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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 [redacted]

DEFENDANTS' MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION FOR STAY PENDING APPEAL

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INTRODUCTION

The Court should deny Teva's motion in its entirety. Teva has not shown that it is entitled to the extraordinary relief it seeks. None of the applicable factors favor a stay, and the Federal Circuit is in a much better position to consider the propriety of any temporary stay in concert with any requests to expedite the appeal.

First, delisting of the Asserted Patents would not cause Teva any irreparable harm. *In the context of this case*, Teva points only to a potential launch at risk by Amneal. But Teva does not explain how that would cause irreparable harm. Moreover, Teva does not need a stay pending appeal to address that eventuality. To the contrary, the more appropriate recourse is for Teva to seek a preliminary injunction at the appropriate juncture. *Outside the context of this case*, Teva argues that while the Asserted Patents are delisted, Teva will lose the opportunity to get notice of future *possible* ANDA filers and thus to trigger a 30-month stay against them. This is both speculative and illusory. When the Asserted Patents are delisted, four other patents will remain listed in the Orange Book for ProAir®. Teva will be notified and have the opportunity to trigger a stay if any of those other four patents are challenged by an ANDA containing a paragraph IV certification.

Second, a stay pending appeal would harm Amneal by substantially increasing the risk that final FDA approval of Amneal's ANDA will be delayed by the 30-month stay during the pendency of Teva's appeal. This risk is heightened further if the Federal Circuit does not substantially expedite Teva's appeal.

Third, Teva's showing on the merits is not sufficient to favor a stay pending appeal. Because the harm factors do not favor a stay pending appeal, Teva is required to make a "strong showing" that it is likely to succeed on the merits of the appeal. Teva tacitly concedes that it cannot do this, arguing only that it satisfies a lower standard, namely that its appeal will present "a

substantial case on the merits." But Teva's argument for this is simply a rehash of the arguments that this Court and the First Circuit already considered and rejected.

Fourth, a stay pending appeal does not serve the public interest. Rather, what serves the public interest is making sure that Amneal's competing product can be made available to the public as soon as the FDA deems it safe and effective. Allowing the Asserted Patents to be delisted will remove the 30-month stay as a barrier to that. Also, a stay pending appeal undermines the public interest reflected in (a) Congress's decision to authorize delisting counterclaims as part of the Hatch-Waxman balancing act, and (b) FDA's decision to require the NDA holder to request delisting within 14 days of any delisting order. Notably, Teva does not actually point to any countervailing public interest, and instead discusses only how a stay would affect the parties to *this case*.

Finally, the Court should deny Teva's alternative request for a 30-day stay. This issue is better decided by the Federal Circuit, which can weigh the parties' positions at the same time it decides the intertwined question of whether and to what extent the appeal will be expedited.

ARGUMENT

I. The Court Should Deny Teva's Request For Stay Pending The Entirety Of Its Appeal

Teva has not shown that a stay pending appeal is warranted here. Indeed, none of the four factors favor a stay.

A. Teva Has Not Demonstrated That It Will Suffer Irreparable Harm Absent A Stay.

Teva argues that if no stay pending appeal is entered and the 30-month stay of FDA approval "is extinguished, Amneal will be allowed to launch, even prior to the resolution" of this case. (Br. at 8.) As an initial matter, Teva does not explain how this would cause irreparable harm.[1]

In any event, Teva inexplicably ignores the existence of preliminary injunction proceedings. If a launch at risk by Amneal really would cause irreparable harm, the proper procedural vehicle for preventing such harm would be a preliminary injunction against launch, not a stay of the delisting order pending appeal. Addressing a potential launch in such proceedings would be far superior to preemptively addressing a potential launch on Teva's current motion to stay. Teva's current motion is being decided on a highly compressed briefing and argument timeline, with little development of the record. Moreover, a preliminary injunction proceeding would be a more proper vehicle to address a potential launch, because unlike the current motion, preliminary injunction proceedings would involve weighing the likelihood of success on the merits of Amneal's defenses to Teva's infringement allegations, such as non-infringement and invalidity.

The real hallmark of Teva's irreparable harm argument is speculation, which is not sufficient to establish irreparable harm. *See, e.g., Sanofi-Aventis U.S. LLC v. Sandoz, Inc.*, No. 07-cv-2762-JAP, 2009 WL 1968900, at *3 (D.N.J. July 1, 2009) (rejecting stay pending appeal where "many of the alleged harms that Plaintiffs claim…appear speculative at best."). Teva argues that delisting "*may be* irreversible" and that "it is *highly uncertain*" how the Asserted Patents could be re-listed if Teva prevailed on appeal. (Br. at 7-8, 18 (emphases added).) Teva also speculates that

[1] Nor could Teva plausibly make such an argument. 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 the third quarter of this year. (Conroy Decl., Exs. A, B.) Despite Amphastar announcing this on May 22, 2024, it does not appear that Teva has attempted to stop them from entering the market.

another company *might* submit an ANDA while the Asserted Patents are delisted, and Teva then further speculates what *might* happen thereafter. (Br. at 9.)

From this speculative premise, Teva argues that *if* someone submits an ANDA while the patents are delisted, Teva *might* never get the benefit of its "statutory rights" to obtain notice of such ANDA submissions and the opportunity to trigger the 30-month stay by suing. (Br. at 9.) This argument both speculative and illusory. Teva ignores that there are *nine* patents listed in the Orange Book for ProAir® HFA, four of which are not subject to this Court's delisting Order. (D.I. 12-11 (Ex. K to Amneal's Counterclaims).) Thus, even when the five Asserted Patents are delisted, those other four patents will remain listed in the Orange Book, and any ANDA filer will have to provide a certification as to those patents. If an ANDA filer submits a paragraph IV certification as to any of those four patents, it will have to notify Teva, and Teva will have the opportunity to sue and trigger a 30-month stay. Moreover, in that same lawsuit, Teva would even be able to assert *the delisted patents*. *Merck Sharp & Dohme Corp. v. Sandoz Inc.*, No. 12-cv-3289-PGS, 2013 WL 591976 (D.N.J. Feb. 14, 2013). Thus, even in Teva's speculative scenario involving other potential ANDA filers, Teva will have lost nothing, even if the patents are delisted and Teva later prevails on appeal.

The only concrete example Teva offers does not support Teva's position. Teva points to the Deva case and argues that if the five Asserted Patents from the Amneal case are delisted, Deva "would make the same arguments about immediate termination of the 30-month stay that Amneal makes here." (Br. at 8-9.) First, Teva is (again) merely speculating about what Deva will do. No counterclaims have been filed yet in that case. Second, staying the delisting Order pending appeal would not prevent Deva from making that argument, if it decided to. Third, delisting the five Asserted Patents will not alone dissolve the 30-month stay at play in the Deva case. This is because

in the Deva case, Teva is asserting *all nine* Orange Book patents for ProAir® HFA, including the four that are *not* the subject of the delisting Order in this case. *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). As Teva itself points out, it only takes one timely-asserted Orange Book patent to trigger the 30-month stay. (Br. at 14, n.2.) Thus, to dissolve the 30-month stay in the Deva case, the other four patents asserted against Deva would also have to be delisted.

B. Amneal Would Be Harmed By A Stay Pending Appeal.

Amneal will be harmed if this Court stays its delisting Order pending appeal. As Teva recognizes, Amneal's ANDA may be approved as early as [redacted][2] In fact, the FDA could approve the ANDA sooner than that. [redacted] The fact that there is some uncertainty over when the FDA will act is actually a reason to deny Teva's motion, not a reason to stay pending appeal.

Indeed, Amneal invested in obtaining early judgment in its favor to get the Asserted Patents delisted and the 30-month stay dissolved as early in the case as possible to ensure that the 30-month stay would not delay its final approval. Amneal should not now be forced into the untenable position of having to wait for Teva's appeal to be resolved to obtain the benefit of having prevailed on its motion. With a stay in place for the life of Teva's appeal, if the appeal is not resolved by November of this year, there is a substantial risk that final FDA approval of Amneal's ANDA will be delayed by the 30-month stay. Any procedural machinations that increase this risk, such as a stay pending appeal, pose harm to Amneal.

[2] [redacted]

Accordingly, the most sensible course here is for this Court to deny Teva's motion. Teva can then promptly move at the Federal Circuit for a stay pending appeal, which could then decide that motion *in concert with* concrete requests to expedite the appeal.[3] Indeed, the Federal Circuit, not this Court, is in the best position to address whether and to what extent a stay is warranted, and to set an appeal schedule accordingly.

C. The Public Interest Does Not Support A Stay.

Delisting the Asserted Patents serves the public interest. A stay pending appeal does not. In calibrating the balance of public interests served by the Hatch-Waxman Act, Congress authorized delisting counterclaims, and the FDA has determined that delisting requests must be made within 14 days of an order requiring such a request. (Br. at 8 (citing 21 C.F.R. § 314.53(f)(2)(i)).) Delaying this result undermines the public interest as reflected in Congressional and regulatory actions. The district court in Jazz noted precisely this in denying Jazz's motion for a stay pending appeal.[4] *Jazz Pharmaceuticals, Inc v. Avadel CNS Pharmaceuticals, LLC,* C.A. No. 21-691-GBW (D. Del. Dec. 5, 2022 Memorandum Order) at 4; *see also Novartis Pharmaceutical Corporation v. Accord Healthcare Inc.*, No. 18-1043, 2020 WL 8187586 at *2 (D. Del. Dec. 10, 2020) (after ANDA filer lost at trial and was ordered to convert its final ANDA approval back to tentative, denying motion to stay pending appeal, in part because such a stay "would undermine congressional intent and the public interest" in view of the "careful balance" struck by the Hatch-Waxman Act).

[3] Although Teva states that it intends to ask for an expedited appeal, it provides no specifics on *when* it will make that motion or *how quickly* Teva would be willing to proceed in the appeal.
[4] Teva suggests that this Court should do what the Federal Circuit did in the *Jazz* case, which is to grant a stay pending appeal. (Br. at 2-3.) Teva ignores that the district court did the *opposite* and denied the motion for a stay pending appeal. The Federal Circuit then granted the stay pending appeal after it had already substantially expedited the appeal, and ultimately decided that appeal a mere three months after the district court's delisting order.

Further, as noted by the FTC, the presence of improperly-listed patents in the Orange Book harms the public interest by deterring development of competing generic products and depriving patients of lower priced competing drugs. (*See* D.I. 61-1 at 31-32.)

Moreover, Teva has failed to show that a stay pending appeal would serve the public interest. As an initial matter, although Teva purports to identify a public interest in granting a stay, Teva's argument is focused on how the delisting would affect *the parties to this case*. Specifically, Teva argues that if the Asserted Patents are delisted, this would "eliminate the established process for a pre-launch determination of Amneal and Teva's respective rights, thereby giving rise to the risk to substantial damages liability for infringement." (Br. 15-16.) Teva then argues that "[t]he 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 under the Hatch-Waxman Act." (Br. at 16.) These arguments do not address the public interest at all.

In any event, these arguments are baseless. First, Teva offers no authority for the proposition that the Hatch-Waxman Act or the 30-month stay guarantees a "pre-launch determination" of rights or "pre-launch certainty." As this Court is well-aware, Hatch-Waxman cases often outlast the 30-month stay, especially on appeal. Second, Teva incorrectly implies that Hatch-Waxman cases descend into disorder when the stay expires or is terminated. This, again, ignores the availability of preliminary injunction proceedings. Third, in the end, any launch at risk by Amneal would *benefit* the public by bolstering public access to this important medication and providing healthy competition that will likely drive prices down.

D. Teva's Prospects For Prevailing On Appeal Do Not Support Granting Teva's Motion.

Teva argues that its appeal will present "a substantial case on the merits," in part because the Federal Circuit will engage in *de novo* review of statutory construction issues. (Br. at 1-2, 11-

15.) Teva argues that this lesser showing is sufficient because the harm factors favor a stay. But as shown above, the harm factors do not favor a stay. Consequently, Teva must make a "strong showing" on the merits of its appeal. But Teva has not even attempted to do so, tacitly conceding that it cannot.

Regardless, Teva's arguments regarding the merits are not strong, because they merely rehash arguments already considered and rejected by this Court and by the First Circuit in *In re Lantus*. Further, Teva incorrectly argues that this 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." (Br. at 2.)[5] The Asserted Patents do not claim a "genus of compounds," and thus the delisting Order does not raise any such issue.

II. The Court Should Deny Teva's Alternative Request For A 30-Day Stay.

The Court should deny Teva's alternative request for a 30-day stay. Teva seeks this temporary stay stating that it would "give Teva the opportunity to move the Federal Circuit to stay the Order…" (Br. at 4-5) and "provide the Federal Circuit the opportunity to assess Teva's basis for a full stay pending appeal." (*Id*. at 16-18.)

But the Federal Circuit does not need this Court to enter such a stay. Teva can seek a temporary stay directly from the Federal Circuit. According to Teva, such requests have been granted numerous times by the Federal Circuit. (*Id*. at 16.) Nor does Teva need another 30 days to do this. Judging by the length of their brief and the volume of case law cited in it, clearly Teva has been preparing to bring these motions for some time.

[5] Curiously, Teva does not identify the "longstanding precedent" it says is "upended."

Second, it makes far more sense for this issue to be decided by the Federal Circuit, which can weigh the parties' positions at the same time it decides the intertwined question of whether and to what extent the appeal will be expedited. Indeed, this is how the issues were handled in the *Jazz* case.[6]

On the other hand, if this Court imposes a 30-day stay, this would unnecessarily pose harm to Amneal. Given that there is some uncertainty over when FDA will act next on Amneal's ANDA, that Teva has not made a concrete proposal for expediting its appeal, and given that the parties have no way of knowing whether and to what extent the Federal Circuit will agree to expedite Teva's appeal, any delay in resolving these issues and in resolving the appeal could ultimately increase the amount of time that final approval of Amneal's ANDA ends up being blocked by the 30-month stay.

CONCLUSION

For all the foregoing reasons, Amneal respectfully requests that the Court deny Teva's motion in its entirety.

Respectfully submitted,

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[6] For the avoidance of doubt, Amneal does not concede that a stay of any duration is warranted, and reserves the right to also oppose a motion to stay brought before the Federal Circuit.

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