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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC., NORTON (WATERFORD) LTD., and TEVA PHARMACEUTICALS USA, INC., Plaintiffs, v. AMNEAL PHARMACEUTICALS OF NEW YORK, LLC, AMNEAL IRELAND LIMITED, AMNEAL PHARMACEUTICALS LLC, and AMNEAL PHARMACEUTICALS INC., Defendants.	[redacted] Civil Action No. 23-cv-20964-SRC-MAH **Oral Argument Requested** *Electronically Filed*

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

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INTRODUCTION

Amneal's Consolidated Brief is based on a fundamental failure to interpret the Listing Statute[1] properly. Amneal argues that Teva's Asserted Patents should be delisted because they do not claim a "drug" and hence cannot meet the requirements that they (a) "claim[] the drug" and (b) are "drug product (formulation or composition) patent[s]." But Amneal's argument depends entirely on its "common sense" understanding of the word "drug," going so far as to quote dictionary definitions of the word, while studiously avoiding quoting or discussing the statutory definition of the term "drug." Contrary to the entire premise of Amneal's argument, the term "drug" is broadly defined in the statute. Moreover, Amneal never addresses the proper interpretation of the statutory term "claims," which in this context refers to whether a patent reads on the product, and not whether the name of a drug is explicitly recited or mentioned. When the Federal Circuit's interpretation of "claims" is combined with the statutory definition of "drug," Amneal's argument that the Asserted Patents fail to "claim[] the drug" in ProAir® HFA, and hence also fail to be "drug product" patents, falls apart.

The FTC fares no better. While the FTC comes to this Court as an amicus, its

[1] All defined terms from Teva's Brief in Support of Plaintiffs' Motion to Dismiss (ECF No. 27) ("Teva Br." or "Opening Brief") have the same meaning in this brief. "Amneal Br." refers to Amneal's Consolidated Brief in Support of Defendants' Rule 12(c) Motion and in Opposition to Plaintiffs' Motion to Dismiss (ECF No. 42). "FTC Br." refers to Federal Trade Commission's Brief as Amicus Curiae (ECF No. 61-1).

brief makes clear it is an advocate who sees Teva as its adversary. Like Amneal, the FTC fails to address the statute ***as written***, rather than as it wishes it were written. The FTC has no special expertise in interpreting the Listing Statute, and its brief is a policy statement about competitive effects of listing patents in the Orange Book. Putting aside that Teva has previously litigated patents concerning ProAir® HFA (in which no other defendant sought to delist the patents) and settled those cases by licensing its patent portfolio, these policy arguments cannot support the FTC's interpretation of the statute. The FTC asserts that the patents cannot be listed because they do not "mention" the active ingredient. But, as with Amneal, the FTC's cramped statutory reading to limit Orange Book listings to only patents that explicitly use the drug's name in the claims is unsupported by the statute.

While Amneal and the FTC now take similar positions concerning the scope of the Listing Statute (although with different reasoning), that synchrony is a new development. Amneal's position that the listing of the patents is "unambiguously improper" (Amneal Br. at 13) is a recent shift by Amneal. Amneal and the FTC repeatedly highlight that the FTC sent Teva a letter concerning the listing of the Asserted Patents. What both fail to note, however, is that Amneal received a similar letter from the FTC about its own patent listings. And until November 21, 2023, just ten days before Amneal filed its counterclaims, Amneal had interpreted the statute as Teva does. Indeed, contrary to the argument now presented, Amneal justified its

prior decision to list such patents in a letter to Congress, explaining that, "[i]n a good faith effort to comply with this statutory requirement given the regulatory guidance at the time, we submitted for listing in FDA's . . . Orange Book" certain patents. Ex. 4,[2] Jan. 10, 2024 Ltr. from Amneal to Congress, at 2. Amneal further explained that it "reasonably believed the patents were properly listed." *Id.* Amneal did not explain its change of heart concerning the scope of the Listing Statute, but noted the existence of this litigation and its challenges concerning Teva's patents. *Id.* Amneal had it right the first time. Properly interpreted, the Asserted Patents meet the requirements of the Listing Statute and belong in the Orange Book. Teva's Motion to Dismiss the Delisting Counterclaims should be granted, and Amneal's Motion for Judgment on the Pleadings should be denied.

Amneal's Antitrust Counterclaims fare no better. First, since the patents are properly listed, there can be no anticompetitive conduct from listing them. But even if the Court concluded that the propriety of the listing could not be determined at this stage of the case, these Antitrust Counterclaims still must be dismissed. Congress adopted a narrow and specific remedy for the conduct challenged by Amneal—a delisting counterclaim, decided by the Court (not a jury), with no right to seek damages. Amneal seeks to avoid the explicit limits imposed by Congress on its

[2] References in Teva's Opening and Consolidated Briefs to "Ex. [#]" refer to the numbered exhibits submitted by Teva with those briefs. The numbering here continues from the last numbered exhibit submitted with Teva's Opening Brief.

rights and remedy. Amneal does not dispute that the foundation of its antitrust case is precisely the same conduct that is now addressed by the delisting counterclaim. Under Supreme Court precedent in *Trinko*, Amneal cannot bring both a delisting and antitrust counterclaim at the same time. No matter the decision on the Delisting Counterclaims, the Court should dismiss the Antitrust Counterclaims with prejudice.

BACKGROUND

The parties' dispute over the interpretation of the Listing Statute arises from the parties' respective Rule 12 motions. On January 26, 2024, Teva filed a Motion to Dismiss the Delisting Counterclaims (Counts 1-5) and Antitrust Counterclaims (Counts 6-10) with prejudice pursuant to Fed. R. Civ. P. 12(b)(6). *See* ECF Nos. 26, 27. On February 20, 2024, after receiving leave to file a motion under Rule 12(c) prior to the counterclaim-Defendants answering the counterclaims (ECF No. 25), Amneal filed its Motion for Judgment on the Pleadings under Fed. R. Civ. P. 12(c) as to the Delisting Counterclaims as well as its Consolidated Brief in opposition to Teva's Motion to Dismiss. *See* ECF Nos. 41, 42. In addition, Amneal "recently informed FTC of this pending litigation along with [its] assertion of several antitrust and patent delisting counterclaims against Teva." Ex. 4 at 2. Shortly thereafter, the FTC sought leave to file as "Amicus Curiae" and filed its proposed Amicus Brief on March 22, 2024. *See* ECF Nos. 51, 54, 61. The Court granted the FTC's Unopposed Motion for Leave to File as Amicus Curiae on March 28, 2024. *See* ECF No. 63.

ARGUMENT

The parties' competing Rule 12 motions on the Delisting Counterclaims center on the interpretation of the governing statute for listing patents in the Orange Book—the Listing Statute. 21 U.S.C. § 355(b)(1)(A)(viii). The disputed language is as follows: The NDA applicant "shall submit" each patent that, *inter alia*, "***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***." *Id.* (emphasis added). Amneal and the FTC argue that the Asserted Patents must "mention" or "recite" the drug substance in order to be properly listed.[3] This narrow reading is not supported by the statute and should be rejected by this Court. Indeed, Amneal's arguments heavily rely on its argument for a "common sense" distinction between a "drug" and a "device."[4] However, Amneal's alleged "common sense" distinction cannot override the explicit statutory definitions of "drug" and "device."

[3] *E.g.*, Amneal Br. at 32 ("Amneal also pleads many supporting factual allegations as to what the claims do not recite."); Teva Br. at 9, 19-20 (collecting Amneal's allegations from its Counterclaims of what the Asserted Patents do not "recite"); FTC Br. at 2 ("In the FTC's view, device patents that do not mention any drug in their claims do not meet the statutory criteria for Orange Book listing . . . .").

[4] *E.g.*, Amneal Br. at 2 ("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." (emphasis in original)).

Each Asserted Patent[5] (1) "claims the drug" for ProAir® HFA as understood under the statutory regime and (2) is a "drug product (formulation or composition) patent." Under a proper construction of the Listing Statute, each Asserted Patent is properly listed. Amneal's counterclaims are based on an incorrect reading of the Listing Statute and corresponding regulations and should be dismissed on that basis. But even under Amneal's reading of the Listing Statute, Amneal's Delisting Counterclaims should be dismissed because they are based entirely on conclusory statements and legal conclusions that cannot form the basis for a well-pleaded claim.

Amneal's Antitrust Counterclaims should similarly be dismissed with prejudice. Amneal fails to respond substantively to most of Teva's arguments from its Opening Brief. And with good reason. Fundamentally, Amneal's Antitrust Counterclaims are barred because *Trinko* forecloses an antitrust claim based on conduct covered by the statutory delisting counterclaim.

I. The Proper Interpretation of the Listing Statute

The Listing Statute requires that an NDA applicant "shall submit" for listing in the Orange Book each patent that "claims the drug" and is a "drug product

[5] In the Amended Complaint, Plaintiffs have asserted five patents. ECF No. 7. Amneal's Delisting Counterclaims are directed to these five patents. On February 28, 2024, Teva provided Amneal its Disclosure of Asserted Claims Pursuant to L. Pat. R. 3.6(b) and identified no claims from the '712 patent. Although all five patents are properly listed, this brief thus focuses on the four patents for which asserted claims have been identified as part of this litigation—the '289, '587, '808, and '889 patents (Exhibits B-E, ECF No. 7-1).

(formulation or composition) patent." 21 U.S.C. § 355(b)(1)(A)(viii). Amneal tries to rewrite the language of the statute to make that obligation merely permissive (Amneal Br. at 4 ("Per this statute, a patent ***can be*** listed in the Orange Book only if . . ."") (emphasis added)), but the Listing Statute makes the patent listing requirements mandatory for important policy reasons—"to put potential generic manufacturers on notice that the brand considers the patent to cover its drug" and "to speed the introduction of low-cost generic drugs to market" (Teva Br. at 18 (quoting cases)). Here, as explained below, each Asserted Patent "claims the drug" and is a "drug product (formulation or composition) patent" and thus must be listed.

A. The Statutory Definition of the Term "Drug" Controls

The term "drug" in "claims the drug" has an explicit and unambiguous definition, and thus the use of this term in the Listing Statute must be construed according to that definition. *See* Teva Br. at 10-11 (discussing 21 U.S.C. § 321(g)(1)(A)-(D)). Indeed, Amneal acknowledges in a footnote that the "definition of 'drug' in § 321(g) does not exclude any section from its applicability" and that this "definition[] appl[ies] to § 355, which contains the Listing Criteria." *See* Amneal Br. at 15 n.3. Amneal, however, then conspicuously ignores the statutory definition of "drug" in the rest of its brief.

Instead, Amneal makes arguments about the "plain," "ordinary," "intuitive," or "common sense" meaning of the term "drug," including definitions of drug

"reflected in general dictionaries." Amneal Br. at 14-15.[6] However, "[w]hen a statute includes an explicit definition, we must follow [it], even if it varies from the term's ordinary meaning." Teva Br. at 11 (quoting *Stenberg v. Carhart*, 530 U.S. 914, 942 (2000)). Amneal ignores this mandate in arguing that "drug" should be given its "ordinary meaning" even though the cases it cites in its brief (at 14-15) emphasize that a word should only be given its "ordinary meaning" when, unlike here, a statute does not include a definition. *See United States v. Geiser*, 527 F.3d 288, 294 (3d Cir. 2008) (analyzing "the ordinary meaning of the words used" only after recognizing the statute "does not define 'persecution'" (citation omitted)); *Bonkowski v. Oberg Indus., Inc.*, 787 F.3d 190, 199-200 (3d Cir. 2015) ("***When words are not defined within the statute***, we construe them 'in accordance with [their] ordinary or natural meaning.'" (emphasis added) (citation omitted)). Thus, Amneal's repeated emphasis on the "plain" and "ordinary meaning" of the term "drug" is inapposite.

Without engaging with the statutory definition of drug, Amneal focuses its argument next on a "common sense" distinction between "drugs" and "devices." *See* Amneal Br. at 2, 21-27. The term "device" also has an explicit statutory definition:

> an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any

[6] Amneal's "common meaning" definition is a dictionary definition that relies upon the Food, Drug, and Cosmetic Act, but has failed to update the definition in light of the statutory amendments discussed herein. *See* Amneal Br., Exs. 1 and 2.

component, part, or accessory, which is--

> (A) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
>
> (B) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
>
> (C) intended to affect the structure or any function of the body of man or other animals, and
>
> ***which does not achieve its primary intended purposes through chemical action within or on the body of man*** or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

21 U.S.C. § 321(h)(1) (emphasis added). Despite the fact that "device" is explicitly defined in the statute, Amneal again ignores the definition and instead turns to descriptions of ProAir® HFA as a "device" in the patents and label as determinative of the patents claiming a device (and not a drug). The use of the word "device" in the Asserted Patents and ProAir® HFA label does not mean the Asserted Patents claim a "device" as defined by the statute, nor that the product as a whole is not a "drug" or "drug product." As with "drug," the statutory definition of "device" must control here. *See supra* p. 8 (collecting cases).

Additional context on the regulatory differences between "drugs" and "devices" is insightful. Drugs and devices are subject to distinct regulatory pathways. "[S]eparate divisions of the FDA are primarily responsible for each product category. Whereas drugs are generally regulated by the FDA's Center for

Drug Evaluation and Research, devices are within the purview of the FDA's Center for Devices and Radiological Health." *Genus Med. Techs. LLC v. FDA*, 994 F.3d 631, 633-34 (D.C. Cir. 2021) (summarizing these separate regulatory regimes). "The FDA holds new drugs to a high standard of pre-market review and approval." *Id.* The distinctions between the regulatory regimes mean that "on average, it is more costly for a sponsor to develop and market a product as a drug than it would be to develop and market an otherwise identical product as a device." *Id.*

As discussed in *Genus* (994 F.3d at 639-40), Congress amended the statutory definition of "drug" in 1990 to remove the exclusion of devices and their components from the definition of "drug." Safe Medical Device Act of 1990 ("SMDA"), Pub. L. No. 101–629, 104 Stat. 4511, 4526 ("[i]n paragraph (g)(1), by striking out '; but does not include devices or their components, parts or accessories'"). Analyzing the legislative history,[7] the *Genus* Court found that the SMDA amendments were meant to "facilitate the regulation of combination products." *Genus,* 994 F.3d at 640. The

[7] The *Genus* Court specified (994 F.3d at 640) that:

> Legislative history confirms that the amendments seek only to facilitate the FDA's regulation of the new category of "combination products." *See* S. Rep. No. 101-513, at 43 (1990) ("Section 19 [of the SMDA] alters the drug and device definitions in [21 U.S.C. § 321]. Language is removed from the drug definition *that will permit an approval of a drug/device combination."*) (emphasis added); *id.* at 30 ("By deleting this language, a product whose primary mode of action is attributable to a drug, but has a device component, may be reviewed under this Act's drug authority.").

Genus Court held that "[e]xcepting combination products, *see* 21 U.S.C. § 353(g), devices must be regulated as devices and drugs—if they do not also satisfy the device definition—must be regulated as drugs." *Id.* at 644.

Amneal's proposed "common sense" distinction between drugs and devices ignores the statutory approach to combination products. When a drug and a device are combined, and the entire combination product meets the definition of "drug," the entire product is regulated as a drug. *See* 21 U.S.C. § 353(g)(1). FDA considers a "metered dose inhaler" ("MDI") to be a "single-entity combination product"—i.e., "[a] product comprised of two or more regulated components (i.e., drug/device, . . .) that are physically, chemically, or otherwise combined or mixed and produced as a single entity." Ex. 5, FDA's Frequently Asked Questions About Combination Products (current as of Aug. 16, 2022), at 2-3. FDA regulates MDIs under the new drug provisions when the primary mode of action for the combination product is attributable to the drug component (as it is here). *See* 21 U.S.C. § 353(g)(1).

Nevertheless, Amneal asserts that "[t]he FDA has long regarded MDIs as a type of 'device,' even if they are incorporated into something that is regulated as a drug product." Amneal Br. at 29. In support, Amneal states that "final FDA guidance in place for more than 30 years states that '*FDA regards all nebulizers and MDI's as prescription devices*.'" *Id.* (emphasis in original) (quoting Amneal Br.,

Ex. 4,[8] Reviewer Guidance for Nebulizers, Metered Dose Inhalers, Spacers and Actuators, at 5 (October 1, 1993) ("1993 Guidance")). Amneal ignores the very next paragraph of the 1993 Guidance where FDA explains when "an aerosol delivery device will be considered a drug product and regulated" by CDER as such:

> Also note the Intercenter Agreements define that ***an aerosol delivery device will be considered a drug product*** and regulated by the Center for Drug Evaluation and Research (CDER), ***when the primary purpose of the device is delivering or aiding in the delivery of a drug and the device is distributed with the drug.*** Therefore, if a device is intended to deliver a specific drug or if the labeling references a specific drug product, the device will be considered a drug product and regulated by CDER.

Amneal Br., Ex. 4, 1993 Guidance, at 5 (emphasis added). There is no dispute that ProAir® HFA meets this standard.

More recent guidance from FDA confirms how FDA regulates MDIs and their components as drug products. FDA recently issued a jurisdictional update to "clarify the regulation of" "[MDIs] and accessories to be used with MDIs, such as spacers, actuators, spacers incorporating actuators, dose counters and locking clips." Ex. 6, FDA's Jurisdictional Update: Metered Dose Inhalers, Spacers and Other Accessories (current as of February 12, 2020), at 1. Consistent with the 1993 Guidance, FDA states that MDIs are regulated as drugs due to the primary mode of action being attributable to the drug component:

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[8] "Amneal Br., Ex. [#]" refers to the numbered exhibits submitted by Amneal with its Consolidated Brief.

> MDIs consist of a pressurized canister containing a drug substance and possibly excipients formulated with a propellant. The formulation is aerosolized through a valve fitted with an actuator (mouthpiece). FDA has concluded that MDIs are drug – device combination products. ***Based on the agency's determination that the primary mode of action of MDIs is attributable to the drug component, the Center for Drug Evaluation and Research (CDER) has regulated these products under the new drug provisions*** of the Federal Food, Drug, and Cosmetic Act (the act).

Id. In this guidance, FDA also explains when dose counters would be regulated under the drug provisions versus the device provisions:

> ***FDA believes that, in most cases, a dose counter must be designed to fit a specific MDI, and labeled for use with a specific MDI***. Therefore, dose counters frequently have been determined to be device components of combination products. ***Based on FDA's determination that the primary mode of action of such a combination product is attributable to its drug component, dose counters have been regulated by CDER under the new drug provisions of the act.***

Id. at 2. Both under the statute, and in practice with FDA, an integrated actuator and dose counter that serve as part of the delivery mechanism for an inhalation product fall within the statutory definition of "drug."

B. "Claims" Should be Given its Meaning Under Patent Law, Which Does Not Require "Reciting" or "Mentioning"

Neither Amneal nor the FTC explicitly address the meaning of the word "claims" in the Listing Statute. Section 355 requires Teva to list any patent that "***claims*** the drug," but does not require that the patent explicitly "mention" or "recite" the drug. As Teva explained in its Opening Brief (at 14-16), the term "claims" must be interpreted to incorporate its well-settled meaning in patent law.

See Jazz Pharms., Inc. v. Avadel CNS Pharms., LLC, 60 F.4th 1373, 1379 (Fed. Cir. 2023) ("An inquiry into whether a patent may be properly listed or delisted from the Orange Book therefore clearly requires a determination of what that patent claims" and "this determination raises issues of patent law."). Under patent law, a patent "claims" a product when the patent "reads on" the product, even if an element of the product is not explicitly "recited" or "mentioned" in the claim. Teva Br. at 15 (citing *United Food & Com. Workers Loc. 1776 & Participating Emps. Health & Welfare Fund v. Takeda Pharm. Co. Ltd.*, 11 F.4th 118, 132-33 (2d Cir. 2021)).

The FTC previously took the same position as Teva in this case, which the Federal Circuit adopted in *Jazz*. In its amicus brief in *Jazz*, the FTC argued that "claims" should be given its ordinary patent law meaning, quoting the ***same*** language that Teva cited in its Opening Brief from *United Food*: "[t]o 'claim[] the drug for which the NDA was submitted,' a patent must 'contain[] a product claim that reads on the drug that is the subject of the NDA." *Compare* FTC *Jazz* Br.[9] at 16 n.26 (quoting *United Food*, 11 F.4th at 132-33 (citation omitted)), *with* Teva Br. at 15 (quoting same). To the extent the FTC's position here is that a patent only "claims" the drug if it explicitly mentions the name of the drug (FTC Br. at 2, 3, 8, 14-17), that position is inconsistent with both the position that the FTC took

[9] "FTC *Jazz* Br." refers to the FTC's Brief as *Amicus Curiae*, *Jazz Pharms., Inc. v. Avadel CNS Pharms., LLC*, No. 1:21-cv-691, ECF No. 227 (D. Del. Nov. 15, 2022).

previously and the Federal Circuit's holding in *Jazz*.

Amneal does not address the case law regarding the interpretation of "claims" to mean "reads on" in the patent sense. Instead, Amneal (Amneal Br. at 21) and the FTC (FTC Br. at 19-20) appear to argue that the First Circuit's *In re Lantus* decision requires that the claims of the Asserted Patents must "mention the drug"—i.e., explicitly recite the name of the drug substance—to "claim the drug." This is an improper expansion of the *In re Lantus* Court's holding. The *In re Lantus* Court repeatedly noted that "mention[ing]" the drug was a lower bar to satisfy than "claims the drug," not a stricter requirement as Amneal and the FTC argue here.[10] The *In re Lantus* Court did not hold that explicitly mentioning the name of the drug at issue was necessary. Putting aside that the First Circuit's *In re Lantus* decision is not binding on this Court, that decision is inapposite as it interprets an old statutory regime. *See* Teva Br. at 13-14. If Amneal and the FTC were correct that *In re Lantus* held that patent claims must explicitly "mention" the name of the drug substance to be properly listed, then *In re Lantus* was wrongly decided. The Listing Statute has no such requirement for the reasons explained here.

[10] *In re Lantus Direct Purchaser Antitrust Litig.*, 950 F.3d 1, 7 (1st Cir. 2020) ("The statute and applicable regulations call for the listing of only patents that claim the pertinent drug or a method of using the drug, and the '864 patent ***does not even mention, much less claim,*** either insulin glargine or any method of using it." (emphasis added)); *id.* at 8 ("the '864 patent ***does not claim or even mention*** the Lantus SoloSTAR" (emphasis added)).

Contrary to the FTC's assertion (FTC Br. at 20), the Second Circuit's decision in *United Food*, issued the year after *In re Lantus*, supports that explicit recitation of the name of the drug is ***not*** the standard for evaluating whether the patent "claims" the drug. The drug product at issue in *United Food* (ACTOS) contains one lone active ingredient (pioglitazone). *United Food*, 11 F.4th at 124. The two patents at issue listed for ACTOS were combination patents that "cover unique compounds containing pioglitazone *and* another active ingredient that, together, yield novel synergies not offered by pioglitazone alone." *Id.* at 127 (emphasis in original). Although these patents explicitly mentioned the name of the drug for which they were listed, pioglitazone, the Second Circuit agreed that "[b]ecause the relevant claims in the [two patents-in-suit] are broader than and different from the scope of ACTOS . . . those claims do not 'read on'—and thus do not claim—that drug." *Id.* at 132–33.[11] The Second Circuit thus held that the key question is whether the branded product met each limitation of the claims; it was because the patents required the presence of two active ingredients, and the branded product had only one active ingredient, that the patents did not claim the product, even though they explicitly recited the active ingredient in the branded product. Consistent with

[11] The FTC asserts that "[t]he Second Circuit concluded that under *Lantus* '[a] patent claim that fails to explicitly include the drug actually makes neither type of claim on the drug' permitted under the listing provisions." FTC Br. at 20-21. However, as noted above, the Second Circuit relied on the patent meaning of "claims" as "reads on" in affirming the district court, not explicit recitation.

Teva's interpretation, *United Food* shows the Asserted Patents need only "claim" the drug to be listed.

C. The FTC and Amneal Misinterpret the Listing Statute's "Drug Product (Formulation or Composition) Patent" Requirement

Next, the FTC argues that even if the Asserted Patents "claim the drug," they still should be delisted because they are not "drug product (formulation or composition) patent[s]."[12] Teva does not dispute that the "drug product (formulation or composition) patent" provision is a separate requirement from the "claims the drug" provision in the Listing Statute, but the FTC misinterprets that requirement. The FTC asserts that a patent "that does not mention any drug in its claims is not a 'drug product (formulation or composition) patent'" (FTC Br. at 17), but the statutory and regulatory regime is not so limited. "Drug product" is defined as "a finished dosage form, e.g., tablet, capsule, or solution, that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients." 21 C.F.R. § 314.3. Under the regulation, to claim a "drug product," a patent must claim a "finished dosage form," and that finished dosage form must "***contain***[] a drug substance." Contrary to the FTC's assertions, nothing in the regulation requires

[12] Amneal has not focused on this argument. Instead, Amneal collapses its "claims the drug" arguments into whether the patents are "drug product (formulation or composition) patent[s]" by arguing that the patents are also not drug product patents because they do not claim a drug. *E.g.*, Amneal Br. at 29 ("Because the Asserted Patents do not claim a drug, they cannot meet the Claims the Drug, Drug Substance, or Drug Product criteria." (footnote omitted)).

that a drug product patent claim specifically mention the drug substance itself.[13]

The FTC argues that the *In re Lantus* decision is instructive on this issue, but that case did not address this statutory language. The *In re Lantus* Court attempted to interpret the "claims the drug" portion of the Listing Statute, but it did not discuss the meaning of the clause "drug product (formulation or composition) patent," so it provides no support for the FTC's argument. Nor could it, as that phrase was absent from the statute as it existed when *In re Lantus* was decided. Teva Br. at 13-14. The Second Circuit in *United Food* at least references the statutory regime after the OBTA amendments, but it too provides the FTC no support for its argument. The *United Food* Court also focused on the "claims the drug" clause and not the "and is a . . . drug product (formulation or composition) patent" clause.

Contrary to the FTC's assertion (FTC Br. at 18-19, 23), FDA's guidance in the June 18, 2003 Federal Register undercuts the FTC's argument that the Asserted

[13] The FTC argues that if Teva's reading is correct, then "there would be no reason to have a separate 'drug substance (active ingredient)' category" as "[t]he active ingredient is undoubtedly a 'component' of the 'drug product,' along with inactive ingredients." FTC Br. 25. The FTC ignores that this is the reality under the governing regulations. If a patent is eligible for listing as claiming ***both*** the drug substance and the drug product, an applicant would only be required to identify ***one*** of these two bases for listing. 21 C.F.R. §§ 314.53(c)(2)(i)(S), (c)(2)(ii)(T); *see* 81 Fed. Reg. 69,580, 69,596 (October 6, 2016). Indeed, while an applicant can list such a patent for both categories (drug substance and drug product), the applicant need not identify each basis on which the patent claims the drug. 21 C.F.R. §§ 314.53(c)(2)(i)(S), (c)(2)(ii)(T); 81 Fed. Reg. 69,580, 69,596 (October 6, 2016). The regulations acknowledge and allow for overlap between the drug substance and drug product listing categories.

Patents are not properly listed as "drug product patents." During the public comment period in the rulemaking process for amending section 314.53(b) in 2003, FDA received comments asking whether FDA "Consider[s] Containers and Delivery Systems to be 'Packaging'" because the proposed regulation "would not have allowed an applicant to list a patent that claimed packaging." *See* Amneal Br., Ex. 12, 68 Fed. Reg. 36,676, 36,680 (June 18, 2003). "These comments distinguished between packaging and devices such as metered dose inhalers and transdermal patches, which are drug delivery systems used and approved in combination with a drug." *Id.* As the FTC acknowledges, FDA stated that "[t]he key factor is whether the patent being submitted claims the finished dosage form of the approved drug product." *Id.* The FTC ignores, however, that FDA listed in this same paragraph "metered aerosols" as an example of "current dosage forms for approved drug products," which is the dosage form for ProAir® HFA. *Id.*[14]

Moreover, as explained in Teva's Opening Brief, the last sentence of section 314.53(b) is explicit about the categories of patents that should not be listed in the Orange Book (i.e., "[p]rocess patents, patents claiming packaging, patents

[14] The FTC has not argued it is entitled to any deference for its views on the statutory listing requirements. Nor could it because the FTC is not entitled to any deference on this issue for multiple reasons, including because the FTC is not charged with administering this statute. *See* Teva. Br. at 20 & n.8. Notably, the FTC is an independent agency, not part of the executive branch, and the Court cannot properly attribute the FTC's statements in the amicus brief to FDA or otherwise assume that FDA shares the views expressed here by the FTC.

claiming metabolites, and patents claiming intermediates"). Teva Br. at 17. As explained in the preceding paragraph, if FDA intended to exclude from being listed patents claiming "drug delivery systems," such as "metered dose inhalers," that are used and approved in combination with a drug (for which it received comments about in 2003), it could have done so like it did for packaging, metabolites, and intermediates, but FDA has not done so. *Id.* As Teva explained in its Opening Brief, it thus must be presumed as a matter of regulatory construction that FDA "act[ed] intentionally and purposely" by not adding patents claiming "drug delivery systems" to the enumerated list of types of patents which should not be listed. Teva Br. at 17 (quoting *Bates v. United States*, 522 U.S. 23, 29-30 (1997)).

While Amneal does not focus on the "drug product" criteria in its brief, Amneal does argue that "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." Amneal Br. at 18. Amneal's suggestion that the legislative history supports applying its drug/device distinction is incorrect. In light of the statutory language, including the explicit definition of "drug," there is no need to resort to a review of the legislative history. The legislative history for the OBTA does not answer the question here; rather, the clear statutory text does. *See Exxon Mobil Corp. v. Allapattah Servs., Inc.,* 545 U.S. 546, 568 (2005) ("As we have repeatedly held, the authoritative statement is the

statutory text, not the legislative history or any other extrinsic material.").

But Amneal is also wrong to suggest the OBTA's legislative history changed the listability criteria to be narrower or in its favor. Amneal cites to a Committee Report for its assertion that "some branded drug manufacturers . . . are submitting patents potentially for the purpose of blocking generic competition." Amneal Br. at 19 (quoting Amneal Br., Ex. 8 at 4). This passage says nothing about what patents do (or do not) meet the listing requirements, nor whether the patents at issue here would meet the legal standard. Rather, this statement and Amneal's references to the footnote citation "are all very general in scope, and none specifically addresses" the exact issue at hand. *Hyundai Steel Co. v. United States*, 19 F.4th 1346, 1354-55 (Fed. Cir. 2021) (rejecting invocation of legislative history to suggest congressional intent on the basis of "very general" statements). Additionally, other parts of the Committee Report cited by Amneal support Teva's interpretation. For example, this Report notes that the OBTA "would codify current regulations ***and practice*** regarding the types of patent and exclusivity-related information listed in the Orange Book." Amneal Br., Ex. 8 at 6 (emphasis added). The practice for more than two decades has been for NDA holders to list patents claiming drug delivery systems, like MDIs, in the Orange Book (Ex. 4 at 2), a practice Amneal itself took part in until 10 days before filing its Counterclaims in this action (*see infra* pp. 25-26). The legislative history, while unnecessary to interpret an unambiguous statute, supports

Teva's interpretation of the statute.

D. Amneal and the FTC's Interpretations of the Listing Statute Could Eliminate the Listing of Many Patents

As discussed above, Amneal (Amneal Br. at 21) and the FTC (FTC Br. at 19-20) appear to argue that *In re Lantus* requires that the claims of the Asserted Patents must "mention the drug"—i.e., explicitly mention or recite the name of the drug substance—in order to "claim the drug." The FTC (FTC Br. at 20) further seems to suggest that to be listed as a "drug product patent," the claims must explicitly "mention . . . the drug product." The implications of such a narrow reading of the statute, requiring the explicit recitation of the active ingredient or even (as the FTC suggests) the "drug product" itself, would wreak havoc well beyond the types of patents at issue in this case.

A strict application requiring a claim to "mention" or "recite" by name the drug at issue could eliminate the listing of patents that the industry has long considered properly listed. Such a standard could result in an argument that a claim to a genus of compounds that does not call out by name the specific active ingredient in a pharmaceutical product cannot be listed because it does not "mention" the drug. The FTC's suggestion that the claims must also "mention" the drug product would further confuse the application of the Listing Statute. The FTC never defines what it means to "mention the drug product." Would a claim to a pharmaceutical formulation that "comprises" an active ingredient and one excipient suffice? Or

would every excipient need to be identified in the claim? Would a marketed trade name for a drug be required? Any suggestion by Amneal or the FTC that their proposed standard would be easy to apply, or would merely eliminate the listing of "device" patents, ignores the reality of the patents obtained and listed throughout the history of the Hatch-Waxman Act and the Orange Book.

E. The FTC's Policy Arguments Do Not Justify Rewriting the Statute

Leaving aside the clear statutory text of the Listing Statute, the FTC devotes much of its amicus brief to policy arguments, asserting that these allegedly improper Orange Book patent listings harm competition. *See* FTC Br. at 4-5, 8, 25-30. The FTC's policy arguments—which mirror the FTC's earlier policy statements cited by Amneal in its brief (*see* Amneal Br. at 34, 36)—fail for several reasons.

First, "no amount of policy-talk can overcome a plain statutory command." *Niz-Chavez v. Garland*, 593 U.S. 155, 171 (2021). Broad appeals to policy cannot displace clear statutory text. A plain reading of the Listing Statute's text does not support Amneal or FTC's interpretation, which should be the end of the matter.

Second, the FTC's policy points are unpersuasive. As an initial matter, the FTC's policy positions are centered on its view that "[i]mproper Orange Book listings harm competition by deterring and delaying entry of lower cost-generics." FTC Br. at 25. However, these broad policy complaints, even if given merit, do not apply here. The FTC ignores that generic versions of ProAir® HFA are already on

the market. FDA granted approval to the first generic version of ProAir® HFA on February 24, 2020. Ex. 7, Drugs@FDA Entry for ANDA No. 203760 (this product has since been discontinued). Lupin received FDA approval for its generic version of ProAir® HFA on August 24, 2020 and currently markets this generic product. Ex. 8, Drugs@FDA Entry for ANDA No. 209954. Additionally, Teva currently distributes an authorized generic of ProAir® HFA under NDA No. 021457.

Third, as explained in Teva's Opening Brief (at 18), Teva's interpretation of the Listing Statute is consistent with the policy aims of the Hatch-Waxman Act. "The purpose of listing a patent in the Orange Book is to put potential generic manufacturers on notice that the brand considers the patent to cover its drug." *In re Restasis (Cyclosporine Ophthalmic Emulsion) Antitrust Litig.*, 333 F. Supp. 3d 135, 149 (E.D.N.Y. 2018). The listing requirement is mandatory—the NDA holder cannot pick which patents to list for a product in the Orange Book; if a patent meets the statutory standard, it must be listed for that product. The mandatory listing requirement furthers the Hatch-Waxman Act's policy goals of providing generic manufacturers notice and incentivizing challenges to listed patents. Under Amneal and the FTC's interpretations, these types of patents would not be listed in the Orange Book. Accordingly, generic manufacturers would lose notice of these patents, creating pre-launch uncertainty for products that the generic has expended

resources in developing.[15]

Finally, the FTC suggests Teva should have delisted its patents immediately upon receiving the FTC's warning letter, but an FTC warning letter has no legal weight. *See Christensen v. Harris Cnty.*, 529 U.S. 576, 587 (2000). Beyond that, both Amneal and the FTC ignore that Amneal itself received such a letter. The letter to Amneal addressed two patents listed in the Orange Book as drug product patents for Amneal's Adrenaclick® (epinephrine injection) product. *See* Ex. 4 at 2. Neither patent explicitly "mentions" or "recites" the name of the active ingredient (epinephrine) in Adrenaclick®. While these patents issued years ago, it was not until November 21, 2023—***after*** Teva filed its Complaint against Amneal and just 10 days ***before*** Amneal filed its Answer and Counterclaims—that Amneal requested delisting. *See* ECF No. 1 (Oct. 6, 2023); ECF No. 12 (Dec. 1, 2023). That Amneal delisted patents in response to an FTC warning letter does not mean Teva is required to do so.

While Amneal now claims that the listing of patents that do not mention or recite the active ingredient is "unambiguously improper" (Amneal Br. at 13), that was not Amneal's position just months ago. Amneal wrote to Congress about its

[15] For example, the Court found three of the patents at issue here valid and infringed in *Teva Branded Pharm. Prods. R&D, Inc. v. Cipla Ltd.*, 678 F. Supp. 3d 559, 563, 589 (D.N.J. June 21, 2023). Cipla would not have been on notice of these patents under the interpretations of the Listing Statute proposed by Amneal and the FTC.

patent listing, explaining it had listed the patents "[i]n a good faith effort to comply with this statutory requirement given the regulatory guidance at the time" and that "Amneal reasonably believed the patents were properly listed." Ex. 4 at 2. Amneal further explained that "[n]umerous inquiries regarding whether these types of patents should be listed in the Orange Book have been made and regulators have declined to provide an opinion." *Id.* Amneal's own conduct, before seeing the strategic advantage to changing its position, confirms Teva's statutory interpretation.

II. Teva's Motion to Dismiss the Delisting Counterclaims Should be Granted

Having set out the correct interpretation of the Listing Statute, Teva next turns to the impact of that statutory interpretation on the pending motions.

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

Under the correct interpretation of the Listing Statute, the Asserted Patents "claim the drug" and are "drug product (formulation or composition) patent[s]." As the Asserted Patents are properly listed in the Orange Book for ProAir® HFA, Teva's Motion to Dismiss Amneal's Delisting Counterclaims should be granted.

First, as explained in Teva's Opening Brief, the Asserted Patents listed for ProAir® HFA claim a "drug" under every prong of its statutory definition. ProAir® HFA is (A) an inhalation aerosol, which is considered a "drug product" by the USP; (B) used in the treatment or prevention of bronchospasm; and (C) an article used to improve the function of breathing. Teva Br. at 22-23. The Asserted Patents claim

components of these aspects of ProAir® HFA, and thus also claim a "drug" under Clause (D) of the definition. *Id.* The Asserted Patents claim the drug product ProAir® HFA[16] as well as components thereof (such as the dose counter).[17] Accordingly, the Asserted Patents "claim the drug" under the Listing Statute.

Second, the Asserted Patents are also "drug product (formulation or composition) patent[s]." As defined in the governing regulations, to claim a "drug product," a patent must claim a "finished dosage form," and that finished dosage form must "contain[] a drug substance." *See* 21 C.F.R. § 314.3. The FTC agrees that FDA identifies "metered aerosol" as an approved "dosage form" and specifically as the dosage form for ProAir® HFA. FTC Br. at 19. The Asserted Patents claim the "finished dosage form" for ProAir® HFA (i.e., metered aerosol) and that dosage form as claimed contains a drug substance.

A closer look at the patents show they are properly listed. Two of the Asserted Patents—the '289 and '587 patents—have claims directed to "[a]n inhaler for metered dose inhalation, the inhaler comprising," *inter alia*, "a medicament canister."[18] These patents claim the metered aerosol dosage form (i.e., "an inhaler for metered dose inhalation") and that dosage form contains a drug substance (e.g., "a medicament canister"). The medicament in the claimed "medicament canister"

[16] *See, e.g.*, '289 patent at claims 1-10; '587 patent at claims 1-22.
[17] *See, e.g.*, '808 patent at claim 1; '889 patent at claim 1.
[18] *See, e.g.,* '289 patent at claim 1; '587 patent at claims 1, 12, 13.

must be a drug substance. The other two patents similarly claim the dosage form for ProAir® HFA. The '889 patent has claims directed to, *inter alia*, "[a]n incremental dose counter for a metered dose inhaler having a body arranged to retain a canister for movement of the canister relative thereto."[19] Like the '289 and '587 patents, the '889 patent claims the metered aerosol dosage form (i.e., "[a]n incremental dose counter ***for a metered dose inhaler***" (emphasis added)) and that dosage form contains a drug substance (e.g., "a body arranged to retain ***a canister***" (emphasis added)). The "canister" is the same as the "medicament canister" of the other patents, and must contain a drug substance. Finally, the '808 patent has claims directed to, *inter alia*, "[a] dose counter for an inhaler, the dose counter having a counter display arranged to indicate dosage information."[20] The '808 patent claims the metered aerosol dosage form (i.e., "for an inhaler") and that dosage form contains a drug substance (e.g., "an inhaler," "dosage information"). Consider, too, ***what*** is counted by a "dose counter"—it is the doses of the drug substance that remain in the drug product. Unlike in *In re Lantus*, a drug substance is thus required by claims of each Asserted Patent.

In sum, these claim terms and others[21] demonstrate that the Asserted Patents

[19] *See, e.g.*, '889 patent at claim 1.
[20] *See, e.g.,* '808 patent at claim 1.
[21] The description of these claims and claim terms here is meant to be illustrative and is thus non-limiting. Other claims and claim terms in the Asserted Patents

"claim the drug" and are "drug product (formulation or composition) patent[s]." While these claims do not explicitly recite the name of the active ingredient "albuterol sulfate," by their terms they clearly require the presence of an active ingredient and thus claim, or "read on," the ProAir® HFA drug product. Thus, the Asserted Patents are properly listed.

B. Amneal Has Failed to Point to Any Allegations that Save Its Delisting Counterclaims

Amneal's Delisting Counterclaims should also be dismissed as they are devoid of factual allegations sufficient to state a claim. As Teva discussed in its Opening Brief, Amneal fails to plead sufficient factual allegations to state a claim that the Asserted Patents do not "claim[] the drug" under the proper interpretation of the Listing Statute. *See* Teva Br. at 21 (discussing how Amneal has not asserted "that ProAir® HFA is not an inhalation aerosol; not an article for use in the treatment or prevention of bronchospasm; not an article used to improve the function of breathing; or not a component of such articles.") In fact, Amneal concedes as much, arguing that "no such facts are required" because "Teva's argument that such allegations are necessary is based on Teva's incorrect interpretation of 'drug.'" Amneal Br. at 31. But Teva's "interpretation" is the statutory definition of "drug." Amneal's admission that it did not include facts that match the statutory definition

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further support that they are properly listed. Teva is not construing any terms for claim construction purposes and reserves all rights in that regard.

demonstrate that its Delisting Counterclaims must be dismissed.

But even under Amneal's incorrect reading of the statute, its allegations are insufficient to state a claim and thus must be dismissed. Amneal argues (Amneal Br. at 31-32) that its counterclaims are "replete with factual allegations sufficient to state a claim for delisting," but proceeds to list only allegations that are "unsupported conclusions" or "legal conclusions cast in the form of factual allegations" that cannot form the basis for adequately pleading a delisting counterclaim. *See Interlink Prods. Int'l, Inc. v. HDS Trading Corp., Inc.*, 2015 WL 12840378, at *2 (D.N.J. Oct. 14, 2015). Teva already addressed these deficiencies in its Opening Brief, including Amneal's failure to plead factual allegations to support its legal conclusion that the Asserted Patents are not "drug product (formulation or composition) patent[s]." *See* Teva Br. at 19-22. And despite Amneal's focus on the device/drug distinction in its Motion, Amneal failed to plead ***any*** factual allegations to support an argument that the Asserted Patents do not claim components that achieve their "primary intended purposes through chemical action within . . . the body of man." 21 U.S.C. § 321(h)(1). Therefore, Amneal has not plead any factual allegations to show that the Asserted Patents do not fall into the exclusion in the statutory definition of "device."

Amneal failed to allege sufficient facts under either Teva or Amneal's reading of the Listing Statute, so its Delisting Counterclaims should be dismissed.

III. Amneal's Motion for Judgment on the Pleadings Should Be Denied

Amneal's Rule 12(c) Motion requesting that this Court grant its Delisting Counterclaims based only on its pleadings should be denied for multiple reasons.

A. Legal Standard

Pursuant to Fed. R. Civ. P. 12(c), "a party may move for judgment on the pleadings" "[a]fter the pleadings are closed." "[P]leadings are 'closed' after the complaint and answer are filed." *Horizon Healthcare Servs., Inc. v. Allied Nat. Inc.*, 2007 WL 1101435, at *3 (D.N.J. Apr. 10, 2007). Under Rule 12(c), "a court must accept all of the allegations in the pleadings of the party against whom the motion is addressed as true and draw all reasonable inferences in favor of the non-moving party." *Allstate Prop. & Cas. Ins. Co. v. Squires*, 667 F.3d 388, 390 (3d Cir. 2012) (citation omitted). A court may grant a Rule 12(c) motion only "if, on the basis of the pleadings, the movant is entitled to judgment as a matter of law." *Fed Cetera, LLC v. Nat'l Credit Servs., Inc.*, 938 F.3d 466, 469 n.7 (3d Cir. 2019) (citation omitted). "The issue is not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims." *Tolmar Therapeutics, Inc. v. Foresee Pharms. Co.*, 2022 WL 13858026, at *2 (D.N.J. Oct. 24, 2022). "A plaintiff can survive a Rule 12(c) motion if her complaint contains sufficient factual matter to show that the claim is facially plausible, thus enabling the court to draw the reasonable inference that the defendant is liable for [the] misconduct alleged."

Bibbs v. Trans Union LLC, 43 F.4th 331, 339 (3d Cir. 2022) (citations omitted).

B. Amneal's Rule 12(c) Motion Should Be Denied for Multiple Reasons

1. Amneal misinterprets the Listing Statute

As discussed above (*supra* Argument § I), Amneal's Rule 12(c) Motion is premised on an incorrect interpretation of the Listing Statute and thus Amneal cannot be entitled to "judgment as a matter of law" on the basis of its pleadings. *Fed Cetera,* 938 F.3d at 469 n.7. Indeed, as noted above, Amneal concedes that "no such facts are required" under Teva's interpretation because "Teva's argument that such allegations are necessary is based on Teva's incorrect interpretation of 'drug.'" Amneal Br. at 32. As explained above (*supra* Argument § II.A), the Asserted Patents are properly listed in the Orange Book for ProAir® HFA under Teva's interpretation.

2. Amneal's Rule 12(c) Motion is procedurally improper

Amneal has not "clearly establishe[d] that no material issue of fact remains to be resolved" even under Amneal and the FTC's interpretations of the Listing Statute. *Tolmar*, 2022 WL 13858026, at *2. Instead, Amneal relies on its own (disputed) allegations in its Counterclaims as true, which is procedurally improper. In resolving Amneal's Motion under Rule 12(c), the Court does not take as true Amneal's allegations in its counterclaims. Rather, the Court would have accepted as true all of the allegations in Teva's pleadings as the non-moving party, if Teva had answered. *Allstate Prop.*, 667 F.3d at 390; *Republic Franklin Ins. Co. v. Travelers*

Cas. Ins. Co. of Am., 2018 WL 1420495, at *2 (D.N.J. Mar. 22, 2018) ("In considering a [Rule 12(c)] motion by the plaintiff for judgment on the pleadings the question for determination is whether on the undenied facts alleged in the complaint and assuming as true all the material allegations of fact in the answer, the plaintiff is entitled to judgment as a matter of law." (citation omitted)). If given the opportunity to answer Amneal's Counterclaims before Amneal filed its motion, Teva would have disputed allegations relied upon by Amneal, so Amneal's Motion must be denied.

Amneal argues that it adequately "allege[d] 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* Amneal Br. at 32. However, as Teva explained, not only are these allegations "conclusory statements, formulaic recitations, and legal conclusions that cannot form the basis for adequately pleading a delisting counterclaim" (Teva Br. at 19-20), they are also disputed. *See Horizon*, 2007 WL 1101435, at *3 ("The court, however, 'need not accept as true legal conclusions or unwarranted factual inferences.'" (citation omitted)). While Teva would admit that these four Asserted Patents do not claim either (9) a method of using a drug or (10) an approved method of using ProAir® HFA, Teva would have denied Amneal's other conclusory allegations.

Amneal's allegation that the Asserted Patents claim a device is also disputed. Amneal accuses Teva of not showing how the Asserted Patents work "through chemical action within or on the body of man" such that they fall into the exclusion in the "device" definition (Amneal Br. at 27), but Teva has not had the opportunity to make that showing in a response to Amneal's counterclaims. Teva could not have predicted in filing its Motion to Dismiss that Amneal would have ignored most of the conclusory allegations in its Counterclaims to focus almost exclusively on the device-versus-drug distinction.

Finally, Amneal's Rule 12(c) Motion should be denied as premature. *See Gant v. Ragone*, 2020 WL 6797125, at *12 (D.N.J. Nov. 19, 2020) ("The Court findi[ng] that [Plaintiffs'] motion for judgment on the pleadings is premature . . . [b]ecause [Defendant] filed a Motion to Dismiss, [Defendant's] Answer is not due until 14 days after the issuance of the order deciding the Motion. Thus, the pleadings have not yet closed."). This Court granted Amneal's request to file a Rule 12(c) motion on counterclaims that Teva has not yet answered before Teva could file an opposition. *See* ECF No. 25. Teva's only response to Amneal's counterclaims was its Motion to Dismiss (*see* ECF Nos. 26, 27), but a motion is not a pleading and cannot be treated as such. Fed. R. Civ. P. 7(a); *see Gant*, 2020 WL 6797125, at *12. If given the opportunity, Teva would have objected to Amneal's request because even if Amneal's interpretation of the statute is credited, there are material issues of

fact that need resolution so Amneal is not entitled to judgment as a matter of law.

3. Even if the Court denies Teva's Rule 12(b)(6) Motion, it should still deny Amneal's Rule 12(c) Motion

To the extent the Court denies Teva's Rule 12(b)(6) Motion because it adopts Amneal's interpretation of the Listing Statute and finds Amneal has plead sufficient factual allegations to state a claim for relief, the Court should still deny Amneal's Rule 12(c) Motion. Even under Amneal's incorrect interpretation of the statute, Amneal's Motion at best shows that there are claim construction issues concerning at least whether the Asserted Patents "claim[] the drug" and are "drug product (formulation or composition) patent[s]" under Amneal's interpretation. *See Jazz Pharms., Inc. v. Avadel Pharms. PLC*, 2021 WL 4860682, at *3 (D. Del. Oct. 19, 2021) (denying Rule 12(c) motion, in part, because "the vast majority of courts have held claim construction to be inappropriate on a motion under Rule 12"); *see, e.g.*, *Tolmar*, 2022 WL 13858026, at *6 (denying Rule 12(c) motion because movant's arguments depend on claim constructions, but claim construction proceedings had not yet occurred). The Court should deny Amneal's Rule 12(c) Motion at least to engage in claim construction proceedings if necessary to determine the scope of what the Asserted Patents claim.[22]

[22] In *Jazz Pharms., Inc. v. Avadel Pharms.*, No. 1-21-cv-00691 (D. Del.), the district court denied Avadel's Original Motion for Judgment on the Pleadings for its delisting counterclaims to engage in claim construction and discovery. (ECF No. 55). After claim construction, Avadel filed a Renewed Motion for Judgment on the

IV. Amneal's Opposition Fails to Salvage its Antitrust Counterclaims

A. Amneal's Improper Listing Antitrust Counterclaims Must Be Dismissed

1. *Trinko* forecloses Amneal's antitrust improper Orange Book listing counterclaims

Amneal fails to show that the *Trinko* doctrine does not defeat its listing-based antitrust claims. Instead, and contrary to what Amneal argues, *Trinko* is on all fours with this case. The Listing Statute plainly creates a new obligation on NDA holders to help their competitors, which would not otherwise exist under traditional antitrust law. The post-2003 statutory delisting counterclaim creates a complete and timely remedy for improper listing that serves the antitrust function, undermining any basis for imposing antitrust enforcement on top of a regulatory regime that Congress said was to be exclusive. And Amneal's search for refuge in legislative history provides no shelter for its claims.

a. The Orange Book listing requirements impose duties on NDA holders to assist competitors that antitrust law does not

Amneal's argument that traditional antitrust principles authorize an antitrust

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Pleadings. (ECF No. 118). The district court granted the Renewed Motion and entered an injunction directing Jazz to delist the patents within fourteen days. (ECF Nos. 231, 232). Jazz filed a motion to (i) stay pending appeal or (ii) stay pending application to the Federal Circuit for a stay pending appeal, which the district court denied. (ECF No. 255). The Federal Circuit entered a stay temporarily staying the district court's injunction during the appeal. (Fed. Cir., No. 23-01186, ECF No. 28). After argument, the Federal Circuit affirmed the order to delist the patent, and ended the stay on the injunction. (Fed. Cir., ECF Nos. 59, 60, 61).

claim by an ANDA filer based on alleged improper Orange Book listing is wrong and ignores basic antitrust principles. As Teva previously explained in its Opening Brief, the Listing Statute imposes a duty on NDA holders to assist ANDA filers in getting their competing generic products to market sooner. Teva Br. at 27-28. But those duties do not arise under traditional antitrust principles. To the contrary, antitrust law generally imposes no duty on any company to aid a competitor.[23] *See Pac. Bell. Tel. Co. v. linkLine Commc'ns., Inc.*, 555 U.S. 438, 448 (2009); *Verizon Commc'ns Inc. v. Law Offs. of Trinko, LLP*, 540 U.S. 398, 411 (2004) ("there is no duty to aid competitors"). And, as *Trinko* holds, while Congress may impose a statutory duty on a company in Teva's position to help its competitor, that does not automatically mean that such a non-antitrust statutory duty can be enforced by antitrust law. *Trinko*, 540 U.S. at 406. *Trinko* specifically held that the plaintiffs there failed to state an antitrust claim based on the defendant's alleged failure to comply with a statutory duty to assist its competitors. Under these basic antitrust principles, Amneal cannot state an antitrust claim based on Teva's alleged failure to help Amneal get its competing product to market, yet that is exactly what Amneal tries to do by basing antitrust claims on Teva's alleged improper Orange Book

[23] *Caraco*, which Amneal repeatedly cites, provides Amneal no support because that case involved the proper scope of the statutory delisting counterclaim; no antitrust claim was involved. *Caraco Pharm. Lab'ys., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 425-26 (2012).

listings. Its improper-listing-based antitrust claims therefore should be dismissed for this simple and straightforward reason.

Amneal seeks to avoid the legal rule that antitrust imposes no duty on a company to help its competitors by disputing that the listing obligations imposed on NDA holders actually are intended to assist generics. Amneal Br. at 40-42. But Amneal simply ignores the wealth of caselaw recognizing that that is exactly what the statutes do. *See* Teva Br. at 27-29. According to the Supreme Court, the entire Orange Book scheme—of which the Listing Statute and the delisting counterclaim are part—has the central purpose of "facilitating the approval of non-infringing generic drugs." *Caraco*, 566 U.S. at 417. That goal obviously benefits generics. Even if, as Amneal asserts, the provisions ***also*** provide certain benefits to NDA holders, that does not negate the fact that it clearly imposes new duties on NDA holders for the benefit of competing generics. Indeed, if the Listing Statute only benefited NDA holders, Congress would not have needed to make listing a mandatory (as opposed to merely a permissive) obligation for NDA holders, as it did. There can be no doubt, therefore, that the listing provisions impose exactly the kind of new statutory duty to aid competitors that falls directly within *Trinko*.

Amneal cites various cases purportedly establishing that improper listing constitutes actionable anticompetitive conduct under traditional antitrust principles, but all save one did not even mention *Trinko*, much less address the *Trinko* issue on

the merits. Those cases therefore provide Amneal no support. *See, e.g.*, *United States v. L.A. Tucker Truck Lines, Inc.*, 344 U.S. 33, 38 (1952) (issue not "raised in briefs or argument nor discussed in the opinion of the Court" cannot be taken as "a binding precedent on th[e] point").

The only case Amneal cites that did address *Trinko*—the *Remeron* decision—***supports*** Teva's argument, and Amneal's reliance on it is particularly misguided. Amneal simply ignores that *Remeron* addressed the regulatory regime ***prior to*** enactment of the statutory delisting counterclaim and declined to apply *Trinko* to claims about patent listings because, prior to 2003, there had been no effective mechanism to challenge and correct an improper Orange Book listing. *In re Remeron Antitrust Litig.*, 335 F. Supp. 2d 522 (D.N.J. 2004). As Teva has already explained in its Opening Brief (at 29-30), enactment of the statutory delisting counterclaim solved the problem *Remeron* recognized as the sole basis for not applying *Trinko* to antitrust claims based on improper listing.[24] *Remeron*, read in

[24] Amneal's attempt (Amneal Br. at 38) to score a "gotcha" by citing Teva's claims in the *Abbott v. Teva* litigation is equally unavailing, because Amneal ignores Teva's actual allegations. Teva did not argue in that case that the patent at issue did not meet the listing requirements of the Orange Book. Instead, Teva alleged that the patent, while otherwise meeting the listing standards, should not have been listed because it was knowingly procured by fraud and thus no claim of infringement could reasonably be asserted. *Abbott Labs. v. Teva Pharms. USA, Inc.*, No. 1:02-cv-1512, Teva's Am. Countercls. (ECF No. 369) ¶¶ 91, 105, 183 (D. Del. July 29, 2005). The statutory delisting counterclaim does not provide a remedy in that situation, and thus the *Trinko* doctrine did not preclude Teva's antitrust claim in that case. But here, where Amneal's allegation is that Teva's patents do not "claim the drug" and thus

light of the 2003 MMA amendment, shows that Teva's motion should be granted.

b. The post-2003 regulatory scheme for addressing patent listings is comprehensive and serves "the antitrust function," displacing antitrust enforcement

Amneal's attempt to minimize the post-2003 regulatory scheme that polices and remedies improper Orange Book listings misunderstands how it works.[25] With the statutory delisting counterclaim, Congress created a regime that marries together the patent expertise of federal judges and FDA's expertise over drug approvals to create a unified regulatory structure that fully addresses the issues raised by claims of improper listing. As the Supreme Court put it in *Caraco*, "[t]he statutory counterclaim we have considered enables courts to resolve patent disputes so the FDA can fulfill its statutory duty." *Caraco*, 566 U.S. at 425.

The complementary operation of the various components of the regulatory structure is easy to see. The Listing Statute requires an NDA holder to list any patent that, among other things, "claims the drug" that is the subject of the NDA. The Federal Circuit has held that "claims" in the statute should be given its ordinary

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cannot be listed, *Trinko* does apply to preclude Amneal's antitrust claims. The situations are completely different, and there is no inconsistency in Teva's positions.

[25] Amneal's argument that the role of the courts in adjudicating delisting counterclaims is not part of the regulatory scheme because it is "an equitable judicial remedy" (Amneal Br. at 45) misunderstands how the various aspects of the scheme work together.

patent-law meaning, requiring "a determination of what that patent claims."[26] *See* Teva Br. at 14. The Supreme Court has recognized, moreover, that the kind of interpretive process necessary to understand what a patent claims falls specifically and uniquely within the expertise of federal judges. *See Markman v. Westview Instruments, Inc*., 517 U.S. 370 (1996). Congress in 2003 thus tapped into the relevant patent-specific expertise of the federal judiciary by adding the delisting counterclaim to the Orange Book regulatory process in conjunction with FDA.[27]

So, under the revised regime since 2003: the court adjudicating a delisting counterclaim in Paragraph IV litigation determines if a patent was properly listed; if not, the court orders the NDA holder to tell FDA to have the patent removed from the Orange Book; once FDA removes the patent from the Orange Book, the patent no longer blocks FDA, and it can approve an ANDA if all other requirements for approval have been met. This comprehensive regulatory scheme provides a complete and timely remedy for improper listing that serves "the antitrust function" as completely as the regime in *Trinko*. As a result, there is no place for an antitrust

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[26] As discussed above (*supra* p. 14), the FTC agreed with this meaning of "claims" in an amicus brief it filed in 2022 in the *Jazz* case.

[27] By limiting delisting claims to counterclaims in Paragraph IV litigation, Congress ensured that the merits of whether the patent is properly listed will be determined by federal judges overseeing infringement litigation about those patents—precisely those who have the relevant expertise. The counterclaim can be adjudicated solely in the context of Paragraph IV litigation, which is tried to the court, and the only available relief is equitable, not monetary, further assuring that the issue will be decided by the court.

claim—either under traditional antitrust principles (because NDA holders have no traditional antitrust duty to aid competitors) or under the statutory regime (because the statutory delisting counterclaim fulfills the antitrust function, and there is no basis or need for antitrust intervention).

Amneal (and the FTC) attempt to chip away at the adequacy and the timeliness of this remedy in their effort to skirt around *Trinko*, but to no avail. First, data confirm that having the delisting counterclaim litigated in the course of the Paragraph IV case will provide timely relief, as the counterclaim will likely get resolved (or the 30-month stay likely will expire) before an ANDA is otherwise eligible for approval.[28] Second, a delisting injunction will lead to complete relief: a

[28] For example, according to FDA, the mean time for an ANDA to obtain tentative approval in Q1 (Oct-Dec 2023) was 41 months—meaning regulatory approval typically takes longer than a 30-month stay. *See* Ex. 9, Generic Drugs Program Monthly and Quarterly Activities Report | FDA, at 4. A recent study of ANDA approval times concluded that "[b]ecause stay periods generally expire well in advance of when generic entry typically occurs, 30-month stays are unlikely to delay the timing of generic entry." Ex. 10, Sunand Kannappan, *et al.*, *The Timing of 30-Month Stay Expirations and Generic Entry: A Cohort Study of First Generics*, 2013-2020, 14 CLIN TRANSL SCI., p. 1917 (2021). The facts here do not undermine this conclusion. Amneal originally alleged that it "reasonably expects to receive FDA approval" based on FDA's GDUFA goal date for review of Amneal's ANDA "in the summer of 2024" – far faster than the data suggest is likely. *See, e.g.*, CC ¶ 121. Amneal subsequently asserted in its Brief, and without citation, that "FDA has scheduled approval of Amneal's ANDA products as early as *this April*." Amneal Br. at 3 (emphasis in original). The FTC copies Amneal's assertion throughout its brief. But discovery has shown, unsurprisingly, that approval is ***not*** imminent. Amneal appears to be citing the date it is scheduled to receive a response from FDA under GDUFA, with no indication that such a response will be an approval. [redacted]

patent removed from the Orange Book poses no ongoing barrier to FDA approval of a generic, remedying any potential anticompetitive effect.[29] Third, while Amneal and the FTC complain that the delisting counterclaim does not permit monetary relief, nothing in *Trinko* requires that monetary remedies be available. The *Suboxone* court invoked *Trinko* to dismiss antitrust claims based on an NDA holder's alleged failure to comply with REMS sharing obligations even though the REMS statute at the time provided no monetary penalty for such failure. *In re Suboxone Antitrust Litig.*, 64 F. Supp. 3d 665, 688 (E.D. Pa. 2014). The question of whether

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[redacted] Even if those dates were to hold, and FDA were to consider Amneal's ANDA approvable by then (a fact Amneal has not even alleged), the Court still has ample time to address the statutory counterclaims before Amneal would be eligible for approval. Here, too, therefore, any statutory remedy would be timely.

[29] The FTC tries to invent a new form of supposed harm from improper listing by suggesting that improper listings "may deter generic competitors" who, seeing a listed patent, "may forgo entry altogether." FTC Br. at 29. This position is pure speculation. The FTC cites no empirical basis supporting its deterrence theory, and courts have properly rejected similar arguments as implausible. *See, e.g., In re Humira (Adalimumab) Antitrust Litig.*, 465 F. Supp. 3d 811, 831 n.13 (N.D. Ill. 2020), *aff'd sub nom. Mayor & City Council of Balt. v. AbbVie Inc.*, 42 F.4th 709 (7th Cir. 2022). Obviously Teva's Orange Book listings did not deter Amneal or other companies that have filed ANDAs for ProAir® HFA. Indeed, the entire history of the industry since enactment of Hatch Waxman in 1984, and the scores of litigated Paragraph IV infringement suits, proves that generic companies have readily filed ANDAs with Paragraph IV certifications challenging patents listed in the Orange Book in order to obtain approval and enter the market.

to allow a monetary remedy for improper listing was a policy decision for Congress to make, which it did in the 2003 statute. If Amneal or the FTC disagree with that policy choice, the right forum to address their views is Congress, not the courts.

2. Amneal's appeal to supposed legislative history is unavailing

Amneal maintains that it may proceed with delisting-based antitrust claims because what it views as the legislative history of the 2003 MMA supposedly permits such claims, notwithstanding enactment of the delisting counterclaim. Amneal Br. at 39. This argument fails for multiple independent reasons.

First, the language Amneal points to is in a Conference Report, not in any statute, and the relevant statute says unambiguously the opposite: there is "no independent cause of action" based on improper listing, which can be challenged only through the statutory counterclaim. 21 U.S.C. § 355(j)(5)(C)(ii)(II). The language of the statute controls. *See Exxon Mobil,* 545 U.S. at 568 ("As we have repeatedly held, the authoritative statement is the statutory text, not the legislative history or any other extrinsic material.").[30]

Second, Congress knows how to enact an "antitrust saving clause" when it

[30] Particularly relevant here, the case goes on to note: "judicial reliance on legislative materials like committee reports, which are not themselves subject to the requirements of Article I, may give unrepresentative committee members—or, worse yet, unelected staffers and lobbyists—both the power and the incentive to attempt strategic manipulations of legislative history to secure results they were unable to achieve through the statutory text." *Exxon Mobil,* 545 U.S. at 568.

wishes but did not do so here. For example, in the CREATES Act, Congress established a statutory remedy for a generic company seeking to develop an ANDA that could not obtain the samples of the NDA product it needed to start the process. *See* Creating and Restoring Equal Access to Equivalent Samples Act of 2019, 21 U.S.C. § 355-2. But Congress also included an explicit antitrust saving clause in the statute, which states: "Antitrust Laws—Nothing in this section shall be construed to limit the operation of any provision of the antitrust laws." *Id.* § 355-2(e)(2). Thus, Congress made sure to preserve any existing antitrust claim explicitly despite enacting a separate statutory remedy. The antitrust saving clause in CREATES is by no means an isolated example.[31] Against this backdrop, Congress's omission of an antitrust saving clause when enacting the statutory delisting counterclaim further confirms that the statutory counterclaim is the sole remedy for alleged improper listing here (as the statute says).[32] Just as with its arguments about what patents must be listed, Amneal simply ignores what the relevant statute does and does not say.

Third, as the Supreme Court made clear in *Trinko*, enactment of a saving

[31] For additional antitrust saving clauses, *see, e.g.*, 15 U.S.C. § 8231 (state-based insurance reform); 12 U.S.C. § 5303 (Wall Street reform and consumer protection); 42 U.S.C. § 17305(b) (prohibitions on market manipulation and false information in energy markets); 42 U.S.C. § 18118(a) (Patient Protection and Affordable Care Act); 16 U.S.C. § 1853a(c)(9) (national fishery management program).

[32] Cases recognize that Congress intended delisting issues to be addressed exclusively through the statutory counterclaim. *See, e.g., Caraco*, 566 U.S. at 423 ("Congress determined to enforce the FDA's new listing provisions . . . through the new counterclaim").

clause in this context would not have changed the outcome in any event. The statute at issue in *Trinko* did contain an antitrust saving clause, but the antitrust claim there still could not proceed because (a) it did not fit within traditional antitrust principles, and (b) the regulatory regime sufficiently served the antitrust function. 540 U.S. at 410-14. Both are true here, too. Indeed, given that there is no statutory saving clause, but only an attempt to rely on legislative history to contradict the plain terms of the statute, the failing in Amneal's argument is even more glaring.

Fourth, the doctrine of implied immunity from antitrust law applies here to preclude Amneal's antitrust claims. Under that doctrine, certain regulatory statutes—even when silent on the topic—are found implicitly to preclude application of the antitrust laws to certain conduct. *See Credit Suisse Sec. (USA) LLC v. Billing*, 551 U.S. 264, 267-68 (2007) (interpreting "the securities laws as implicitly precluding the application of the antitrust laws to the conduct alleged in this case"). In *Trinko*, the Supreme Court considered, but did not apply, applied immunity because the presence of the antitrust saving clause there precluded doing so. 540 U.S. at 405-06. Here, where there is no saving clause, the rationale for implied immunity applies in full force. Applying the factors identified in *Credit Suisse*, it is clear that (1) the regulatory system under the FDCA supervises the same activities Amneal seeks to challenge through antitrust law; (2) evidence – including the recent example of a patent delisting that resulted from an ANDA filer's statutory delisting

counterclaims[33] – shows that the authority under the FDCA is being exercised; and (3) there is a possibility that allowing proceedings under both the FDCA and antitrust law could lead to conflicts, including with respect to who decides whether a patent is properly listed (judge or jury) and what the available scope of remedies may be (with FDCA explicitly precluding monetary remedies but antitrust law permitting treble damages). Also, given that issues around patent listings "lie squarely within an area of . . . market activity that the [FDCA] seeks to regulate," all of these factors point to implied repeal of the antitrust laws here. *Credit Suisse*, 551 U.S. at 276.

For each of these independent reasons, the non-binding (and not enacted) language of a conference report does not save Amneal's antitrust claim.

3. The FTC's amicus brief does not prop up Amneal's counterclaims

The FTC's amicus brief does nothing to change the proper analysis or outcome here. The FTC's legal arguments largely mirror Amneal's, and they fail for the same reasons. To the extent the FTC cites additional cases, it does so only for very broad propositions that have no specific application or relevance to this dispute.[34] And while part of the FTC's mandate involves antitrust enforcement, the

[33] *Jazz Pharms.*, 60 F.4th 1373.

[34] For example, the *AbbVie* decision cited by the FTC (FTC Br. at 39) had nothing to do with alleged improper listing, let alone *Trinko*; it was addressing the "delicate task" of applying *Noerr-Pennington* immunity to allegations of sham litigation under the Hatch-Waxman Act. *FTC v. AbbVie Inc.*, 976 F.3d 327, 361 (3d Cir. 2020). The FTC is even further off base citing (FTC Br. at 34) to *SmithKline Corp. v. Eli Lilly*

FTC's legal views about the application of antitrust enforcement to Orange Book listings are entitled to no deference. *See Christensen*, 529 U.S. at 587.

Second, the FTC's citation to studies generally addressing the price effects of generic entry adds nothing here. As discussed above, if a patent were improperly listed, and if a resulting 30-month stay did threaten to delay generic entry, a successful delisting counterclaim would lift the stay and clear the path for approval of otherwise-approvable generic products. Antitrust is not needed to lift the stay—and, indeed, the timelines for obtaining an antitrust remedy likely would be much longer than for a delisting counterclaim, given all the additional elements (such as market power) required to prove an antitrust claim that are not part of the statutory counterclaim. There is no reason, therefore, why antitrust needs to be layered on top of the statutory counterclaim in this context to achieve the effects the FTC cites.

In addition, while the FTC purports to be providing context on how

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& Co., 575 F.2d 1056, 1065 (3d Cir. 1978), which was decided years before Hatch Waxman was even acted, has nothing to do with Orange Book listings and instead was about multi-product rebate bundling. *Steward Health Care*, which the FTC also cites (FTC Br. at 34 n.111), involved no allegation that a statute created a new obligation to deal with competitors that did not previously exist—as was the case in *Trinko* and is the case here. *See Steward Health Care Sys., LLC v. Blue Cross & Blue Shield*, 997 F. Supp. 2d 142 (D.R.I. 2014). Instead, *Steward* involved allegations that the defendant improperly terminated a pre-existing voluntary course of dealing, which sometimes can be actionable under traditional antitrust principles. *Id.* at 152-155. *Trinko* would not apply in those circumstances in any event, so *Stewart* has no bearing here.

"[i]mproper Orange Book listings appear to be part of a widespread problem" for inhaler products (FTC Br. at 28), the FTC fails to acknowledge the market facts relating to ProAir® HFA and Amneal's ANDA.[35] Even putting aside all the other inhaler products on the market (brand and generic), this is not a drug for which only the NDA product is available, sold as a brand, with no competing generics. As discussed above, the first generics to ProAir® HFA were approved in 2020; Teva has licensed the patents at issue to at least one additional ANDA filer, which has not launched its product apparently for its own reasons; and Teva itself sells the NDA product as an authorized generic. *See supra* pp. 2, 23-24. The FTC's supposed "context" therefore has nothing to do with the case actually before the Court.

Third, the FTC's brief appears to be motivated, at least in part, by the desire to protect its own enforcement agenda concerning allegedly improper listings. But the question of the FTC's authority to pursue claims for wrongful patent listings is not before the Court. All the Court needs to decide is whether Amneal, an ANDA applicant that is actively pursuing statutory delisting counterclaims in this litigation, also can state an antitrust claim under the Sherman Act based on the same alleged

[35] Teva acknowledges that not all of these facts are contained in the Complaint or the Answer/Counterclaims, but given that the FTC itself has strayed beyond the pleadings, the Court should have the benefit of a balanced presentation. Teva presents these facts solely for those purposes.

improper listings.[36] For all the reasons already discussed, Amneal cannot do so, and the Court need go no further in deciding this issue.

B. Sham Litigation

Amneal's opposition arguments about sham litigation are an exercise in misdirection. Amneal never addresses head on Teva's arguments showing that Amneal's allegations do not plausibly allege sham litigation as a matter of law. Instead, Amneal tries desperately to convince the Court that its sham allegations have nothing to do with invalidity, or that they somehow plead noninfringement alone as an independent basis for the sham claim untethered to the allegations about invalidity. Amneal's defense of its claims rests entirely on that premise. But Amneal's revisionist version of its pleadings is demonstrably wrong, and Amneal cannot escape the plain words of its own allegations. Based on the allegations that Amneal actually pled, the sham litigation counterclaims should be dismissed.

To be sure, Amneal does assert a ***defense*** of noninfringement to Teva's patent claims. But that defense alone—even if it were meritorious, which Teva disputes—

[36] For example, the current FTC takes the position that it can proceed with a claim for improper listing under Section 5 of the FTC Act (which the FTC alone can enforce), and that it can proceed under Section 5 even if the same conduct does not violate the Sherman Act. *See* FTC Br. at 4-5 & n.9, 30-31 & n.99 (citing Fed. Trade Comm'n, Federal Trade Commission Statement Concerning Brand Drug Manufacturers' Improper Listing of Patents in the Orange Book, at 5-6 (Sept. 14, 2023)). While Teva reserves all rights to oppose any such arguments, the Court need not address them in connection with Amneal's counterclaims.

could not support a sham litigation claim. *Pro. Real Est. Invs. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60 n.5 (1993) ("*PRE*"). To state a claim of sham, Amneal ***also*** must plead facts plausibly alleging that Teva's infringement claims are objectively baseless; otherwise, Teva's assertion of its patents is protected by *Noerr-Pennington*. *Id*. at 59-60. Amneal's counterclaims make only one allegation in that regard (CC ¶¶ 104, 285): Teva's infringement claims purportedly are sham precisely and only because Amneal alleges in a circular fashion that any construction of Teva's patents that would support an infringement finding would render the patents invalid.

Thus, contrary to Amneal's opposition papers, its sham claim inescapably ***does*** rely on invalidity arguments. Without Amneal's invalidity allegation, its counterclaims plead no plausible basis that could support a finding that Teva's infringement claims are sham, because Amneal pled no other reason why Teva's infringement allegations purportedly lack a reasonable basis. Simply having a noninfringement position—which, absent Amneal's invalidity allegations, is all it had alleged—is not enough to render the infringement claim sham. *PRE*, 508 U.S. at 60 n.5; *AstraZeneca AB v. Mylan Labs., Inc.*, 2010 WL 2079722, at *4 (S.D.N.Y. May 19, 2010) (dismissing sham claim under Rule 12).

Dealing with Amneal's actual allegations, it is clear that the sham claim fails for all the reasons Teva already identified, and which Amneal's opposition fails to rebut. First, Teva showed that its claims cannot be sham because the information

available to it from Amneal's Detailed Statement at the time Teva filed suit gave no notice of Amneal's invalidity allegations. *See* Teva Br. at 36-37. Amneal does not dispute the legal principle that the inquiry is focused on whether the lawsuit was sham at the time it was initiated, and Amneal concedes that its Detailed Statement addressed only noninfringement. *See, e.g.,* Amneal Br. at 51 (admitting that Amneal's notice letter "assert[ed] noninfringement" and that its Detailed Statement addressed "its noninfringement position"). Amneal does not even try to argue (nor could it) that its offer to provide access to its ANDA and samples put Teva (or would have put a reasonable company in Teva's position) on notice of the details of Amneal's invalidity arguments. Amneal thus has no response on the merits to Teva's argument that Amneal cannot show that Teva's claims were sham at the time they were pled, which alone suffices to require dismissal.[37]

Second, Teva showed that, based on the *Cipla* court's prior rejection of invalidity challenges to Teva's patents, Teva's allegation that Amneal's proposed generic product would infringe valid patent claims cannot be objectively baseless. Teva Br. at 34-35 (discussing *Teva Branded Pharm. Prods. R&D, Inc. v. Cipla Ltd.*,

[37] Amneal's attempt (Amneal Br. at 49 & n.22) to rely on allegations in its Answer to support the timeliness of its claim is unavailing. Nothing in Amneal's Answer alleges that its Detailed Statement disclosed its invalidity contentions, and the statement itself (which governs over inconsistent pleadings) proves that it did not. Further, Amneal's Answer by definition was filed after Teva's complaint and thus could not have been considered by Teva before it filed.

2023 WL 4996825 (D.N.J. June 21, 2023)[38]). Here, too, Amneal's only response is one of misdirection: it ignores the centrality of invalidity allegations to its sham claim and merely asserts that "whether the Cipla product and Amneal's product are the same or different . . . is a question of fact." Amneal Br. at 55. That assertion in no way rebuts the obvious point that the *Cipla* decision provides a reasonable basis for concluding that Teva's patents are valid, and thus that—because Amneal's defense of noninfringement also requires proof of invalidity—Teva's allegations of infringement are objectively reasonable.

Third, Teva showed that Amneal's sham allegations fail *Twombly*'s basic pleading standards. Teva Br. at 37-38. Amneal cites certain cases in opposition (Amneal Br. at 49-51), but they do nothing to shore up those failings, because those cases involved sham claims that (unlike Amneal's) turned solely on questions of noninfringement not requiring any proof about invalidity, and thus are not on point.[39] In *Takeda*, the court held that allegations of having provided the NDA holder a detailed statement enumerating the bases for noninfringement, before the patent infringement claim was filed, were sufficient at the Rule 12 stage to plead sham.

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[38] In Teva's Opening Brief, the *Cipla* decision was referenced using its Westlaw citation (2023 WL 4996825). This Brief has updated the citation to *Teva Branded Pharm. Prods. R&D, Inc. v. Cipla Ltd.*,678 F. Supp. 3d 559 (D.N.J. 2023) to reflect its publication.

[39] To the extent Amneal suggests (Amneal Br. at 55) that *Noerr-Pennington* immunity can never be resolved at the Rule 12 stage, Teva has already shown that to be incorrect. *See* Teva Br. at 32-33.

Takeda Pharm. Co. Ltd. v. Zydus Pharms. (USA) Inc., 358 F. Supp. 3d 389, 396 (D.N.J. 2018). But in that case, the sham claim turned entirely on questions of infringement. The parties in *Takeda* also had previously litigated infringement of the patents, and the Federal Circuit had ruled on the governing claim construction that drove the infringement analysis. *Id*. at 396-97. Against that background, the ANDA filer's detailed statement plus its offer to provide samples to the NDA holder demonstrated that that there was no viable basis on which to claim infringement.

By contrast, the facts here are not comparable to those in *Takeda*. Amneal's Detailed Statement was silent about invalidity, and the provision of samples did not disclose invalidity arguments. Also, Amneal cannot rely on any prior litigation comparable to what happened in *Takeda* to buttress its claim. To the contrary, the relevant prior litigation here is the *Cipla* case, which rejected an invalidity challenge to the relevant patents. That prior litigation ***defeats*** Amneal's claim, as it provides an objectively reasonable basis as a matter of law to conclude that Teva's patents are not invalid, and thus to proceed with infringement claims here.

Amneal's reliance (Amneal Br. at 49-51) on *Otsuka* is equally unavailing, for the same reasons. That case also allowed the sham litigation allegations to proceed based on allegations that the ANDA filer had provided a detailed statement that supplied "allegedly dispositive evidence of noninfringement." *Otsuka Pharm. Co. v. Torrent Pharms. Ltd., Inc.*, 118 F. Supp. 3d 646, at 656 (D.N.J. 2015). Here,

Amneal's Detailed Statement indisputably did no such thing. Amneal's sham allegation necessarily relies on its position that a claim construction supporting infringement would render the patents invalid, but the bases for that position were entirely absent from the Detailed Statement, which never mentioned an invalidity basis. Further, to the extent Amneal argues that it alleged the labels and legal standards associated with sham litigation (*e.g.*, Amneal Br. at 56), *Otsuka* confirms that such pleadings do not suffice under *Twombly*. 118 F. Supp. 3d at 656.

For all these reasons, the Court should dismiss the sham litigation allegations.

C. Amneal's Remaining Counterclaims Fail

All of Amneal's arguments for its remaining Antitrust Counterclaims depend on its arguments that it has stated valid antitrust claims for both improper listing and sham litigation. It had no independent basis for those counterclaims. Thus, they all fail for the same reasons already discussed.

CONCLUSION

For the foregoing reasons and those in Plaintiffs' Opening Brief (ECF No. 27), Plaintiffs respectfully request that the Court dismiss Defendants' Counterclaim Counts 1-10 with prejudice. In addition, Plaintiffs respectfully request that the Court deny Defendants' Rule 12(c) Motion for Judgment on the Pleadings (ECF No. 41) as to Defendants' Counterclaim Counts 1-5.

Dated: April 15, 2024

Respectfully submitted,

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