FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC., NORTON (WATERFORD) LTD., AND TEVA PHARMACEUTICALS USA, INC., Plaintiffs, v. AMNEAL PHARMACEUTICALS OF NEW YORK, LLC, AMNEAL IRELAND LIMITED, AMNEAL PHARMACEUTICALS LLC, AND AMNEAL PHARMACEUTICALS INC. Defendants.	**Civil Action No. 23-20964 (SRC)** **OPINION & ORDER**

CHESLER, U.S.D.J.

This matter comes before the Court on two motions: 1) the motion to dismiss by Plaintiffs Teva Branded Pharmaceutical Products R&D, Inc., Norton (Waterford) Ltd., and Teva Pharmaceuticals USA, Inc. (collectively, "Teva"); and 2) the motion for partial judgment on the pleadings, pursuant to Federal Rule of Civil Procedure 12(c), by Defendants Amneal Pharmaceuticals Of New York, LLC, Amneal Ireland Limited, Amneal Pharmaceuticals LLC, and Amneal Pharmaceuticals Inc. (collectively, "Amneal.") For the reasons that follow, the motion to dismiss will be denied, and the motion for partial judgment on the pleadings will be granted.

This case arises out of a patent infringement dispute under the Hatch-Waxman Act between Teva and Amneal. Teva holds approved NDA No. 021457 for ProAir® HFA (albuterol sulfate) Inhalation Aerosol ("ProAir® HFA"), and owns certain patents listed in the Orange Book as covering this product: U.S. Patent Nos. 8,132,712 (the "'712 patent"), 9,463,289 (the "'289 patent"), 9,808,587 (the "'587 patent"), 10,561,808 (the "'808 patent"), and 11,395,889 (the "'889 patent") (collectively, the "Patents at issue" or the "Inhaler Patents"). Amneal has filed ANDA No. 211600, seeking to make and sell a generic version of ProAir® HFA. The following facts are undisputed. The Amneal ANDA contains a paragraph IV certification that the proposed product will not infringe any valid claim of the Patents at issue. After Amneal sent Teva the required notice letter, Teva filed the instant suit. The Amended Complaint asserts claims for patent infringement of the Patents at issue. Amneal filed an Amended Answer to the Amended Complaint asserting, *inter alia*, twelve counterclaim counts. Counterclaim Counts 1-5 seek declarations ordering Teva to delist the Patents at issue from the Orange Book. Counterclaim Counts 6-9 allege violations of the Sherman Act, and Count 10 alleges a violation of the New Jersey Antitrust Act, N.J.S.A. § 56:9. Counterclaims 11 and 12 are not at issue on these motions.

The Federal Trade Commission ("FTC") requested and was granted leave to file a brief as *amicus curiae*.

I. Teva's motion to dismiss Counterclaim Counts 6-10

Teva moves to dismiss Counterclaim Counts 1-10. The Court first considers the motion to dismiss the antitrust counterclaims, Counterclaim Counts 6-10. Teva contends that the

antitrust counterclaims are premised on two forms of alleged anticompetitive conduct: 1) improper Orange Book listing; and 2) sham litigation.

Teva contends that antitrust law provides no cause of action for improper Orange Book listing. First, Teva argues that because "Teva's patents are properly listed as a matter of law . . . any claim based on purported improper listing necessarily fails." (Pls.' MTD Br. at 25.) Later in this Opinion, this Court will consider and address Amneal's motion for judgment on the pleadings; as will be explained, the Court concludes that Teva's patents are *not* properly listed in the Orange Book as a matter of law. This conclusion does not support a Rule 12(b)(6) dismissal of an antitrust claim for improper Orange Book listing.

Second, Teva argues that, even if the Court were to find that the listings are improper, given the Trinko doctrine, "antitrust law does not create a cognizable claim for Amneal based on purported improper listing in any event." (Pls.' MTD Br. at 25.) In short, Teva argues that the instant case is analogous to Trinko, but this Court is not persuaded. The Supreme Court's syllabus for Trinko states the relevant key points of that case:

> The Telecommunications Act of 1996 imposes upon an incumbent local exchange carrier (LEC) the obligation to share its telephone network with competitors.
> . . .
> *Held:* Respondent's complaint alleging breach of an incumbent LEC's 1996 Act duty to share its network with competitors does not state a claim under § 2 of the Sherman Act.
> . . .
> (c) Traditional antitrust principles do not justify adding the present case to the few existing exceptions from the proposition that there is no duty to aid competitors.

Verizon Communs., Inc. v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398, 398-99 (2004). Teva argues that the Listing Statute, 21 U.S.C. § 355, imposes upon an NDA holder an analogous obligation:

> [T]he Hatch-Waxman Act created a statutory obligation on a brand drug company to list patents in the Orange Book in order to help generic drug companies compete with the brand company by getting FDA approval for and launching their competing generic products more quickly. This duty is, for all relevant purposes, indistinguishable from the statutory duty imposed on incumbent service providers at issue in *Trinko*.

(Pls.' MTD Opening Br. at 28.)

Teva has failed to persuade this Court that the statutes at issue in the two cases are analogous. As the statement from the Supreme Court's Syllabus makes clear, the key attribute of the statutory provision at issue was that it "imposes . . . the obligation to share its telephone network with competitors." Trinko, 540 U.S. at 398. The Listing Statute does not impose any analogous obligation on the holder of an NDA. In fact, the Listing Statute says nothing about competitors or other drug companies; it speaks only about certain information that must be submitted "to the Secretary as part of the application." 21 U.S.C. § 355(b)(1)(A). That subsection, 21 U.S.C. § 355(b)(1)(A), lists eight subparagraphs which set forth what must be submitted to the Secretary as part of the application.

Teva offers nothing more than *ipse dixit* in support of its argument that the duty imposed by the Listing Statute is "indistinguishable" from the statutory duty at issue in Trinko. Teva's opening brief quotes the Supreme Court's discussion of the Hatch-Waxman Act in Caraco: "To facilitate the approval of generic drugs as soon as patents allow, the Hatch-Waxman Amendments and FDA regulations direct brand manufacturers to file information about their patents." Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S, 566 U.S. 399, 405 (2012). This says nothing about anyone helping competitors or cooperating with competitors. Teva has given this Court no basis to find that the Listing Statute imposes on NDA applicants a duty to aid competitors.

Furthermore, the FTC aptly summarizes the bases for distinguishing Trinko from the instant case as follows:

> *Trinko* is inapplicable because Amneal's counterclaims are not an expansion of antitrust law, the FDA does not directly police the Orange Book, and the statutory amendment to add a delisting counterclaim does not transform a patent enforcement framework into an antitrust regulatory scheme.

(FTC *Amicus* Br. at 33.) The FTC contends that the FDA's ministerial role[1] in Orange Book listings differs greatly from the extensive scheme for FCC regulation of telecommunications competition described in Trinko. The Telecommunications Act of 1996 established the regulatory scheme of interest in Trinko:

> The Telecommunications Act of 1996, Pub. L. 104-104, 110 Stat. 56, imposes certain duties upon incumbent local telephone companies in order to facilitate market entry by competitors, and establishes a complex regime for monitoring and enforcement. . .
>
> The 1996 Act sought to uproot the incumbent LECs' monopoly and to introduce competition in its place. Central to the scheme of the Act is the incumbent LEC's obligation under 47 U.S.C. § 251(c) to share its network with competitors.

Trinko, 540 U.S. at 401-2 (citations omitted). Teva does not contend that, in enacting the Orange Book listing provisions of the Hatch-Waxman Act, Congress sought to uproot any monopolies, nor that, as to the Orange Book, the FDA has any enforcement function. The only enforcement mechanism Teva points to is the delisting counterclaim – but this is plainly a judicial remedy[2] (as Teva admits), not an enforcement power entrusted to a regulator.

---

[1] See Jazz Pharms., Inc. v. Avadel CNS Pharms., LLC, 60 F.4th 1373, 1378 (Fed. Cir. 2023) ("Notably, the FDA does not verify that submitted patents actually meet statutory listing criteria, nor does the FDA proactively remove improperly listed patents. *See Apotex, Inc. v. Thompson*, 347 F.3d 1335, 1347 (Fed. Cir. 2003) ('[T]he FDA's . . . duties with respect to Orange Book listings are purely ministerial.')")

[2] In Trinko, the Supreme Court expressed skepticism that, where continuing supervision is needed, a court could serve as an effective enforcer. Id. at 415 ("An antitrust court is unlikely to

Compare this judicial remedy to the "regulatory structure" the Supreme Court described in Trinko:

> One factor of particular importance is the existence of a regulatory structure designed to deter and remedy anticompetitive harm. Where such a structure exists, the additional benefit to competition provided by antitrust enforcement will tend to be small, and it will be less plausible that the antitrust laws contemplate such additional scrutiny. Where, by contrast, there is nothing built into the regulatory scheme which performs the antitrust function, the benefits of antitrust are worth its sometimes considerable disadvantages. . . .
>
> The regulatory framework that exists in this case demonstrates how, in certain circumstances, regulation significantly diminishes the likelihood of major antitrust harm.

Id. at 412 (citations omitted). Teva has not demonstrated that the Orange Book listing provisions at issue comprise a regulatory structure designed to deter and remedy anticompetitive harm. In the absence of such a regulatory structure, the Supreme Court stated, it is more plausible that antitrust law provides additional scrutiny.

Having reviewed the enforcement mechanisms established by the Telecommunications Act of 1996, the Supreme Court concluded that "the [regulatory] regime was an effective steward of the antitrust function." Id. at 413. In the instant case, Teva does not even claim that there is any regulator with enforcement powers. This Court is not persuaded that availability of the judicial remedy of delisting significantly diminishes the likelihood of major antitrust harm, nor that this remedy alone is an effective steward of the antitrust function. As the FTC points out, the judicial delisting remedy does not provide for damages; that remedy alone cannot be an effective steward of the antitrust function.

---

be an effective day-to-day enforcer of these detailed sharing obligations.")

In sum, *amicus* FTC has persuasively distinguished Trinko. Teva has failed to persuade that Trinko is analogous and forecloses Amneal's antitrust counterclaims.

Teva argues as well that the plain language of the Listing Statute precludes an antitrust claim predicated on improper listing, citing 21 U.S.C. § 355(j)(5)(c)(ii)(II), which states:

> (ii) Counterclaim to infringement action.
>
> > (I) In general. If an owner of the patent or the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or (c) on the ground that the patent does not claim either—
> >
> > (aa) the drug for which the application was approved; or
> > (bb) an approved method of using the drug.
> >
> > (II) No independent cause of action. Subclause (I) does not authorize the assertion of a claim described in subclause (I) in any civil action or proceeding other than a counterclaim described in subclause (I).

Again, Teva presents only an *ipse dixit* conclusion about the meaning of 21 U.S.C. § 355(j)(5)(c)(ii)(II), without analysis or argument. On its face, subclause (II) delimits the authority of subclause (I), which authorizes the assertion of a counterclaim to correct Orange Book information in particular cases. The clear purpose of subclause (II) is to bar an independent suit seeking the relief stated in subsection (I) in the absence of a Hatch-Waxman infringement suit; it is designed to prevent the filing of claims for correction of the Orange Book as independent actions.

Amneal has asserted Counterclaim Counts 1-5, seeking orders of correction, and these appear to be permitted by 21 U.S.C. § 355(j)(5)(c)(ii); Teva does not argue that Counts 1-5 are not permitted by 21 U.S.C. § 355(j)(5)(c)(ii). Teva does not explain how 21 U.S.C. §

355(j)(5)(c)(ii) impacts the assertion of the Counterclaim Counts 6-10 under antitrust law. Counts 6-10 do not seek any order requiring the holder to correct or delete Orange Book information. Counts 6, 9, and 10 reference improper listing in the Orange Book as an example of an anticompetitive act. (Am. Answer at ¶¶ 281, 318, 322.) Count 7 does not mention the Orange Book. Count 8 references improper listing of patents in the Orange Book as an example of "a predatory scheme to monopolize the Relevant Market." (Am. Answer at ¶ 310.) Counterclaim Counts 6-10 do not seek correction or deletion of information in the Orange Book and do not fall within the ambit of 21 U.S.C. § 355(j)(5)(c)(ii)(I).

The Court finds that subsections (I) and (II) neither authorize nor prohibit Counterclaim Counts 6-10. Teva has offered nothing to support its contention that the plain language of these subsections prohibits the assertion of the antitrust counterclaims.

Teva next argues that Counterclaim Count 7, for sham litigation in violation of the Sherman Act, fails to state a valid claim. Teva's arguments for dismissal are all variants of the contention that Count 7 is unlikely to succeed at trial or summary judgment. As the Supreme Court stated in Twombly, "of course, a well-pleaded complaint may proceed even if it strikes a savvy judge that actual proof of those facts is improbable, and 'that a recovery is very remote and unlikely.'" Bell Atl. Corp. v. Twombly, 550 U.S. 544, 556 (2007) (quoting Scheuer v. Rhodes, 416 U.S. 232, 236 (1974).) Teva does no more here than argue that recovery on Count 7 is remote and unlikely; Plaintiff does not argue that Count 7 fails to plead a legally cognizable claim for relief.

Next, Teva argues that Count 6, alleging an anticompetitive scheme, fails to state a claim because the counterclaim components of that scheme all fail to state valid claims. Because this

Court has concluded that Amneal has pled viable claims for anticompetitive conduct, it is not persuaded that Count 6 is invalid because all the other counterclaims are also invalid.

The Court concludes that Teva has failed to persuade that any of the antitrust counterclaims fail to state a legally cognizable claim for relief, and the Rule 12(b)(6) motion to dismiss the antitrust counterclaims will be denied.

II. Counterclaim Counts 1-5 and the Listing Statute

As to the delisting counterclaims, Counts 1-5, Teva moves to dismiss them too. Amneal cross-moves for judgment on the pleadings on Counterclaim Counts 1-5. The Third Circuit has stated:

> We analyze a motion for judgment on the pleadings under Federal Rule of Civil Procedure Rule 12(c) under the same standards that apply to a Rule 12(b)(6) motion. 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. A court may grant a Rule 12(c) motion if, on the basis of the pleadings, the movant is entitled to judgment as a matter of law. 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.)

In short, Teva contends that the delisting claims are premised on erroneous interpretations of the Listing Statute. As to Amneal's motion for judgment on the pleadings, Amneal and *amicus* the FTC argue that the listing of the Inhaler Patents in the Orange Book is improper and not authorized by the Listing Statute. Both of these motions turn on issues of interpretation of the Listing Statute.

The Listing Statute states, in relevant part:

(b) Filing application; contents.

> (1)
> (A) Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a). Such persons shall submit to the Secretary as part of the application—
> . . .
> (viii) the patent number and expiration date of each patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug, and that—
> (I) claims the drug for which the applicant submitted the application and is a drug substance (active ingredient) patent or a drug product (formulation or composition) patent; or
> (II) claims a method of using such drug for which approval is sought or has been granted in the application.

21 U.S.C. § 355. Although the Orange Book is not mentioned by name in the statute, the parties agree that 21 U.S.C. § 355(b)(1)(A)(viii) states the fundamental requirements to effect the listing of a patent in the Orange Book. Subsection § 355(b)(1)(A)(viii) authorizes the listing of certain patents of three kinds: drug substance patents, drug product patents, and method of use patents. Teva contends that the Inhaler Patents are drug product patents, and that they are properly listed pursuant to § 355(b)(1)(A)(viii)(I).

Subsection § 355(b)(1)(A)(viii)(I) states two requirements: 1) the patent must "claim[] the drug for which the applicant submitted the application;" and 2) the patent must be directed to a drug substance or a drug product. This Court finds that the listing issue in this case turns on the interpretation of the first element and concludes, in short, that the Inhaler Patents do not claim the drug for which the applicant submitted the application.

There is no dispute that the Inhaler Patents contain no claim for the active ingredient at issue, albuterol sulfate. Amneal contends that the Inhaler Patents do not meet the requirement that they claim the relevant drug. The FTC agrees.

Teva points out that the word "drug" in § 355 is expressly defined in 21 U.S.C. § 321(g)(1):

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

The Court acknowledges that this definition includes articles intended for use in the treatment of disease, and that the ProAir® HFA inhaler falls within its scope. The problem for Teva is that this broad statutory definition of drug does not suffice to establish that the Inhaler Patents claim the drug for which Teva submitted its application, NDA No. 021457.[3] Teva offers the FDA approval letter for this NDA, dated October 29, 2004; the first line of this letter states: "Please refer to your new drug application (NDA) dated January 30, 2003, received January 31, 2003, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for albuterol sulfate HFA Inhalation Aerosol." (Answer Ex. A at 1.) According to the FDA, the drug for which the applicant submitted the NDA is "albuterol sulfate HFA Inhalation Aerosol."

Furthermore, the Amended Complaint states:

> 45. Teva Branded is the holder of New Drug Application ("NDA") No. 021457, under which FDA approved the commercial marketing of ProAir® HFA (albuterol sulfate) Inhalation Aerosol on October 29, 2004. ProAir® HFA (albuterol sulfate) Inhalation Aerosol is indicated for the treatment or prevention of bronchospasm in patients 4 years of age and older with reversible obstructive

[3] It is not sufficient that a patent claim a drug that falls within the scope of the definition of "drug" in 21 U.S.C. § 321(g)(1); the statute requires that the patent claim ***the*** drug for which the applicant submitted ***the*** application. Teva overlooks the significance of the statutory language that modifies the phrase, "the drug."

> airway disease and for the prevention of exercise-induced bronchospasm in patients 4 years of age and older.
>
> 46. On October 1, 2022, the manufacturing of branded ProAir® HFA (albuterol sulfate) Inhalation Aerosol was discontinued. Teva USA currently distributes an authorized generic of ProAir® HFA (albuterol sulfate) Inhalation Aerosol under NDA No. 021457 in the United States.

Teva has thus premised this case on the factual allegation that the subject of NDA No. 021457 was the product, "ProAir® HFA (albuterol sulfate) Inhalation Aerosol." It is undisputed that no claim in any of the Inhaler Patents discloses albuterol sulfate.

The First Circuit construed the phrase, a patent which "claims the drug for which the applicant submitted the application," as used in § 355, in Cesar Castillo, Inc. v. Sanofi-Aventis U.S., LLC (In re Lantus Direct Purchaser Antitrust Litig.), 950 F.3d 1, 3 (1st Cir. 2020). Teva objects that, despite Lantus being a 2020 case, Congress has since changed the language of § 355 with the passage of the Orange Book Transparency Act ("OBTA"). Indeed, the OTBA did make changes to the language of § 355, but the key phrase, "claims the drug for which the applicant submitted the application," has not changed. At the time the First Circuit decided Lantus, the listing provision in § 355 required that the NDA applicant list a patent which "claims the drug for which the applicant submitted the application," and the current Listing Statute contains the same requirement today. Congress may have amended parts of the Listing Statute, but the OTBA did not change this particular requirement for listing a patent in the Orange Book: a listed patent must still claim the drug for which the applicant submitted the application.

In Lantus, Sanofi a filed a supplemental NDA "to sell insulin glargine in a disposable injector pen device called the Lantus SoloSTAR." Lantus, 950 F.3d at 5. The patent at issue, the '864 patent, was directed to drive mechanisms used in drug delivery devices. Id. In short,

the First Circuit found that the '864 patent did not claim the drug for which the applicant submitted the application. Id. at 8. Moreover, the First Circuit rejected the idea that § 355 authorizes the listing of "patents that claim only components of a proposed drug." Id. at 9. The Court concluded:

> More importantly, even assuming that the drive mechanism claimed by the '864 patent is itself a drug, we still find Sanofi falling short of its goal because the drive mechanism is not the "drug for which [Sanofi] submitted" the NDA. 21 U.S.C. § 355(b)(1). For that reason alone the patent for the drive mechanism does not qualify for listing in the Orange Book as claiming the Lantus SoloSTAR.
> . . .
> The statute and regulations clearly require that only patents that claim the drug for which the NDA is submitted should be listed in the Orange Book. The '864 patent, which neither claims nor even mentions insulin glargine or the Lantus SoloSTAR, does not fit the bill.

Id. at 9-10.

The facts of Lantus are parallel to those of the instant case. The Inhaler Patents are directed to components of a metered inhaler device, but do not claim or even mention albuterol sulfate or the ProAir® HFA. The applicant filed an NDA for an albuterol sulfate HFA Inhalation Aerosol. The statutory requirement that each patent "claim[] the drug for which the applicant submitted the application" is not met.

The FTC points out that the Second Circuit followed the relevant reasoning of Lantus in United Food & Commer. Workers Local 1776 v. Takeda Pharm. Co., 11 F.4th 118, 134 (2d Cir. 2021). United is a meaty opinion and much could be said about it, but two points are most relevant: 1) the Second Circuit decided United after passage of the OBTA and agreed with the pre-OBTA Lantus decision about the interpretation of "claims the drug for which the applicant submitted the application" in the Listing Statute; and 2) "claims" in the Listing Statute has the meaning established in patent law: "patent claims 'are the numbered paragraphs which

particularly point out and distinctly claim the subject matter which the applicant regards as his invention" (United, 11 F.4th at 132 (quoting Corning Glass Works v. Sumitomo Elec. U.S.A., Inc., 868 F.2d 1251, 1258 (Fed. Cir. 1989)). Applying the Second Circuit's analysis to the instant case, because the Inhaler Patents plainly do not regard an "albuterol sulfate HFA Inhalation Aerosol" as that which was invented, they do not claim the drug for which the applicant submitted the NDA application.

Teva offers two strategies that attempt to expand the scope of the key phrase in § 355, "claims the drug." First, Teva proffers a confusing set of arguments about the meaning of the word, "claims." Teva begins with the uncontroversial proposition that the word "claims" in the Listing Statute "should be given its meaning under patent law." (Pls.' MJP Opp. Br. at 13.) Somehow, Teva ends up at the position that "a patent 'claims' a product if the patent would be infringed by the product." (Id. at 15.) In support, Teva relies on the Second Circuit's decision in United Food. (Id.) The problem for Teva is that, as just stated, the Second Circuit in United Food based its entire analysis on this fundamental principle: "patent claims 'are the numbered paragraphs which particularly point out and distinctly claim the subject matter which the applicant regards as his invention." (United, 11 F.4th at 132 (quoting Corning Glass Works v. Sumitomo Elec. U.S.A., Inc., 868 F.2d 1251, 1258 (Fed. Cir. 1989)). Thus, a patent claims *only* that subject matter that it has particularly pointed out as the invention, and no more. This is inconsistent with Teva's contention that a patent claims all products that are infringing. Furthermore, the Second Circuit carefully explained the difference between the meaning of "claims" in patent law and "infringement." Id. at 134. In short, Teva has failed to persuade that, applying the common meaning of "claims" in patent law, any claim in any of the Inhaler

Patents particularly identifies the subject of the NDA application, an albuterol sulfate HFA Inhalation Aerosol, as the invention.

Second, Teva points to the broad statutory definition of "drug." The Court agrees with Teva that the statute, 21 U.S.C. § 321(g)(1), expressly gives the term, "drug," a broad scope, and specifically includes "articles intended for use as a component of any article" intended for use for the treatment of disease. Given the broad statutory definition of "drug," the Inhaler Patents do claim articles intended for use as a component of the ProAir® HFA (albuterol sulfate) Inhalation Aerosol, and it is undisputed that the albuterol sulfate HFA Inhalation Aerosol is intended for the treatment of disease. The problem for Teva is that this determination does not suffice to establish that the Inhaler Patents "claim[] the drug for which the applicant submitted the application," as required by the Listing Statute. Teva's arguments overlook the statutory phrase which modifies "drug:" "for which the applicant submitted the application." The drug for which the applicant submitted the application is "albuterol sulfate HFA Inhalation Aerosol." The Inhaler Patents do not contain any claims which claim "albuterol sulfate HFA Inhalation Aerosol." In short, the fact that the statutory definition of "drug" expressly includes devices for treating disease, and their components, does not nullify the restrictive action of the modifying phrase, "for which the applicant submitted the application." Teva tries hard to get around the effect of this modifying phrase, but fails to do so.

Lastly, as already noted, Teva maintains that the Inhaler Patents have been listed as "drug product" patents, within the meaning of § 355. The relevant Regulation defines "drug product" as follows: "Drug product is 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(b). As the FTC observes, the Regulations also state: "For patents that claim a drug product, the applicant must submit information only on those patents that claim the drug product, as is defined in § 314.3, *that is described in the pending or approved NDA*." 21 C.F.R. § 314.53(b)(1)(italics added). The Inhaler Patents do not claim the "finished dosage form" that is the subject of NDA No. 021457.

Furthermore, the FTC cites a response to public comments made by the FDA during the 2003 rulemaking process for the Regulation, 21 C.F.R. § 314.53:

> (Comment 3) Most comments agreed that patents claiming packaging should not be submitted for listing. However, some comments stated that patents claiming devices or containers that are "integral" to the drug product or require prior FDA approval should be submitted and listed. 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.
>
> (Response) We agree that patents claiming a package or container must not be submitted. Such packaging and containers are distinct from the drug product and thus fall outside of the requirements for patent submission. However, we have clarified the rule to ensure that if the patent claims the drug product as defined in § 314.3, the patent must be submitted for listing.
>
> Section 314.3 defines a "drug product" as "* * * a finished dosage form, for example, tablet, capsule, or solution, that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients." The appendix in the Orange Book lists current dosage forms for approved drug products. The list includes metered aerosols, capsules, metered sprays, gels, and pre-filled drug delivery systems. *The key factor is whether the patent being submitted claims the finished dosage form of the approved drug product.* Patents must not be submitted for bottles or containers and other packaging, as these are not "dosage forms."

68 Fed. Reg. 36676, 36680 (italics added). The Inhaler Patents do not claim the finished dosage form of the approved drug product.

The Court concludes that the Inhaler Patents do not meet a key requirement of the Listing Statute: they do not claim "the drug for which the applicant submitted the application," NDA No.

021457, ProAir® HFA (albuterol sulfate) Inhalation Aerosol. Nor do the Inhaler Patents claim the "finished dosage form" that is the subject of that NDA application. Because the Inhaler Patents fail to meet these requirements, that have been improperly listed in the Orange Book.

As to Counterclaim Counts 1-5, Teva's motion to dismiss will be denied. Amneal has demonstrated that, on the basis of the pleadings, it is entitled to judgment as a matter of law on Counterclaim Counts 1-5. Amneal's motion for judgment on the pleadings will be granted.

For these reasons,

IT IS on this 10th day of June, 2024

ORDERED that Plaintiff's motion to dismiss Counterclaim Counts 1-10 (Docket Entry No. 26) is **DENIED**; and it is further

ORDERED that Defendant's motion for partial judgment on the pleadings (Docket Entry No. 41) is **GRANTED**; and it is further

ORDERED that Judgment is entered in Defendants' favor as to Counts 1-5 of Defendants' Counterclaims; and it is further

ORDERED that it is the Judgment of this Court that U.S. Patent Nos. 8,132,712, 9,463,289, 9,808,587, 10,561,808, and 11,395,889 have been improperly listed in the Orange Book in regard to the drug product that is the subject of NDA No. 021457; and it is further

ORDERED that, pursuant to 21 U.S.C. § 355(j)(5)(c)(ii)(I), Teva must correct or delete the relevant Orange Book patent information listings to reflect the Judgment of this Court.

/s Stanley R. Chesler
STANLEY R. CHESLER. U.S.D.J.