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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

REPLY BRIEF IN SUPPORT OF DEFENDANTS' RULE 12(c) MOTION

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Amneal submits this reply memorandum in support of Amneal's Motion for Judgment on the Pleadings as to Counterclaims 1-5 (the de-listing counterclaims).

INTRODUCTION

The issue presented by Amneal's motion remains straightforward. Teva's asserted device patents must meet two requirements of the Listing Statute. First, they must "claim[] the drug for which the applicant submitted the application." 21 U.S.C. § 355(b)(1)(A)(viii). Second, they must be "drug product (formulation or composition) patent[s]." *Id.* The asserted patents meet neither requirement.

Under *In re Lantus*[1], whether a patent "claims the drug for which the applicant submitted the application" turns on the language of the patent claims. If the drug is neither mentioned nor described in the claim language, the patent cannot be listed. Here, there is no dispute that the device patent claims at issue do not mention or describe albuterol sulfate, or the ProAir® HFA combination drug product. Accordingly, the asserted patents must be de-listed.

The *In re Lantus* interpretation of the Listing Statute has never been questioned or rejected by any court in adjudicating the statute; by Congress in amending the statute; by the FDA in administering the statute; or by the Federal Trade Commission ("FTC") in enforcing the statute. Indeed, the FTC's *amicus*

[1] *In re Lantus Direct Purchaser Antitrust Litig.*, 950 F.3d 1 (1st Cir. 2020).

curiae brief expressly reaffirms its adoption and endorsement of *In re Lantus* in the FTC's enforcement role.

Teva simply declares that *In re Lantus* was wrongly decided, and repeats the same arguments expressly rejected by the First Circuit in that case. Teva argues that even if a device claim does not mention or describe "the drug for which the applicant submitted the application," the patent nevertheless "claims the drug" if the device has been incorporated as a "component" into a combination drug product. Specifically, Teva insists that the claimed inhaler devices here are transformed from devices to drugs, because the devices are "components" of the ProAir® HFA product with albuterol sulfate.

The Court should reject Teva's "component" argument for the same reasons that the First Circuit rejected the same argument in *In re Lantus*. The Listing Statute does not make any provision for "components" of "drug products" – but rather only for "the drug for which the applicant submitted the application." 21 U.S.C. § 355(b)(1)(A)(viii). Neither the legislative history nor administrative guidance provides any basis to list patents claiming device "components" of combination drug products. Further, even if the claimed aerosol device could be transformed into a drug, it still would not be the particular drug for which Teva submitted its application – that is, ProAir® HFA or albuterol sulfate.

In addition, the asserted patents do not meet the second requirement of the Listing Statute – that is, being "drug product (formulation or composition) patent[s]." 21 U.S.C. § 355(b)(1)(A)(viii). It is undisputed that a "drug product" is a "finished dosage form . . . that contains a drug substance." 21 C.F.R. § 314.3. As explained by Amneal and the FTC, the claimed inhaler devices and components thereof do not meet the FDA's definition of a "finished dosage form." Moreover, they do not "contain[] a drug substance." The claims of Teva's asserted patents do not mention or describe the ProAir® HFA finished dosage form or the albuterol sulfate drug substance it contains.

Teva tries to get around the statutory definition of "drug product" by rephrasing or paraphrasing it, with one critical word change. Teva begins with the actual definition of a "finished dosage form . . . containing a drug substance." But then Teva changes the wording to: "finished dosage form" which "*must* contain a drug substance." Having thus altered the definition by injecting its own unsupported editorialization, Teva then argues that the patent claims' inclusion of a medicament canister meets Teva's new definition of something that "must contain a drug substance." Teva does not cite any authority for rewriting the statutory definition. The Court should reject Teva's unsupported gambit.

Finally, Teva improperly raises the defense of implied immunity for the first time in its reply brief on the motion to dismiss Amneal's antitrust counterclaims.

Instead of moving to strike, Amneal demonstrates the legal insufficiency of Teva's argument in the final section of the Argument below.

Amneal's motion should be granted for the reasons explained below, in Amneal's opening brief, and in the *amicus curiae* brief of the FTC.

ARGUMENT

I. Teva's Patents Fail the First Requirement of the Listing Statute.

Plainly, the asserted patents do not "claim[] the drug for which the applicant submitted the application." 21 U.S.C. § 355(b)(1)(A)(viii). The claims do not mention, describe, or in any way refer to the ProAir® HFA product or to albuterol sulfate. Under *In re Lantus*, the lack of any such mention or description means that the claims do not meet the first requirement of the Listing Statute.

Teva simply declares that *In re Lantus* was wrongly decided, without citing any criticism of the decision by a court, the FDA, or Congress – and despite the adoption of *In re Lantus* by the FTC in its latest guidance. Instead, Teva repeats the unsuccessful arguments made by Sanofi in that case. Teva argues that: (1) it had a duty to list its device patents because those devices are integral parts of the ProAir® HFA combination product; and (2) the claimed device components of the

ProAir® HFA combination product must be drugs in view of the definition of "drug" at 21 U.S.C. § 321(g). (Teva Opp. Br. at 9-13).[2]

The statutory language and legislative history of the Listing Statute, however, do not support Teva's assertions. The statutory language is focused on what the patent actually claims. The statutory language does not support transforming a claimed device into a drug if it is used with a combination drug product. Likewise, nothing in the legislative history suggests that Congress intended such an interpretation.

Nor does the FDA's guidance on the Listing Statute support Teva's interpretation. The FDA has made clear that "[t]he *key factor* is whether the patent being submitted claims the finished dosage form of the approved drug product." (Amneal Br., Ex. 12, 68 Fed. Reg. at 36680 (emphasis added).) Teva fails to cite any FDA guidance in which the agency declared that device patent claims shall be

[2] Teva also attempts to deflect by noting that Amneal and others had listed patents that the FTC found improperly listed under its current guidance. (Teva Opp. Br. at 2-3, 25-26.) Teva barely mentions, however, that Amneal and others have de-listed those patents in response to the FTC's new guidance. Teva decided to defy the FTC by refusing to de-list the asserted patents, and by maintaining this case. Indeed, Teva has doubled-down on its defiance by bringing another ANDA action on the same patents with respect to ProAir® HFA product. *See Teva Branded Pharmaceutical Products R&D, Inc. v. Deva Holding A.S.*, No. 2:2024-cv-04404 (D.N.J. complaint filed March 29, 2024).

considered as drug patent claims, if the devices are incorporated into a combination product.

Instead, Teva begins with the finished combination drug product, ProAir® HFA, and works its way backwards into the Listing Statute. Teva points out that the FDA decided to regulate inhaler combination products as drugs "when the primary purpose of the device is delivering or aiding in the delivery of a drug *and the device is distributed with the drug*." (Amneal Br., Ex. 4, 1993 Guidance, at 5 (emphasis added).) This statement was based on FDA's determination that the "primary mode of action" of such a combination product "is *attributable to the drug component*." (Teva Opp. Br., Ex. 6, FDA's Jurisdictional Update: Metered Dose Inhalers, Spacers and Other Accessories, at 1-2 (emphasis added).)

The presence of the drug component within the combination product was the critical aspect of the FDA's decision to regulate the combination product as a drug. Without the drug component – *i.e.*, with just the device component – the product would be regulated as a device. Applying the FDA's above reasoning, the FDA would regard the claims at issue here as directed to *devices, not drugs*, because there is nothing in the claims that requires the devices to be distributed with the drug, and there is no drug component in the claims – let alone albuterol sulfate.

Teva argues that because of the FDA's administrative decision to regulate ProAir® HFA as a drug through the FDA's Center for Drug Evaluation and

Research ("CDER"), it necessarily follows that every component of ProAir® HFA is a drug – including each device claimed by Teva's patents and incorporated in the ProAir® HFA product. Finally, Teva concludes that because the claimed device components of ProAir® HFA must be drugs, the patents at issue necessarily claim the drug for which Teva submitted its application.

No court decision or FDA guidance holds that the administrative decision to regulate combination products as drugs was intended, or is recognized, to transform device components of combination products into drug components. There is no support in law or logic for Teva's notion that a device component transforms into a drug or drug substance just because CDER reviews the combination product.

Indeed, the Food, Drug, and Cosmetic Act ("FDCA") prohibits the FDA from classifying as a "drug" anything that meets the statutory definition of a "device." *Genus Medical Techs. LLC v. FDA*, 994 F.3d 631, 644 (D.C. Cir. 2021). Teva makes no attempt to argue against the merit and applicability of this central holding of *Genus Medical*. Here, there can be no reasonable dispute that all of Teva's claimed mechanical devices meet the statutory definition of a device, because they are each an "apparatus" and/or "component" or "part" that do not achieve their primary intended purposes "through chemical action within or on the body of man" or by "being metabolized." 21 U.S.C. § 321(h)(1). Under the

proper construction of the FDCA in *Genus Medical*, Teva's pure device claims cannot be treated as claiming a "drug," "drug product," or a "drug substance."

Instead of taking on *Genus Medical*, or offering a novel basis for interpreting the listing requirements in favor of its position, Teva merely repeats Sanofi's failed arguments from *In Re Lantus*. Here, Teva argues that because its patents claim an inhaler or inhaler-component part of the ProAir® HFA drug product, they necessarily claim the drug product, and thus claim the drug for which Teva filed its application. (Teva Opp. Br. at 9-13.) Sanofi had likewise argued that "because the drive mechanism is an integral part of Lantus SoloSTAR, a patent that claims the drive mechanism claims a part of a drug product, and thus 'claims the drug.'" *In re Lantus*, *950* F.3d at 8.

The First Circuit in *In re Lantus* rejected that proposition, finding that it lacked any statutory or regulatory basis:

> We see nothing in the statute or regulations that welcomes such a further expansion of the already stretched statutory terms, whereby an integral part of an injector pen becomes the pen itself, and in turn is a drug.
>
> One would not think, for example, that a patent claiming only a transmission system must be read as also claiming any car in which it is used.

Id. Further, the *In re Lantus* court observed that the FDA had not adopted a similar argument:

> The FDA has already passed on opportunities to stretch the statutory terms in this way. In 2003, the FDA addressed commentary to a proposed rule that ''would not have allowed an applicant to list a patent that claimed packaging.'' 68 Fed. Reg. at 36,680. Some of that commentary argued that ''patents claiming devices or containers that are 'integral' to the drug product . . . should be submitted and listed.'' *Id.*
>
> The FDA acknowledged those comments but did not adopt them. *See id.* Instead it responded by reiterating that: ''[t]he key factor is whether the patent being submitted claims the finished dosage form of the approved drug product.'' *Id.*

Id. at 8.

Teva here also advances the Sanofi argument from *In re Lantus* regarding the general definition of "drug" in 21 U.S.C. § 321(g). (Teva Opp. Br. at 9-13.) But the *In re Lantus* court rejected that argument for compelling reasons. First, the court pointed out Congress's knowledge that some drugs had "components" made it all the more significant that Congress chose not to include in the Listing Statute any reference to patents claiming only "components":

> That definition of "drug" in section 321(g)(1) demonstrates that Congress knew that some drugs had "components"; thus the absence of any mention of "components" in the provisions setting out which patents should be filed cuts against any attempt to interpret the statute and its implementing regulations as requiring or allowing listing of patents that claim only components of a proposed drug. *See* 21 U.S.C. § 355(b)(1).

Id. at 9.

Second, the *In re Lantus* court observed that even if a device component of a combination product could be "deemed" a "drug," it would still not meet the listing requirement because it would not be the "drug for which the applicant submitted the application":

> 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 sNDA. 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.

Id. at 9. Here, even if the claimed inhaler device component could be deemed a drug, it still would not be the drug for which Teva filed its application – *i.e.*, albuterol sulfate drug substance or the ProAir® HFA combination drug product.

This Court should adopt the *In re Lantus* interpretation of the Listing Statute, and find that the asserted device patents here do not meet the first requirement of the Listing Statute, because they do not "claim[] the drug for which the applicant submitted the application." Accordingly, the Court should grant Amneal's motion for judgment on the pleadings of its de-listing counterclaims.[3]

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[3] Teva argues that even if the Court rejects Teva's interpretation, in favor of *In re Lantus*, Amneal's motion nevertheless should be denied, at least pending claim construction – *with the 30 month stay still in place*. (Teva Opp. Br. at 35.) Teva fails, however, to identify any claim term whose proper construction allegedly

II. Teva's Patents Fail the Second Requirement of the Listing Statute

The second requirement of the Listing Statute at issue here is that the patents must be "drug product (formulation or composition) patent[s]." A "drug product" is defined by FDA as "*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) (emphasis added).

Accordingly, the patent must claim "a finished dosage form . . . that contains a drug substance . . . ." *Id.* The Teva patents at issue claim neither.

The finished dosage form of ProAir® HFA is a combination inhaler product containing albuterol sulfate inhaler. None of the patent claims mention or refer to ProAir® HFA or albuterol sulfate. As in *In re Lantus*, the patents here instead "claim[] several versions of a device that can be combined with other components to produce the finished dosage form of the approved drug product." *In re Lantus*, 950 F.3d at 8.

Further, the claimed devices here do not "contain[] a drug substance." In order to argue to the contrary, Teva relies on word games. Teva changes "a finished dosage form . . . that contains a drug substance" into a "finished dosage

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"claims the drug" or is a "drug product." Teva's unsupported assertion is just an attempt to buy more time to profit from the anti-competitive effects of its ill-gotten 30-month stay.

form. . . that *must* contain[] a drug substance." (Teva Opp. Br. at 17, 27-28.) From there, Teva argues that some of its claims "*must* contain a drug substance" because they include a canister and dose counter – each of which contemplates being combined with an unspecified drug substance, *but not* necessarily the albuterol sulfate drug substance of ProAir® HFA. By this sleight of hand, Teva glosses over the critical difference between a device that contains a particular drug substance (ProAir® HFA), on the one hand, and a patented device that is designed to work with any of a multitude of unclaimed drug substances, on the other. Indeed, as the FTC notes, Teva maintains the asserted patents in the Orange Book for more than twenty different drugs. (FTC Br. at 16.)

Thus, the claimed devices here are not "finished dosage forms" and do not "contain[] a drug substance," as required to be "drug product (formulation or composition) patent[s]" under the second requirement of the Listing Statute. This provides a second, independent ground upon which the Court should grant Amneal's motion for judgment on the pleadings of its de-listing counterclaims.

III. Teva's Untimely Implied Immunity Argument Lacks Any Merit.

For the first time in its reply brief, Teva raises the argument of implied immunity with respect to its motion to dismiss Amneal's antitrust counterclaims. Instead of moving to strike this untimely assertion, Amneal submits the following demonstration of why Teva's untimely argument is substantively meritless.

Implied *immunity* comes into play where a statute and accompanying regulatory scheme permit something the antitrust laws forbid. In other words, they must be "clearly incompatible." *Credit Suisse Sec. (USA) LLC v. Billing*, 551 U.S. 264, 279 (2007). In the absence of an express savings clause, implied immunity, which is "an implied repeal of the antitrust laws," "would be found only where there is a plain repugnancy between the antitrust and regulatory provisions." *Id.* at 272 (quoting *Gordon v. New York Stock Exch., Inc.*, 422 U.S. 659 (1975)) (internal quotations and citations omitted); *see also id.* at 271 ("[R]epeal [of the antitrust laws] is to be regarded as implied only if necessary to make the Securities Exchange Act work, and even then only to the minimum extent necessary.") (quoting *Silver v. New York Stock Exch.*, 373 U.S. 341, 357) (1963) (internal quotations omitted).

Ignoring the binding framework for any implied immunity analysis, Teva's attempt to assert implied immunity from antitrust scrutiny fails. As an initial, and dispositive, matter, there is no repugnancy between the FDCA and the antitrust laws because neither sanctions the improper listing of patents in the Orange Book or the delay in generic competition that follows such improper listing. *See id.* at 274 (finding implied immunity because securities law permitted the resale price maintenance that the antitrust laws forbid).

Second, unlike the SEC and the securities laws at issue in *Credit Suisse* (*see id.* at 283 (noting active SEC enforcement of the rules and regulations at issue)), the FDA, which is the agency tasked with administering the FDCA, does not police Orange Book listings or enforce the requirements for them, and has expressly disclaimed on multiple occasions any responsibility for doing so. *See* Oversight of the U.S. Food and Drug Administration: Hearing Before the H. Comm. on Oversight & Accountability, 118th Cong. (2024) (statement of Dr. Robert Califf, Comm'r, FDA) ("Our role in the Orange Book is ministerial. . . . As FDA Commissioner, that decision [whether a patent is frivolously listed] is really an FTC decision."); *Apotex, Inc. v. Thompson*, 347 F.3d 1335, 1347 (Fed. Cir. 2003) (describing the FDA's role with respect to Orange Book listing as "purely ministerial").

Third, unlike the securities laws at issue in *Credit Suisse*, the FDCA does not provide a private right of action for competitors and consumers to recover damages stemming from the anticompetitive effects of improper Orange Book listings. *See Credit Suisse*, 551 U.S. at 277 (observing "[p]rivate individuals who suffer harm as a result of a violation of pertinent statutes and regulations may also recover damages.") and 283 (noting harmed investors could obtain damages under the securities laws).

And finally, because neither the FDCA nor the antitrust laws permit improper listing, there is no risk here of the type of conflict that concerned the court in *Credit Suisse* – that the antitrust laws will be found to forbid something that the FDCA allows. *See id.* at 275-76 (explaining the risk that application of both securities and antitrust law "would produce conflicting guidance, requirements, duties, privileges or standards of conduct."); 282 (describing the risk that the threat of treble damages under the antitrust laws would chill joint conduct the securities laws permit or encourage).

For these reasons, Teva's argument that it enjoys implied immunity from the antitrust laws must be rejected out of hand.

CONCLUSION

For the foregoing reasons, Amneal respectfully requests that the Court grant Amneal's Rule 12(c) motion for judgment on the pleadings as to Counts 1-5 of Amneal's counterclaims (D.I. 12) and, pursuant to 21 U.S.C. § 355(j)(5)(C)(ii), order Teva to withdraw the Asserted Patents from the Orange Book.

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Respectfully submitted,

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