No. 24-1936

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC., NORTON (WATERFORD) LTD., and TEVA PHARMACEUTICALS USA, INC.,

Plaintiffs-Appellants,

v.

AMNEAL PHARMACEUTICALS OF NEW YORK, LLC, AMNEAL IRELAND LIMITED, AMNEAL PHARMACEUTICALS LLC, and AMNEAL PHARMACEUTICALS INC.,

Defendants-Appellees.

Appeal from the U.S. District Court
for the District of New Jersey
No. 23-cv-20964 (SRC), Judge Stanley R. Chesler

[NON-CONFIDENTIAL] APPELLANTS' MOTION FOR A STAY PENDING APPEAL

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June 21, 2024

CERTIFICATE OF INTEREST

Counsel for Teva Branded Pharmaceutical Products R&D, Inc., Norton (Waterford) Ltd., and Teva Pharmaceuticals USA, Inc. (collectively "Teva" or "Plaintiffs"), certifies the following:

1. **Represented Entities.** Provide the full names of all entities represented by undersigned counsel in this case. Fed. Cir. R. 47.4(a)(1).

   Teva Branded Pharmaceutical Products R&D, Inc.; Norton (Waterford) Ltd.; and Teva Pharmaceuticals USA, Inc.

2. **Real Party in Interest.** Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities. Fed. Cir. R. 47.4(a)(2).

   None

3. **Parent Corporations and Stockholders.** Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities. Fed. Cir. R. 47.4(a)(3).

   Teva Branded Pharmaceutical Products R&D, Inc.: Teva Pharmaceutical Industries, Ltd.

   Norton (Waterford) Ltd.: Teva Pharmaceutical Industries, Ltd.

   Teva Pharmaceuticals USA, Inc.: Teva Pharmaceutical Industries, Ltd.

4. **Legal Representatives.** List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).

   Goodwin Procter LLP: Louis L. Lobel; Thomas V. McTigue IV

   Williams & Connolly LLP: Kathryn S. Kayali

   Walsh, Pizzi, O'Reilly, Falanga LLP: Liza M. Walsh, Selina M. Ellis, Hector D. Ruiz, Christine P. Clark

5. **Related Cases.** Provide the case titles and numbers of any case known to be pending in this court or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. Do not include the originating case number(s) for this case. Fed. Cir. R. 47.4(a)(5).

Teva Branded Pharm. Prods. R&D, Inc. v. Deva Holding A.S., No. 2:24-cv-04404 (D.N.J. complaint filed March 29, 2024).

6. **Organizational Victims and Bankruptcy Cases.** Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6).

Not applicable

Dated: June 21, 2024

/s/ *William M. Jay*
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Counsel for Appellants

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CONFIDENTIAL MATERIAL OMITTED

The material omitted in the text on pages 1, 7, 8, 17, and 18 refers to confidential information regarding the timing and circumstances of FDA's tentative approval of Defendants-Appellees' product. This information is subject to a protective order in the district court.

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INTRODUCTION

This is an appeal to stay an injunction ordering plaintiffs-appellants (collectively "Teva") to remove five patents from FDA's Orange Book. If the injunction is not stayed, there will be immediate, likely irreversible, consequences for not just this Hatch-Waxman litigation, but *all* cases involving the same product and the same patents. The delisted patents could no longer be the basis for a 30-month stay of approval for any of the multiple generic applications now on file. Even if the patents were restored to the Orange Book, that would not restore any 30-month stays. And it is far from clear that the patents even *can* be returned to the Orange Book once delisted. For these reasons, in the one previous appeal from a delisting injunction that has come before this Court, the Court granted a stay pending expedited review. *Jazz Pharms., Inc. v. Avadel CNS Pharms., LLC*, 60 F.4th 1373, 1378 (Fed. Cir. 2023). And in the current case, the balance of the harms tips even more sharply against the generic defendants-appellees (collectively "Amneal"): FDA has told Amneal that it does not expect to take its next action on Amneal's generic application before [redacted], and an expedited briefing schedule will allow for presentation of the issues to this Court on a similar timeframe.

On the merits, the district court's decision is clearly incorrect as a matter of both statutory interpretation and claim construction. Under the relevant statute, whether each patent must be listed in the Orange Book, or must instead be delisted,

turns on whether the patent "claims the drug for which the [new drug] applicant submitted the [new drug] application." 21 U.S.C. § 355(b)(1)(A)(viii). A "drug" encompasses the entirety of the relevant drug product—which, here, includes a metered-dose inhaler. Without doing any claim construction, the district court simply assumed that the patents here do not claim the drug product because they do not specifically mention the drug's *active ingredient*; the court drew an untenable distinction between what a patent "claims" and what "infringes" a patent. It is well-established that "[i]t is the claims that define the metes and bounds of the patentee's invention." *Thorner v. Sony Comp. Ent. Am. LLC*, 669 F.3d 1362, 1367 (Fed. Cir. 2012). For a drug product to infringe a patent, it must fall within those metes and bounds—and therefore must, contrary to the district court's understanding, be claimed by that patent. This Court's review of these issues is *de novo*, and Teva is highly likely to succeed in its appeal. Indeed, the district court *agreed* that Teva had at least raised a substantial question on the merits and faces substantial harm. Ex. 1 (Transcript of June 13, 2024 Stay Hearing) at 18-19.

A court considers four factors when deciding whether to grant a stay pending appeal. *Standard Havens Prods. Inc. v. Gencor Indus., Inc.*, 897 F.2d 511, 512 (Fed. Cir. 1990). Here, all four factors favor a stay: Teva is likely to succeed on the merits; Teva will be irreparably harmed absent a stay; Amneal will not be harmed (let alone irreparably) by a stay; and the public interest favors a stay. *See id.*

To facilitate this Court's review, the district court granted a stay of its injunction for 30 days. Ex. 2. That stay expires July 15 at 11:59 p.m. Before the stay expires, this Court should grant this motion and stay the injunction pending Teva's appeal—or, if it needs more time to consider this motion fully, should grant an administrative stay pending consideration of the stay motion. If the Court were to deny the stay, Teva requests that at a minimum the stay be extended for three business days after this Court's ruling, to permit Teva to evaluate an application to the Circuit Justice.

Once the stay expires, and Teva is forced to delist the patents, the harm to Teva will become truly irreparable.

BACKGROUND

1. This case involves Teva's ProAir® HFA (albuterol sulfate) Inhalation Aerosol, a drug product that includes a metered-dose inhaler to deliver the active ingredient. FDA considers a "metered dose inhaler" ("MDI") to be a "single-entity combination product"—*i.e.*, a drug and a device "combined or mixed and produced as a single entity." FDA, *Frequently Asked Questions About Combination Products* (Aug. 16, 2022), https://www.fda.gov/combination-products/about-combination-products/frequently-asked-questions-about-combination-products. Where, as here, the primary mode of action for the metered-dose inhaler is attributable to the drug, FDA regulates metered-dose inhalers as drugs. *See* 21 U.S.C. § 353(g)(1). FDA

thus approved ProAir® HFA under the statute and regulations governing New Drug Applications (NDAs).

The sponsor of any NDA is required to list in FDA's "Orange Book" any patent that (as relevant here) "claims the drug for which the applicant submitted the application and is … a drug product (formulation or composition) patent." 21 U.S.C. § 355(b)(1)(A)(viii)(I) (the "Listing Statute"). FDA regulations make clear that a "drug product" includes the "finished dosage form." 21 C.F.R. § 314.3; *see id.* § 314.53(b)(1) (cross-referencing this definition). And a finished dosage form includes "metered aerosols." 68 Fed. Reg. 36,676, 36,680 (June 18, 2003).

Teva accordingly listed the patents at issue in this appeal. Several of the patents are explicitly directed to the entire inhaler, *e.g.*, "an inhaler for metered dose inhalation," including the "medicament canister" and other aspects. Others refer specifically to a "dose counter for an inhaler" in the claims.

2. Amneal seeks to bring to market a generic version of Teva's ProAir® HFA product before these patents expire. Amneal submitted Paragraph IV certifications concerning all the patents listed in the Orange Book for ProAir® HFA. Teva brought suit within 45 days of receiving Amneal's notice letter, creating a 30-month stay on FDA approval of Amneal's ANDA that would expire in February 2026.[1]

[1] Another generic company, Deva Holding A.S. ("Deva"), has likewise submitted an

In an amended complaint, Teva narrowed its case to the patents at issue here, the '712, '289, '587, '808, and '889 patents (the "Asserted Patents").[2] Amneal counterclaimed for an injunction compelling Teva to delist the Asserted Patents from the Orange Book,[3] *see* 21 U.S.C. § 355(j)(5)(C)(ii)(I), and moved for judgment on the pleadings on those counterclaims under Rule 12(c).

3. The district court granted Amneal's motion and entered an injunction ordering Teva to delist the Asserted Patents. The district court agreed that the Asserted Patents claim a "drug" under the relevant regulatory definitions, but nonetheless found that the Asserted Patents are not properly listable for ProAir® HFA because "they do not claim 'the drug for which the applicant submitted the application,' … ProAir® HFA (albuterol sulfate) Inhalation Aerosol." Ex. 3 (District Court Opinion Granting Injunction) at 16-17. The district court construed the Listing Statute to require that a listable patent recite in the claims "the drug for which the applicant submitted the application" explicitly. The court acknowledged that the word "claims" should be given its meaning under patent law, but drew a

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ANDA with a Paragraph IV certification to the same patents. Teva timely filed a separate suit against Deva, No. 2:24-cv-04404 (D.N.J.), creating a 30-month stay on FDA approval of Deva's ANDA product as well.

[2] In full, the Asserted Patents are 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"). The patents were publicly filed as ECF No. 7-1 (Exs. A-E) in the proceeding below.

[3] Amneal also asserted antitrust counterclaims not at issue on appeal.

distinction between the scope of the "claims" and the "products that are infringing." Ex. 3 at 14.

The court then held that the Asserted Patents were listed as patents on a "drug product," *i.e.*, a "finished dosage form," but "do not claim the 'finished dosage form' that is the subject of [the NDA]." *Id.* at 15-16. The court did not engage in any claim construction, but nonetheless concluded that the Asserted Patents "do not claim or even mention albuterol sulfate or the ProAir® HFA." *Id.* at 13. In the court's view, to claim "the drug for which the applicant submitted the application" in this case, the patent would have to recite "albuterol sulfate HFA Inhalation Aerosol." *Id.* at 15.

4. Teva moved to stay the injunction pending this appeal or, in the alternative, for 30 days to permit this Court to consider a stay application. After a hearing, the district court granted the alternative request for a 30-day stay.

On Teva's likelihood of success on the merits, the district court acknowledged that "at a minimum there is at least a real substantial issue about whether or not I was right or wrong." Ex. 1 at 15. On irreparable harm, the district court acknowledged "there is substantial harm to Teva if this decision is not stayed at least for enough time for them to present it to" this Court. *Id.* at 18-19. On the balance of the equities, the court found "no harm to Amneal because they can't conceivably go on the market." *Id.* at 19. Amneal's ANDA has not been tentatively approved

by FDA, and Amneal acknowledged that "the expectation of the FDA" is that it would most likely take action on the ANDA in "either date of date or date of date depending on whether or not they have to do an action." *Id.* at 12. And on the public interest, as Amneal conceded, there would be no harm to the public interest from a 30-day stay. *Id.* at 18-19.

The court accordingly granted a stay through July 15 at 11:59 p.m. Ex. 2. In a separate motion, the parties have agreed to expedite this appeal and proposed competing schedules.

LEGAL STANDARD

The test for stays involves four factors: "(1) whether the stay applicant has made a strong showing that [it] is likely to succeed on the merits; (2) whether the applicant will be irreparably injured absent a stay; (3) whether issuance of the stay will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies." *Nken v. Holder*, 556 U.S. 418, 433-34 (2009) (citation omitted). When "the [nonmerits] factors militate in [the movant's] favor," it need only show "a substantial case on the merits." *E.g.*, *Standard Havens*, 897 F.2d 511 at 513 (emphasis and citation omitted). Here, all four factors support a stay pending appeal.

ARGUMENT

In the only previous appeal from an order to delist a patent from the Orange

Book, this Court granted the stay—even though it ultimately affirmed. *See Jazz*, 60 F.4th at 1378. In this case, Teva's likelihood of success is strong, the injury is just as irreparable as in *Jazz*, and the balance of the harms tips sharply in Teva's favor because FDA is unlikely to act on Amneal's application before [redacted] date [redacted]—and there is no reason to believe the ANDA will be approved even at that date. Expediting the appeal as the parties have proposed would likely avoid even the possibility of harm to Amneal. And preserving the 30-month stay until this appeal is resolved serves the public interest, reflected in the Hatch-Waxman statute, by avoiding burdening the court system with unnecessary TRO and preliminary-injunction litigation that would be brought to the court on an emergency basis. This Court should grant the stay.

I. Teva Is Likely To Succeed on the Merits, Because The District Court Misinterpreted the Statute and the Patents.

The district court acknowledged in granting the 30-day stay that its interpretation of the Listing Statute raises a "substantial" question for appeal. And because of Teva's strong showing of irreparable harm (discussed below), that would suffice by itself. *Standard Havens*, 897 F.2d at 513. But that understates matters: in light of multiple errors by the district court, each of which this Court will review *de novo*, Teva is likely to succeed on the merits.

The Listing Statute mandates that an NDA applicant "shall submit" for listing in the Orange Book each patent that (1) "claims the drug for which the [NDA holder] submitted the application" and (2) is a "drug product (formulation or composition)

patent." 21 U.S.C. § 355(b)(1)(A)(viii). The district court both misinterpreted what the statute means by the "claims" phrase and failed to construe what the patents actually claim.

The district court appeared to acknowledge that a product can infringe a patent even if the claim language does not expressly recite the product by name. But the court oddly rejected "Teva's contention that a patent claims all products that are infringing." Ex. 3 at 14. The court emphasized that the claims of each patent must "particularly point out" the claimed subject matter, *id.* (citation omitted), but that is true of every patent—and the scope of claimed subject matter is determined by claim construction, not by looking for magic words in the claims. A patent "claims" a product when the patent "reads on" the product, even if an element of the product is not explicitly mentioned in the claim. *See Allen Eng'g Corp. v. Bartell Indus., Inc*., 299 F.3d 1336, 1345 (Fed. Cir. 2002). In other words, if selling the NDA product would "infringe" a patent, then the patent "claims" that product and is listable. *Apotex, Inc. v. Thompson*, 347 F.3d 1335, 1344 (Fed. Cir. 2003) ("The listing decision thus requires what amounts to a finding of patent infringement, except that the 'accused product' is the drug that is the subject of the NDA.").

A genus claim, for instance, claims every species without mentioning any of them. When Teva pointed out this flaw in the district court's reasoning, Amneal responded only that these patents are not genus claims. That is disputed, *see* p. 12,

infra, but even setting that dispute aside, the point is that the district court's magic-words test rules out patent claims that should plainly be listed in the Orange Book, *such as* genus claims. This Court has made clear that "what a patent claims" under "these statutes and regulations" "should be derived using the tools and framework of patent law, including claim construction." *Jazz*, 60 F.4th at 1379. But the district court failed to conduct such an analysis, looking only for what words were explicitly recited in the claims.

For "drug product" patents like these, what matters is whether the patents "claim the drug product … that is described in the pending or approved NDA." 21 C.F.R. § 314.53(b)(1). That is because the relevant statutory definition of a "drug" includes not just the active ingredient, but the entirety—specifically including any "component"—of any "article[]" used for the "treatment[] or prevention of disease." 21 U.S.C. § 321(g)(1)(B), (D).

Here the drug product is a metered-dose inhaler. FDA expressly distinguished "drug delivery systems used and approved in combination with a drug," *specifically including* "metered dose inhalers" like ProAir® HFA, from the type of "packaging and containers" that cannot be the basis for an Orange Book listing. 68 Fed. Reg. at 36,680. The district court block-quoted this discussion, emphasizing that "[t]he key factor is whether the patent being submitted claims the finished dosage form of the approved drug product," Ex. 3 at 16 (quoting 68 Fed. Reg. at 36,680) (emphasis

omitted). But it missed the point that "metered aerosols" *are* finished dosage forms. 68 Fed. Reg. at 36,680.

These patents claim the metered-dose inhaler. While the district court did not engage in *any* claim construction, that point is apparent even without full claim construction. For example, 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."[4] *See, e.g.,* '289 patent at claim 1 (ECF No. 7-1 at 46); '587 patent at claims 1, 12, 13 (ECF No. 7-1 at 78).[5] As another example, a third patent has claims directed to "[a] metered dose inhaler comprising a medicament canister." *See, e.g.*, '712 patent at claim 16. That is the drug product that FDA reviewed and approved in Teva's NDA. Selling ProAir® HFA, or an exact duplicate of that product, infringes these patents—which is why they "claim" the drug product. *Apotex*, 347 F.3d at 1344.

The district court misinterpreted the statute to require that the patent expressly claim the active ingredient, but that not only misinterprets the meaning of "claim" in patent law, it renders part of the statute surplusage. The Listing Statute

[4] To defeat the 30-month stay, Amneal must win its delisting counterclaim as to *all* of the patents. Thus, a substantial likelihood of success as to *any* of the Asserted Patents should suffice for a stay pending appeal. Teva expects to brief the listability of all five Asserted Patents in its merits briefing.

[5] Unless otherwise specified, ECF citations are to the docket entries in the underlying district court proceeding.

specifically provides that NDA sponsors must list *both* any "drug substance (active ingredient) patent" *and* any "drug product (formulation or composition) patent." 21 U.S.C. § 355(b)(1)(A)(viii)(I). The existence of the second category makes clear that listable patents are not limited to patents claiming the active ingredient.

The district court relied upon the Second Circuit's decision in an antitrust case, *United Food & Commercial Workers Local 1776 v. Takeda Pharmaceutical Co. Ltd.*, 11 F.4th 118 (2d Cir. 2021), to interpret the statutory term "claims." The district court noted that the Second Circuit observed that the patent claims "are the numbered paragraphs which particularly point out and distinctly claim the subject matter which the applicant regards as his invention." Ex. 3 at 14 (*quoting United*, 11 F.4th at 132). But the district court then ignored the further discussion in *United* at the conclusion of the same paragraph: "[A] patent 'claims' an invention 'when each of the claim limitations "reads on," or in other words, is found in' the invention." *United*, 11 F.4th at 132 (quoting *Allen Eng'g*, 299 F.3d at 1345).[6] But had the district court engaged in claim construction before granting Amneal final judgment and an injunction on its counterclaims, it would not have needed to make that mistake. The district court thought "[t]here is no dispute that the [Asserted Patents] contain no

[6] The patents in *United* ultimately did not "claim the drug" because they claimed a combination of two active ingredients, and the drug in question had only one. FDA listed those patents only as "method of use" patents, not drug-substance or drug-product patents.

claim for the active ingredients at issue, albuterol sulfate." Ex. 3 at 10. This is not true. While the claims of the Asserted Patents do not explicitly recite the name of "ProAir® HFA (albuterol sulfate)," they require a metered dose inhaler and the presence of an active ingredient and thus "claim," or "read on," the ProAir® HFA drug product.

Thus, the district court's conclusion that all of the patents are directed only to "components of a metered inhaler device," *id.* at 13, is incorrect. The patents include claims directed to the inhaler as a whole, with certain additional, specific required attributes.

The district court looked for support to another antitrust decision, *In re Lantus Direct Purchaser Antitrust Litigation*, 950 F.3d 1 (1st Cir. 2020), but that court similarly misinterpreted the statute. *Lantus* held that the antitrust plaintiffs had plausibly alleged that the patent at issue was not listable "because the claims of the [listed] patent do not mention the drug for which the [supplemental NDA] was submitted." 950 F.3d at 8. But the term "drug" as defined in the statute is broader than the active ingredient, and the statutory verb "claims" encompasses far more than what the patent "mentions" by name, as this Court has previously explained. *Jazz*, 60 F.4th at 1379 (noting that tools of claim construction should be used to determine what the patent "claims"). Just reviewing the numbered claims of the patents for an explicit "mention" of the active ingredient or branded product name

does not answer the question whether the patent "claims" the "drug."

Under the proper construction of the Listing Statute, the Asserted Patents satisfy the element that they "claim[] the drug for which the [NDA applicant] submitted the application," as well as all other elements of the Listing Statute.

II. Teva Will Be Irreparably Harmed Absent a Stay, Because It Will Irrevocably Lose Statutory Rights.

Teva will be irreparably harmed absent a stay, because complying with the injunction and immediately delisting the patent will have consequences—for this litigation and others—that may be irreversible once the patent is delisted. Chief among these is the statutory 30-month stay, which Teva would lose with respect to Amneal *and* Deva (*see* note 1, *supra*) *and* any additional ANDA filer[7]—and which Teva could not regain even if the patents were relisted. An order to take action that is both irreversible and not compensable is the very definition of irreparable harm. The district court recognized the "substantial" harm that Teva would face once its injunction takes effect, Ex. 1 at 18; because that harm is irreparable, the same harm justifies a stay pending the Court's expedited consideration of the merits of the appeal.

[7] While other patents asserted against Deva have not been ordered delisted, Teva would lose the stay associated with the five patents that have been ordered delisted for Deva and any subsequent ANDA filer. Deva did not disclose the details of its ANDA under an Offer of Confidential Access, and therefore Teva may need to rely on only the patents that have been ordered delisted as that litigation proceeds into discovery.

The 30-month stay currently prevents FDA from approving Amneal's ANDA because Teva timely sued Amneal on Orange Book-listed patents. *See* 21 U.S.C. § 355(j)(5)(B)(iii). Amneal has already taken the position that delisting the patents will itself immediately extinguish the 30-month stay. *See* ECF No. 48 (Amneal's Consolidated Brief on the Merits) at 31; Ex. 4 (Amneal's Opposition to Stay Pending Appeal) at 2, 5. Delisting would also permit Amneal to withdraw its Paragraph IV certification, allowing the ANDA to be approved without regard to the Asserted Patents or the outcome of this litigation. *See* 21 C.F.R. §§ 314.94(a)(12)(viii)(B), 314.107(b)(1)(i).

Even if Teva successfully appeals the district court's order, the protections of the 30-month stay would be irreversibly lost in this and other cases once the patents are delisted. For a 30-month stay to apply, the patents must be listed in the Orange Book *before* the ANDA is filed. 21 U.S.C. § 355(j)(5)(B)(iii). Amneal's and Deva's ANDAs are both on file already. For those two ANDA filers—and any more generics that file applications after the patents are delisted—FDA would not recognize a 30-month stay if Teva resubmitted the patents after a reversal and FDA listed them effective at that time. The permanent loss of such a "statutory entitlement … [i]s a harm that [is] sufficiently irreparable" to support a stay because "[o]nce the statutory entitlement has been lost, it cannot be recaptured." *Apotex, Inc. v. FDA*, No.

Civ.A. 06-0627, 2006 WL 1030151, at *17 (D.D.C. Apr. 19, 2006) (citing *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1067 (D.C. Cir. 1998)), *aff'd*, 449 F.3d 1249 (D.C. Cir. 2006). Thus, Teva has shown that a stay is needed to avoid injury that is concrete, non-speculative, imminent, and irreparable: as against both Amneal and Deva, and possibly others, once the Asserted Patents are removed from the Orange Book, they can *never* be the basis for a 30-month stay again.

It gets worse. It appears that any company with an ANDA on file would not even need to *certify* to the Asserted Patents if they were restored to the Orange Book. *See* 21 C.F.R. § 314.94(a)(12)(vi). That would mean that Teva could not even sue on those patents based on the artificial act of infringement under Hatch-Waxman, nor could it obtain the statutory remedy for Hatch-Waxman cases, 35 U.S.C. § 271(e)(4)(A). Rather, Teva would be limited to pursuing exactly what Hatch-Waxman seeks to avoid—a preliminary injunction, a jury trial after launch, and money damages.

Below, Amneal called Teva's irreparable-harm argument "speculative," but it never disputed that *it* will be permanently free of the 30-month stay. Rather, it contended that Teva can look to *other* Orange Book-listed patents as the basis for a stay or a Hatch-Waxman case against any future filers. But as Amneal well knows, once Teva reviewed the specifics of Amneal's ANDA,

Teva concluded that those other patents could not reasonably be asserted against Amneal—and, it follows, against other ANDA filers with materially similar specifications.

Harm is irreparable when it cannot be undone. *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1381 (Fed. Cir. 2006). Absent a stay, that is exactly what will happen here—even if this Court later reverses the injunction.

III. Amneal Would Suffer No Harm from a Stay Pending An Expedited Appeal, Because It Does Not Have Even Tentative Approval

While Teva will be irreparably harmed absent a stay, Amneal will not be harmed *at all* by a stay pending expedited consideration of this appeal. Amneal's product is not marketable at this time, as it has not achieved even tentative FDA approval. Currently, FDA's [redacted] for review of Amneal's [redacted] to its ANDA is [redacted] if no [redacted] is required and [redacted] if an [redacted] is required. *See* Ex. 5 (Mar. 12, 2024 Letter from FDA to Amneal). Moreover, FDA has done no more than indicate that it will provide its next response to Amneal on that date—there is no indication as to whether that response will be an approval or a request for further information to continue to assess the ANDA.[8] The district court recognized that "there is no harm to Amneal" during the period while

[8] Amneal tried unsuccessfully to [redacted] of its application, but FDA denied both [redacted] and [redacted]. *See* Ex. 6 (April 17, 2024 Letter from Amneal to FDA); Ex. 7 (May 9, 2024 Email from FDA); Ex. 8 (May 15, 2024 Letter from FDA to Amneal).

"they can't conceivably go on the market," Ex. 1 at 19; that will remain the case at least through [redacted], and Amneal has shown only a *possibility* of harm thereafter, because the outcome of FDA's review remains uncertain. Expediting the appeal more than mitigates Amneal's concern.

If the Court grants the stay, the 30-month stay remains in place, and Amneal subsequently obtains tentative approval from FDA, then the merits panel would be able to revisit the stay at that time, with the benefit of full consideration of the merits. By contrast, if the Court denies the stay and the Asserted Patents are delisted, there will *be* no tentative approval because there will be no 30-month stay—FDA will simply issue a decision on Amneal's ANDA whenever it is ready, with no notice to anyone.

IV. The Public Interest Favors a Stay To Preserve Congress's Decision to Avoid Burdening the Courts with Emergency Litigation

The public interest favors a stay. Hatch-Waxman is a compromise that provided NDA holders and their prospective competitors pre-launch certainty about their respective rights. *See Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 677-78 (1990). The 30-month stay substitutes for pitched battles over preliminary injunctions in every brand-vs.-generic case. And the Paragraph IV certification enables pre-launch determination of the parties' rights, without exposing the generic to substantial damages liability and without the expense and uncertainty of a jury trial.

Amneal insisted that the immediate termination of the 30-month stay, requiring the parties to go through a preliminary injunction fight whenever Amneal obtains approval and is ready to launch, is consistent with the public interest. The district court rightly rejected that argument, calling it "anathema" because it "creates havoc with the court's docket and it delays handling other cases." Ex. 1 at 19. And Amneal cannot claim that getting its own product on the market makes a difference to the public interest; it does not have FDA approval and, if the appeal is expedited, likely will not have it before decision.

CONCLUSION

Teva respectfully requests that this Court stay the injunction pending appeal. If the Court has not ruled on this motion by July 15, 2024, Teva respectfully requests that the Court administratively extend the district court's stay of the injunction until this Court rules on the motion. If the Court were to deny the stay, Teva requests that at a minimum the stay be extended for three business days after this Court's ruling, to permit Teva to evaluate an application to the Circuit Justice.

June 21, 2024

Respectfully submitted,

/s/ William M. Jay

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CERTIFICATE OF COMPLIANCE

This motion complies with the type-volume limitations of Federal Rule of Appellate Procedure 27(d)(2)(A) because it contains 4,712 words, excluding the parts of the motion exempted by Federal Rule of Appellate Procedure 32(f) and Federal Circuit Rule 32(b)(2).

This motion complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6). The motion has been prepared in a proportionally spaced typeface using Microsoft Word 365 in 14-point Times New Roman font.

Dated: June 21, 2024

/s/ William M. Jay
William M. Jay

FORM 31. Certificate of Confidential Material **Form 31**
July 2020

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

CERTIFICATE OF CONFIDENTIAL MATERIAL

Case Number: No. 24-1936

Short Case Caption: Teva Branded Pharmaceutical Products R&D, Inc. v. Amneal Pharmaceuticals of New York, LLC

Instructions: When computing a confidential word count, Fed. Cir. R. 25.1(d)(1)(C) applies the following exclusions:

- Only count each unique word or number once (repeated uses of the same word do not count more than once).
- For a responsive filing, do not count words marked confidential for the first time in the preceding filing.

The limitations of Fed. Cir. R. 25.1(d)(1) do not apply to appendices; attachments; exhibits; and addenda. *See* Fed. Cir. R. 25.1(d)(1)(D).

The foregoing document contains 13 number of unique words (including numbers) marked confidential.

☑ This number does not exceed the maximum of 15 words permitted by Fed. Cir. R. 25.1(d)(1)(A).

☐ This number does not exceed the maximum of 50 words permitted by Fed. Cir. R. 25.1(d)(1)(B) for cases under 19 U.S.C. § 1516a or 28 U.S.C. § 1491(b).

☐ This number exceeds the maximum permitted by Federal Circuit Rule 25.1(d)(1), and the filing is accompanied by a motion to waive the confidentiality requirements.

Date: 06/21/2024

Signature: /s/ William M. Jay

Name: William M. Jay

No. 24-1936

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC., NORTON (WATERFORD) LTD., and TEVA PHARMACEUTICALS USA, INC.,

Plaintiffs-Appellants,

v.

AMNEAL PHARMACEUTICALS OF NEW YORK, LLC, AMNEAL IRELAND LIMITED, AMNEAL PHARMACEUTICALS LLC, and AMNEAL PHARMACEUTICALS INC.,

Defendants-Appellees.

Appeal from the U.S. District Court
for the District of New Jersey
No. 23-cv-20964 (SRC), Judge Stanley R. Chesler

DECLARATION OF WILLIAM M. JAY IN SUPPORT OF APPELLANTS' MOTION FOR A STAY PENDING APPEAL

June 21, 2024

I, William M. Jay, hereby declare:

1. I am over the age of twenty-one, of sound mind, and competent to make this declaration. I am also qualified to give testimony under oath. Each of the facts listed below is within my personal knowledge and is true and correct.

2. I am a partner with the law firm Goodwin Procter LLP, counsel of record for Appellants Teva Branded Pharmaceutical Products R&D, Inc., Norton (Waterford) Ltd., and Teva Pharmaceuticals USA, Inc. (collectively "Teva") in this matter. I make this declaration from personal knowledge and, if called to testify, I could and would testify competently thereto.

3. Attached hereto as Exhibit 1 is a true and correct copy of the transcript from the June 13, 2024 hearing in the proceedings below, Case No. 23-cv-20964-SRC-MAH (D.N.J.), on Teva's motion for a stay pending appeal.

4. Attached hereto as Exhibit 2 is a true and correct copy of the Order Granting in Part Motion to Stay the Court's June 10, 2024 Order, filed in the proceedings below on June 13, 2024 (ECF No. 98).

5. Attached hereto as Exhibit 3 is a true and correct copy of the Opinion & Order denying Teva's motion to dismiss and granting defendants-appellees' (collectively, "Amneal's") motion for partial judgment on the pleadings, entered by the Court in the proceedings below on June 10, 2024 (ECF No. 88).

6. Attached hereto as Exhibit 4 is a true and correct copy of Amneal's

Opposition to Stay Pending Appeal, filed under seal in the proceedings below on June 12, 2024 (ECF No. 94).

7. Attached hereto as Exhibit 5 is a true and correct copy of the March 12, 2024 Letter from FDA to Amneal, filed under seal in the proceedings below on April 15, 2024 (ECF No. 64-11).

8. Attached hereto as Exhibit 6 is a true and correct copy of the April 17, 2024 Letter from Amneal to FDA, filed under seal in the proceedings below on June 11, 2024 (ECF No. 91, Ex. A).

9. Attached hereto as Exhibit 7 is a true and correct copy of the May 9, 2024 Email from FDA, filed under seal in the proceedings below on June 11, 2024 (ECF No. 91, Ex. B).

10. Attached hereto as Exhibit 8 is a true and correct copy of the May 15, 2024 Letter from FDA to Amneal, filed under seal in the proceedings below on June 11, 2024 (ECF No. 91, Ex. C).

11. Attached as Exhibit 9 is a true and correct copy of the Notice of Appeal, filed in the proceedings below on June 11, 2024 (ECF No. 92).

12. Exhibits 1 and 4-8 are being filed under seal because they refer to confidential information regarding the timing and circumstances of FDA's tentative approval of Amneal's product. This information is subject to a protective order in the district court.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: June 21, 2024 */s/ William M. Jay*

William M. Jay

CERTIFICATE OF SERVICE

I hereby certify that on June 21, 2024, I electronically filed the foregoing using the Court's CM/ECF system, which will send notifications to all counsel registered to receive electronic notices, and served the foregoing by electronic mail to all counsel of record (pursuant to their written consent under Fed. R. App. P. 25(c)(2)(B)), at the addresses below.

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/s/ William M. Jay
William M. Jay

INDEX TO THE DECLARATION OF WILLIAM M. JAY IN SUPPORT OF APPELLANTS' MOTION FOR A STAY PENDING APPEAL

EXHIBIT NO.	DESCRIPTION
1	Transcript of June 13, 2024 District Court Stay Hearing UNDER SEAL
2	District Court Stay Order, ECF No. 98 (June 13, 2024)
3	District Court Injunction Order, ECF No. 88 (June 10, 2024)
4	Amneal's Opposition to Stay Pending Appeal, ECF No. 94 (June 12, 2024) UNDER SEAL
5	March 12, 2024 Letter from FDA to Amneal, ECF No. 64-11 UNDER SEAL
6	April 17, 2024 Letter from Amneal to FDA, ECF No. 91, Ex. A (June 11, 2024) UNDER SEAL
7	May 9, 2024 Email from FDA, ECF No. 91, Ex. B (June 11, 2024) UNDER SEAL
8	May 15, 2024 Letter from FDA to Amneal , ECF No. 91, Ex. C (June 11, 2024) UNDER SEAL
9	Notice of Appeal, ECF No. 92 (June 11, 2024)

Exhibit 1
(Confidential Filed Under Seal)

Exhibit 2

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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC., NORTON (WATERFORD) LTD., and TEVA PHARMACEUTICALS USA, INC., Plaintiffs, v. AMNEAL PHARMACEUTICALS OF NEW YORK, LLC, AMNEAL IRELAND LIMITED, AMNEAL PHARMACEUTICALS LLC, and AMNEAL PHARMACEUTICALS INC., Defendants.	Civil Action No. 23-cv-20964-SRC-MAH **ORDER GRANTING IN PART MOTION TO STAY THE COURT'S JUNE 10, 2024 ORDER** *Filed Electronically*

THIS MATTER having been brought before the Court upon Plaintiffs Teva Branded Pharmaceutical Products R&D, Inc., Norton (Waterford) Ltd., and Teva Pharmaceuticals USA, Inc.'s (collectively, "Teva" or "Plaintiffs") Motion to Stay the Court's June 10, 2024 Order (D.E. 88) pending the resolution of Teva's appeal, or in the alternative, a 30-day stay to permit resolution of Teva's application to the United States Court of Appeals for the Federal Circuit for a stay pending appeal; and the Court having

considered the papers and arguments of the parties; and for good cause having been shown:

IT IS on this 13th day of June, 2024;

ORDERED, for the reasons set forth on the record on June 13, 2024, that Plaintiffs' alternative request in its Motion for a 30-day stay to permit resolution of an application to the United States Court of Appeals for the Federal Circuit for a stay pending appeal is **GRANTED**; and it is further

ORDERED that the Court's June 10, 2024 injunction Order (D.E. 88) is hereby **STAYED** for a period of 30 days from today's date (which period, under Fed. R. Civ. P. 6(a)(1)(C), shall expire at 11:59 p.m. EDT on July 15, 2024); and it is further

ORDERED that the parties shall meet and confer and propose to the Federal Circuit a briefing schedule for Teva's application for a stay and a briefing schedule for the appeal.

s/ Stanley R. Chesler

Hon. Stanley R. Chesler, U.S.D.J.

Exhibit 3

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.,	**Civil Action No. 23-20964 (SRC)**
Plaintiffs,	**OPINION & ORDER**
v.	
AMNEAL PHARMACEUTICALS OF NEW YORK, LLC, AMNEAL IRELAND LIMITED, AMNEAL PHARMACEUTICALS LLC, AND AMNEAL PHARMACEUTICALS INC.	
Defendants.	

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.

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[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.

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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.

Exhibit 4
(Confidential Filed Under Seal)

Exhibit 5
(Confidential Filed Under Seal)

Exhibit 6
(Confidential Filed Under Seal)

Exhibit 7
(Confidential Filed Under Seal)

Exhibit 8
(Confidential Filed Under Seal)

Exhibit 9

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

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

NOTICE IS HEREBY GIVEN that Plaintiffs Teva Branded Pharmaceutical Products R&D, Inc., Norton (Waterford) Ltd., and Teva Pharmaceuticals USA, Inc. (collectively, "Teva" or "Plaintiffs") hereby appeal to the United States Court of Appeals for the Federal Circuit pursuant to Federal Rule of Appellate Procedure 3 and 28 U.S.C. § 1295 from the Court's Order and Opinion entered on June 10, 2024 granting an injunction (D.E. 88), as well as any and all other judgments, orders, opinions, rulings, and findings that merge therein or are pertinent or ancillary to the foregoing that are adverse to Plaintiffs.

Payment of the required $605 fee is provided with this Notice of Appeal. This fee includes the $600 fee for docketing a case on appeal required by 28 U.S.C. § 1913 and Federal Circuit Rule 52(a)(2), and the $5 fee for filing a notice of appeal required by 28 U.S.C. § 1917.

Dated: June 11, 2024

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