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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

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

PLAINTIFFS' MEMORANDUM IN SUPPORT OF THEIR MOTION FOR STAY PENDING APPEAL, OR IN THE ALTERNATIVE, A STAY PENDING APPLICATION TO THE FEDERAL CIRCUIT FOR A STAY PENDING APPEAL

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INTRODUCTION

Plaintiffs Teva Branded Pharmaceutical Products R&D, Inc., Norton (Waterford) Ltd., and Teva Pharmaceuticals USA, Inc. (collectively "Teva" or "Plaintiffs") respectfully move this Court to stay its Opinion and Order (ECF No. 88) granting the Motion for Judgment on the Pleadings filed by Defendants Amneal Pharmaceuticals of New York, LLC, Amneal Ireland Limited, Amneal Pharmaceuticals LLC, and Amneal Pharmaceuticals Inc. (collectively, "Amneal" or "Defendants"). Teva specifically seeks a stay pending appeal of the paragraphs of the Order that hold "Judgment is entered in Defendants' favor as to Counts 1-5 of Defendants' Counterclaims"; U.S. Patent Nos. 8,132,712, 9,463,289, 9,808,587, 10,561,808, and 11,395,889 (collectively, the "Asserted Patents") "have been improperly listed in the Orange Book in regard to the drug product that is the subject of NDA No. 021457"; and that direct Teva to "correct or delete the relevant Orange Book patent information listings." ECF No. 88 at 17. In the alternative, Teva respectfully requests a one-month stay of the judgment and affirmative injunction to allow Teva to file an application to the Federal Circuit for a stay pending appeal and to allow the Federal Circuit time to rule on that application.

A stay pending appeal will allow the Federal Circuit to address *de novo* questions as to the scope of 21 U.S.C. § 355(b)(1)(A)(viii) (the "Listing Statute"). This Court held the Asserted Patents do not "claim[] the drug for which the applicant

submitted the application" because "no claim in any of the [Asserted Patents] discloses albuterol sulfate." ECF No. 88 at 12. But Teva respectfully submits that this Court's ruling is inconsistent with the Federal Circuit precedent. When asking the question "what does the patent claim" in construing the Listing Statute, "the answer should be derived using the tools and framework of patent law, including claim construction." *Jazz Pharms., Inc. v. Avadel CNS Pharms., LLC*, 60 F.4th 1373, 1379 (Fed. Cir. 2023). In accordance with these principles, a patent "claims" the product when it "reads on" the product, even if an element of the product is not explicitly recited in the claim. *See Allen Eng'g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1345 (Fed. Cir. 2002). The Court's ruling upends longstanding precedent, including by suggesting that a claim to a genus of compounds that does not call out by name the specific active ingredient in a pharmaceutical product cannot be listed in the Orange Book. A stay pending appeal will provide Teva with the ability to obtain meaningful appellate relief and afford the Federal Circuit the opportunity to review *de novo* the disputed gatekeeping provision of the Hatch-Waxman Act.

The Federal Circuit granted a stay pending appeal in the only case in which a District Court ordered the delisting of a patent pursuant to the provision of the statue that gives rise to delisting counterclaims. *See Jazz*, 60 F.4th at 1378. After being ordered to delist, Jazz Pharmaceuticals filed a notice of appeal to the Federal Circuit simultaneously with a motion to stay the injunction pending appeal, and the Federal

Circuit stayed the injunction pending resolution of the merits of the appeal. *Id.* This Court should follow the same procedure, and stay its order during the pendency of the appeal.

SUMMARY OF ARGUMENT

All of the applicable factors justify staying the Court's injunction and judgment pending an expedited appeal. First, Teva will be irreparably harmed if the Order is not stayed as Teva will lose the ability to obtain meaningful relief on appeal. If Teva is forced to delist the Asserted Patents, Teva will immediately lose the protections of the statutorily provided 30-month stay of approval for Amneal's ANDA. But such harm would not be cabined to Amneal's ANDA. Teva would also lose the protections of a 30-month stay for other current and future ANDAs. Even if the Federal Circuit overturns this Court's Order on appeal, these harms likely cannot be undone.

Second, and in contrast to the irreparable harm that Teva will experience absent a stay, Amneal will not suffer any harm by a stay while the Federal Circuit decides Teva's expedited appeal.[1] Amneal does not have tentative approval and Amneal's product is not marketable at this time. In fact, there is no indication that FDA will grant Amneal approval in the near future. As the 30-month stay is not what is preventing Amneal's launch, a stay on the order concerning delisting of the patents

[1] If this Court grants the stay pending appeal, Teva will seek to expedite the appeal of the current order.

during the appeal will not impact Amneal.

Third, Teva's appeal presents a substantial case on the merits. The proper interpretation of the Listing Statute will be reviewed *de novo* by the Federal Circuit. Specifically, Teva raises the question whether the phrase "claims the drug for which the [NDA holder] submitted the application" in the Listing Statute should be read to require explicit recitation of the active ingredient in the NDA product, as this Court held, or whether a patent that "reads on" the drug that is subject of the NDA is sufficient, as Teva has proposed for the proper interpretation of the controlling statute. This raises, at least, "real legal issues [] to be submitted to the Federal Circuit for review." *Nippon Steel & Sumitomo Metal Corp. v. POSCO*, No. 12-2429, 2014 U.S. Dist. LEXIS 160979, at *3 (D.N.J. Nov. 14, 2014) (J. Chesler).

Finally, the public interest favors a stay to ensure the Order does not upset the compromise that Congress and FDA reached in implementing the Hatch-Waxman Act. Specifically, this Order would eliminate the pre-launch certainty that the Hatch-Waxman Act provides, and instead force the parties to litigate these issues outside of the orderly proceedings provided under Hatch-Waxman, thereby causing an ANDA filer to risk substantial damages liability for infringement.

This Court should stay its Order pending appeal to allow Teva the opportunity to seek an expedited appeal. In the alternative, and at a minimum, this Court should issue a temporary stay for one month to give Teva the opportunity to move the Federal

Circuit to stay the Order pending appeal pursuant to Federal Rule of Appellate Procedure 8.

STATEMENT OF FACTS

This is a Hatch-Waxman case, in which Amneal seeks to bring to market a generic version of Teva's ProAir® HFA product. As is required under the Hatch-Waxman Act, Amneal provided notice concerning the patents listed in the Orange Book, and Teva brought suit within 45 days (*see* ECF No. 1 (Complaint)), creating a 30-month stay on FDA approval of Amneal's ANDA (*see* 21 U.S.C. § 355(j)(5)(B)(iii)). In its Answer, Amneal included counterclaims to delist the Asserted Patents, and alleged antitrust violations. *See* ECF No. 12. Teva moved to dismiss (*see* ECF Nos. 26, 27), and Amneal moved for judgment on the pleadings concerning delisting the patents (ECF Nos. 41, 42).

On June 10, 2024, this Court issued its Opinion and Order granting Amneal's motion under Federal Rule of Civil Procedure 12(c) for partial judgment on the pleadings as to Amneal's Delisting Counterclaims, Counts 1-5. ECF No. 88. The accompanying Order directs Teva by mandatory injunction under 21 U.S.C. § 355(j)(5)(C)(ii)(I) to "correct or delete the relevant Orange Book patent information listings." *Id.* at 17.

Teva promptly filed its notice of appeal. As an injunction, the Order is immediately appealable to the Federal Circuit. 28 U.S.C. § 1292(a)(1), (c)(1).

ARGUMENT

Four factors guide the availability of a stay pending appeal: "(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 interested in the proceeding; and (4) where the public interest lies." *Standard Havens Prod., Inc. v. Gencor Indus., Inc.*, 897 F.2d 511, 512 (Fed. Cir. 1990); *see also In re Revel AC, Inc.*, 802 F.3d 558, 568 (3d Cir. 2015) (applying same standard). However, "the four stay factors can effectively merge," so that "[w]hen harm to applicant is great enough, a court will not require 'a strong showing' that [the] applicant is 'likely to succeed on the merits.'" *Standard Havens*, 897 F.2d at 513 (citing *Hilton v. Braunskill*, 481 U.S. 770, 776 (1987)); *see also Merial Ltd. v. Cipla Ltd.*, 426 F. App'x 915, 915 (Fed. Cir. 2011) ("To obtain a stay, pending appeal, a movant must establish a strong likelihood of success on the merits, or, failing that, nonetheless demonstrate a substantial case on the merits provided that the harm factors militate in its favor."); *Chamberlain Grp., Inc. v. Lear Corp.*, No. 05-3449, 2007 WL 1238908, at *2 (N.D. Ill. Apr. 25, 2007) ("The Federal Circuit has indicated that each factor need not be given equal weight, and a show of substantial injury may diminish the need for a 'strong showing' of success on the merits.") (citing *Standard Havens*, 897 F.2d at 512-13). In fact, "a strong showing of irreparable harm combined with the Federal Circuit's *de novo*

review" can be sufficient to warrant a stay pending appeal. *Butamax Advanced Biofuels LLC v. Gevo, Inc.*, No. 11-54, 2012 WL 2675232, at *2 n.2 (D. Del. July 6, 2012).

Here, all four factors support a stay pending appeal. Alternatively, at a minimum, all four factors support a one-month stay to give Teva an opportunity to seek a stay pending appeal from the Federal Circuit.

I. THE COURT SHOULD STAY THE JUDGMENT AND ITS MANDATORY INJUNCTION PENDING APPEAL

A. Teva Will Be Irreparably Harmed Absent a Stay

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. *See Council on Am. Islamic Relns. v. Gaubatz*, 667 F. Supp. 2d 67, 76 (D.D.C. 2009) (irreparable harm exists where, absent relief, "the very rights [movant] seeks to protect will have been destroyed"). Chief among these is the statutory 30-month stay, which currently prevents FDA from approving Amneal's ANDA because Teva sued Amneal on Orange Book-listed patents within 45 days of Teva's receipt of Amneal's Notice Letter. *See* 21 U.S.C. § 355(j)(5)(B)(iii). The statutory stay of final FDA approval of Amneal's ANDA applies only for patents listed in the Orange Book. *See* 21 U.S.C. § 355(j)(5)(B)(iii). Since the Order directs Teva to delist the Asserted Patents, Teva

must submit an amendment to its NDA within 14 days of the Order, and FDA will in turn remove the Asserted Patents from the Orange Book listing. 21 C.F.R. § 314.53(f)(2)(i). Amneal has already taken the position that such delisting will immediately extinguish the 30-month stay. *See* ECF No. 42 at 31. In addition, Amneal may change its Paragraph IV certification to eliminate the certification to the Asserted Patents. *See* 21 C.F.R. § 314.94(a)(12)(viii)(B). If Amneal is correct and the stay is extinguished, Amneal will be allowed to launch, even prior to the resolution of the patent infringement case, if its ANDA is approved.

And even if Teva successfully appeals this Court's order, Teva would likely be unable to regain the protections of the 30-month stay if the patents are delisted before the appeal. This is because, if Teva were to delist the Asserted Patents as the injunction requires, even if the injunction is reversed, it is highly uncertain whether and how the Asserted Patents can be restored to the Orange Book. Ordinarily, for patents to be timely filed with FDA, they must be listed within 30 days of issuance. 21 U.S.C. § 355(c)(2). Untimely listed patents generally do not qualify for a 30-month stay for ANDAs submitted before the listing. *See* 21 C.F.R. § 314.94(a)(12)(vi). There is no precedent for re-listing patents that are more than 30 days old, and no guarantee FDA would reinstate the 30-month stay in such circumstances.

Furthermore, the harm to Teva if it is forced to delist would not be limited just to Amneal's ANDA which is the subject of this litigation. For example, Teva timely

filed suit against another company that is seeking to make a generic version of Teva's ProAir® HFA, which triggered a 30-month stay of final FDA approval of that ANDA product. *See 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). That other company would make the same arguments about immediate termination of the 30-month stay that Amneal makes here.

In addition, 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). Therefore, once the Asserted Patents are delisted, any other generic drug company could file an ANDA seeking to make a generic version of ProAir® HFA without having to provide the statutory Paragraph IV notice to Teva concerning the Asserted Patents or have any regulatory stay of approval of such ANDA applications based upon the Asserted Patents. Even if the Asserted Patents were restored to the Orange Book, it is far from clear that a 30-month stay would ever apply to an ANDA filed during the period of delisting.

Stays pending appeal are appropriate when, as here, they are "necessary to mitigate the damage that can be done during the interim period before a legal issue is finally resolved on its merits. The goal is to minimize the costs of error." *In re A & F Enterprises, Inc. II*, 742 F.3d 763, 766 (7th Cir. 2014). A stay of this Court's Order would minimize the costs of error to Teva by preserving the status quo, in which the

Asserted Patents remain listed in the Orange Book to allow the Federal Circuit to review this Court's order. *Providence J. Co. v. Fed. Bureau of Investigation*, 595 F.2d 889, 890 (1st Cir. 1979) (stay most favored "[w]here, as here, the denial of a stay will utterly destroy the status quo, irreparably harming appellants"). As this Court has held in previously granting a stay pending appeal, irreparable harm is established when "the bell cannot be unrung." *Nippon Steel*, 2014 U.S. Dist. LEXIS 160979, at *2. Absent a stay, Teva will be irreparably harmed because the Federal Circuit will not be able to restore Teva's lost statutory rights even if it reverses the Order.

B. Defendants Would Not Be Harmed By a Stay

While Teva will be irreparably harmed absent a stay, Amneal will not be harmed by a stay while the Federal Circuit decides Teva's expedited appeal. Amneal's product is not marketable at this time, as it has not achieved even tentative FDA approval. Currently, [redacted]

[redacted]

Accordingly, Amneal is unable to launch even if this Court denied a stay pending appeal, so Amneal will not be harmed by such a temporary stay.

C. Plaintiffs Present a Substantial Case on the Merits

In its opinion issued on June 10, 2024, the Court 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,' NDA No. 021457, ProAir® HFA (albuterol sulfate) Inhalation Aerosol." ECF No. 88 at 16-17. For the last two decades, NDA holders—including both Plaintiffs and Defendants in this case—have listed patents claiming drug delivery systems, even when the claims of the patents do not verbatim recite the name of the active ingredient. This ruling suggests that longstanding practice is inconsistent with the Listing Statute. Teva respectfully submits that the established precedent supporting Teva's position is the correct interpretation of the Listing Statute. At a minimum, Teva has raised a substantial question of law regarding the proper interpretation of the Listing Statute that the Federal Circuit will need to review *de novo*.

The interpretation and application of "claims the drug for which the [NDA

holder] submitted the application" in the Listing Statute turn on questions of statutory construction, which "is a matter of law that [the Federal Circuit] review[s] *de novo*." *Hawkins v. United States*, 469 F.3d 993, 1000 (Fed. Cir. 2006). Specifically, the Federal Circuit will need to decide whether the Listing Statute requires that to be listable, a patent must explicitly recite the name of the drug for which the applicant submitted the application, as this Court held, or whether under the Listing Statute a patent with a claim that "reads on" the drug, even if that drug is not specifically recited by name, sufficiently "claims the drug for which the [NDA holder] submitted the application," as Teva argued.

The Listing Statute mandates that an NDA applicant "shall submit" for listing in the Orange Book each patent that "claims the drug for which the [NDA applicant] submitted the application." 21 U.S.C. § 355(b)(1)(A)(viii). The Court agreed with Teva that the term "drug" is broadly defined in the statute, "and that the ProAir® HFA inhaler falls within its scope." ECF No. 88 at 11. Despite this conclusion, the Court held that the patents in dispute do not "claim[] the drug for which the [NDA holder] submitted the application." *Id.* at 16-17. The term "claims" has a well-settled meaning in patent law that governs in interpreting the Listing Statute. *See Jazz*, 60 F.4th at 1379; *Solar Energy Indus. Ass'n v. United States*, 86 F.4th 885, 895 (Fed. Cir. 2023) ("Ordinarily, Congress uses words consistent with their well-understood meaning."). Specifically, under patent law, a patent "claims" a product when the claim language

"reads on" the product, even if an element of the product is not explicitly mentioned in the claim. *See Allen Eng'g Corp*., 299 F.3d at 1345. What a patent "claims" "should be derived using the tools and framework of patent law, including claim construction," *Jazz*, 60 F.4th at 1379, and not based upon mere review of the explicitly recited words of the claims. In other words, if after claim construction a product would infringe a patent's claims, then the patent "claims" that product, even if certain specific elements (such as the active pharmaceutical ingredient) are not explicitly recited by name in the claims. Here, there is no dispute that the Asserted Patents "read on" ProAir® HFA.

The Asserted Patents are also "drug product (formulation or composition) patent[s]." *See* 21 U.S.C. § 355(b)(1)(A)(viii)(I). Under the controlling regulations, a "drug product" is "a finished dosage form . . . that contains a drug substance." 21 C.F.R. § 314.3. FDA identifies "metered aerosol" as an approved "dosage form" and specifically as the dosage form for ProAir® HFA. *See* ECF No. 27, Ex. 3, Appendix C, Orange Book (44th ed. 2024) at 3-11, C-1; 68 Fed. Reg. 36,676, 36,680 (June 18, 2003). The patents claim a metered dose inhaler and therefore, they claim the "finished dosage form" for ProAir® HFA (i.e., metered aerosol) and that dosage form as claimed contains a drug substance.

A plain reading of the Asserted Patents demonstrates that they "claim the drug for which the [NDA applicant] submitted the application" and are "drug product" patents. *See* 21 U.S.C. § 355(b)(1)(A)(viii)(I). While these claims 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. 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."[2] These patents claim the metered aerosol dosage form (i.e., "an inhaler for metered dose inhalation") and that dosage form contains a drug substance (e.g., "a medicament canister"). The medicament in the claimed "medicament canister" is a drug substance. Teva respectfully submits that this Court's conclusion that the patents are directed only to "components of a metered inhaler device," ECF No. 88, at 13, is incorrect—the claims are directed to the inhaler as a whole, with certain additional specific required attributes. 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 as Teva explained in its briefs and at argument.

In interpreting the Listing Statute, this Court has construed the term "claims" in

[2] *See, e.g.,* '289 patent at claim 1; '587 patent at claims 1, 12, 13. So long as any one of the patents is properly listed, Teva will be able to maintain the 30-month stay on approval of Amneal's ANDA. Thus, while Teva here outlines its argument in support of all four patents, a substantial question concerning whether any one of the patents is properly listed is sufficient to support the request for a stay pending appeal.

the Listing Statute to require explicit recitation of at least the active ingredient in the drug product. Under this Court's ruling, a claim to a genus of compounds that does not call out the specific name of the pharmaceutical product for which the NDA applicant submitted the application could not be listed because it does not claim "the drug for which the [NDA applicant] submitted the application." *See* 21 U.S.C. § 355(b)(1)(A)(viii)(I). Such a reading upends longstanding precedent as to the listability of patents in the Orange Book. This Court should stay its Order to provide the Federal Circuit an opportunity to review this substantial question of law regarding the proper interpretation of the Listing Statute *de novo*.

D. The Public Interest Favors a Stay to Avert the Irrevocable Loss of Patent Rights

The public interest favors a stay. Under the Hatch-Waxman Act, one "purpose of listing a patent in the Orange Book is to put potential generic manufacturers on notice that the brand considers the patent to cover its drug." *In re Restasis (Cyclosporine Ophthalmic Emulsion) Antitrust Litig.*, 333 F. Supp. 3d 135, 149 (E.D.N.Y. 2018). The compromise of Hatch-Waxman 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). Even if Teva is forced to delist, the Asserted Patents would not go away, but simply eliminate the established process for a pre-launch determination of Amneal and Teva's respective rights, thereby

giving rise to the risk of substantial damages liability for infringement. The public interest is served by providing all parties pre-launch certainty, and to avoid the need to litigate these issues outside of the orderly proceedings provided under the Hatch-Waxman Act.

II. IN THE ALTERNATIVE, THIS COURT SHOULD GRANT A ONE-MONTH STAY TO ALLOW TIME FOR TEVA TO PETITION THE FEDERAL CIRCUIT FOR A STAY PENDING APPEAL

At a minimum, this Court should grant a one-month stay while Teva petitions the Federal Circuit to stay the injunction pending appeal. *See* Fed. R. App. P. 8(a); *see also Takeda Pharms. U.S.A., Inc. v. Mylan Pharms., Inc.*, No. 19-2216, 2020 WL 419488, at *3 (D. Del. Jan. 27, 2020), *aff'd*, 967 F.3d 1339 (Fed. Cir. 2020) (ordering defendant "to maintain the status quo" so plaintiff could "seek immediate relief" in the Federal Circuit); *Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, No. 04-1371, 2008 WL 5351038, at *1 (D. Del. Dec. 22, 2008) (granting "temporary stay allowing the Federal Circuit to decide whether a permanent stay pending appeal should issue"). The Federal Circuit has granted such relief in numerous cases, including in the only matter where a court previously ordered the delisting of a patent from the Orange Book. *See Jazz*, 60 F.4th at 1378.[3]

[3] *See also, e.g.*, *Well Cell Glob. LLC v. Calvit*, 2023 WL 6156082, at *1 (Fed. Cir. 2023); *DePuy Synthes Prods., Inc. v. Veterinary Orthopedic Implants, Inc.*, 990 F.3d 1364, 1367 (Fed. Cir. 2021); *Bio-Rad Labs.*, 967 F.3d 1353, 1362 n.2 (Fed. Cir. 2020); *Galderma Lab'ys, L.P. v. Teva Pharms.*, 799 F. App'x 838, 842 (Fed. Cir. 2020);

At a minimum, a one-month stay should issue here to provide the Federal Circuit the opportunity to assess Teva's basis for a full stay pending appeal. Because this appeal raises issues of statutory construction that will be subject to *de novo* review by the Federal Circuit, a temporary stay would allow that court to bring its expertise as to the Hatch-Waxman Act to bear on the questions of statutory interpretation raised by Teva's appeal.

The equities even more forcefully compel at least a temporary stay. Thirty days for the Federal Circuit to consider Teva's stay motion presents no risk of harm to Amneal as it has not received FDA approval and is not expected to even get its next response from FDA concerning the possible approval of its ANDA until at least November. Conversely, denial of such a stay risks denying Teva a meaningful opportunity even to seek emergency relief (i.e., a stay pending appeal) from the Federal Circuit. The Order requires Teva to correct or delete the relevant Orange Book patent information pursuant to 21 U.S.C. § 355(j)(5)(D)(ii)(I). As discussed above, once Teva

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Dodocase VR, Inc. v. MerchSource, LLC, 767 F. App'x 930, 933 (Fed. Cir. 2019); *Cont'l Serv. Grp., Inc. v. United States*, 722 F. App'x 986, 993 (Fed. Cir. 2018); *Integrated Tech. Corp. v. Rudolph Techs., Inc.*, 629 F. App'x 972, 975 (Fed. Cir. 2015); *Energy Recovery, Inc. v. Hauge*, 745 F.3d 1353, 1356 (Fed. Cir. 2014); *Apple Inc. v. Samsung Elecs. Co.*, 695 F.3d 1370, 1373 (Fed. Cir. 2012); *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Pat. Litig.*, 424 F. App'x 952, 953 (Fed. Cir. 2011); *Fred Hutchinson Cancer Rsch. Ctr. v. BioPet Vet Lab, Inc.*, 412 F. App'x 308 (Fed. Cir. 2011); *Marine Plymer Techs., Inc. v. Hemcon, Inc.*, 396 F. App'x 686 (Fed. Cir. 2010); *SynQor, Inc. v. Artesyn Techs., Inc.*, 410 F. App'x 320, 321 (Fed. Cir. 2011); *NSK Corp. v. United States*, 422 F. App'x 885 (Fed. Cir. 2011).

has delisted a patent, it may immediately lose the protection of the statutory 30-month stay against Amneal and other generic competitors, and it may not be able to win effective relief even if it prevails on appeal and establishes that the patent should never have been delisted.

CONCLUSION

For these reasons, it is respectfully submitted that this Court should stay the Order pending Teva's expedited appeal to the Federal Circuit or, at a minimum, stay the Order for one month so that the Federal Circuit will have a meaningful opportunity to consider Teva's appellate stay application in an orderly fashion.

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