acquire or maintain that power. *Verizon Commc'ns., Inc. v. Law Offs. of Trinko, LLP*, 540 U.S. 398, 408 (2004). Even assuming *arguendo* for purposes of this motion that Teva has monopoly power in a properly defined relevant market,[13] Amneal still has failed to allege the required element of anticompetitive conduct.

Amneal relies on two purported forms of anticompetitive conduct: (1) improper Orange Book listing, and (2) sham litigation. But as discussed in detail below, antitrust law provides Amneal no cause of action for purportedly improper Orange Book listing, and the counterclaims fail to plausibly allege that Teva's patent

[12] Even though this Court can and should dismiss the Antitrust Counterclaims at this juncture for the reasons discussed herein, if any such counterclaim survives dismissal, the Antitrust Counterclaims should be bifurcated and discovery as to those claims stayed until resolution of Teva's patent claims and Amneal's Delisting Counterclaims. *Fresenius Kabi USA, LLC v. Fera Pharms., LLC*, 2017 WL 2213123, at *5 (D.N.J. May 19, 2017) ("severance and stay of antitrust counterclaims in patent infringement suits has become 'standard practice.'" (citation omitted)).

[13] Should the Antitrust Counterclaims proceed past Rule 12, Teva reserves all rights to challenge all aspects of monopoly power.

claims against Amneal are sham. Thus, no form of the alleged conduct underlying the counterclaims can support an antitrust claim, whether viewed individually or in combination, and Counts 6–10 of the counterclaims should be dismissed.

A. Amneal Has No Cognizable Antitrust Claim for Improper Orange Book Listing

Amneal's attempt to take the same conduct underlying its statutory counterclaim for delisting and transform that conduct into an affirmative antitrust claim fails for at least two reasons. First, Teva's patents are properly listed as a matter of law (*see supra* Argument § I.C), so any claim based on purported improper listing necessarily fails. Second, antitrust law does not create a cognizable claim for Amneal based on purported improper listing in any event; Amneal's sole cause of action is the statutory delisting counterclaim it is pursuing in Counts 1–5. Therefore, even if the Court were ultimately to conclude that some or all of Teva's patents were improperly listed (which Teva disputes), Amneal could not state an antitrust cause of action based on alleged improper listing as a matter of law.

1. The *Trinko* doctrine

The doctrine compelling dismissal of Amneal's improper-listing-based antitrust claims derives from the Supreme Court's decision in *Trinko*. The *Trinko* doctrine establishes that where Congress imposes a new statutory duty on a company to cooperate with competitors and also establishes a regulatory remedy for breaches of that statutory obligation, a plaintiff has no cause of action relating to that same

conduct under antitrust law. That is exactly the situation presented by Amneal's improper listing allegations, so those allegations cannot form the basis for any antitrust claim.

In *Trinko*, the Supreme Court addressed allegations that an incumbent long-distance telephone service provider had failed to comply with a statutory duty, imposed by the 1996 Telecommunications Act, to cooperate with new competitors seeking to provide long-distance phone service. Even if such violations had occurred, the Court held that they still could not support an antitrust claim as a matter of law because the statute also established a "regime for monitoring and enforcement" of those duties. *Trinko*, 540 U.S. at 401. "That Congress created these duties . . . does not automatically lead to the conclusion that they can be enforced by means of an antitrust claim." *Id*. at 406. As the Court explained:

> Antitrust analysis must always be attuned to the particular structure and circumstances of the industry at issue. Part of that attention to economic context is an awareness of the significance of regulation. As we have noted, "careful account must be taken of the pervasive federal and state regulation characteristic of the industry." "[A]ntitrust analysis must sensitively recognize and reflect the distinctive economic and legal setting of the regulated industry to which it applies."
>
> One factor of particular importance is the existence of a regulatory structure designed to deter and remedy anticompetitive harm. Where such a structure exists, the additional benefit to competition provided by antitrust enforcement will tend to be small, and it will be less plausible that the antitrust laws contemplate such additional scrutiny.

Id. at 411–12 (internal citations omitted). Applying those principles, the *Trinko* Court held that the enforcement mechanism within the Telecommunications Act itself "was an effective steward of the antitrust function," *id.* at 413, and that plaintiff's attempt to turn a violation of the statutory duty to cooperate in that case into an antitrust claim failed as a matter of law. *Id*. at 415–16.

2. *Trinko* forecloses Amneal's improper listing antitrust claim

The *Trinko* doctrine applies with full force to Amneal's attempt to state an antitrust claim based on Teva's purported improper listing of patents in the Orange Book. First, as in *Trinko*, the relevant statutory regime "imposes certain duties upon [NDA holder] companies in order to facilitate market entry by competitors." *Trinko*, 540 U.S. at 401. As relevant here, the Hatch-Waxman Act requires the NDA holder to file patent information for any patent which "claims the drug for which the applicant submitted the application" and with respect to 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."[14] 21 U.S.C. § 355(b)(1)(A)(viii). "The purpose of listing a patent in the Orange Book is to put potential generic manufacturers on notice that the brand considers the patent to cover its drug." *In re Restasis*, 333 F. Supp. 3d at 149. And, as the Supreme Court has

[14] There is no plausible argument that, absent the statute, antitrust law independently imposes a duty on Teva to assist Amneal in bringing its proposed generic version of ProAir® HFA to market in competition with Teva's product.

recognized, the purpose of providing this notice is "[t]o facilitate the approval of generic drugs as soon as patents allow." *Caraco*, 566 U.S. at 405. Thus, the Hatch-Waxman Act created a statutory obligation on a brand drug company to list patents in the Orange Book in order to help generic drug companies compete with the brand company by getting FDA approval for and launching their competing generic products more quickly. This duty is, for all relevant purposes, indistinguishable from the statutory duty imposed on incumbent service providers at issue in *Trinko*.

Second, and again as in *Trinko*, the relevant statute creates a "regime for monitoring and enforcement" of the statutory duty imposed on the NDA holder to cooperate with generics. 540 U.S. at 401. That enforcement regime includes the delisting counterclaim Congress enacted in 2003 specifically to police Orange Book listings and to provide a statutory remedy in the event of potential improper listings. That provision allows a defendant in Paragraph IV patent litigation to "assert a counterclaim seeking an order requiring the [NDA] holder to correct or delete the patent information submitted by the holder . . . on the ground that the patent does not claim . . . the drug for which the application was approved." 21 U.S.C. § 355(j)(5)(C)(ii)(I). In other words, the generic company defendant in patent litigation can file a counterclaim seeking an order compelling the NDA holder to delist a counterclaim that was improperly listed. This counterclaim enforces the listing requirement—and the limits on it—by creating a judicial remedy that cures

an improper listing by having it removed. Once delisted, the patent can no longer create an automatic stay of ANDA approval, thus remedying the potential competition-based concern that improper listing otherwise presents.

Indeed, the delisting counterclaim was enacted precisely to serve this "antitrust function" (in the words of *Trinko*, 540 U.S. at 413). Prior to 2003, there had been no effective mechanism to challenge and correct an improper Orange Book listing.[15] This problem had been highlighted by a high-profile case involving the brand drug BuSpar and a study by the FTC on generic entry. Both identified the possibility that an NDA holder could use an improperly-listed patent to obtain a 30-month stay of an ANDA's approval to which it was not otherwise entitled, potentially delaying generic entry, and there was no effective legal remedy to prevent that result. *Caraco*, 566 U.S. at 408. Congress responded by creating the delisting counterclaim, establishing for the first time a legal pathway for an ANDA filer to obtain a judicial order requiring the NDA holder to correct or delete an Orange Book listing if it was improper. *Id*. The statute also was designed to ensure that such relief would be timely: by requiring that any challenge to a listing would be presented as a counterclaim to Paragraph IV patent litigation, it allows a court to address the listing challenge at the same time that the FDA is evaluating whether to

[15] Before 2003, courts had held that a generic drug company did not have a private right of action to challenge an Orange Book listing. *See Mylan Pharms., Inc. v. Thompson*, 268 F.3d 1323 (Fed. Cir. 2001).

approve the ANDA, minimizing the risk that an improper Orange Book listing would delay generic entry.

The foregoing discussion shows the *Trinko* doctrine applies fully to Amneal's antitrust counterclaims premised on improper listing. The Orange Book statutory regime imposes a similar duty to cooperate and establishes a similar mechanism to monitor, enforce, and remedy breaches. As a result, any claim by Amneal based on the allegation that Teva's filing of the patents at issue was improper is cognizable only under the Delisting Statute's statutory counterclaim, not as an antitrust claim in this or any other litigation.[16]

Indeed, the Orange Book statutory regime goes one step further than the statute addressed in *Trinko* and, by its plain language, precludes an antitrust claim based on allegedly improper listing. The statute states expressly that any challenge to an Orange Book listing can be maintained ***solely*** as a delisting counterclaim. 21 U.S.C. § 355(j)(5)(C)(ii)(II); *see also Avadel CNS Pharms., LLC v. Becerra*, 638 F. Supp. 3d 23, 32 (D.D.C. 2022) ("Congress made explicit that the counterclaim it

[16] Courts have applied *Trinko* to bar antitrust claims in other comparable situations in the pharmaceutical industry where, as here, statutes and regulations establish non-antitrust remedies for the conduct at issue. *See, e.g., In re Suboxone Antitrust Litig.*, 64 F. Supp. 3d 665, 685–88 (E.D. Pa. 2014) (granting motion to dismiss antitrust claim premised on brand company's alleged non-cooperating with generics with the respect to REMS implementation, citing *Trinko*, because the statute governing REMS implementation "provides for increased FDA oversight and diminishes the need for antitrust scrutiny.").

created was available only in response to a patent infringement suit brought by the patentholder within the 45-day period"). Moreover, "[t]he availability of this unique counterclaim is a 'clear marker[] of legislative intent' that Congress meant to channel Orange Book-listing challenges through the FDCA's remedial scheme." *Avadel*, 638 F. Supp. 3d at 32–33. Although this statutory limitation is not necessary for *Trinko* to apply, its existence further reinforces that the delisting counterclaim is the sole remedy available to Amneal, to the exclusion of an antitrust claim.

Amneal gets no support for its claims from the 2004 decision in *In re Remeron Antitrust Litigation*, 335 F. Supp. 2d 522 (D.N.J. 2004). That case considered whether, during the period ***before*** the delisting counterclaim was enacted in 2003, *Trinko* barred an antitrust claim based on an Orange Book listing that was allegedly improper as being too late. *Remeron* allowed the antitrust claim to go forward because, as the statutory regime existed before 2003, and in contrast to *Trinko*, "the FDA regulators have (and choose to exert) significantly less authority over Orange Book listings because the Hatch-Waxman Act places the power to decide which patents to list on the private company that holds the NDA." *Id.* at 530. As a result, *Remeron* found, in the pre-2003 period, "there exist[ed] no regulatory scheme so extensive as to supplant antitrust laws." *Id*. at 531.

But the enactment of the delisting counterclaim in 2003 changed all that. The power of deciding whether a patent should remain in the Orange Book no longer

rests with the NDA holder; Congress created a statutory structure—nonexistent at the time addressed by *Remeron*—giving the ***courts*** the power to adjudicate that issue, in the context of the specific statutory counterclaim authorized in Hatch-Waxman patent litigation. In other words, by creating the delisting counterclaim, Congress filled the regulatory void identified by *Remeron* and created a regime that serves the antitrust function. Now there ***is*** a regulatory structure that supplants antitrust law, so *Trinko* applies fully and there is no cause of action under antitrust to challenge Orange Book listings. The sole remedy is the statutory delisting counterclaim, which Amneal invokes in Counts 1–5.

For all these reasons, Amneal's allegations about Teva's purportedly improper Orange Book listings—regardless of their merits—do not plead cognizable anticompetitive conduct as a matter of law. The Court therefore should dismiss Count 8, as well as Counts 6, 9, and 10 to the extent they rely on allegations of purported improper listing.

B. The Antitrust Counterclaims Fail to Plead Sham Litigation as a Matter of Law

Amneal's counterclaims alleging that Teva violated the antitrust laws because its patent infringement action purportedly constitutes "sham litigation" should be dismissed.[17] The burden of pleading (and proving) sham litigation is, by design,

[17] Counterclaim Counts 7, 8, 9, and 10.

difficult to meet, and Amneal's counterclaims fail to do so.

"Any antitrust claim based on a party's pursuit of litigation must surmount the high bar of the *Noerr-Pennington* doctrine. 'Rooted in the First Amendment and fears about the threat of chilling political speech,' the *Noerr–Pennington* doctrine provides immunity from antitrust liability for parties who petition the government for redress." *Indivior Inc. v. Alvogen Pine Brook LLC*, 2023 WL 6936749, at *12 (D.N.J. July 10, 2023) (quoting *In re Lipitor Antitrust Litig.*, 868 F.3d. 231, 264 (3d Cir. 2017)). Under the *Noerr-Pennington* doctrine, immunity is withheld only if the lawsuit is "a mere sham" to suppress competition. *Pro. Real Est. Invs., Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 56 (1993) ("*PRE*"). "The sham . . . exception is narrow," *Takeda Pharm. Co. Ltd. v. Zydus Pharms. (USA) Inc.*, 2021 WL 3144897, at *11 (D.N.J. July 26, 2021), as an antitrust plaintiff's claim must satisfy an "exacting two-step test [that] properly places a heavy thumb on the scale in favor of the defendant." *Hanover 3201 Realty LLC v. Vill. Supermarkets, Inc.*, 806 F.3d 162, 180 (3d Cir. 2015). First, the lawsuit "must be objectively baseless in the sense that no reasonable [party] could realistically expect success on the merits." *PRE*, 508 U.S. at 60. Second, the suit or petition must be subjectively intended to "use . . . the governmental process—as opposed to the outcome of that process—as an anticompetitive weapon." *Id*. at 60–61 (emphasis omitted). Importantly, a court should not even consider the second, subjective prong of the test unless the first,

objective baselessness prong, is satisfied. *Id*. at 60.

Further, a counterclaim-plaintiff faces "an uphill battle" when alleging that a patent infringement suit under the Hatch-Waxman Act (like the one at issue here) was a sham because "the submission of an ANDA is, by statutory definition, an infringing act." *In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132, 147, 149 (3d Cir. 2017). Therefore, an infringement suit "filed in response to an ANDA with a paragraph IV certification could only be objectively baseless if no reasonable person could disagree with the assertions of noninfringement or invalidity in the [Paragraph IV] certification." *Id*. at 149.

Moreover, Amneal brings these counterclaims against a backdrop of recent litigation: Teva ***won*** at trial against a different generic company when asserting three of the same patents at issue here. *See Teva Branded Pharm. Prods. R&D, Inc. v. Cipla Ltd.*, 2023 WL 4996825 (D.N.J. June 21, 2023) ("*Cipla*").[18] In the *Cipla* litigation, the defendant sought to market a generic version of another Teva respiratory drug product administered through an inhaler for metered-dose inhalation and that incorporates a dose counter. There, as here, Teva asserted that the proposed generic product infringed Teva's patents claiming inhalers and components thereof. After trial, the Court held that the generic device infringed each

[18] The *Cipla* trial involved the '289, '587, and '808 patents, each of which Teva has asserted against Amneal in this litigation.

patent and the defendant had failed to prove that the patents are invalid. *Id*. at *23.

Against this background, Amneal's counterclaims fail to meet the demanding standard required for pleading a plausible sham-litigation claim, for several independent reasons. To begin with, Amneal does not even mention the *Cipla* litigation, let alone attempt to explain how Teva's lawsuit asserting the patents at issue here could be objectively baseless, at least in part based on invalidity, when Teva ***won*** in asserting the same patents against another generic product.[19] This failure on Amneal's part is fatal for purposes of its sham-litigation counterclaims. The *Cipla* litigation – regardless of the outcome of the appeal Cipla has filed – was not sham as a matter of law: "A winning lawsuit is by definition a reasonable effort at petitioning for redress and therefore not a sham." *PRE*, 508 U.S. at 60 n.5; *accord Indivior*, 2023 WL 6936749 at *14 (lawsuit cannot have been sham when plaintiff prevailed in district court regardless of outcome on appeal). Amneal never even attempts to explain—or plausibly plead—how Teva's patent lawsuit against Amneal could be objectively baseless when the *Cipla* case on the same patents was not. To

[19] While Teva asserts two additional patents here that were not asserted at trial in *Cipla* (the '712 and '889 patents), Amneal provides no allegations why the results as to those patents would be any different. To the contrary, the counterclaims routinely lump together the five patents at issue as the "Asserted Patents" and make allegations about them as an undifferentiated collective. Furthermore, the Third Circuit has held that "the whole case has to be a sham" for the sham exception to apply, so the claims involving the two other patents do not change the analysis. *See Avaya Inc., RP v. Telecom Labs, Inc.*, 838 F.3d 354, 413 (3d Cir. 2016).

be sure, for ***patent*** law purposes, Amneal is not precluded from making its own challenge to Teva's patents in the ProAir® HFA litigation. But Amneal cannot, for ***antitrust*** purposes, simply ignore the *Cipla* decision, because it bears directly on the objective-reasonableness analysis.[20] Amneal cannot escape Rule 12 by putting its head in the sand. This failing alone requires dismissal.

The closest Amneal comes to attempting to satisfy its pleading burden is Paragraph 104 (repeated in Paragraph 285). Amneal alleges that "if the Amneal device is deemed to literally infringe the Asserted Patents, then axiomatically, the Asserted Patents would be invalid as anticipated." CC ¶¶ 104, 285. This allegation, too, falls woefully short, for several reasons.

To begin with, Amneal first raised this allegation too late as a matter of law for it to support a claim of sham litigation. As another court in this district recently explained, the relevant inquiry is "whether a lawsuit is objectively baseless at the time it is initiated." *Indivior*, 2023 WL 6936749, at *14; *accord In re Wellbutrin*, 868 F.3d at 148 ("The essential question is . . . whether the suit was a sham at the time it was filed."). At the time Teva filed its patent claims against Amneal, the information available to Teva as to the bases for Amneal's defenses was contained

[20] In light of the District Court issuing its findings of fact and conclusions of law following trial, the relevant facts from that case are not in dispute and therefore may be considered by this Court on this motion. *See, e.g., Indivior Inc. v. Dr. Reddy's Lab'ys S.A.*, 2020 WL 4932547, at *8 (D.N.J. Aug. 24, 2020); *see also ADP, LLC v. Ultimate Software Grp., Inc.*, 2018 WL 1151713, at *3 & n.3 (D.N.J. Mar. 5, 2018).

in Amneal's Detailed Statement. *See supra* Background § I.B. But Amneal did not raise ***any*** invalidity argument of any sort in its Detailed Statement. *See* Ex. 1, Amneal's Detailed Statement, at 1–32.[21] Nor did Amneal assert—as it (conclusorily) alleges now—that any construction of Teva's patents that could support a valid infringement theory would necessarily render the patents invalid.

Thus, the only allegation Amneal relies on to allege sham is one Amneal never asserted before Teva filed its complaint. Simple logic dictates this post-complaint argument (even if credited, which it should not be) cannot demonstrate that the patent litigation was objectively baseless ***at the time it was filed***. Indeed, by resting its sham litigation counterclaims solely on new arguments ***not*** set out in its Detailed Statement, Amneal effectively concedes that Teva had an objectively reasonable basis to file suit when it did, based on the limited defenses Amneal had set forth in its Detailed Statement. That is end of the matter. *In re Wellbutrin*, 868 F.3d at 149.

Second, and in any event, the allegations of Paragraphs 104 and 285 are entirely conclusory and fail basic pleading standards. As the Supreme Court held in *Twombly*—itself an antitrust case—a pleading offering merely "labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." 550 U.S. at 555; *see also Best Deals*, 2023 WL 3072756, at *3. Amneal's

[21] The Court may consider Amneal's Detailed Statement as Amneal incorporated it in its Counterclaims (CC ¶¶ 19–24). *See Nasyrova*, 2015 WL 382846, at *5.

allegations are exactly that. Without any factual support, Amneal simply alleges that the device in its ANDA Product "is itself prior art to the Asserted Patents" and therefore Amneal cannot infringe literally or under the doctrine of equivalents. *See* CC ¶¶ 104, 285. These legal conclusions supported by only conclusory allegations are insufficient to meet Amneal's pleading burden. *See Interlink Prods.*, 2015 WL 12840378, at *2 ("[A] court . . . will not accept bald assertions, unsupported conclusions, unwarranted inferences, or sweeping legal conclusions cast in the form of factual allegations." (citing *Iqbal*, 556 U.S. at 678–79)).

C. The Counterclaims Do Not Allege a Viable "Overall Scheme"

Amneal fares no better by combining its sham litigation (Count 7) and improper listing (Count 8) allegations into a single claim for a purported "overall scheme to monopolize" (Count 6). *E.g.*, CC ¶ 292. To be sure, antitrust law provides that a court should not "tightly compartmentaliz[e]" a plaintiff's proof and view each piece in isolation. *See Continental Ore Co. v. Union Carbide & Carbon Corp.*, 370 U.S. 690, 699 (1962). This principle, however, does not salvage an antitrust claim when, as here, each component of the purported "overall scheme" independently is not actionable under antitrust. As antitrust courts repeatedly point out: "Nothing plus nothing times nothing still equals nothing." *Zenith Radio Corp. v. Matsushita Elec. Indus. Co.*, 513 F. Supp. 1100, 1311 (E.D. Pa. 1981); *accord Pac. Bell Tel. Co. v. linkLine Commc'ns, Inc.*, 555. U.S. 438, 457 (2009) ("Two wrong claims do not

make one that is right."); *Mayor of Baltimore v. AbbVie Inc.*, 42 F.4th 709, 715 (7th Cir. 2022) ("As the district judge saw things, 0 + 0 = 0. We see this the same way."); *In re Suboxone Antitrust Litig.*, 2017 WL 3967911, at *8 & n.10 (E.D. Pa. Sept. 8, 2017) ("Logically . . . if none of the alleged conduct is exclusionary or anticompetitive, it cannot collectively violate. . . the Sherman Act.").

In addition, the law is clear that certain kinds of conduct can never be part of an overall scheme (also known as a "monopoly broth" claim). *E.g., Valassis Commc'ns, Inc. v. News Corp.*, 2019 WL 802093, at *10 (S.D.N.Y. Feb. 21, 2019) ("Not all actions of an alleged violator may be properly considered . . . as ingredients in a 'monopoly broth.'"). And non-sham litigation has been specifically identified by the Supreme Court as something that cannot be included in an overall-scheme claim. *United Mine Workers of Am. v. Pennington*, 381 U.S. 657, 670 (1965) ("efforts to influence public officials do not violate the antitrust laws . . . either standing alone or as part of a broader scheme"); *accord Abbott Labs. v. Teva Pharms. USA, Inc.*, 432 F. Supp. 2d 408, 430 (D. Del. 2006) ("Plaintiffs may not use litigation conduct to support a claim of an overall scheme to monopolize if they cannot prove that the litigation was a sham"). As discussed above, Amneal has not plausibly alleged sham litigation. As a result, the "overall scheme" claim in Count 6 pleads nothing more than improper listing, which itself is not actionable anticompetitive conduct for antitrust purposes, as described above. For this reason, too, the "overall

scheme" claim in Count 6 fails.

D. The Remaining Antitrust Counterclaims Fail

In Count 9, Amneal purports to allege a claim for attempted (as opposed to actual) monopolization under federal law. That claim, too, is premised on Amneal's allegations about purported sham litigation and improper listing. *See* CC ¶ 318. But the requirement for anticompetitive conduct is the same for both attempted and actual monopolization. *See, e.g., Eisai, Inc. v. Sanofi Aventis U.S., LLC*, 821 F.3d 394, 402 & n.11 (3d Cir. 2016) (affirming summary judgment on actual and attempted monopolization counts on the same basis of failing to show anticompetitive conduct). Therefore, the attempted monopolization claim in Count 9 fails for all the same reasons already discussed.

Similarly, Amneal's claims in Count 10 under the New Jersey state antitrust laws also fail, for the same reasons discussed above. "[T]he New Jersey Antitrust Act shall be construed in harmony with ruling judicial interpretations of comparable federal antitrust statutes." *State v. N.J. Trade Waste Ass'n*, 472 A.2d 1050, 1056 (1984). Courts accordingly have applied the same law to both federal and New Jersey antitrust claims and have dismissed the latter on the same basis as the former. *See, e.g., Eisai*, 821 F.3d at 402 & n.11.

CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that the Court dismiss Defendants' Counterclaim Counts 1–10 with prejudice.

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Respectfully submitted,

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