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

TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC., NORTON (WATERFORD) LTD., and TEVA PHARMACEUTICALS USA, INC. Plaintiffs, v. 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 [redacted] *Oral Argument Requested* REDACTED - PUBLIC VERSION

CONSOLIDATED BRIEF IN SUPPORT OF DEFENDANTS' RULE 12(c) MOTION AND IN OPPOSITION TO PLAINTIFFS' MOTION TO DISMISS

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Defendants Amneal Pharmaceuticals of New York, LLC, Amneal Ireland Limited, Amneal Pharmaceuticals LLC, and Amneal Pharmaceuticals Inc. (collectively, "Amneal") respectfully submit this consolidated brief in support of Amneal's Motion for Judgment on the Pleadings as to Counterclaims 1-5 (the delisting counterclaims in D.I. 12) and in opposition to Plaintiffs Teva Branded Pharmaceutical Products R&D, Inc., Norton (Waterford) Limited, and Teva Pharmaceuticals USA, Inc.'s (collectively, "Teva") motion to dismiss Counterclaims 1-10.

INTRODUCTION

Amneal is asking the Court to promptly remove a prejudicial barrier imposed by Teva's abuse of the Hatch-Waxman Act. Teva improperly listed the asserted device patents in the Orange Book, and then sued Amneal to trigger a stay delaying FDA approval of Amneal's generic ProAir® HFA medication until 2026.

Amneal's requested remedy is an order compelling Teva to delist those patents promptly. The FTC and numerous congresspeople have called for exactly that, but Teva has refused. Only this Court has the power to order the patents to be delisted by granting judgment as a matter of law on Amneal's well-plead delisting counterclaims. This Court should exercise its power to remedy the mounting harms to Amneal and patients who need this vital and affordable medication.

By statute, the Orange Book is reserved exclusively for *drug* patents, and precludes listing *device* patents. Yet Teva has listed its *device* patents in the Orange Book for ProAir® HFA. This cannot be squared with the governing statute or with common sense. A device is not a drug, and Teva's device patents should be delisted.

For this reason, judgment as a matter of law is appropriate. The statute prohibits listing patents that do not claim a drug or a method of using that drug. Under that same statute, a device is not a drug, and does not transform into one when used in a drug/device combination product. This not only comports with common sense and the plain meaning of the statute, it is confirmed by an array of appellate authority and standard interpretive sources, including the legislative history and FDA regulations and publications.

The dispositive and publicly available facts here are as clear as the law. These are device patents, plain and simple. On their face, they claim inhaler devices, and do not claim any drug or a method of using any drug. This is not subject to any cognizable or plausible dispute. The patents themselves repeatedly and literally call inhalers "devices." The ProAir® HFA label refers to its inhaler as a device. The approval packet published by FDA for ProAir® HFA confirms that its inhaler is a device. Teva cannot rewrite the patents now to forestall judgment on the pleadings.

Amneal is hardly alone in seeking to delist the ProAir® HFA patents. The FTC has concluded that the patents must be delisted and has publicly demanded that Teva delist them. What is more, a chorus of congresspeople have joined in the call for Teva to delist its patents. Teva has refused.

This delisting is urgent. The FDA has scheduled approval of Amneal's ANDA products as early as *this April*, but the 30-month stay triggered by this lawsuit does not expire until February 2026. If Teva had not submitted its device patents for listing in the first place, or not enforced them, there would be no stay. Delisting them now will lead to dissolution of Teva's ill-gotten stay. But while these patents remain listed, the stay remains in effect, and the harm and prejudice mounts against both Amneal and the public. Amneal will be delayed from selling and lose its investments in its ANDA product, and the public will continue to be deprived access to Amneal's affordable asthma medication.

As for Teva's motion to dismiss, it is meritless across the board. For the same reasons that the Court should grant Amneal's Rule 12(c) motion, Amneal has sufficiently pleaded its delisting counterclaims. And for the reasons detailed below, Amneal has sufficiently pleaded its antitrust counterclaims. The Court should deny Teva's motion.

BACKGROUND

The factual and regulatory context giving rise to Hatch-Waxman litigations is well-known to this Court and is detailed in Amneal's counterclaims. (D.I. 12, Counterclaims ("CC") ¶¶ 13-39.) Below is the background most salient to these motions.

I. Statutory and Regulatory Background

A. The Statutory Criteria for Listing Drug Patents in the Orange Book

The Federal Food, Drug, and Cosmetic Act (the "FDCA"), as amended by the Hatch-Waxman Act and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), governs approval of drugs and devices in the United States. 21 U.S.C. §§ 301 *et seq*. Anyone who wants to sell a new drug in the United States must submit a new drug application ("NDA") to the United States Food and Drug Administration ("FDA"). By statute, that application must provide certain information, including about patents that meet the criteria stated in 21 U.S.C. § 355(b)(1)(A)(viii).

Per this statute, a patent can be listed in the Orange Book only if it is one:

> (viii)…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.

Id. (emphases added). For brevity herein, (a) the lead paragraph of section (viii) is termed the "Reasonably Assert" criterion; (b) the first part of clause (I) is termed the "Claims the Drug" criterion; (c) the second part of clause (I) is termed the "Drug Substance" criterion; and (d) the third part of clause (I) is termed the "Drug Product" criterion. Collectively, these are referred to herein as the "Listing Criteria."

To qualify for listing, a patent must meet the Reasonably Assert criterion and satisfy either clause (I) or (II). Under clause (I), a patent must meet the Claims the Drug criterion and either the Drug Substance or the Drug Product criterion. *Id*. Under clause (II), a patent must claim a method of using the NDA drug.

Applicants are prohibited from submitting information for any patent that does not meet the Listing Criteria. 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."). FDA's implementing regulation underscores this statutory prohibition, noting that "the applicant must submit information *only on those patents*" that meet the statutory criteria. 21 C.F.R. § 314.53(b)(1) (emphasis added).

The FDA publishes submitted patent information online in the "Orange Book." 21 C.F.R. § 314.53(f); *Jazz Pharms., Inc. v. Avadel CNS Pharms., LLC.*, 60 F.4th 1373, 1377 (Fed. Cir. 2023).

B. Paragraph IV Litigation and Delisting Counterclaims

When an Abbreviated New Drug Application ("ANDA") is submitted to the FDA, it must include a certification as to each patent listed in the Orange Book for the corresponding NDA product. 21 U.S.C. § 355(j)(2)(A)(vii)(II)-(IV). If the ANDA certifies that one or more listed patents is invalid or will not be infringed (a "PIV Certification"), the ANDA applicant must notify the NDA holder and provide a detailed statement explaining why each such patent is invalid or not infringed. 21 U.S.C. § 355(j)(2)(B)(iv)(II).

The filing of a PIV Certification triggers the right of the NDA holder to file a patent infringement suit. *See* 35 U.S.C. § 271(e)(2)(A). If the NDA holder sues within 45 days of receiving notice of the PIV filing, final FDA approval of the ANDA is stayed for 30 months, unless the patent litigation is resolved sooner. 21 U.S.C. § 355(j)(5)(B)(iii). If the NDA holder does not sue within that 45-day period, the FDA may approve the ANDA immediately. *Id*.

If an infringement action is brought against an ANDA applicant in response to a PIV Certification, the ANDA applicant may, in addition to seeking remedies under antitrust theories, "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).

Importantly, an ANDA applicant cannot force removal of an improperly listed patent from the Orange Book by petitioning the FDA. The FDA has adopted a "ministerial" approach to curating the Orange Book. It does not verify that patents meet the Listing Criteria, and absent a request from the NDA holder, the FDA does not remove patents from the Orange Book. *Apotex, Inc. v. Thompson*, 347 F.3d 1335, 1347 (Fed. Cir. 2003); *see infra* Section V.B.1.b. (explaining FDA's role concerning the Orange Book). Although the FDA has a "listing dispute" process, the FDA will not adjudicate the dispute and will not remove any disputed patent unless the NDA holder requests removal of that patent. 21 C.F.R. § 314.53(f).

II. Factual Background

This Hatch-Waxman case exists because Teva improperly listed various patents for its ProAir® HFA product in the Orange Book, then sued Amneal upon receiving notice of Amneal's PIV certifications as to those patents.

A. Teva Improperly Listed the Asserted Patents in the Orange Book, then Sued Amneal to Trigger the 30-Month Stay.

Teva Branded Pharmaceutical Products R&D, Inc. holds approved NDA No. 021457 for ProAir® HFA (albuterol sulfate) Inhalation Aerosol ("ProAir® HFA"). (D.I. 7, ¶ 45.) Teva improperly listed several device patents in the Orange Book for ProAir® HFA, including 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").

(D.I. 7, ¶¶ 1, 49, 53, 57, 61, and 65; D.I. 12-11.) Each Asserted Patent is also listed in the Orange Book for at least one other NDA product, in addition to ProAir® HFA. (D.I. 12, CC ¶¶ 86-98, 164, 190, 218, 244, and 270; D.I. 12-14 through 12-22.)

Amneal submitted ANDA No. 211600 ("Amneal's ANDA") to the FDA seeking approval to market its generic version of ProAir® HFA ("Amneal ANDA Products"). (D.I. 12, CC ¶ 16.) By letter dated August 24, 2023 ("Amneal Notice Letter"), Amneal Pharmaceuticals of New York, LLC notified Teva that Amneal's ANDA had been submitted to the FDA containing a PIV Certification as to the Asserted Patents, among others. (D.I. 1 ¶¶ 1, 10.) With that letter, Amneal provided a detailed statement of the factual and legal bases for Amneal's noninfringement position (the "Detailed Statement") and offered Teva access to and provided the ANDA and samples of the accused product, before the filing of this lawsuit. (D.I. 12, Answer ¶¶ 10, 77, 78, 83, and 84, CC ¶ 19.)

Teva sued Amneal on October 6, 2023. (D.I. 1.) Through its amended complaint, Teva alleges infringement of the five Asserted Patents, all of which are listed in the Orange Book for ProAir® HFA. (D.I. 7, ¶ 1; D.I. 12-11.) Teva filed this lawsuit in time to trigger a 30-month stay, which does not expire until February 28, 2026. (D.I. 12, CC ¶¶ 23, 101-02.)

Amneal extensively pleads delisting counterclaims for all five Asserted Patents and attaches numerous documents to its counterclaims. (D.I. 12, CC ¶¶ 13-

100 (background), 134-270 (Counts 1-5), and exhibits thereto.) Amneal also extensively pleads antitrust counterclaims. (*Id*. at CC ¶¶ 13-133 (background), 271-323 (Counts 6-10).)

Teva has moved to dismiss the delisting and antitrust counterclaims. (D.I. 26.) Amneal now moves for judgment on the pleadings under Rule 12(c) on its delisting counterclaims, and the Court set a consolidated briefing schedule for the two motions. (D.I. 25, 35.)

B. The Asserted Patents Claim Only Devices.

The Asserted Patents do not claim drugs, drug products, or any method of using any drug. (D.I. 12, CC ¶¶ 76-85, 139-149, 170-180, 196-206, 224-234, 250-260; *see also* D.I. 7-1, 15 (Ex. A at cols. 9-10), 46 (Ex. B at cols. 21-22), 78-79 (Ex. C at cols. 21-23), 111 (Ex. D at cols. 21-22), and 143 (Ex. E at cols. 21-22).) Instead, they claim inhaler devices and dose counter devices that are part of inhaler devices. (D.I. 12, CC ¶¶ 153-59, 184-85, 210-13, 238-39, 264-65.)

The five Asserted Patents contain a total of 86 claims. Two claims of the '712 patent claim the "use of a dose counter" for preventing either miscounting (claim 18) or undercounting (claim 19) in an inhaler, without claiming any drug. (D.I. 7-1 at 15 (Ex. A at col. 10).) The other 84 claims claim either a dose counter or a metered dose inhaler having a dose counter. (D.I. 7-1 at 15, 46, 78-79, 111, and 143.)

Below are illustrative independent claims directed to inhalers:

1. 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.

('289 patent, cl. 1 (D.I. 7-1 at 46).)

1. 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.

('587 patent, cl. 1 (D.I. 7-1 at 78).)

Below are illustrative independent claims directed to dose counters:

1. 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.

('889 Patent, cl. 1 (D.I. 7-1 at 143).)

1. 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.

('808 patent, cl. 1 (D.I. 7-1 at 111).)

1. 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.

('712 patent, cl. 1 (D.I. 7-1 at 15).)

As can be seen, none of these claims requires a drug, a drug substance, a drug product, or a method of using a drug. Instead, each claim requires certain mechanical structures and positional, spatial and/or movement relationships between or among the structures. The dependent claims are the same in this respect. (D.I. 7-1 at 15, 46, 78-79, 111, and 143.)

C. The FTC Already Concluded and Demanded that the Asserted Patents Must Be Delisted.

The United States Federal Trade Commission (the "FTC") determined that the Asserted Patents are not properly listed in the Orange Book for ProAir® HFA, and demanded that Teva delist them. On November 7, 2023, the FTC sent Teva a letter (the "FTC Delisting Letter") stating that all Asserted Patents (plus others) are "improperly or inaccurately listed in the Orange Book" for ProAir® HFA. (D.I. 12-12.) The letter also explains that such improper Orange Book listings may result in a 30-month stay of FDA approval of "competing generic drug applications" and may "disincentivize investments in developing generic drugs, which risks delaying or thwarting competitive entry." (D.I. 12-12 at 3; *see infra* Section V.B. (detailing FTC's description of the anticompetitive implications of Teva's actions).) Several congresspeople have joined in the call, urging Teva to delist the Asserted Patents. (D.I. 24 at 1-2.)

LEGAL STANDARDS

A motion for judgment on the pleadings under Federal Rule of Civil Procedure Rule 12(c) is subject to the same legal standard as to a motion to dismiss under Rule 12(b)(6). *Bibbs v. Trans Union LLC*, 43 F.4th 331, 339 (3d Cir. 2022). Although in general the Court must accept as true the allegations in the pleadings of the non-moving party and draw all reasonable inferences in favor of the non-moving party, *id*., it need not accept as true such allegations that contradict matters properly subject to judicial notice or by exhibit, including the content of a patent, "such as the claims and the patent specification." *Secured Mail Solutions LLC v. Universal Wilde, Inc.*, 873 F.3d 905, 913 (Fed. Cir. 2017); *see also Gupta v. Wipro Limited*, 749 F. App'x. 94, 97 (3d Cir. 2018); *Beteiro, LLC v. BetMGM, LLC*, 626 F. Supp. 3d 789, 795 (D.N.J. 2022) (citing *Secured Mail Solutions*, 873 F.3d at 913); *Garcia v. New Jersey State Prison*, No. 05-cv-3159, 2007 WL 2669332, at *1 (D.N.J. Sept. 6, 2007). A court may grant a Rule 12(c) motion if, on the basis of the pleadings, the movant is entitled to judgment as a matter of law. *Bibbs*, 43 F.4th at 339.

ARGUMENT

The plain meaning of the Listing Criteria excludes device patents from the Orange Book, consistent with the common sense and logic that a device is not a drug, and is not transformed into a drug when used as part of a drug/device combination product.

These commonsense conclusions and plain meaning of the Listing Criteria are amply supported by an array of interpretive and judicial authority. The legislative history clearly shows that Congress intended to exclude from the Orange Book the very kind of device patents at issue here. The FDA regulations bear this out, and the appellate authority uniformly confirms it. Indeed, the listing of the Asserted Patents is so unambiguously improper that the FTC itself, and an array of congresspeople, have publicly demanded that Teva delist these patents.

The Asserted Patents should be removed from the Orange Book immediately. At bottom, the analysis is simple. The Asserted Patents meet none of the Listing Criteria[1] because they do not claim "the drug," a "drug substance," a "drug product," or a method of using a drug. Instead, the Asserted Patents claim only ***devices***, which according to the governing statute, are not drugs.

Nor is there any plausible set of allegations, let alone facts, that Teva could adduce in this case to avoid this conclusion as a matter of law. The proper interpretation of the governing statute is clear and consistent with common sense. And on their face, the Asserted Patents do not qualify for listing in the Orange Book under that proper interpretation. Teva cannot re-write the statute or the Asserted Patents, so those patents must be delisted.

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[1] None of the Asserted Patents meets the "Reasonably Assert" criterion, but Amneal is not relying on that failure as a basis for granting Amneal's Rule 12(c) motion.

I. By Statute, a Device Is Not a Drug.

A plain reading of the statute mirrors the intuitive notion that a device patent does not satisfy the Listing Criteria. This conclusion is supported by the legislative history, applicable FDA regulations, and appellate authority.

The plain meaning of "drug" excludes devices. When a statute's language is plain, it must be enforced according to its terms. *Sebelius v. Cloer*, 569 U.S. 369, 381 (2013). "When determining a statute's plain meaning, [the] starting point is the ordinary meaning of the words used." *U.S. v. Geiser*, 527 F.3d 288, 294 (3d Cir. 2008) (cleaned up). Here, the ordinary meaning of "drug" does not include a device. This is reflected in general dictionaries, which have long expressly excluded devices from the definition of "drug" as follows: "a substance intended for use as a component of a medicine *but not a device or a component, part, or accessory of a device*." (*See, e.g.*, Conroy Ex. 1,[2] Merriam-Webster's Collegiate Dictionary (2002) at 355 (emphasis added); Conroy Ex. 2, Merriam-Webster's Collegiate Dictionary (2020) at 383 (emphasis added).) Absent express statutory direction to the contrary, it defies common sense to say that an inhaler device or its dose counter accessory are "drugs." The Court "should avoid constructions that produce odd or absurd

[2] "Conroy Ex. [X]" refers to exhibit [X] attached to the Declaration of Rebekah Conroy, filed herewith.

results or that are inconsistent with common sense." *Bonkowski v. Oberg Indus., Inc.*, 787 F.3d 190, 200 (3d Cir. 2015) (quotation omitted).

Critically, as a matter of law, under the FDCA, FDA cannot classify a "device" as a "drug." *Genus Medical Techs. LLC v. FDA*, 994 F.3d 631, 632-33 (D.C. Cir. 2021). As detailed in *Genus Medical*, the FDCA defines both "drug" and "device."[3] Although the two definitions overlap, the "device" definition excludes products that work primarily through "chemical action within or on the body of man" or through "metabolization." *Genus Medical*, 994 F.3d at 637-38; 21 U.S.C. § 321(h)(1).

In *Genus Medical*, the D.C. Circuit considered the "purely legal" question of whether in view of these definitions, "the FDCA grants [the FDA] discretion to classify as a 'drug' any product that meets the statutory definition of a 'device'." *Id.* at 632, 644. After analyzing the definitions and considering "the text, statutory structure and legislative history" of the FDCA, the court held that the FDCA prohibits FDA from classifying something as a "drug" if it meets the definition of a

[3] *Id.* at 633; *see* 21 U.S.C. §§ 321(g)(1), (h)(1). The definition of "device" in § 321(h)(1) specifies that it does not apply in certain sections of Title 21, but that list of exclusions does not include § 355. The definition of "drug" in § 321(g) does not exclude any sections from its applicability. Thus, both definitions apply to § 355, which contains the Listing Criteria.

"device." *Id*. at 632-33, 644. Indeed, the court held that it would be an abuse of discretion for FDA to do that.[4]

Necessarily then, the FDCA prohibits the FDA from classifying a device *patent* as if it were a drug *patent*. By extension, if a patent claims only a device, it fails not only the Claims the Drug criterion, but also the Drug Substance and Drug Product criteria. This is because a patent that claims only a device does not claim any drug substance or drug product. Axiomatically, one cannot claim a "*drug* substance" or a "*drug* product" without somewhere claiming a *drug*.

Although the statute does not define a "drug substance (active ingredient) patent" or a "drug product (formulation or composition) patent,"[5] common sense dictates that a drug substance patent must claim a drug substance and a drug product patent must claim a drug product. After all, the claims define the invention. *See, e.g.*,

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[4] Teva argues that the definition of "drug" once was amended to remove language expressly excluding devices, implying that devices are now included within the definition of "drug." (D.I. 27 at 12.) *Genus Medical* expressly rejected that argument. *Genus Medical*, 994 F.3d at 639-640. This Court should, too.

[5] In the general definitions section of the FDCA, the term "drug product" is defined, but that definition is expressly limited to §§ 335a and 335b, indicating that the definition does not apply to § 355. 21 U.S.C. § 321(dd). That definition of "drug product" is "a drug subject to regulation under section 355, 360b, or 382 of this title or under section 262 of title 42." *Id*. If this definition were applicable to the Listing Criteria in § 355, such that "drug product" simply means "drug" as defined in § 321(g)(1), the result would be the same, because a patent claiming only a device could not claim a "drug," and thus could not claim a "drug product."

Allen Engineering Corp. v. Bartell Indus., Inc., 299 F.3d 1336, 1344 (Fed. Cir. 2002).

The FDA regulation implementing the Listing Criteria confirms this commonsense understanding. That regulation explains that listable patents:

> consist of drug substance (active ingredient) patents, drug product (formulation and composition) patents, and method-of-use patents. For patents that claim the drug substance, *the applicant must submit information only on those patents that* ***claim*** *the drug substance* that is the subject of the pending or approved NDA *or that* ***claim*** *a drug substance* that is the same as the active ingredient that is the subject of the approved or pending NDA.
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> * * * * *
>
> 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.

21 C.F.R. § 314.53(b)(1) (emphases added).

That same implementing regulation also suggests that a "drug product" patent must require the presence of a drug substance. The regulation defines "drug product" as "a finished dosage form . . . *that contains a drug substance* . . . ." 21 C.F.R. § 314.3 (emphasis added); 21 C.F.R. § 314.53 (incorporating definition of "drug product" from 21 C.F.R. § 314.3).[6] Logically, if a "drug product" requires the

[6] Likewise, the term "dosage form," which appears in the definition of "drug product," is also defined as requiring the presence of a drug substance. *Id*.

presence of a drug substance, then a drug product *patent* must also require the presence of a drug substance.[7]

Moreover, the legislative history of the Orange Book Transparency Act of 2020 ("OBTA") confirms that the Drug Substance and Drug Product criteria exclude device patents and should be narrowly construed. The only substantive change the OBTA made to the Listing Criteria was to add the Drug Substance and Drug Product criteria; the other criteria were merely reworded. *Compare* Conroy Ex. 8, H.R. Rep. No. 116-47 at 9-10 (2019) (reciting then-existing law in brackets, which included that "[t]he applicant shall file . . . any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug . . . .") *with* Conroy Ex. 9, Orange Book Transparency Act of 2020, Pub. L. No. 116-

[7] Teva argues that because the FDA regulation prohibits submitting certain kinds of patents (process, packaging, metabolites, and intermediates) for listing, "other types of patents" are listable. (D.I. 27 at 17.) Teva is wrong, at least with respect to device patents. Nothing in the regulation suggests that the list of excluded patents is exhaustive. Also, Teva's argument improperly relies on the inclusion/exclusion principle of statutory interpretation, even though 21 C.F.R. § 314.53 is a *regulation*, not a statute. Finally, even if applicable to a regulation, the principle is not implicated here, because the FDA did not *include* device patents elsewhere in the regulations, only to *exclude* them from the recitation of un-listable patent types.

290, 134 Stat. 4889 at Section (b)(1)(A)(viii) (Jan. 5, 2021) (adding clause (I) with the Drug Substance and Drug Product criteria).

As the Committee Report[8] for the OBTA demonstrates, the Drug Substance and Drug Product criteria were introduced expressly to preclude Orange Book listing of the very type of device patents that Teva improperly listed for ProAir® HFA. Committee reports are a particularly authoritative source for interpreting a statute. *Garcia v. U.S.*, 469 U.S. 70, 76 (1984). Here, when the Committee Report set forth the "Background and Need for Legislation," it explained that:

> While FDA has issued regulations clarifying certain types of patents that must be submitted . . . and certain types that must not be submitted, many patents are complex and may not fall clearly into the types identified by FDA. As a result, **some branded drug manufacturers . . . are submitting patents potentially for the purpose of blocking generic competition.**[3] . . . This legislation would help to ensure that the Orange Book is accurate and up-to-date, by specifying what information must be submitted to FDA and what information should be listed . . . .

Conroy Ex. 8, H.R. Rep. No. 116-47 at 4 (2019) (emphasis added) (footnote in original).

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[8] This report was prepared by the Committee on Energy and Commerce. Congressional committee reports accompany legislative measures when they are reported for chamber action and explain the proposed legislation and its intended effects in detail. These reports also offer the assigned committee's findings and recommendations.

To support the observation that some branded drug manufacturers may be submitting patents "for the purpose of blocking competition," in footnote 3, the Committee Report cited a 2018 article published in *Nature Biotechnology*. *Id*. That article analyzed the proliferation of device patents in the Orange Book for drug-device combination products, including, most commonly, *inhalers*. (*See* Conroy Ex. 3 at 142-43 (reporting that "[t]he most common such products were inhalers . . ." and that "market exclusivity extensions" from drug delivery device patents listed with the FDA were "particularly common among pens and inhalers.").) The supporting data for this article expressly included the Orange Book listing for ProAir® HFA.[9]

Further, amendments made to the OBTA before it was passed into law show that the Drug Substance and Drug Product criteria should be narrowly construed.

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[9] Supporting Data to Ex. 3 at row 7 (available at https://static-content.springer.com/esm/art%3A10.1038%2Fnbt.4078/MediaObjects/41587_2018_BFnbt4078_MOESM2_ESM.xlsx) (last accessed Feb 20, 2024) (listing ProAir® HFA by name). The Court may consider the substance of this article and its supplemental information without converting Amneal's motion to a motion for summary judgment. The article is a public document and is referred to in the legislative history. It is not offered for the truth of the statements it contains, but rather for the fact that it contains those statements. It therefore can be considered for the purposes of statutory interpretation, a legal question, and the Court may take judicial notice of it without converting to summary judgment. *See* Fed. R. Evid. 201; *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007); *Oran v. Stafford*, 226 F.3d 275, 289 (3d Cir. 2000).

The relevant amendments to that language imposed by the Senate are shown below in strikethrough[10]:

> …claims the drug for which the applicant submitted the application and is a drug substance (~~including~~ active ingredient) patent or a drug product (~~including~~ formulation and composition) patent…

Removing the open-ended modifier "including" from the parentheticals shows that those categories are specific and required, not illustrative or open-ended.

Finally, the First Circuit has already held that it is improper to list a patent in the Orange Book when, as here, it claims only a device. In *In re Lantus*, the listed patents claimed part of the drive mechanism of a drug injector pen. *In re Lantus Direct Purchaser Antitrust Litig.*, 950 F.3d 1, 5 (1st Cir. 2020). The injector pen was a component of an insulin injector drug product. *Id*. The First Circuit found that "because the claims . . . do not mention the drug[,]" the patent does not "claim the drug[.]" *Id*. at 8. The court then concluded that the patent was improperly listed in the Orange Book. *Id*.

II. By Statute, a Device Does Not Transform into a "Drug" When Used in a Drug/Device Combination Product.

Teva argues that the Asserted Patents are properly listed because a patent claiming a "component" of a drug necessarily claims a "drug." (D.I. 27 at 12-14.)

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[10] Strikethrough generated through a comparison of the original bill with the Senate amendment. *Compare* Conroy Ex. 8, H.R. Rep. No. 116-47 at 2 (2019) *with* Conroy Ex. 10, Congr. Rec. Vol. 166, No. 206 at S7242 (SA 2693) (Dec. 7, 2020).

As applied to patents claiming only devices, Teva's argument cannot be squared with the Listing Criteria, the FDCA's provisions governing combination products, or the FDA's regulations for such products. Moreover, Teva's argument has already been rejected by the First Circuit in *In re Lantus.* 950 F.3d at 5.

First, despite the FDCA repeatedly recognizing that drugs can have components, there is *no reference* to "components" in the Listing Criteria. "[W]here 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." *Rodriguez v. U.S.*, 480 U.S. 522, 525 (1987). This principle is especially telling here, because the subsection adjacent to (but not part of) the Listing Criteria expressly requires NDA applicants to submit "a full list of the articles used as *components* of such drug," and "samples of such drug and of the articles used as *components* thereof." *See* 21 U.S.C. § 355(b)(1)(A)(ii) and (v) (emphases added).

In other words, Congress told NDA applicants that they must provide information about (and samples of) the components of their NDA drug products, but in the very next breath, did not authorize them to list in the Orange Book patents claiming such components. This shows that the Listing Criteria do not permit listing of patents that claim only a component of a drug product.

Second, the First Circuit has already rejected Teva's argument. *In re Lantus*, 950 F.3d at 5. There, the listed patent claimed part of the drive mechanism for a drug injector pen component of an insulin injector drug/device combination product. *Id*. The court found that the patent was not properly listed because it did not claim the drug. *Id*. Responding to the argument that a component meets the FDCA's definition of "drug" in § 321(g), the court explained that "the absence of any mention of 'components' in the [Listing Criteria] cuts against any attempt to interpret the statute and its implementing regulations as requiring or allowing listing of patents that claim only components of a proposed drug." *Id*. at 9.

Third, the FDCA recognizes that a "device" does not become a "drug" merely through incorporation into a drug/device combination product. The statute expressly distinguishes between the "drug constituent part" and the "device constituent part," of a drug/device combination. 21 U.S.C. § 353(g)(4). It also permits applicants to submit separate applications for the drug constituent part and the device constituent part. 21 U.S.C. § 353(g)(5). Thus, per the FDCA, a device remains just a device, even when used in a drug/device combination product.

The FDA's implementing regulations for drug/device combination products confirms this reading of the statute. First, the regulations incorporate the separate definitions of "drug" and "device" from §§ 321(g) and (h), thus implicating the

reasoning from *Genus Medical*, discussed above. 21 C.F.R. §§ 3.2(f), (g).[11] Second, the regulations expressly recognize that in a drug/device combination product, the drug constituent part(s) and the device constituent part(s) contribute different modes of action, which remain separately identifiable. 21 C.F.R. § 3.2(k) ("Because combination products are comprised of more than one type of regulated article (biological product, device, or drug), and each constituent part contributes a biological product, device, or drug mode of action, combination products will typically have more than one identifiable mode of action."). Third, the regulations *prohibit* classifying a constituent part of a drug/device combination product as having a "drug mode of action" if that constituent part has a "device" mode of action. 21 C.F.R. §§ 3.2(k)(2), (3) ("A constituent part has a drug mode of action if it meets the definition of drug…and it does not have a . . . device mode of action.") (emphasis added).

Consistent with the section of the FDCA governing combination products, these regulations show that in FDA's considered view, a device remains a device, even when made part of a drug/device combination product. Logically, a patent claiming solely a device remains a device patent (and does not claim a drug), even

[11] 21 C.F.R. §§ 3.2(f) and (g) refer to sections 201(h) and 201(g)(1) of "the act," which are, respectively, 21 U.S.C. §§ 321(g)(1) and (h)(1). *See* 21 C.F.R. § 3.2(a).

when an embodiment of that claimed device is made part of a drug/device combination product.

Fourth, the legislative history of the Listing Criteria reinforces the reasoning of *In re Lantus*. Congress amended the NDA submission requirements and the Listing Criteria of § 355(b) on January 5, 2021, through enactment of the OBTA (Conroy Ex. 9) shortly after *In re Lantus* was decided. Teva implies that OBTA revisions to the Listing Criteria undermine the reasoning and conclusion of *In re Lantus*. (D.I. 27 at 13-14.) Teva has it exactly backwards.

Not only does the reasoning of *In re Lantus* still fully apply after the OBTA, it applies with *greater force*. It still applies, because neither the prior version of the Listing Criteria nor the current version uses the term "component," despite continued use of "component" in the *other* NDA submission requirements, as discussed above.

In re Lantus applies with even greater force, because after *In re Lantus* was decided, Congress passed on an opportunity to legislatively overrule it via the OBTA, and instead narrowed the Listing Criteria. Indeed, as noted above, on December 7, 2020, about ten months after *In re Lantus* was decided, and about two months before the OBTA bill passed into law, the Senate amended the Listing Criteria in the pending bill. *See* Conroy Ex. 10, Congr. Rec. Vol. 166, No. 206, at S7242 (SA 2693) (Dec. 7, 2020).

Notably, those amendments did not add any drug "component" language to the Listing Criteria. Instead, they *further narrowed* the Drug Substance and Drug Product criteria by striking the word "including" from the parentheticals. Congress is presumed to be aware of the existing legal landscape when it passes legislation. *Miles v. Apex Marine Corp.*, 498 U.S. 19, 32 (1990). Thus, in the wake of *In re Lantus*, Congress could have amended the OBTA bill to permit the listing of patents claiming only "components" of a drug product, but did not, and instead narrowed the criteria. This underscores that device patents have no place in the Orange Book.[12]

Teva also reframes its "component" argument in terms of patent law, arguing that the Asserted Patents "claim[] the drug for which the applicant submitted the application," because a patent "claims" a product if the product would infringe the claim, which can occur "even if the product has elements that are not explicitly recited by the claim." (D.I. 27 at 15.) Teva's argument cannot be squared with the

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[12] Teva argues that the FDA regulation implementing the Listing Criteria "require[s] listing patents covering any of the components of the drug product that contribute to the drug product's 'finished dosage form.'" (D.I. 27 at 16-17.) This unsupported leap in logic cannot overcome the statutory prohibition on treating a "device" as a "drug." It also improperly departs from the language of the statute and the regulation to introduce the overbroad and illogical concept that anything that "contribute[s]" to a finished dosage form is itself a "drug." Nor can it be squared with the definitions of "drug product" and "dosage form" incorporated into that same regulation, both of which require the presence of a drug substance. 21 C.F.R. § 314.3.

Listing Criteria, at least as applied to claims directed solely to devices. As explained above, a patent claiming solely a device cannot satisfy the Claims the Drug, Drug Substance, or Drug Product criteria, and incorporation into a combination product does not change that result.

III. The Asserted Patents Must Be Delisted.

A. The Asserted Patents Do Not Claim a Drug, Drug Substance, or Drug Product.

As Amneal amply pleaded in its counterclaims, the Asserted Patents claim only devices, and none of the claims of the Asserted Patents requires a drug of any kind. (D.I. 12, CC ¶¶ 68, 77-85, 104, 141-149, 160-163, 172-180, 186-189, 198-206, 214-217, 226-234, 240-243, 252-260, 266-269 and 285.) This is not a close call. The patents are clear on their face. These allegations are verifiable by simply reviewing the Asserted Patents.

Plainly, the claimed inhalers and dose counters meet the statutory definition of "device." On their face, the claimed inhaler devices themselves, and their dose counters, are each an "apparatus" or "machine" and do not work "through chemical action within or on the body of man or other animals." 21 U.S.C. § 321(h)(1). Nor do the inhalers or their dose counters get "metabolized." In its motion to dismiss, Teva does not argue against any of these obvious truths.

Nor could Teva plausibly deny them. Even if Teva attempted to, the Court need not (and should not) accept such assertions, because they would contradict the

Asserted Patents, which are public documents issued by the federal government and attached to the pleadings. The Court need not accept as true allegations that contradict matters properly subject to judicial notice or by exhibit, including the content of a patent, "such as the claims and the patent specification." *See, e.g.*, *Secured Mail Solutions*, 873 F.3d at 913; Fed. R. Evid. 201.

Moreover, to the extent the Asserted Patents claim some aspect of ProAir® HFA, they claim only the inhaler and/or dose counter parts of that product, parts that both Teva itself and the FDA have described repeatedly—and quite literally—as "devices." The Asserted Patents themselves repeatedly describe inhalers as devices. (*See, e.g.*, D.I. 7-1 at 11 ('712 patent at col. 1, ll. 47-65) (twice referring to an inhaler as "the device" and referring to metered dose inhalers as "devices"), 68 ('587 patent at col. 1, ll. 41, 55, 67 and col. 2, ll. 26, 33, 35) (referring to "inhaler devices").)

As another example, the ProAir® HFA label identifies "the parts of [the] ProAir® HFA inhaler *device*" as the "red plastic actuator," the "protective dust cap," the "metal canister," and the "dose counter attached to the back of the actuator." (D.I. 12-5 at 21 (emphasis added).) That label does not identify the active ingredient or the inactive ingredients contained in the canister as part of that "device."

As yet another example, the approval packet for ProAir® HFA identifies the inhaler as a "device," and indicates that a separate "device performance" review was conducted as part of the approval process. (D.I. 12-4 at 13, 15, 24.) The "device

performance" section of the FDA's Clinical Review refers to the metered dose inhaler as an "MDI device." (D.I. 12-4 at 58-59, 102, 109.) The Clinical Review also contains a section entitled "Medical *device* incidents or malfunctions," which refers to the MDI inhalers as devices. (D.I. 12-4 at 109-110 (emphasis added).) Further, the approval packet indicates that the "drug formulation" of a predecessor albuterol-HFA multidose inhaler was "albuterol with HFA propellant," and distinguishes that "formulation" from the actuator and canister. (D.I. 12-4 at 27, 52.)

The FDA has long regarded MDIs as a type of "device," even if they are incorporated into something that is regulated as a drug product. Indeed, final FDA guidance in place for more than 30 years states that "*FDA regards all nebulizers and MDI's as prescription devices*."[13]

Because the claims of the Asserted Patents claim solely devices, they cannot claim a "drug." *See Genus Medical*, 994 F.3d at 632-33; *In re Lantus.* 950 F.3d at 5. Because the Asserted Patents do not claim a drug, they cannot meet the Claims the Drug, Drug Substance,[14] or Drug Product criteria.

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[13] (Conroy Ex. 4, Reviewer Guidance for Nebulizers, Metered Dose Inhalers, Spacers and Actuators, at 5, 13 (October 1, 1993) (emphasis added).) The Court may take judicial notice of this public, government-issued document without converting Amneal's motion to one for summary judgment. *See* Fed. R. Evid. 201; *Tellabs,* 551 U.S. at 322; *Oran*, 226 F.3d at 289.

[14] In its motion to dismiss, Teva does not argue that the Asserted Patents are "drug substance (active ingredient) patents." Nor could they; the Orange Book entry

B. The Asserted Claims Do Not Claim a Method of Using Any Drug.

The Asserted Patents are not listable under clause (II) of the Listing Criteria because none of the Asserted Patents contains a claim to a method of using any drug, let alone the NDA drug. (D.I. 7-1 at 15, 46, 78-79, 111, and 143.) The only two claims in the Asserted Patents that recite the "use" of anything are the claims to the "use of a dose counter" device to prevent miscounting or undercounting in metered dose inhaler devices in the '712 patent. Plainly, such claims do not claim the use of any drug, let alone a method of using the NDA drug. (*Id*. at 15 (claims 18 and 19).)

Teva cannot plausibly contend otherwise. Indeed, had the Asserted Patents met the Listing Criteria under clause (II), Teva would have had to identify that method and the associated approved use for publication in the Orange Book. *See* 21 C.F.R. §§ 314.53(b), (c)(1), (c)(2)(ii), (c)(2)(ii)(P), and (e). As reflected by the blank "patent use code" column in the Orange Book listing for ProAir® HFA, Teva did not do that. (D.I. 12-11.)

IV. The Court Should Order Teva to Immediately Request Delisting of the Asserted Patents.

Because the Asserted Patents are improperly listed in the Orange Book, the Court can and should order Teva to withdraw the Asserted Patents from the Orange

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for ProAir® HFA does not identify any of the listed patents as drug substance patents. (D.I. 12-11 at 1.)

Book. *See* 21 U.S.C. § 355(j)(5)(C)(ii); 21 C.F.R. § 314.53(f)(2)(i). This will nullify Amneal's PIV certifications on those patents, and Amneal can then inform the FDA that with respect to the other listed patents for ProAir®, Teva did not bring and maintain a suit for infringement of those patents within 45 days of receipt of the Amneal Notice Letter. This will dissolve the 30-month stay, which never should have been triggered in the first place.[15]

V. The Court Should Deny Teva's Motion to Dismiss.

A. The Court Should Deny Teva's Motion to Dismiss Amneal's Delisting Counterclaims, Because Amneal Has Stated a Claim for Delisting of Each Asserted Patent.

As explained above, Amneal is entitled to judgment as a matter of law in its favor on its delisting counterclaims (Counts 1-5). The arguments and authorities presented above directly refute the purported bases for Teva's motion to dismiss. This alone defeats Teva's motion to dismiss these counts.

Teva also argues that Amneal's delisting allegations are conclusory or purely legal in nature. (D.I. 27 at 19-20.) This is spurious. Amneal's counterclaims are

[15] According to official FDA records, a generic version of ProAir® HFA was first marketed by the first-to-file generic applicant on February 26, 2020, which was more than 180 days ago. (D.I. 12, CC ¶¶ 63-65; D.I. 12-10 at 2.) Thus, there is no ANDA applicant currently eligible for 180-day generic exclusivity, and if such exclusivity once existed, it has expired or has been extinguished. Accordingly, pending exclusivity is not a barrier to removal of the Asserted Patents from the Orange Book. 21 C.F.R. § 314.53(f)(2)(i).

replete with factual allegations sufficient to state a claim for delisting. For example, Amneal alleges that the Asserted Patents claim only devices, not drugs. (D.I. 12, CC ¶¶ 61, 68, 104, 285.) Relatedly, Amneal also alleges that none of the Asserted Patents claim (1) a drug, (2) the drug for which the applicant submitted the ProAir® NDA, (3) a drug substance, (4) an active ingredient, (5) the active ingredient in ProAir® HFA, (6) a drug product, (7) a drug formulation, (8) a drug composition, (9) a method of using a drug, or (10) an approved method of using ProAir® HFA. (*See, e.g.*, *id.* ¶¶ 77-79, 81-83, 139-141, 143-144, 146-149, 170-172, 174-175, 177-180, 196-198, 200-201, 203-206, 224-226, 228-229, 231-234, 250-252, 254-255, 257-260.) Further, Amneal alleges that none of the Asserted Patents is a "drug substance (active ingredient) patent" or a "drug product (formulation or composition) patent." (*See, e.g.*, *id.* ¶¶ 80-81, 142, 145, 173, 176, 199, 202, 227, 230, 253, 256.) Amneal also pleads many supporting factual allegations as to what the claims do not recite. (*See, e.g.*, *id.* ¶¶ 84-85, 160-163, 186-189, 214-217, 240-243, 266-269.)

Teva then argues that Amneal's delisting counterclaims fail to state a claim because Amneal has not asserted various facts about ProAir® HFA. (D.I. 27 at 21.) But no such facts are required, as the Listing Criteria are focused on what the listed patents claim and what kind of patents they are. Further, Teva's argument that such allegations are necessary is based on Teva's incorrect interpretation of "drug."

Teva next criticizes Amneal's allegations regarding what the claims of the Asserted Patents "recite," noting that "the Listing Statute does not require that the listed patents 'recite' anything." (*Id.* at 21.) This ignores Amneal's extensive allegations on what the Asserted Patents do not claim, cited above.

Teva concludes by arguing that the counterclaims must be dismissed because they are properly listed. (*Id.* at 22-24.) This is merely a circular reprise of Teva's incorrect interpretation of the Listing Criteria.

B. The Court Should Deny Teva's Motion to Dismiss Amneal's Counterclaim Counts 6-10 Because Amneal has Sufficiently Pleaded Antitrust Claims.

The Court should deny Teva's motion to dismiss Amneal's antitrust counterclaims, because Amneal adequately alleges that Teva unlawfully insulated, extended, and protected its monopoly in the market for ProAir® HFA and its generic equivalents by listing patents in the Orange Book that failed to meet statutory criteria and then engaging in sham litigation. Specifically, by improperly listing the Asserted Patents and bringing baseless litigation, Teva invoked a statutory 30-month stay of approval, which delayed competition and injured Amneal. Teva's acts – whether considered independently or as part of an overall scheme – violate Section 2 of the Sherman Act and N.J. Stat Ann. §§ 56:9-1 et. seq. (D.I. 12, Counterclaim Counts 6-10.)

The FTC agrees. In a letter to Teva dated November 7, 2023, the FTC explained that "patents improperly listed in the Orange Book may delay lower-cost generic drug competition[,]" because "[b]y listing their patents in the Orange Book, brand drug companies may benefit from an automatic, 30-month stay of FDA approval of competing generic drug applications" and "disincentivize investments in developing generic drugs." (D.I. 12-12.)

In that letter, FTC identified the Asserted Patents as "improperly or inaccurately listed in the Orange Book" and warned Teva that such improper listings "prevent[] or delay[] generic drug entry." (*Id.*; *see also* D.I. 12, CC ¶¶ 69-70.) FTC also cited its earlier Policy Statement, which explains that inaccurate listings like Teva's may give rise to monopolization claims under Section 2 of the Sherman Act. (*See* Conroy Ex. 5, FTC Statement Concerning Brand Drug Manufacturers' Improper Listings of Patents in the Orange Book ("FTC Policy Statement") (Sept. 14, 2023).)

Amneal's allegations, which incorporate FTC's Delisting Letter, illustrate FTC's exact concerns. Specifically, Amneal alleges that "[b]ecause [Teva] had improperly listed the Asserted Patents in the Orange Book, [Amneal was] required to submit Paragraph IV Certifications . . . in order to seek approval from the FDA to engage in the commercial manufacture, use, offer of sale, sale, and/or importation of the Amneal ANDA Products prior to the expiration of the Asserted Patents." (D.I.

12, CC ¶ 101; *see also* 21 U.S.C. § 355(j)(5)(B)(ii)(A)(iv).) Amneal timely notified Teva of the submission of Amneal's ANDA and Paragraph IV Certifications. (D.I. 12, CC ¶ 101; *see also* 21 U.S.C. § 355(j)(5)(B)(ii)(A)(iii).)

In response to Amneal's Paragraph IV Certifications, and notwithstanding the detailed information provided by Amneal explaining why its product did not infringe the Asserted Patents, Teva filed this lawsuit within 45 days and triggered the Hatch-Waxman Act's 30-month stay of final approval of Amneal's ANDA. That stay will not expire until February 28, 2026. (D.I. 12, CC ¶¶ 23 (citing 21 U.S.C. § 355(j)(5)(B)(iii)), 102.) But for Teva's improper Orange Book listing and baseless patent infringement lawsuit, there would be no 30-month stay (*id.* at ¶ 102), and Amneal would be able to launch its lower-priced generic product much earlier. (*Id.* at ¶ 121.) Therefore, and for the reasons set forth more fully below, Amneal's counterclaims 6-10 are sufficient to allege a violation of the antitrust laws.

1. Amneal Has Sufficiently Pleaded An Antitrust Claim Based on Improper Orange Book Listing.

Relying on the Supreme Court's opinion in *Verizon Commc'ns, Inc. v. Trinko, LLP*, ("*Trinko*"), 540 U.S. 398 (2004), Teva argues that antitrust law creates no cognizable claim based on the improper listing of patents in the Orange Book, and that the delisting counterclaim described in the FDCA provides Amneal's only available remedy. (D.I. 27 at 25-32.) FTC pronouncements, decades of antitrust cases, Teva's arguments in prior litigation, the legislative history of the MMA, and

Trinko itself all contradict Teva's current position. The Sherman Act provides a remedy in the form of treble damages to deter and address the anticompetitive harm occasioned by the delay in generic entry when a patentee lists patents in the Orange Book that do not belong there. The FDCA provides an equitable remedy to excise a bogus listing that stands in the way of competition moving forward. These causes of action are in no way redundant or conflicting, and the availability of one claim does not block the other.

a. All three branches of government—and Teva itself—recognize antitrust claims based on improper Orange Book listings.

As the FTC explained in its letter to Teva, "the Supreme Court recognizes that improper Orange Book listings have prevented or delayed generic drug entry since at least the 1990s." (D.I. 12-12 (citing *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S,* 566 U.S. 399, 408 (2012)).) Since then, "courts have consistently recognized that improperly listing patents in the Orange Book may constitute an 'improper means' of maintaining or acquiring monopoly power." (Conroy Ex. 6, FTC Amicus Brief in *Mylan v. Sanofi* at 15.) In its September 2023 Policy Statement, FTC again affirmed that "improperly listing patents in the Orange Book may constitute an 'improper means' of competition . . . [and] be worthy of enforcement scrutiny from government and private enforcers under a monopolization theory." (*See* Conroy Ex. 5, FTC Policy Statement at 5-6.)

Indeed, antitrust claims predicated on improper Orange Book listings have been commonplace for decades. *See, e.g., United Food & Com. Workers Local 1776 v. Takeda Pharm. Co.*, 11 F.4th 118, 137-138 (2d Cir. 2021) (holding "in order to allege a monopolization claim; [plaintiffs] need only have plausibly alleged that Takeda had market power and that it incorrectly listed its combination patents as claiming ACTOS, causing their antitrust injuries"); *In re Lantus*, 950 F.3d at 7, 11 (finding a complaint plausibly alleged that Sanofi's improper listing in the Orange book was an 'improper means of maintaining [monopoly] power" and noting the "fact that Sanofi must align its conduct with regulatory requirements does not . . . mean that Sanofi gets a free pass from antitrust scrutiny"); *Rochester Drug Co-op., Inc. v. Braintree Lab'ys*, 712 F. Supp. 2d 308, 316-18 (D. Del. 2010) (holding that plaintiffs' improper listing allegations, when considered as part of an alleged overarching scheme to delay generic competition, were sufficient to allege Sherman Act § 2 antitrust claims); *In re Gabapentin Pat. Litig.*, 649 F. Supp. 2d 340, 359 (D.N.J. 2009) (holding that generic manufacturer adequately pleaded Sherman Act § 2 antitrust counterclaims by alleging that plaintiff engaged in an overall anticompetitive scheme including improper listing of relevant patents in the Orange Book); *In re Remeron Antitrust Litig.*, 335 F. Supp. 2d 522, 528 (D.N.J. 2004) (holding that late listing of patents in the Orange Book can give rise to a § 2 claim, and "[n]o authority ha[d] been cited to support the proposition that the antitrust laws

have been superseded by the Hatch-Waxman Act or by FDA regulations"); *In re Loestrin 24 Fe Antitrust Litig.*, 433 F. Supp. 3d 274, 315 (D.R.I. 2019) (allowing "sham Orange Book listing" claim to go to trial); *In re Buspirone Pat. Litig.*, 185 F. Supp. 2d 363, 372-73 (S.D.N.Y. 2002) (holding that improper Orange Book listing is not conduct immune from Sherman Act § 2 liability under the *Noerr-Pennington* doctrine).

In fact, ***Teva itself*** has brought monopolization counterclaims premised on improper Orange Book listings in at least one patent infringement action. *See Abbott Lab'ys v. Teva Pharms. USA, Inc.*, No. 1:02-cv-1512, Teva's Amended Counterclaims ¶¶ 11, 276-360, D.I. 369-1 (D. Del. 2005) (arguing that "Abbott's and Fournier's wrongful Orange Book listings are actionable on their own, and the wrongful listings are separately actionable as components of an overall scheme to monopolize").

Teva reverses course here and seeks to upend well-settled precedent, in part by pointing to the MMA. In 2003, the MMA added provisions to the FDCA allowing patent litigation defendants to bring a counterclaim seeking the equitable remedy of delisting. *See* 21 U.S.C. § 355(j)(5)(C)(ii)-(iii).[16] But Teva's argument that the MMA

[16] To be sure, nothing in the delisting provisions bar Amneal's antitrust claim. Subsection I of the delisting provisions provides that an ANDA "applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the

changed everything not only overlooks the above precedent (including the First Circuit's decision in *Lantus*) decided *post-MMA*. It also ignores that, just before sending the MMA to President Bush for signature, both the Senate and House of Representatives approved a Conference Report clearly stating that Congress did not intend for the MMA's delisting remedy to supersede or prohibit other causes of action seeking money damages based on improper Orange Book listing, for example, antitrust claims like those Amneal brings here. Congress explained:

> [The MMA provisions related to delisting counterclaims] prohibit[] the recovery of damages resulting from a successful counterclaim in a paragraph IV patent suit by an ANDA applicant seeking removal of a patent listed in the Orange Book. ***It is not the intent of Congress to prohibit recovery by a counterclaimant in a paragraph IV suit of anti-trust or any other damages as a result of the improper listing of a patent in the Orange Book.*** The language found in this section simply means that ***in the absence of any other cause of action***, a ruling in favor of the counterclaimant resulting in the removal of the patent does not entitle the counterclaimant to recover damages.

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patent information submitted by the holder . . . ." 21 U.S.C. § 355(j)(5)(C)(ii)(I). Subsection II states that "Subclause (I) does not authorize the assertion of a claim described in subclause (I) in any civil action or proceeding other than a counterclaim described in subclause (I)." *Id.* § 355(j)(5)(C)(ii)(II). Therefore, the function of § 355(j)(5)(C)(ii)(II) is to prohibit claims that seek delisting unless they are brought as a counterclaim in infringement litigation. It does not prohibit an antitrust counterclaim.

(Conroy Ex. 11, H.R. Rep. No. 108-391, at 836 (2003) (emphasis added).)[17]

In short, Teva's argument ignores well-established precedent and express congressional intent in a manner inconsistent with Teva's own prior conduct. Teva's basis to alter all of the above law is a novel interpretation of *Trinko*, 540 U.S. 398 (2004), that no court has ever adopted, as explained more fully below.

b. *Trinko* does not bar Amneal's antitrust counterclaims.

Even if Supreme Court precedent could compel a regulatory interpretation inconsistent with express congressional intent (it cannot), *Trinko* provides no basis to do so. In *Trinko*, the Supreme Court considered whether the antitrust laws should be *expanded* to create an exception to the general rule that a firm can refuse to deal with whomever it pleases. *Trinko* involved the Telecommunications Act of 1996, through which Congress required local exchange carriers ("LECs") to cooperate with their competitors in certain circumstances, and provided a cause of action to address a LEC's "insufficient assistance in the provision of service to rivals." *Trinko* 540 U.S. at 407-411. In that context, the Supreme Court declined to expand the

[17] Conference Reports like the 2003 MMA report are agreements on legislation negotiated between the House and Senate via conference committees. These reports reflect attempts of the conference committee to resolve disagreements between the House and Senate. Reports are printed and submitted to each chamber for consideration. If the report is accepted by both Chambers, as was the case with this report, the bill is enrolled and sent to the president.

Sherman Act's reach to require LECs to assist their competitors and "cautioned against expanding Sherman Act Section 2 liability when such expansion has the potential to conflict with the duties imposed by a separate regulatory scheme." *In re Remeron*, 335 F. Supp. 2d at 530 (citing *Trinko*, 540 U.S. at 411). The Supreme Court explained that where a regulatory structure "designed to deter and remedy anticompetitive harm . . . exists, the additional benefit to antitrust enforcement will tend to be small, and it will be less plausible that the antitrust laws contemplate such additional scrutiny." *Trinko*, 540 U.S. at 411. Importantly, *Trinko* did not address the circumstances, if any, under which well-established antitrust claims might be superseded by a regulatory scheme.

In an effort to squeeze its position into the *Trinko* mold, Teva casts the Hatch-Waxman provisions on Orange Book listing as creating a regulatory scheme designed to deter and remedy anticompetitive harm by imposing on patentees a duty to cooperate with their would-be generic competitors by listing patents in the Orange Book. That is incorrect. Orange Book listing primarily benefits the patentee, and the regulatory structure does not impose on patentees a "duty to cooperate" by listing patents in the Orange Book.[18] Even if Hatch-Waxman could be characterized as

[18] To support this narrative, Teva extols the supposed benefits to generics of patents being listed in the Orange Book. Those arguments are dubious at best: the requirement that NDA holders list patents that meet statutory criteria in the Orange

requiring patentees to "cooperate" by submitting patents for listing, Amneal's claim is not based on that purported duty. Rather, the gravamen of Amneal's claim is that Teva highjacked the statutory and regulatory structure by *improperly* listing patents – ensuring a 30-month stay of approval of any ANDA, and injuring Amneal. A long history of antitrust jurisprudence, which Congress recognized and explicitly intended to continue, prohibits abuse of a statutory process to delay generic competition.[19]

Book provides generic manufacturers like Amneal with notice. But that benefit is nominal, as the subject patents are otherwise publicly available and therefore discoverable, without the need for Orange Book listing. Instead, the primary benefits of the listing provisions inures to the patent holder, which, by listing a patent, can obtain: (i) the right to receive notice of any ANDA from applicants seeking FDA approval of a generic . . .; (ii) a grace period of forty-five days in which to bring a patent infringement suit against any such applicant before the applicant can file a declaratory judgment action; and (iii) . . . a stay of up to thirty months of the FDA's approval of the ANDA. *In re Buspirone*, 185 F. Supp. 2d at 372 (noting that a patentee can bring an infringement action without an Orange Book listing, and "[w]hat listing does is simply provide the owner of a patent with a number of additional and automatic benefits under the Hatch-Waxman Amendments").

[19] *In re Suboxone Antitrust Litig.*, 64 F. Supp. 3d 665 (E.D. Pa. 2014) is distinguishable for this very reason. There, the Eastern District of Pennsylvania analyzed a claim that Reckitt had "delayed ANDA approvals by feigning cooperation in the REMS process." 64 F. Supp. 3d at 675. Thus, the claim – unlike the counterclaims here – was arguably a "failure to cooperate" claim, and the court's conclusion rested on the principle that "the antitrust laws do not create a duty for competitors to work together." *Id.* at 686. In addition, although the *Suboxone* court found plaintiffs' failure to cooperate claims were not independently actionable, it allowed plaintiffs' claim that Reckitt engaged in an "overarching scheme to prevent or delay generic competition" to proceed, and that scheme included the Reckitt's failure to cooperate in the REMS process.

Moreover, *Trinko* is inapposite because, here, there is no complex regulatory scheme that serves to deter and remedy the harm to competition brought about by improper patent listings. *See Trinko*, 540 U.S. at 412. In *Trinko*, when LECs complained about Verizon's practices, the Federal Communications Commission ("FCC") investigated, levied a substantial fine, established "sophisticated measurements to gauge remediation," required weekly reporting, and set a schedule of penalties if Verizon failed to comply. *See id.* at 413. A separate local body, the New York Public Service Commission, imposed additional fines on Verizon and instituted a daily reporting requirement. *See id.* Finding that this statutory regime was "an effective steward of the antitrust function," the Supreme Court declined to recognize an exception that would otherwise allow "failure to cooperate" antitrust claims to be brought to achieve the same end. *See id.*

The Orange Book listing mechanism is very different. While the FCC and New York Public Service Commission engaged in extensive investigatory, penal, and oversight activities, the FDA's role with respect to Orange Book listing is "purely ministerial." *Apotex, Inc.*, 347 F.3d at 1347; *see also* 21 C.F.R. § 314.53(d)-(f) (describing FDA processes); Conroy Ex. 12, 68 Fed. Reg. 36682-36683 (FDA confirming its ministerial role, and observing "it would be inappropriate and impractical for us to create regulatory mechanisms for reviewing patent listings . . . we lack both the resources and the expertise to resolve such matters."); *In re Actos*

End-Payor Antitrust Litig., 417 F. Supp. 3d 352, 375 (S.D.N.Y. 2019) (describing the lack of "direct regulatory consequence" for improper Orange Book submissions "because the FDA does not affirmatively police these listings"); *In re Buspirone*, 185 F. Supp. 2d at 370-373 (declining to find *Noerr-Pennington* applies to Orange Book listing activity because "FDA's actions are non-discretionary and do not reflect any decision as to the validity of the representations in an Orange Book listing).

Indeed, the Southern District of New York in *In re Actos* recognized that the absence of FDA enforcement creates a powerful incentive for patent holders to misuse the Orange Book for anticompetitive ends, and that monopolization claims are necessary to "adequately deter NDA applicants from succumbing to their incentive to flout the Act's listing requirements." 417 F. Supp. 3d at 375.

For the same reason, no court has ever held that *Trinko* bars antitrust claims premised on improper Orange Book listings, and at least one court in this district has explicitly rejected that proposition. *In re Remeron*, 335 F. Supp. 2d at 522. *Remeron* involved allegations that the patentee, Organon, had delayed listing a patent in the Orange Book to hinder generic competition. *Id.* at 526. Organon made the same argument that Teva makes here – that FDA's regulation of the Orange Book bars plaintiffs' antitrust claims under *Trinko*. *Id.* at 530. Judge Hochberg rejected that argument, finding the Orange Book/Hatch-Waxman regulatory scheme not "so

extensive as to supplant antitrust laws" and that "[n]o authority ha[d] been cited to support the proposition that the antitrust laws have been superseded by the Hatch-Waxman Act or by FDA regulations."[20] *Id.* at 531.

Teva suggests that the delisting counterclaim, is, in and of itself, a 'regime for monitoring and enforcement' of the statutory duty imposed on the NDA holder to cooperate with generics." (D.I. 27 at 28.) But – setting aside that the delisting counterclaim does not enforce a duty to "cooperate" by properly listing patents, but rather the negative duty not to highjack the regulatory scheme by *improperly* listing patents that do not belong in the Orange Book – the delisting counterclaim, on its face, is not a regulatory scheme; it is an equitable judicial remedy. More importantly, the delisting counterclaim neither provides a remedy for the harms to competition alleged in Amneal's antitrust counterclaims, nor deters any patentee from listing improper patents in the first place. *See Am. Home Healthcare Servs., Inc. v. Floyd Mem'l Hosp. & Health Servs.*, No. 4:17-cv-00089, 2018 WL 1172995, at *6 (S.D.

[20] Teva's citation to *Avadel CNS Pharms., LLC v. Becerra*, 638 F. Supp. 3d 23 (D.D.C. 2022) is of no moment. That case held that *Avadel* could not proceed under the Administrative Procedures Act (APA), because its action sought "the precise end envisioned by Congress" in the delisting provisions: a declaratory judgment requiring delisting of certain contested patents. *Id.*; *see also id.* at 32 ("the inquiry centers on the remedies available to the plaintiff and the ability of those remedies to put the plaintiff in the position in which they seek to be placed"). Here, Amneal is not proceeding under the APA, and it is not seeking to delist the patents through its antitrust claims.

Ind. Mar. 5, 2018) (noting that for *Trinko* to apply, "the regulatory scheme must have regulations built into the scheme that serve the antitrust function" and that the court looks for "a regulatory structure that is designed to deter and remedy anti-competitive harm"). A successful delisting counterclaim corrects the Orange Book, but does not provide any other remedy or deterrent. *See* 21 U.S.C. § 355(j)(5)(C)(iii) ("An applicant shall not be entitled to damages in . . . counterclaim under clause (ii)."). Patentees face no liability for improper listings, which not only delay approval of ANDAs but up to 30 months, but also may deter ANDA filings in the first place. (*See* D.I. 12-12 at 3.) By contrast, the treble damages provided under the Sherman Act compensate ANDA filers for the harms suffered from improper listings, and deter such conduct going forward, encouraging the introduction of lower-cost generic medications and enhancing competition. *See Am. Soc'y of Merch. Eng'rs v. Hydrolevel Corp.*, 456 U.S. 556, 575-76 (1982) (observing that "treble damages serve as a means of deterring antitrust violations and of compensating victims"); *In re Actos,* 417 F. Supp. 3d at 375 (recognizing the importance of monopolization claims to "adequately deter NDA applicants from succumbing to their incentive to flout the Act's listing requirements").

Accordingly, neither § 355(j)(5)(C)(ii)(II) nor *Trinko* bar Amneal's antitrust counterclaims, and this Court should deny Teva's motion to dismiss on that ground.

2. Amneal Has Sufficiently Pleaded Sham Litigation.

Teva seeks dismissal of Amneal's antitrust claims based on sham litigation, asserting that it is entitled to *Noerr-Pennington* immunity because: (i) Amneal did not plead that Teva's patent infringement lawsuit was objectively baseless; (ii) Teva won at trial against Cipla in asserting three of the same patents at issue here; and (iii) Amneal's sham litigation claim is based solely on untimely assertions of patent invalidity. (D.I. 27 at 32-38.)

Teva's arguments are without merit. First, Amneal sufficiently pleaded that Teva lacked an objective and subjective basis to assert infringement. Second, whether the product at issue in the Cipla litigation infringed is immaterial to whether Teva had a basis to assert patent infringement against Amneal, and, in any event, is a question of fact that cannot be resolved on a motion to dismiss. And finally, Amneal's sham litigation allegations are timely and based on both non-infringement and invalidity.

As an initial matter, *Noerr-Pennington* immunity is not presumed in lawsuits filed in response to a paragraph IV certification. Teva asserts that "a counterclaim-plaintiff faces 'an uphill battle' when alleging that a patent infringement suit under the Hatch-Waxman Act" is a sham because it is a congressionally sanctioned response to a paragraph IV certification. (D.I. 27 at 34.) However, as the Third Circuit pointed out in *In re Wellbutrin XL Antitrust Litigation Indirect Purchaser*

Class, a case on which Teva relies, "[b]ecause a paragraph IV certification is defined as a technical act of infringement, it allows a patent owner to sue, ***but it does not speak to whether the disclosed generic drug does, in fact, infringe the cited patent***." 868 F.3d 132, 144 n.6 (3d Cir. 2017) (emphasis added). Moreover, "nothing in a paragraph IV certification necessarily compels the institution of an infringement suit." *Otsuka Pharm. Co. v. Torrent Pharms. Ltd., Inc.*, 118 F. Supp. 3d 646, 660 (D.N.J. 2015). Indeed, it is "commonplace for NDA owners ***not*** to file suit after analyzing the contents of an ANDA filer's notice and certification . . . ." *Id.* (emphasis added); *Takeda Pharm. Co. Ltd. v. Zydus Pharms. (USA) Inc.*, 358 F. Supp. 3d 389, 395 (D.N.J. 2018) (relying on *Otsuka* and rejecting the argument a lawsuit after paragraph IV certification is *per se* reasonable). Thus, a patent holder that files a lawsuit in response to a paragraph IV certification is not immune from antitrust liability if the lawsuit is a "sham"—that is, both "objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits" and subjectively baseless in that it is "an attempt to interfere directly with the business relationships of a competitor." *Prof'l Real Estate Inv'rs., Inc. v. Columbia Pictures Indus. Inc.*, 508 U.S. 49, 60-61 (1993).

a. Amneal adequately pleaded that Teva lacks an objectively reasonable basis to maintain its patent infringement claim.[21]

Amneal has adequately alleged that Teva lacks an objectively reasonable basis to maintain its patent infringement claim. Amneal alleges (and Teva admits) that Amneal provided Teva with: (i) a detailed statement setting forth the factual and legal bases for Amneal's noninfringement positions; (ii) ANDA excerpts; and (iii) samples of the accused product. (*See* D.I. 12, Answer ¶¶ 77, 78, 83, 84[22]; CC ¶¶ 19, 22, 103-105, 285, 287-288, 300-302; D.I. 27-1 (Walsh Decl. Ex. 1).) This information confirmed to Teva that it could not reasonably expect to succeed on its patent infringement claim. At a minimum, it creates a dispute of fact.

Courts in this district have repeatedly found that similar allegations are sufficient to support sham litigation claims. *See Otsuka*, 118 F. Supp. 3d at 656

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[21] Teva does not challenge the sufficiency of Amneal's allegations supporting subjective baselessness, which focuses on the wrongdoer's subjective intent. *Takeda Pharm. Co. Ltd.*, 358 F. Supp. at 394. Nor could it. Amneal has sufficiently alleged that Teva's patent claims are subjectively baseless. (D.I. 12, CC ¶¶ 287-302.)

[22] In its counterclaims, Amneal incorporates by reference its Answers to the First Amended Complaint ("FAC"). (D.I. 12, CC ¶ 1.) In reviewing a motion to dismiss, the Court may consider facts alleged in the pleadings, exhibits, matters of judicial notice, pleadings incorporated by reference, and documents referenced in pleadings. *S. Cross Overseas Agencies, Inc. v. Kwong Shipping Grp. Ltd.*, 181 F.3d 410, 426 (3d Cir. 1999). This includes allegations made in an answer to a complaint and incorporated by reference into a counterclaim. *Youell v. Grimes*, No. 00-cv-2207, 2001 WL 121955, at *4 (D. Kan. Feb. 8, 2001); *Miller Indus. Towing Equip. Inc. v. NRC Indus.*, 659 F. Supp. 3d 451, 461-62 (D.N.J. 2023).

(holding that allegations that Torrent provided a detailed statement of its position on non-infringement and that no reasonable litigant in Osuka's position could expect to succeed on the merits was sufficient to overcome *Noerr-Pennington* immunity at the motion to dismiss stage); *Takeda*, 358 F. Supp. 3d at 396, 397 n.5 (finding that allegations that Zydus provided Takeda with a detailed statement explaining why its amended ANDA did not infringe were "standing alone . . . sufficient to meet the sham litigation exception"); *Miller Indus. Towing Equip. Inc.*, 659 F. Supp. 3d at 464 (finding allegation that the claimant "reached out to [Plaintiff] to explain why Plaintiff lacked any credible basis for alleging infringement" to be sufficient).

The opinions in *Otsuka* and *Takeda* are conclusive. In *Otsuka*, Judge Simandle denied Otsuka's motion to dismiss Torrent's antitrust counterclaims for sham patent-infringement litigation, explaining that Torrent's provision to Otsuka of a detailed statement of noninfringement along with access to the ANDA were sufficient to plausibly allege sham litigation:

> . . . Torrent specifically alleges that it provided a "detailed statement of the factual and legal bases" for its position on the non-infringement of Torrent's ANDA, and that it subsequently provided the confirming "portions" of Torrent's ANDA. Torrent therefore alleges that the infringement claims asserted by Otsuka in this litigation lack an objectively reasonable basis, because "[n]o reasonable litigant could expect to secure favorable relief against Torrent upon the merits under the ′615 and ′796 patents." Moreover, because Otsuka "initiated litigation" despite Torrent's allegedly dispositive evidence of noninfringement, Torrent submits that Otsuka filed this action "in bad faith, for an improper purpose, and as a means of

> directly interfering with," forestalling, frustrating, and preventing competition by Torrent, and not in order to "obtain an adjudication of a valid claim."

Otsuka, 118 F. Supp. 3d at 656 (internal citation omitted).

Similarly, in *Takeda*, Judge Wolfson denied Takeda's motion to dismiss, finding that Zydus "sufficiently alleged facts to show that Takeda's 'petition[ing]' activity constitutes sham litigation." *Takeda*, 358 F. Supp. 3d at 396. In particular, the court noted that Zydus's provision of a "detailed statement explaining why [its] amended ANDA and its lansoprazole [ODT] tablets do not infringe the patents-in-suit, in addition to a letter further articulating numerous reasons why there could be no infringement" were "standing alone . . . sufficient to meet the sham litigation exception." *Id.* In its reasoning, the court further considered that Zydus offered Takeda access to its ANDA "from which Takeda could have confirmed that the ANDA product does not infringe," even though Takeda allegedly ignored those offers. *Id.* at 397.

Here, like in *Takeda* and *Otsuka*, Amneal alleges (and Teva admits) that on August 24, 2023, well before Teva filed its patent infringement lawsuit, Amneal provided Teva with a notice letter asserting noninfringement and attaching a detailed statement of the factual and legal bases for its noninfringement position (the "Detailed Statement"). (D.I. 12, Answer ¶¶ 10, 77, 84; CC ¶ 19; D.I. 27-1 (Walsh Decl. Ex. 1).) Indeed, Teva admits in Paragraph 84 of the FAC that the basis for

Amneal's Paragraph IV certification was "noninfringement" with the specifics being provided in the Detailed Statement, including details of the features claimed in Teva's patents but not present in Amneal's product. Although it is sufficient at the motion to dismiss stage that Amneal alleged its provision of the Detailed Statement to Teva, that Detailed Statement (which is incorporated into Amneal's counterclaims) further confirms the sufficiency of Amneal's pleading, because it outlines the features missing from Amneal's accused product, rendering it noninfringing:

Features Not Present in Amneal's Accused Product	**Detailed Statement Citation**
U.S. Patent No. 8,132,712 – Independent Claims 1, 18, and 19: • [redacted] • [redacted]	pp. 5-6.
U.S. Patent No. 9,463,289 – Independent Claim 1: • [redacted]	pp. 7-8.
U.S. Patent No. 9,808,587 – Independent Claims 1 and 12: • [redacted]	pp. 11-12.

[redacted] U.S. Patent No. 9,808,587 – Independent Claim 13: • [redacted]	
U.S. Patent No. 10,561,808 – Independent Claim 1: • [redacted] • [redacted]	pp. 26-27.
U.S. Patent No. 11,395,889 – Independent Claim 1: • [redacted] • [redacted]	pp. 31-32

Further, as noted above and as alleged in Amneal's counterclaims, at the time Amneal provided its Detailed Statement, Amneal offered Teva access to its ANDA, and Amneal did in fact give Teva access both to its ANDA and samples of Amneal's accused product prior to the filing of this action. (D.I. 12, Answer ¶¶ 78, 83.) This *offer* of access alone (which occurred on August 24, 2023) provides a sufficient

factual basis to support sham litigation claims at the motion to dismiss stage. *See Takeda*, 358 F. Supp. 3d at 397.

Importantly, Amneal's counterclaims expressly allege that because Teva was made aware of the legal and factual bases for noninfringement in the Detailed Statement, Teva could not expect to succeed on its patent infringement claims. D.I. 12, CC ¶¶ 22, 103, 104, 105, 285.) Given all this, whether Teva could have reasonably expected success requires "inquiry into issues of fact, which cannot be resolved in the context of a motion to dismiss, and prior to discovery." *Otsuka*, 118 F. Supp. 3d at 657 (citing cases) ("'objectively and subjectively baseless' infringement claims turns[] upon issues of reasonableness and intent-issues which are premature to consider upon the present record.").

b. The outcome of the Cipla litigation does not compel dismissal of Amneal's sham litigation claim.

To justify its patent infringement lawsuit, Teva argues that it "won at trial" when asserting infringement against Cipla's "respiratory drug product administered through an inhaler for metered-dose inhalation and that incorporates a dose counter." (D.I. 27 at 34.) That Teva proved Cipla's product infringed some of the Asserted Patents does not mean that Teva had an objective basis to claim that Amneal's product infringed. Teva cites no authority for that proposition. Additionally, Teva provides no detail on Cipla's product, how it compares to Amneal's, or why they should be treated identically for purposes of Teva's patent infringement claim here.

Nor could Teva make such assertions. A comparison of publicly available images from the Cipla litigation and Amneal's accused product demonstrate that the Cipla product is different. (*See* Conroy Ex. 7 at 4-5 and D.I. 27-1 (Walsh Decl. Ex. 1) at 2.) But even if Teva did provide more detail, whether the Cipla product and Amneal's product are the same or different such that Teva's victory in the Cipla litigation provides a reasonable basis for this lawsuit against Amneal is a question of fact that is not appropriate for determination at the motion to dismiss stage.

Therefore, Teva's purported bases for filing its patent litigation—Amneal's filing of a paragraph IV certification and Teva's prior success against Cipla—do not entitle Teva to *Noerr-Pennington* immunity *per se* or warrant dismissal of Amneal's counterclaims. To the contrary, whether a "sham litigation" has been filed "require[s] inquiry into issues of fact, which cannot be resolved in the context of a motion to dismiss, and prior to discovery." *Otsuka*, 118 F. Supp. 3d at 657. Indeed, "district courts within this Circuit have routinely prohibited parties from invoking the protections of *Noerr-Pennington* at the dismissal stage of a case in the context of patent suits, at which time the factual record remains undeveloped and insufficient for the purpose of determining whether a 'sham litigation' has been filed." *Takeda*, 358 F. Supp. 3d at 394; *S3 Graphics Co. v. ATI Techs. ULC*, No. 11-cv-1298, 2014 WL 573358, at *3 (D.N.J. Feb. 11, 2014) (holding that the issue of *Noerr-Pennington* immunity is "not proper before discovery"); *Hoffman La Roche Inc. v.*

Genpharm Inc., 50 F. Supp. 2d 367, 380 (D.N.J. 1999) ("Reasonableness is a question of fact, and the Court cannot make such factual determinations on a factual controversy roiled by a motion to dismiss.").

c. Amneal's sham litigation claim is timely.

Teva seeks dismissal of Amneal's sham litigation claim on the ground that "the only allegation Amneal relies on to allege sham"—that the patents at issue are invalid—is "too late as a matter of law" because Amneal "did not raise any invalidity argument of any sort in its Detailed Statement." (D.I. 27 at 37.)

It is not true that Amneal is "resting its sham litigation counterclaims solely" on invalidity. *Id*. Amneal's counterclaims repeatedly plead that Amneal's accused product does not ***infringe,*** in addition to allegations that the patents are invalid. (D.I. 12, CC ¶ 22 ("**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** . . . .") (emphasis added); *see also* CC ¶¶ 103, 104, and 285.) Amneal also asserted a counterclaim for declaratory judgment of noninfringement. (D.I. 12, CC ¶¶ 325-327.) Specifics on the basis for noninfringement are provided in the Detailed Statement, the ANDA, and the produced samples, all of which are incorporated into Amneal's counterclaims and can be considered on this motion.

3. Amneal Has Sufficiently Pleaded a Viable "Overall Scheme."

Teva makes the unremarkable assertion that "nothing plus nothing times nothing still equals nothing" as support for its argument that Amneal did not allege an overall scheme. (D.I. 27 at 38.) But, as set forth above, Amneal has not alleged "nothing." The cases Teva cites for the proposition that "certain kinds of conduct can never be part of an overall scheme," do not identify sham litigation or improper patent listing as the sort of conduct included in that category, and they have nothing to do with sham litigation or improper patent listing claims. *See, e.g.*, *Valassis Commc'ns, Inc. v. News Corp.*, 2019 WL 802093, at *10 (S.D.N.Y. Feb. 21, 2019) (involving claims of predatory bidding and pricing actions on motion for summary judgment); *Zenith Radio Corp. v. Matsushita Elec. Indus. Co.*, 513 F. Supp. 1100, 1311 (E.D. Pa. 1981) (reviewing evidence of causal antitrust injury on a motion for summary judgment); *United Mine Workers of Am. v. Pennington*, 381 U.S. 657, 670 (1965) (involving non-sham litigation). And, indeed, there are plenty of cases finding that sham litigation and improper patent listings *can* be part of an overall scheme.[23] *See, e.g.*, *Rochester Drug Co-op., Inc.*, 712 F. Supp. 2d at 318-19 (denying

[23] While Teva argues that "***non***-sham litigation has been specifically identified by the Supreme Court as something that cannot be included in an overall scheme," (D.I. 27 at 39 (emphasis added)), that point does not support dismissal of Amneal's counterclaims, as Amneal's overall scheme is not based on non-sham litigation, but rather sham litigation.

motion to dismiss antitrust claims involving, in part, improper Orange Book listing and sham litigation); *In re Neurontin Antitrust Litig.*, No. 02-cv-1830, 2009 WL 2751029 at *17-23 (D.N.J. Aug. 28, 2009) (same); *In re Gabapentin Pat. Litig.*, 649 F. Supp. 2d at 359 (same).

4. Amneal's Remaining Counterclaims Are Valid.

Teva seeks dismissal of Amneal's attempted monopolization counterclaim (Count 9) and monopolization under the New Jersey Antitrust Act counterclaim (Count 10) for the same reasons it seeks dismissal of Amneal's sham litigation and improper Orange Book listing counterclaims. For the reasons explained above, Teva's motion to dismiss Counts 8 and 9 of Amneal's counterclaims should be denied.

* * *

Accordingly, for all of the reasons set forth above, this Court should deny Teva's motion to dismiss Amneal's antitrust counterclaims and permit those claims to proceed as pleaded.

CONCLUSION

For the foregoing reasons, Amneal respectfully requests that the Court grant Amneal's Rule 12(c) motion for judgment on the pleadings as to Counts 1-5 of Amneal's counterclaims (D.I. 12) and, pursuant to 21 U.S.C. § 355(j)(5)(C)(ii), order Teva to withdraw the Asserted Patents from the Orange Book. In addition, Amneal

respectfully requests that the Court deny Teva's motion to dismiss (D.I. 26) Counts 1-10 of Amneal's counterclaims.

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Respectfully submitted,

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