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 United States District Court for the District of New Jersey
Case No. 2:23-cv-20964, Judge Stanley R. Chesler

[NON-CONFIDENTIAL] APPELLEES' OPPOSITION TO PLAINTIFFS' MOTION TO STAY PENDING APPEAL

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June 28, 2024

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF INTEREST

Case Number 2024-1936

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

Filing Party/Entity Amneal Pharmaceuticals of New York, LLC; Amneal Ireland Limited; Amneal Pharmaceuticals LLC; Amneal Pharmaceuticals, Inc

Instructions:

1. Complete each section of the form and select none or N/A if appropriate.
2. Please enter only one item per box; attach additional pages as needed, and check the box to indicate such pages are attached.
3. In answering Sections 2 and 3, be specific as to which represented entities the answers apply; lack of specificity may result in non-compliance.
4. Please do not duplicate entries within Section 5.
5. Counsel must file an amended Certificate of Interest within seven days after any information on this form changes. Fed. Cir. R. 47.4(c).

I certify the following information and any attached sheets are accurate and complete to the best of my knowledge.

Date: 06/28/2024

Signature: /s/ Steven A. Maddox

Name: Steven A. Maddox

1. Represented Entities. Fed. Cir. R. 47.4(a)(1).	**2. Real Party in Interest.** Fed. Cir. R. 47.4(a)(2).	**3. Parent Corporations and Stockholders.** Fed. Cir. R. 47.4(a)(3).
Provide the full names of all entities represented by undersigned counsel in this case.	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. ☑ None/Not Applicable	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. ☐ None/Not Applicable
Amneal Pharmaceuticals of New York, LLC		See attached.
Amneal Ireland Limited		See attached.
Amneal Pharmaceuticals LLC		See attached.
Amneal Pharmaceuticals, Inc.		See attached.

☑ Additional pages attached

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).

☐ None/Not Applicable ☐ Additional pages attached

Melissa Hatch O'Donnell, Robin P Sumner, and Andrew P Zappia of Troutman Pepper Hamilton Sanders LLC		
Rebekah R. Conroy and Shalom D. Stone of Stone Conroy LLC		

5. Related Cases. Other than the originating case(s) for this case, are there related or prior cases that meet the criteria under Fed. Cir. R. 47.5(a)?

☑ Yes (file separate notice; see below) ☐ No ☐ N/A (amicus/movant)

If yes, concurrently file a separate Notice of Related Case Information that complies with Fed. Cir. R. 47.5(b). **Please do not duplicate information.** This separate Notice must only be filed with the first Certificate of Interest or, subsequently, if information changes during the pendency of the appeal. Fed. Cir. R. 47.5(b).

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).

☑ None/Not Applicable ☐ Additional pages attached

3. **Parent Corporations and Stockholders.** Fed. Cir. R. 47.4(a)(3).
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.

Amneal Pharmaceuticals of New York, LLC:
Wholly owned by Amneal Pharmaceuticals LLC

Amneal Ireland Limited:
Wholly owned by Amneal Pharmaceuticals Holding GmbH, which is wholly owned by Amneal UK Holding Company Ltd., which is wholly owned by Amneal Pharmaceuticals LLC

Amneal Pharmaceuticals LLC:
Wholly owned by Amneal Pharmaceuticals, Inc.

Amneal Pharmaceuticals, Inc.:
None/Not Applicable

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A description of the redacted information appears on the following page.

CONFIDENTIAL MATERIAL OMITTED

The material omitted in the text on page 17 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

The Court should deny Teva's motion for a stay pending appeal. Teva will not suffer irreparable harm. Teva's mere speculation about scenarios in which it might lose its 30-month stay is not sufficient to establish irreparable harm. In any event, even that speculative harm would not be irreparable. The benefit to Teva of a 30-month stay is to prevent launch of a competing ANDA product for the prescribed period of time. If Teva loses a stay or cannot obtain one because the Asserted Patents are delisted then relisted, Teva could seek appropriate injunctive relief to obtain the very same benefit.

Further, the odds of prevailing on the merits are stacked deeply here against Teva. Most notably, Teva's position has been squarely rejected by the First Circuit in *Lantus*, which involved substantially similar facts and rejected essentially the same arguments that Teva presents here. The Second Circuit in *United Food* expressly embraced the central holding of *Lantus*, a holding that eviscerates Teva's core position. On top of that, Teva's position that its device patents "claim the [NDA] drug" cannot be squared the D.C. Circuit's recent holding in *Genus Medical* that the FDA is prohibited from treating a "device" as a "drug"—a holding Teva did not address below or in the current motion. Although this Court will conduct its own *de novo* review on questions of statutory interpretation, these decisions show that Teva is not likely to succeed on the merits.

What is more, Teva's central premise, equating "claims" with infringement, has already been rejected by a prior panel of this Court. Indeed, interpreting an analogous statutory requirement of "a patent which claims a product," this Court held that "the plain meaning of 'claims' is not the same as the plain meaning of infringement." *Hoechst-Roussel Pharmaceuticals, Inc. v. Lehman*, 109 F.3d 756, 759 (1997).

Finally, a stay pending appeal would materially increase the risk of substantial harm to Amneal, and a stay would run contrary to the strong public interest in expediting access to affordable, critical asthma medications.

LEGAL STANDARDS

"A stay is an intrusion into the ordinary processes of administration and judicial review, and accordingly is not a matter of right, even if irreparable injury might otherwise result to the appellant." *Nken v. Holder*, 556 U.S. 418, 427 (2009). Thus, the party requesting a stay bears the burden of showing that the particular circumstances of the case justify an exercise of judicial discretion based on four factors:

> (1) whether the stay applicant has made a strong showing that he 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…; and (4) where the public interest lies.

Id. at 433-34 (2009); *ePlus, Inc v. Lawson Software, Inc.*, 431 Fed.Appx. 920 at *1 (Fed. Cir. July 14, 2011).

Importantly, the first two factors are the most critical, and neither is satisfied by mere *possibilities*. *Nken*, 556 at 434-35 (stating that "more than a mere possibility of relief is required" and "simply showing some possibility of irreparable injury fails to satisfy the second factor") (cleaned up).

ARGUMENT

Teva has not met its burden to show that a stay is justified based on the circumstances at play in this appeal. Even under an expedited schedule, none of the factors favor a stay, and the Court should deny Teva's motion.

I. Teva Has Failed to Show that it Will Be Irreparably Harmed.

Teva has not shown that it will suffer irreparable harm if the five Asserted Patents are delisted while this appeal is pending. Teva's arguments to the contrary are incorrect, and at best speculative. Speculation about potential harm is not sufficient to establish that this factor favors a stay. *Nken v. Holder*, 556 U.S. 418, 434-35 (2009) (holding that it is not sufficient to simply show "some possibility of irreparable injury"); *Koninklijke Philips N.V. v. Thales USA, Inc.*, 39 F.4th 1377 (Fed. Cir. 2022) (noting that it is not sufficient to show a "mere possibility or speculation of harm") (citing *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008)).[1]

[1] *Koninklijke* and *Winter* addressed standards for obtaining preliminary injunction, which substantially overlap with those for obtaining a stay pending appeal. *Nken*, 556 U.S. at 434.

Teva asserts that in the *Jazz* case, this Court granted a stay pending expedited appeal because (a) 30-month stays cannot be restored upon relisting of patents and (b) a lack of clarity as to whether delisted patents can ever be relisted. (Teva Br. at 1 (citing *Jazz Pharmaceuticals, Inc. v. Avadel CNS Pharmaceuticals*, LLC, 60 F.4th 1373, 1378 (2023).) Teva is incorrect. The cited *Jazz* decision did not indicate why the stay was granted.

Here, Teva posits three scenarios as allegedly giving rise to irreparable harm if the Asserted Patents are delisted and Teva later prevails on its appeal. The first is specific to *Amneal's ANDA*. The second is specific to *Deva's ANDA*. The third is a hypothetical in which an ANDA filer submits its ANDA while the patents are delisted. As explained below, none of these scenarios demonstrate that Teva will suffer any irreparable harm.[2]

As to Amneal's ANDA, Teva has not shown that it would be irreparably harmed if Amneal's 30-month stay is dissolved before this Court decides Teva's appeal. As an initial matter, Teva provides *no authority* for its fatalist proposition that FDA would refuse to reinstitute the 30-month stay if Teva succeeded on appeal. (Teva Br. at 15.)

[2] Teva hyperbolically refers to alleged consequences in "*all* cases involving the same product and the same patents" and for "the multiple generic applications now on file." (Teva Br. at 1.) The only two cases identified are this case and the Deva case. Teva does not identify any other "generic applications now on file."

Even if the FDA did not reinstitute Amneal's 30-month stay, that could be repaired by an injunction. Specifically, if it is ultimately determined that the Asserted Patents are listable, Teva could seek to enjoin Amneal from selling its ANDA product until the original expiration date of the 30-month stay. To the extent Amneal had not yet sold any of its ANDA product by then, such an injunction would restore the status *quo ante*, repairing the alleged harm. To the extent Amneal had already been selling its ANDA product, the injunction could prevent further sales. And if Amneal were ultimately found liable for those sales, damages would be a sufficient remedy.[3]

To be sure, if Teva prevailed in this appeal, injunctive proceedings would be the better vehicle than this motion to stay for delivering justice. Indeed, injunctive proceedings necessarily would be more robustly informed, as the case would be in a more advanced stage, the briefing could be less truncated, and the court would have the opportunity to weigh the merits of Amneal's non-infringement and invalidity defenses, not just the merits of Amneal's delisting arguments.

[3] Teva does not argue that a *launch* of Amneal's ANDA product would cause irreparable harm, likely because Lupin's generic version of ProAir® HFA has been on the market for years, and a second generic version (from a company called Amphastar) is expected to enter the market as early as next week. (D.I. 95-1, 95-2 in Case No. 2:23-cv-20964 (D.N.J.).) Despite Amphastar announcing this on May 22, 2024, it does not appear that Teva has attempted to stop them from entering the market.

Teva suggests that preliminary injunctions have no place in Hatch-Waxman litigation. (Teva Br. at 16, 18-19.) This is incorrect. The Hatch-Waxman statute expressly contemplates the use of preliminary injunctions for preventing launch and setting and resetting ANDA approval dates. 21 U.S.C. § 355(j)(5)(B)(iii)(IV). Indeed, the 30-month stay often expires during Hatch-Waxman litigations, leading to preliminary injunction proceedings. *See, e.g., Warner Chilcott Lab'ys Ireland Ltd. v. Mylan Pharms. Inc.*, 451 F. App'x 935, 936 (Fed. Cir. 2011) (vacating the district court's preliminary injunction preventing the generic company from marketing its ANDA product); *Sciele Pharma Inc. v. Lupin Ltd.*, 684 F.3d 1253, 1256 (Fed. Cir. 2012) (vacating the district court's preliminary injunction preventing the generic company from marketing its ANDA product); *Abbott Lab'ys v. Sandoz, Inc.*, 566 F.3d 1282, 1285-86 (Fed. Cir. 2009) (affirming denial of the patentee's motion for a preliminary injunction seeking to enjoin multiple generic companies from marketing their ANDA products, including Teva); *King Pharms., Inc. v. Sandoz, Inc.*, No. 08-5974, 2010 WL 1957640, at *6 (D.N.J. May 17, 2010) (denying the plaintiff's motion for a preliminary injunction seeking to enjoin the defendant from marketing its ANDA product).

As to the Deva ANDA, Teva cannot show irreparable harm, because merely delisting the five Asserted Patents will not dissolve Deva's 30-month stay. Deva filed Paragraph IV certifications against *all nine* Orange Book patents and Teva

timely sued Deva on all nine of those patents. Thus, to dissolve Deva's 30-month stay, *all nine* Orange Book patents would also have to be delisted.

Teva tacitly acknowledges this, but then argues that absent a stay in this case, "Teva would lose the [Deva] stay associated with the five [Asserted Patents]." (Teva Br. at 14, n.7.) This is misleading and nonsensical. There is only one Deva stay. And so long as even a single patent asserted against Deva remains listed, that stay will not be lost.

Against this reality, Teva merely speculates that it "may" drop the other four patents from the Deva case, thereby leading to dissolution of the Deva stay if the five Asserted Patents are delisted. (Teva Br. at 14, n.7.) But such non-committal and self-serving speculation does not establish irreparable harm. *Nken*, 556 at 434-35. In any event, even if the Deva stay were dissolved and Teva thereafter prevailed in this appeal, that harm could be repaired by an injunction, as explained above. (*Supra* at 5-6.)

Notably, staying the district court's order (the "Delisting Order") will not prevent Deva from seeking to delist all nine patents. Indeed, Deva has already moved to dismiss the complaint in the Deva, arguing that the logic of the Delisting Order extends to all nine patents. (*See* D.I. 11-1 in C.A. No. 2:24-cv-04404 (D.N.J.) at 6-8.) Thus, there is good reason to expect Deva to press for delisting of all nine Orange

Book patents asserted against it, *irrespective* of whether the Delisting Order is stayed pending appeal in this case.

As to Teva's hypothetical future ANDA filers, Teva is piling speculation on top of speculation. First, Teva speculates that "possibly other[]" ANDA filers could be lurking. (Teva Br. at 16.) Teva *doubly* speculates that those hypothetical filers *might* submit their ANDAs while the Asserted Patents are delisted. (*Id*. at 15.) Teva then *triply* speculates that those ANDAs *might* have specifications that are "materially similar" to Amneal's ANDA, and thus subject to infringement assertions only on the five delisted patents. (*Id*. at 17.) Teva is counting angels on the head of a pin, not demonstrating irreparable harm.

Even if the stars align, and while the Asserted Patents are delisted, someone submits an ANDA containing a paragraph IV certification as to any of the other four patents, Teva could still assert infringement under the Hatch-Waxman Act and obtain a 30-month stay. And in such action, Teva could even assert the Asserted Patents. In *Merck Sharp & Dohme Corp. v. Sandoz Inc.*, No. 12-cv-3289, 2013 WL 591976 (D.N.J. Feb. 14, 2013), at the time the ANDA was filed, two patents should have been listed in the Orange Book, but due to an error by FDA, only one of the two patents was actually listed. *Id*. at *2. The ANDA filers submitted paragraph IV certifications only as to the listed patent. *Id*. The second patent was later added to the Orange Book, and the NDA holder brought Hatch-Waxman infringement counts

under 35 U.S.C. § 271(e) as to both patents. *Id*. The ANDA filers moved to dismiss the 271(e) count as to the patent that had not been listed at the time the ANDAs were filed. *Id*. at *1, 3. Relying on this Court's decision in *AstraZeneca Pharm. LP v. Apotex Corp.*, 669 F.3d 1370, 1375 (Fed. Cir. 2012), the district court denied the motion to dismiss, holding that a paragraph IV certification was not necessary to give rise to a claim for infringement under 271(e). *Id*. at *3-4.

Even in Teva's triply speculative hypothetical scenario (where it ultimately only asserted the five Asserted Patents), and it could not obtain or keep a 30-month stay, Teva could seek to repair such alleged harm by injunction, as explained above. (*Supra* at 5-6.)

Teva argues that no future ANDA filer would have to certify to patents that had been restored to the Orange Book. (Teva Br. at 16.) This is not supported by any facts or relevant authority. Teva cites only 21 C.F.R. § 314.94(a)(12)(vi). (*Id*.) But this regulation does not address certification requirements for patents that are restored to the Orange Book. Instead, it addresses certification requirements when an NDA holder fails to submit its patent for listing in the Orange Book within 30 days of the patent *being issued*. There is no allegation here that Teva did not submit the Asserted Patents for listing within 30 days of the patents being issued.

II. Teva Is Not Likely to Succeed on the Merits of this Appeal.

Teva cannot meet its burden to make a strong showing that it is likely to succeed in this appeal. To succeed, Teva will have to persuade this Court away from its own prior decision and the decisions from three different sister circuits, the central holdings of which are antithetical to Teva's core positions. Those decisions signal Teva's low likelihood of success, even in a posture of *de novo* review. In the end, Teva's tortured interpretation of the Listing Statute cannot be squared with the statutory language or FDA's key definitions and guidance, and Teva's argument that the district court should have engaged in claim construction is forfeited and/or waived, and incorrect on its face.

First, *this Court has already rejected Teva's central premise*, which is "if selling the NDA product would 'infringe' a patent, then the patent 'claims' that product and is listable." (Teva Br. at 9.) Specifically, in *Hoechst-Roussel Pharmaceuticals, Inc. v. Lehman*, 109 F.3d 756 (1997), this Court interpreted the term "a patent which claims a product" in the patent term extension statute. Applying the plain meaning of "claims" under patent law, this court explained that "*the plain meaning of "claims" is not the same as the plain meaning of infringement*." *Id*. at 759 (emphasis added). In addition to drawing on general patent law principles, the panel drew on the fact that the patent term extension provision used the term

"claims," whereas "infringement" was employed elsewhere in the same statute. *Id*. at 760.

This distinction, and the reasoning in *Hoeschst*, apply with even greater force here, because the Listing Statute itself already *separately requires* a listable patent to be one "for which a claim of patent infringement could reasonably be asserted" against an unlicensed use of the NDA product. 21 U.S.C. § 355 (b)(1)(A)(viii). This not only shows that "claims" is not the same as "would be infringed by," in the Listing Statute, it shows that Teva's interpretation would nullify the "claims the drug" requirement of the statute, and thus cannot be correct. *Splane v. West*, 216 F.3d 1058, 1068 (Fed. Cir. 2000) ("We must construe a statute, if at all possible, to give effect and meaning to all its terms."). Thus, the "claims the drug" provision requires more than "infringement" by the NDA product, and is not satisfied merely by showing that the NDA product infringes the patent.

Second, decisions from both the First Circuit and Second Circuit demonstrate that Teva is unlikely to succeed in this appeal. The First Circuit held in *Lantus* that it is improper to list a patent in the Orange Book when, as here, it claims only a device component of a drug-device combination product, and does not refer in the claims to any active ingredient. *In re Lantus Direct Purchaser Antitrust Litig.*, 950 F.3d 1, 5 (1st Cir. 2020). The Second Circuit in *United Food* expressly approved the core holding of *Lantus*, noting that "a patent claim that fails to explicitly include the

[NDA] drug" does not "claim the drug." *United Food & Com. Workers Local 1776 v. Takeda Pharm. Co.*, 11 F.4th 118, 137-138 (2d Cir. 2021). Here, Teva merely asserts that in *Lantus* was wrongly decided, and offers the same arguments expressly rejected in that case.

Third, as noted by the district court, Teva's interpretation ignores the specificity of the Listing Statute language, which requires that the patent "claim *the* drug for which the applicant submitted the application," not merely *any* drug, or any component that could be found in the drug product. Teva's interpretation also ignores that the Listing Statute says nothing about listing patents claiming only a *device component* of a drug product.

This absence of any provision authorizing listing of patents claiming "components" of drugs is especially telling, because in the adjacent provisions of the statute listing other NDA submission requirements, Congress directed applicants to submit "a full list of the articles used as *components* of [the NDA] drug," as well as "samples…of the articles used as *components*" of the NDA drug. 21 U.S.C. § 355 (b)(1)(A)(ii) and (v) (emphases added). Yet the only arguable drug component referred to in the patent listing provisions is the "drug substance (active ingredient)." 21 U.S.C. § 355 (b)(1)(A)(viii)(I). This strongly suggests that Congress did not intend to authorize listing of patents claiming other components of an NDA drug, such as device components. *Rodriguez v. U.S.*, 480 U.S. 522, 525 (1987) ("[W]here

Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.").

Relatedly, Teva's logic—that (1) a patent "claims the [NDA] drug" if the NDA product would infringe the patent and (2) any "component" of a drug is actually itself a "drug"—would lead to absurd results. For example, by such logic, a patent claiming the alloy percentages of a metal spring in an inhaler component of a drug would itself "claim the drug." This cannot be what Congress intended.

Fourth, Teva still never has addressed *Genus Medical*, in which the D.C. Circuit analyzed the statutory definition of "drug" and "device," and held that as a matter of law under the FDCA, when something meets the statutory definition of a "device," the FDA is *prohibited* from treating it as a "drug." *Genus Medical Technologies LLC v. United States Food and Drug Administration*, 994 F.3d 631, 644 (D.C. Cir. 2021). It follows that if what the patent claims meets the statutory definition of a "device," the FDA is prohibited from treating that patent as if it claims a "drug." That is precisely the situation with the Asserted Patents, and Teva has simply failed to address this independent basis for affirmance.

Fifth, Teva is unlikely to establish that the Asserted Patents meet the separate requirement that they be "drug product" patents. Indeed, contrary to the FDA's implementing regulations, definitions, and guidance, the Asserted Patents do not

claim the *finished* NDA product because they do not require the presence of any active ingredient, let alone the albuterol sulfate active ingredient of the NDA product. This is a standalone basis for affirmance.

Specifically, FDA directs applicants to submit as drug product patents only "those patents that claim the drug product, as is defined in § 314.3, that is described" in the relevant NDA. 21 C.F.R. § 314.53. FDA defines "drug product" as "a finished dosage form…*that contains a drug substance*…". 21 C.F.R. § 314.3 (emphasis added). The FDA also defines "dosage form" in part as "*containing the active and inactive ingredients*." *Id*. (emphasis added). Finally, the FDA has explained that in determining whether a patent can be listed as a "drug product" patent, "the key factor is whether the patent being submitted *claims the finished dosage form of the approved drug product*." 68 Fed. Reg. 36676, 36680 (emphasis added).

Individually and collectively, these definitions and this guidance show that the Asserted Patents are not "drug product" patents. Contrary to FDA's guidance, the Asserted Patents do not claim "the finished dosage form of the approved drug product." Contrary to the definitions of "drug product" and "dosage form," the Asserted Patents do not require the presence of any drug substance or active ingredient, let alone require the presence of the albuterol sulfate drug substance of the approved product at issue. Accordingly, the Asserted Patents do not meet the second requirement that they be "drug product" patents.

Teva argues that the Asserted Patents claim "the drug product that FDA reviewed and approved in Teva's NDA" because the claims are directed to inhalers, irrespective of whether the claims require the presence of any active ingredient. (Teva Br. at 10-11.) This is not correct. The drug product that the FDA approved is not a standalone inhaler device with no active ingredient; it necessarily contains albuterol sulfate as the active ingredient. According to FDA, it is the *finished* product containing albuterol sulfate, and not just the device component of that finished product, that the Asserted Patents must claim in order to be listable as "drug product" patents.

Finally, Teva complains that the district court erred by not engaging in claim construction. This argument is forfeited and/or waived, and meritless. Teva never asked the district court to hold its decision in abeyance pending claim construction. In fact, despite making cursory and conclusory statements about what the claims "require," Teva expressly disavowed offering any claim construction below. (D.I. 69 in 23-cv-20964 (D.N.J.) at 28-29, n.21 ("Teva is not construing any terms for claim construction purposes…").) *See, e.g., Chem. Eng'g Corp. v. Essef Indus., Inc.*, 795 F.2d 1565, 1572 (Fed. Cir. 1986); *In re Google Tech. Holdings LLC*, 980 F.3d 858, 862 (Fed. Cir. 2020).

In any event, claim construction is not required to affirm the district court's order. Teva offers only vague and conclusory statements that the Asserted Patents

require the presence of an unnamed "medicament." (Teva Br. 13). But even assuming that the Asserted Patents require some unnamed medicament (they do not), Teva has not argued that the claims require the presence of *albuterol sulfate*, the drug in ProAir® HFA. Indeed, it is undisputed the Asserted Patents do not mention albuterol sulfate anywhere, let alone have any claim limitations requiring the presence of albuterol sulfate. The district court did not need to engage in claim construction to conclude that the Asserted Patents did not claim the drug for which Teva submitted its ProAir® HFA NDA. Nor would this Court need to engage in claim construction to affirm on that basis.

III. A Stay Pending Appeal Would Substantially Harm Amneal.

Teva argues that a stay pending expedited appeal will not harm Amneal "at all." Not so. Every day that Amneal ends up stuck with tentative approval instead of final approval would impose substantial economic harm to Amneal. That harm would *mount daily* while Amneal remains delayed from entering the market, and it is unclear how long that would go on.[4] Imposing a stay pending appeal harms Amneal by increasing the risk that Amneal would remain stuck behind the 30-month

[4] Contrary to Teva's suggestion (Teva Br. at 17-18), the district court did not find that Amneal would not be harmed by a stay pending appeal. Rather, although Teva moved in the district court for a stay pending appeal, the court did not grant that relief, and instead granted only a stay for 30 days to give this Court time to rule on Teva's stay application. (*Id*. at Ex. 2.)

stay while the procedure for delisting and getting final approval plays out in the courts and at the FDA.

Thus, contrary to Teva's assertions, any uncertainty over when the FDA will approve the ANDA is a reason to *deny* a stay pending appeal, not a reason to grant it. Although the FDA has set a DATE goal date for its next action on the ANDA,[5] FDA could approve the ANDA *at any time*. Indeed, the FDA has stated that it would strive to act prior to its own goal date. (Teva Br., Ex. 8 at AMN_PA0058081.)

Even if the FDA did not approve the ANDA until DATE under Teva's proposed expedited schedule, Amneal could be stuck with tentative approval instead of final approval for weeks or months thereafter. Indeed, under Teva's proposed schedule, argument before this Court would not be held until November 4 at the earliest. (Doc. 5-1 at 5.) This would be followed by an *indeterminate period* for this Court to reach its decision, which would be followed by an *indeterminate period* for Teva to pursue yet another stay from the Circuit Justice, which Teva has already signaled it intends to do. (Teva Br. at 19.) Even after these judicial procedures run their course, Amneal would still have to wait for up to an additional *two weeks* for Teva to request delisting, followed by another *indeterminate period* of time for the

[5] Amneal believes that the alternative goal date of DATE, which applies only if an ACTION is required, is not applicable, as all the necessary ACTION have been conducted already, with EVENT.

FDA to act on Teva's request, and then yet another *indeterminate period* for FDA to convert Amneal's tentative approval to final approval. All the while, the harm to Amneal would mount daily.[6] Denying Teva's motion for stay pending appeal would avoid these harmful delays.

IV. The Public Interest Does Not Favor a Stay.

The public has a strong interest in speeding and maximizing access to critical, affordable asthma medication. Having Amneal's ANDA product on the market as soon as possible serves this public interest by increasing access to this medication and driving healthy competition, which will likely drive down the cost of this medication for patients. Underscoring this public interest, the Federal Trade Commission agrees that the Asserted Patents should be delisted, demanding that Teva do so, and submitting an amicus brief in the district court proceedings to advocating for delisting. (*See* D.I. 61 and 61-1-1 in Case No. 2:23-cv-20964.) A stay pending appeal erects an unjustified barrier to delisting the Asserted Patents and thus runs contrary to the public interest.

Ignoring this compelling public interest, Teva instead argues that the Hatch-Waxman scheme guarantees "pre-launch certainty" and "substitutes for pitched

[6] For these same reasons, Teva's suggestion that the parties revisit the propriety of a stay only after Amneal obtains tentative approval is no better, and perhaps worse, as it effectively *guarantees* that Amneal will be unable to launch upon FDA approval.

battles over preliminary injunctions in every brand-vs.-generic case." (Teva Br. at 18.) Teva's argument is wrong, as explained above. (*Supra* at 5-6.) And in any event, Teva's argument addresses the interests of Teva and its competitors, not the interests of *the public*.

CONCLUSION

The Court should deny Teva's motion for a stay pending appeal, especially in light of the speculative nature of Teva's alleged irreparable harm, and the lack of any substantial likelihood of Teva's success on the merits.

Respectfully submitted,

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I, Steven A. Maddox, hereby certify that on June 28, 2024 the foregoing document was filed with the Court, and served on counsel of record for Defendants-Appellees via electronic mail at the addresses listed below.

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UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

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

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