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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

AMNEAL'S RESPONSIVE CLAIM CONSTRUCTION BRIEF

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GLOSSARY OF TERMS

Term	Description
The ’289 patent	U.S. Patent No. 9,463,289
The ’587 patent	U.S. Patent No. 9,808,587
The ’808 patent	U.S. Patent No. 10,561,808
The ’889 patent	U.S. Patent No. 11,395,889
The Asserted Patents	The ’289, ’587, ’808, and ’889 Patents
The Inhaler Terms	Term 1: *“An inhaler for metered dose inhalation”* Term 4: *“an inhaler”* Term 6: *“a metered dose inhaler”*
The Dose Counter Terms	Term 3: *“A dose counter for an inhaler”* Term 5: *“An incremental dose counter for a metered dose inhaler”*
The Canister Terms	Term 2: *“medicament canister”* Term 7: *“canister”*
Op. Conroy Decl.	Declaration of Rebekah Conroy, submitted with Amneal’s Opening Claim Construction Brief
Resp. Conroy Decl.	Declaration of Rebekah Conroy, submitted herewith
Amneal Ex. __	Exhibit number __ attached to the Op. Conroy Decl. or the Resp. Conroy Decl.
Teva Br.	Plaintiffs’ Opening Claim Construction Brief
Teva Ex. __	Exhibit number __ attached to the Declaration of Liza M. Walsh in Support of Plaintiffs’ Opening Claim Construction Brief

I. INTRODUCTION

Defendants Amneal Pharmaceuticals of New York, LLC, Amneal Ireland Limited, Amneal Pharmaceuticals LLC, and Amneal Pharmaceuticals, Inc. (collectively, "Amneal" or "Defendants") respectfully submit this Responsive Claim Construction Brief to address the seven disputed claim terms (Terms 1-7) in U.S. Patent Nos. 9,463,289 ("the '289 patent") (Amneal Ex. 1), 9,808,587 ("the '587 patent") (Amneal Ex. 2), 10,561,808 ("the '808 patent") (Amneal Ex. 3), and 11,395,889 ("the '889 patent") (Amneal Ex. 4) (collectively, the "Asserted Patents").

Despite Teva's characterization of Amneal's constructions as limiting the claims to "only the device with no active drug," (Teva Br. at 1), Amneal's constructions are not limited to empty inhalers or canisters. Rather, Amneal's constructions are indifferent to whether the device contains an active drug, encompassing both devices that do contain an active drug and those that do not.

Teva's constructions, however, improperly narrow the claims under the guise of "plain and ordinary" meaning. But no matter how often Teva repeats the mantra that its constructions are the plain and ordinary meaning, that does not make it so. Teva would need to show lexicography or disclaimer to narrow the meaning of the terms in the way it seeks, which Teva does not even attempt to do. Thus, the Court should reject Teva's constructions for the Inhaler, Dose Counter, and Canister Terms.[1]

[1] As in Amneal's opening brief, Amneal will address the disputed terms together in three groups. Amneal believes this grouping is appropriate given the similarities between Teva's arguments for the terms within these three groups. Amneal will separately address, where applicable, any differences between Teva's arguments for these terms. Thus, Amneal's brief will address Terms 1-7 in the same order as its opening brief: (1) "an inhaler for metered dose inhalation" (Term 1, '289 and '587 patents), "an inhaler" (Term 4, '808 patent), and "a metered dose inhaler" (Term 6, '889 patent); (2) "A dose counter for an inhaler" (Term 3, '808 patent) and "An incremental dose counter for a metered dose inhaler" (Term 5, '889 patent); and (3) "medicament canister" (Term 2, '289 and '587 patents) and "canister" (Term 7, '889 patent).

With the Inhaler Terms, Teva has not shown a valid reason to depart from the general rule that claim preambles are not limiting. These claim preambles do not provide essential structure or give necessary life, meaning, and vitality to the claims. Instead, these preambles merely reflect a descriptive name for the limitations in the claim body (e.g., "an inhaler") or an intended use (e.g., "for metered dose inhalation").

Even considering Teva's Inhaler Term constructions, however, the plain meaning of "inhaler" does not require an active drug. The specification reflects a broader plain meaning, acknowledging the optional nature of an active drug in an inhaler. Moreover, this broader meaning is also reflected in a related Orange Book patent where the same inventors explicitly claimed an inhaler "containing an active drug." That language would be superfluous if Teva's constructions were correct. Moreover, that language shows that the inventors knew how to require "an active drug" in the claims, but did not do so with the Asserted Patents here. But even if an inhaler required an active drug, that would not justify Teva's constructions because the claims need not recite every component necessary to enable operation of a working device.

With the Dose Counter Terms, Teva still has not shown a valid reason to depart from the general rule that claim preambles are not limiting for much of the same reasons as with the Inhaler Terms. Teva's arguments are even farther afield here because the preamble language of a dose counter "for" an inhaler does not even require an inhaler to be present, let alone an active drug.

The plain meaning of the Canister Terms—"medicament canister" and "canister"—similarly does not require that the canister contain an active drug. Again, the intrinsic record demonstrates that the inventors knew how to claim a "medicament canister containing an active drug," which is language existing in a related, unasserted Orange Book patent claim. Teva might

wish that the inventors had decided to include this limitation in the Asserted Patents. But Teva cannot change that decision through claim construction.

Ultimately, Teva's proposed constructions are not driven by ascertaining the true "plain and ordinary meaning" of the disputed terms. Rather, they are a futile attempt to make Teva's patents listable in the Orange Book and to further delay this case. Amneal respectfully requests that the Court reject Teva's attempt to do so.

II. ARGUMENT

A. The Inhaler Terms Are Not Limiting, and the Court Should Reject Teva's Constructions. (Terms 1, 4, and 6)

As detailed in Amneal's opening brief, the preambles of the Inhaler Terms are not limiting and require no construction. (Amneal Br. at 5-9.) Teva dedicates the majority of its brief arguing otherwise, but its arguments do not change the fact that these preambles merely reflect the descriptive name and intended purpose of the inhaler.

Even if the preambles were limiting, Teva's constructions are wrong as reflected in evidence that even Teva cites. The "plain and ordinary" meaning that Teva proposes is an improper attempt to narrow the claims without lexicography or disavowal. Teva also mischaracterizes Amneal's construction as "limit[ing] the inhaler to just the 'device' (with no medicine)[.]" (Teva Br. at 10-11.) But Amneal's construction is not limiting in this way. It is indifferent to whether the claimed device contains medicine. Rather, Teva's constructions improperly limit the claims.

The table below repeats the competing proposed constructions of the Inhaler Terms (Terms 1, 4, and 6).

No.	Claim Term	Teva's Proposed Construction	Amneal's Proposed Construction
1	*"An inhaler for metered dose inhalation"* '289 patent, claim 1 '587 patent, claims 1, 12	The preamble is limiting. Plain and ordinary meaning in view of the claims, specification, and prosecution history, which is: "An inhaler for metered dose inhalation containing an active drug capable of being dispensed via the inhaler to the lungs"	The phrase "An inhaler for metered dose inhalation" is part of the preamble and is not limiting. Therefore, no construction is necessary. To the extent the Court finds that this phrase is limiting and requires construction, this phrase should be construed as "An inhaler device for metered dose inhalation"
4	*"an inhaler"* '808 patent, claim 1	The preamble is limiting. Plain and ordinary meaning in view of the claims, specification, and prosecution history, which is: "an inhaler containing an active drug capable of being dispensed via the inhaler to the lungs"	The phrase "an inhaler" is part of the preamble and is not limiting. Therefore, no construction is necessary. To the extent the Court finds that this phrase is limiting and requires construction, this phrase should be construed as "an inhaler device"
6	*"a metered dose inhaler"* '889 patent, claim 1	The preamble is limiting. Plain and ordinary meaning in view of the claims, specification, and prosecution history, which is: "a metered dose inhaler containing an active drug capable of being dispensed via the inhaler to the lungs"	The phrase "a metered dose inhaler" is part of the preamble and is not limiting. Therefore, no construction is necessary. To the extent the Court finds that this phrase is limiting and requires construction, this phrase should be construed as "a metered dose inhaler device"

(ECF No. 111-1, Joint Claim Construction and Prehearing Statement, Exhibit A at 10, 27, and 38.)

1. The claim preambles are not limiting.

Teva repeatedly emphasizes the intended purpose of an inhaler and its use with an active drug as a basis for finding the preambles limiting, but such arguments do not warrant departing from the "general rule" that claim preambles are not limiting. *Aspex Eyewear, Inc. v. Marchon*

Eyewear, Inc., 672 F.3d 1335, 1347 (Fed. Cir. 2012); Teva Br. at 11-15, 25-27, 33-34. Instead, these claim preambles merely provide a descriptive name and describe an intended use. The Inhaler Term preambles do not provide essential structure and are not necessary to give life, meaning, or vitality to the claims. In short, the Inhaler Term preambles are not limiting, and Teva's argument to the contrary is incorrect for several reasons below.

First, although Teva contends that some "parts of an inhaler" are missing from the body of the claims, (Teva Br. at 11), Teva fails to identify a single missing part, and fails to identify what "structure" the word "inhaler" supposedly provides. To the contrary, the claim body of the '289 patent, for example, specifies "a main body having a canister housing," "a medicament canister," and "a dose counter." (*See, e.g.*, Amneal Ex. 1, '289 patent at claim 1.) Although Teva ignores the "main body" limitation in its brief, (Teva Br. at 11), that limitation provides the essential structure that Teva seeks. (*See, e.g.*, Amneal Ex. 1, '289 patent at Fig. 1 and 12:13-16 (describing Figure 1's depiction of the "main body 10" of the inhaler).) Thus, without providing essential structure, the preamble word "inhaler" is merely a "descriptive name to the set of limitations in the body of the claim that completely set forth the invention." *Am. Med. Sys., Inc. v. Biolitec, Inc.*, 618 F.3d 1354, 1359 (Fed. Cir. 2010) (quoting *IMS Tech., Inc. v. Haas Automation, Inc.*, 206 F.3d 1422, 1434-35 (Fed. Cir. 2000)). Nothing in the claim language suggests that the term "inhaler" limits the invention beyond the limitations in the body of any claims. *Id.*

Second, Teva's cited cases regarding essential structure are inapposite. (Teva Br. at 11.) *Lemoine* concerned the lengthy preamble phrase "[a] shotgun magazine receiver assembly for converting a conventional shotgun having a trigger assembly and barrel into a magazine loaded shotgun, said receiver assembly comprising[.]" *Lemoine v. Mossberg Corp.*, No. 2020-2140, 2021

WL 4199934, at *1 (Fed. Cir. Sep. 15, 2021). The court found that, without the preamble, it was "difficult to make sense" of terms directed to "mating," "receiving," or "communicating" the claimed invention to or with components of the "conventional shotgun" from the preamble. *Id.* at *2. No such difficulty exists here because the limitations in the claim body are directed to the structures themselves (e.g., "a main body having a canister housing," "a medicament canister," and "a dose counter"), and not to the interaction of those structures with the preamble language.

Rowe does not help Teva, either. That case involved a claim in "Jepson" form, which is an unconventional claim form that is not present here. *Rowe v. Dror*, 112 F.3d 473, 479 (Fed. Cir. 1997). The Jepson form itself "suggest[ed] the structural importance of the recitations found in the preamble" because, when "this [Jepson] form is employed, the claim preamble defines not only the context of the claimed invention, but also its scope." *Id.*

Third, the specification neither "emphasizes the importance of the essential structure of the inhaler" nor "repeatedly discloses that the claimed invention ***is*** an 'inhaler[.]'" (Teva Br. at 12.) Teva relies solely on a passage from the '289 patent at 1:25-2:37, but nothing in this passage supports these assertions. First, the entire passage is in the "Background of the Invention," and is therefore not describing the invention itself. Second, nothing in this passage identifies an "inhaler" as a structure, let alone states or suggests that an inhaler structure is "essential." Third, nothing in this passage states that the invention itself is an inhaler. Fourth, even if the specification did use the word "inhaler" to refer to the invention as a whole, such language would support treating the preamble as "a label for the overall invention and not a limitation on the claims." *Am. Med. Sys., Inc.*, 618 F.3d at 1360. Finally, the intrinsic record emphasizes the specific components of the invention, which are detailed both in the specification and in the claim bodies (not the preambles).

(*See, e.g.*, Amneal Ex. 1, '289 patent at 11:11-12:8 (describing figures with detailed depictions of the components).)

Fourth, the word "inhaler" does not provide important context beyond a descriptive name for the limitations in the claim body. (Teva Br. at 13.) Teva contends that, if the preamble was not limiting, the claims "would be read as if the structure elements could be incorporated into ***any*** type of apparatus—not just an 'inhaler[.]'" (*Id.*) But Teva fails to explain what other types of apparatus might exist, or how a person of ordinary skill in the art looking at the claim body would see a "main body having a canister housing," a "medicament canister," and a "dose counter," and think that the claim body could be incorporated into anything other than an inhaler. Again, the word "inhaler" is merely a descriptive name. *Am. Med. Sys., Inc.*, 618 F.3d at 1360.

Fifth, Teva's argument that a single claim provides antecedent basis for all "inhaler" preambles is baseless. (Teva Br. at 13-14.) Claim 1 of the '587 patent refers to "reducing rocking of the medicament canister relative to **the main body** of the inhaler." (Amneal Ex. 2, '587 patent at claim 1 (emphasis added).) The "inhaler" here is incidental to this claim limitation, which is directed to reducing rocking of the "medicament canister" relative to the "main body"—both limitations that are present in the claim body. *See Sentient Sensors, LLC v. Cypress Semiconductor Corp.*, No. 19-cv-1868, 2021 WL 289410, *5-6 (D. Del. Jan. 28, 2021) (finding that preamble term "an instrument controller" was not limiting even though it provided antecedent basis for the phrase "the instrument controller" in the body where "[t]he preamble language [was] used merely to give a descriptive name to those components [in the claim body] as a whole"); *Sentient Sensors, LLC v. Cypress Semiconductor Corp.*, No. 19-cv-1868, 2021 WL 1966406, *2-3 (D. Del. May 17, 2021) (denying reargument on the "instrument controller" preamble because "antecedent basis was not dispositive in this case").

Sixth, the prosecution history does not support Teva because that history did not implicate the preamble language. (Teva Br. at 14-15.) In the passage that Teva cites, for example, the inventors stated that "[s]imply conforming **the housing** to **the shape of the canister** would increase airflow resistance of the inhaler . . . ." (Teva Ex. 8 at 6-7 (emphases added).) This passage is describing the purported importance of the relationship between components that are not found in the preamble—"the housing" and "the canister." The inventors did not point to the preambles to distinguish the prior art by, for example, arguing that the prior art was not an "inhaler." *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002) ("preamble language merely extolling benefits or features of the claimed invention does not limit the claim scope without clear reliance on those benefits or features as patentably significant").

2. Teva's proposed constructions do not reflect the plain meaning.

Even if the preambles were limiting, the Court should reject Teva's constructions, which do not reflect the plain and ordinary meaning of the Inhaler Terms. (Teva Br. at 15-19.) Teva's constructions are inconsistent with the intrinsic and extrinsic record.

a. The common meaning of "inhaler" does not require the presence of an active drug.

Despite Teva's assertion that the "common meaning of 'inhaler' requires the presence of an active drug," (Teva Br. at 15), the opposite is true. The intrinsic record reflects this understanding.

For example, the specification recognizes that an "inhaler" need not include a "medicament canister" at all. The specification states that "[e]ach of the above ***inhalers*** in accordance with aspects of the present invention ***may have*** a medicament canister mounted thereto." (Amneal Ex. 1, '289 patent at 9:12-14 (emphases added).) If an "inhaler" already required the presence of an active drug, it would make no sense for the inventors to state that an inhaler "may" have a

medicament canister mounted thereto, particularly in light of Teva's argument that the medicament canister itself must always contain an active drug. (Teva Br. at 20.) Furthermore, Figure 1 of the specification depicts "a main body of ***an embodiment of an inhaler*** related to the invention," and that figure does not include a "medicament canister" at all:

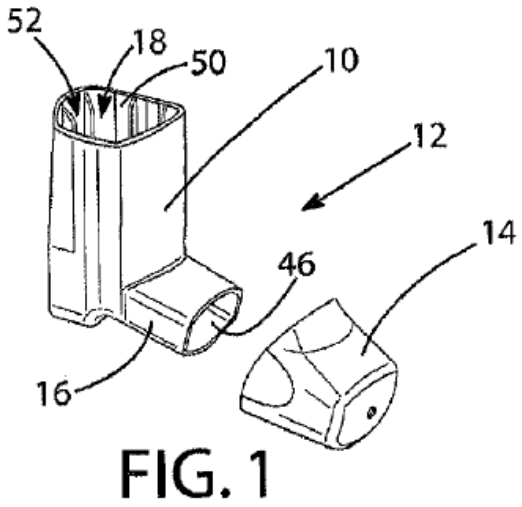

FIG. 1

(Amneal Ex. 1, '289 patent at 11:11-13, Fig. 1.)

The specification also recognizes that even an inhaler with a medicament canister can be empty. The specification describes "[a] drawback of self-administration from an ***inhaler*** is that it is difficult to determine ***how much active drug and/or propellant are left in the inhaler, if any, especially of the active drug*** and this is potentially hazardous for the user since dosing becomes unreliable and backup ***devices*** [are] not always available." (Teva Br. at 12 (quoting '289 patent at 1:49-54) (emphases added).) Teva relies on this specification passage, but fails to acknowledge its import. As explained in Amneal's Opening Brief, this passage recognizes not only that an inhaler is a device, but also that an inhaler does not cease being an inhaler when it is empty. (Amneal Br. at 12, 19.)

Beyond the specification, the claims in a related patent recognize that an inhaler does not "require[ ] the presence of an active drug" as Teva contends. (Teva Br. at 15.) U.S. Patent

No. 10,086,156 ("the '156 patent") is an Orange Book patent that Teva has listed for ProAir HFA, but has not asserted against Amneal.[2] (Amneal Ex. 8; ECF No. 12-11 at 1 (Exhibit K to Amneal's Counterclaims, reflecting the '156 patent in the list of ProAir® HFA Orange Book patents).) Claim 1 of the '156 patent recites, in part:

> A dose counter for ***a metered dose inhaler*** having a body arranged to retain a medicament canister . . . the ***medicament canister containing an active drug*** . . . .

(Amneal Ex. 8, '156 patent at claim 1 (AMN_PA0058084 at -8114) (emphasis added).) If the inhaler already required the presence of an active drug, as Teva contends, the "containing an active drug" language in the related '156 patent would be superfluous. *See, e.g.*, *Wasica Fin. GmbH v. Cont'l Auto Sys., Inc.*, 853 F.3d 1272, 1288 n.10 (Fed. Cir. 2017) (noting that it is "highly disfavored to construe terms in a way that renders them void, meaningless, or superfluous"); *Versa Corp. v. AG-Bag Int'l Ltd.*, 392 F.3d 1325, 1330 (Fed. Cir. 2004) (rejecting construction that would render claim superfluous); *TMI Prods., Inc. v. Rosen Entm't Sys., L.P.*, 610 F. App'x 968, 972 (Fed. Cir. 2015) (rejecting construction that would render other limitations redundant).

The "containing an active drug" language in the '156 patent is also evidence that the inventors knew how to include such a limitation in their claims, but elected not to do so with the Asserted Patents here. *See Enzo Biochem, Inc. v. Applera Corp.*, 599 F.3d 1325, 1333 (Fed. Cir. 2010) (rejecting construction that added a limitation where "applicants knew how to claim . . . but specifically omitted that language from the claims"); *Move, Inc. v. Real Estate All. Ltd.*, 413 F.

[2] The '156 patent is relevant because it is in the same family as the Asserted Patents, lists the same eight inventors, and claims priority to the same provisional applications filed in 2010. (*Compare* Amneal Ex. 8, '156 patent at Cover *with* Amneal Ex. 1, '289 patent at Cover.) Such related patents are relevant when construing the Asserted Patents. *See In re Rambus Inc.*, 694 F.3d 42, 48 (Fed. Cir. 2012) (where patent claims from the same family as the patent-in-suit explicitly included a "single" semiconductor limitation, finding those claims relevant as a basis to reject limiting the claims of the patent-in-suit to a "single" semiconductor).

App'x 280, 284-85 (Fed. Cir. 2011) (finding that it was improper to import a limitation into a claim that was explicit in a related patent but not in the construed patent).

b. Teva's remaining intrinsic evidence does not support its constructions, and actually supports Amneal.

Despite considerable intrinsic evidence to the contrary above, Teva tries to marshal support from other claims, agreed-upon claim constructions, the specification, and the prosecution history. As described below, however, these sources do not help Teva.

The other claims in the Asserted Patents do not support Teva's constructions. (Teva Br. at 16-17, 29-31, 38-39.) With respect to the '289 and '587 patents, Teva points to the "medicament canister" term. (*Id.* at 16.) But the "medicament canister" need not contain a "medicament" for the reasons described above in Section II.A.2.a., and further in Section II.C. below. And, despite Teva's contention, the term "dose counter" still makes sense even "if there were no drug to be dosed." (*Id.*) If the "dose counter" counts the doses remaining, it must reach zero at some point. The '808 patent claims do not support Teva, either. (*Id.* at 29-31.) The purpose of a "counter display" and "regulat[ing] motion" make sense even where no active drug is available to be dosed. For example, when the active drug has been spent, one would hope that the "dosage information" would indicate that no doses are remaining. With respect to the '889 patent, Teva merely repeats the same arguments about the "canister" and "dose counter." (*Id.* at 38-39.)

For several reasons, the parties' agreed-upon constructions do not have the import that Teva ascribes to them. (Teva Br. at 16-17.) First, the constructions are meant to clarify the relationship between components explicitly recited in the claim bodies, not the contents of the "medicament canister" or the overall "inhaler." For example, one agreed-upon construction clarifies what "vertical" means: "where vertical means substantially parallel to the primary direction of the movement of the medicament canister when it is pressed downward by the user to

expel medicament." (ECF No. 111-1 at 3-4.) Second, the constructions use conditional language—for example, describing a vertical orientation "when" the medicament canister is pressed downward. Conditional language such as this does not require "medicament," just like it does not require a "user." *Beijing Choice Elec. Tech. Co., Ltd. v. Contec Med. Sys. USA, Inc.*, No. 18-cv-825, 2020 WL 220087, at *5-6 (N.D. Ill. Jan. 14, 2020) (construing the term "when" in "when the user presses down a button" "according to its conditional meaning to mean 'if, or in the event that, the user presses a button'"). Third, simply because a canister is "pressed downward by the user ***to expel medicament***" does not mean that medicament is necessarily expelled. Rather, the construction is referring to the user's reason for pressing downward on the medicament canister. Teva's statement that the "inhaler must contain a medicament for it to be expelled when the inhaler is used" misstates the language of this construction. (Teva Br. at 16.) Finally, these constructions are merely the same constructions that the parties agreed to in a prior case, which Amneal agreed to in an effort to minimize the disputes presented to the Court. *See, e.g., Teva Branded Pharm. Prods. R&D, Inc. v. Cipla Ltd.*, No. 20-cv-10172 (D.N.J. July 6, 2021), Joint Claim Construction and Prehearing Statement, ECF No. 102, at 3-5. Merely assenting to these prior constructions cannot affect the meaning of the remaining disputed claim terms.

Teva cites several specification passages, but, as explained above in Section II.A.2.a., those passages actually support Amneal. (Teva Br. at 17, 30-31, 37-38.) In essence, although an inhaler can contain an active drug, the specification recognizes that this is not required. Even Teva's quote from the specification recognizes that "[m]etered dose inhalers ***can*** comprise a medicament-containing pressurized canister . . . ." (Teva Br. at 17 (citing '289 patent at 1:27-29) (emphasis added).) The specification also states that "[e]ach of the above ***inhalers*** in accordance with aspects of the present invention ***may have*** a medicament canister mounted thereto." (Amneal Ex. 1, '289

patent at 9:12-14 (emphases added).) And, as explained in Amneal's Opening Brief, the specification recognizes that no active drug may be left in an inhaler. (Amneal Br. at 12.) Thus, Teva is wrong when stating that "an 'inhaler' without an active drug is not an 'inhaler.'" (Teva Br. at 17.) It is merely an empty inhaler.

Teva's other specification passages similarly support Amneal. (Teva Br. at 17-18.) For example, Teva relies on a patent cited in the specification (EP '227) for its statement that: "[m]etered dose medicament inhalers are well known for dispensing medicament to the lungs of a patient, for treating asthma for example." (Teva Ex. 10 at 1:24-26.) Again, this passage merely describes the purpose of an inhaler. No party is disputing what an inhaler can do; the parties are disputing what is claimed. Teva also relies on the '289 patent's description of the user priming the inhaler to indicate that "200 doses are remaining." (Amneal Ex. 1, '289 patent at 17:4-10.) But this is just one embodiment, and again it merely explains a use of the inhaler. Presumably, with continued use, the "200 doses remaining" would reach zero.

The prosecution history does not support Teva, either. (Teva Br. at 18-19.) As described above in Section II.A.1., during prosecution, the inventors were not distinguishing the claims on the basis that they claimed an "inhaler" where the prior art did not. Rather, the inventors were discussing the relationship between "the housing" and "the shape of the canister." (Teva Ex. 8 at 6-7.)

c. Teva's extrinsic evidence also supports Amneal.

Teva resorts to selective dictionary definitions, but those definitions also support Amneal. (Teva Br. at 15-16, 30-31, 37-38.) For example, Teva quotes the Merriam-Webster's Medical Desk Dictionary definition of "inhaler" as "**a device** by means of which **usu[ally]** medicinal material is inhaled." (Teva Ex. 9 at 397 (emphasis added).) Like Amneal's construction, this definition recognizes that an "inhaler" is "a device." (Amneal Br. at 9-11.) This definition also

does not require the presence of an active drug. Instead, it states that "**usu[ally]** medicinal material" is inhaled using that device. Teva's other definitions are for the word "inhalation," and are directed to the act of inhaling, not the "inhaler" itself. (Teva Ex. 9 at 396.)

Teva's last piece of extrinsic evidence, the FDA Guidance, merely states that "MDIs represent a reliable, convenient dosing device for delivery of medications to the lungs." (Teva Ex. 7 at 2.) This passage again refers to an MDI as a "dosing ***device***," which is in turn used "for delivery of medications to the lungs." That does not suggest that the medication itself is necessarily part of the claimed device.

d. Even if Teva were correct, that would not warrant adopting its constructions.

Even if Teva were correct that the preambles are limiting and that the common meaning of "inhaler" requires the presence of an active drug, all of that still would not justify Teva's constructions because "the claims need not recite every component necessary to enable operation of a working device." *Rambus Inc. v. Infineon Tech. Ag*, 318 F.3d 1081, 1093 (Fed. Cir. 2003). "[E]ven if 'all of the embodiments discussed in the patent' included a specific limitation, it would not be 'proper to import from the patent's written description limitations that are not found in the claims themselves.'" *Cadence Pharms. Inc. v. Exela PharmSci Inc.*, 780 F.3d 1364, 1369 (Fed. Cir. 2015) (quoting *Flo Healthcare Solutions, Inc. v. Kappos*, 697 F.3d 1367, 1375 (Fed. Cir. 2012)). "As we have previously made clear, the fact that an unclaimed element may be necessary for a device to function as claimed does not, standing alone, allow courts to treat the unclaimed element as a claim limitation." *Respironics, Inc. v. Zoll Med. Corp.*, 656 F. App'x 531, 535-36 (Fed. Cir. 2016) (citing *SiRF Tech., Inc. v. Int'l Trade Com'n.*, 601 F.3d 1319, 1330 (Fed. Cir. 2010)); *Markem-Imaje Corp. v. Zipher Ltd.*, 657 F.3d 1293, 1301 (Fed. Cir. 2011) ("That a device

will only operate if certain elements are included is not grounds to incorporate those elements into the construction of the claims.").

For example, "[a] claim to an engine providing motive power to a car should not be construed to incorporate a limitation for an exhaust pipe, though an engine may not function without one." *Markem-Imaje Corp.*, 657 F.3d at 1301; *Rodime PLC v. Seagate Tech., Inc.*, 174 F.3d 1294, 1303 (Fed. Cir. 1999) (applicant need not claim every function of a working device). Likewise, a claim to an inhaler for metered dose inhalation should not be construed to incorporate all of the limitations that Teva seeks to import (i.e., "an active drug capable of being dispensed via the inhaler to the lungs"), even though the inhaler may not function without them.

Without plain and ordinary meaning on its side, Teva would need to show lexicography or disavowal to narrow the Inhaler Terms to require "an active drug capable of being dispensed via the inhaler to the lungs." *Thorner v. Sony Comput. Entm't Am. LLC*, 669 F.3d 1362, 1365-66 (Fed. Cir. 2012). But no lexicography or disavowal exists here, and Teva does not contend otherwise.

B. The Dose Counter Terms Are Not Limiting, and the Court Should Reject Teva's Constructions. (Terms 3 and 5)

With the Dose Counter Terms, Teva improperly attempts to include an inhaler as a requirement of the claims. (Teva Br. at 25-27, 33-34.) As detailed below, however, the claimed dose counter "for" an inhaler merely recites an intended use, which is not limiting.

The table below repeats the competing proposed constructions of the Dose Counter Terms (Terms 3 and 5).

No.	Claim Term	Teva's Proposed Construction	Amneal's Proposed Construction
3	*"A dose counter for an inhaler"* '808 patent, claims 1	The preamble is limiting.	The phrase "A dose counter for an inhaler" is part of the preamble and is not limiting. Therefore, no construction is necessary.

No.	Claim Term	Teva's Proposed Construction	Amneal's Proposed Construction
		Plain and ordinary meaning in view of the claims, specification, and prosecution history, which is: "A dose counter used in connection with an inhaler"	To the extent the Court finds that this phrase is limiting and requires construction, this phrase should be construed as "A dose counter for an inhaler device"
5	*"An incremental dose counter for a metered dose inhaler"* '889 patent, claim 1	The preamble is limiting. Plain and ordinary meaning in view of the claims, specification, and prosecution history, which is: "An incremental dose counter used in connection with a metered dose inhaler"	The phrase "An incremental dose counter for a metered dose inhaler" is part of the preamble and is not limiting. Therefore, no construction is necessary. To the extent the Court finds that this phrase is limiting and requires construction, this phrase should be construed as "An incremental dose counter for a metered dose inhaler device"

(ECF No. 111-1, Joint Claim Construction and Prehearing Statement, Exhibit A at 22 and 33-34.)

1. The claim preambles are not limiting.

For many of the same reasons as with the Inhaler Terms and the additional reasons below, Teva has again provided no valid reason to depart from the general rule that the Dose Counter Term preambles are not limiting. *Aspex Eyewear, Inc.*, 672 F.3d at 1347.

As an initial matter, the preamble phrases "[a] dose counter for an inhaler" and "[a]n incremental dose counter for a metered dose inhaler" do not "require[ ] an inhaler." (Teva Br. at 25-26, 33.) This preamble language merely describes the intended purpose of the "dose counter," and an intended purpose is not a basis to limit a claim preamble. *Eko Brands, LLC v. Adrian Rivera Maynez Enters., Inc.*, 946 F.3d 1367, 1376-77 (Fed. Cir. 2020) (for claims reciting "[a] beverage brewing device ***for*** use with a single serve beverage brewer," finding that claim did not require a beverage brewer and that the mention of a beverage brewer was "only as a reference

point to define the purpose and structure of the brewing device"); *Nippon Steel & Sumitomo Metal Corp v. POSCO*, No. 12-cv-2429-SRC, 2014 WL 2534929, at *7 (D.N.J. June 4, 2014) (finding a preamble not limiting where "the preamble phrase at issue looks most like a statement of intended use"); *Omega Patents, LLC v. Geotab USA, Inc.*, 660 F. Supp. 3d 274, 280-81 (D. Del. 2023) (Bryson, C.J., sitting by designation) (finding that claim preamble reciting "[a] multi-vehicle compatible tracking unit ***for*** a vehicle comprising a vehicle data bus extending throughout the vehicle" was directed to just the tracking unit having the capability to be used with a vehicle and not the vehicle itself).

The specification does not provide a basis to incorporate an inhaler into the claims, either. (Teva Br. at 26, 33.) The specification does not become "meaningless" if the preambles are not limiting. It is still relevant to the entire claim body whether or not the preambles are limiting. And again, the overall purpose of the dose counter does not expand the structural scope of the claims in the way that Teva proposes. *Eko Brands, LLC*, 946 F.3d at 1377. If Teva was right, a claim to "a tire for a car" would mandate a construction that required the whole car and all the fluids needed to make the car run, such as fuel.

Like with the Inhaler Terms, the Dose Counter Term preambles are not essential to terms in the claim body. (Teva Br. at 26-27, 34.) With respect to the '808 patent, the preamble is not necessary to understanding that "the dose-counter elements claimed in the claim body are to be used in connection with an inhaler." (Teva Br. at 27.) The claims are not method claims, and the intended use is not limiting. *Eko Brands, LLC*, 946 F.3d at 1377. That the '808 patent claim also requires a "counter display arranged to indicate dosage information" is merely describing the arrangement and purpose of the counter display. Likewise, the "drive system arranged to move the counter display . . . in response to actuation input" similarly describes the arrangement and

purpose of the drive system, which is not found in the preambles. With respect to the '889 patent, the preamble does not provide essential context for the term "canister" for the same reasons provided above in Section II.A.1. with respect to the '289 and '587 patents. (Teva Br. at 34.) The '889 patent preamble also does not provide essential context for the phrase "an actuator arranged to be driven and to drive an incremental output member in a count direction in response to canister motion" because this limitation describes the arrangement and purpose of the actuator, which is not found in the preambles. (*Id.*)

2. Teva's proposed constructions do not reflect the plain meaning.

Even if the preambles were limiting, the Court should reject Teva's constructions, which do not reflect the plain meaning of "for" and are inconsistent with the intrinsic and extrinsic record. (Teva Br. at 27-31, 34-38.)

As an initial matter, contrary to Teva's argument, Amneal's constructions do not limit the preamble to a metered dose inhaler device "with no medicine." (Teva Br. at 35.) As explained above in Section II.A.2.a., Amneal's constructions, like the plain language of the claims themselves, are agnostic to the presence of medicine in the claimed devices.

Furthermore, Amneal does dispute whether "the claimed dose counter requires the presence of a metered dose inhaler." (Teva Br. at 35; *see also id.*at 28.) Amneal's constructions maintain the word "for" because that word is merely stating an intended purpose of the dose counter. That intended purpose does not transform into a claim requirement. *Eko Brands, LLC*, 946 F.3d at 1377. The specification language that Teva cites merely repeats this "for" language. (Teva Br. at 28, 35-36.) And Teva's "used in connection with" language improperly morphs the claim into a method claim. (Amneal Br. at 14-15.)

Picking and choosing some dictionary definitions of "for" does not help Teva. (Teva Br. at 28-29, 36.) Teva relies on Merriam-Webster's definition of "for" as "used as a function word

to indicate purpose," but this definition supports Amneal because it reflects an intended purpose. (Teva Ex. 14 at 488.) Similarly, Teva's reliance on Webster's Unabridged 2002's definition of "for" as "used by or in connection with" also supports Amneal. (Teva Ex. 13 at 886.) This definition is merely one of several definitions in this dictionary of the word "for." But even considering this definition, it gives a useful example in angle brackets immediately following this definition: "used by or in connection with **<are these the tires [for] this car>**[.]" (Teva Ex. 13 at 886 (emphasis added).) The dictionary's example of "tires [for] this car" again reflects an intended purpose. Put another way, a claim to "a tire for a car" would not require a car to be present merely because the tire is to be used in connection with a car. Likewise, a claim to "a dose counter for an inhaler" does not require the inhaler to be present merely because the dose counter is to be used in connection with an inhaler. *Omega Patents, LLC*, 660 F. Supp. 3d at 280-81; *Eko Brands, LLC*, 946 F.3d at 1377.

Even if Teva were correct about the plain meaning of "for," that still would not justify Teva's constructions because "the claims need not recite every component necessary to enable operation of a working device." *Rambus Inc.*, 318 F.3d at 1093; *Cadence Pharms. Inc.*, 780 F.3d at 1369; *Respironics, Inc.*, 656 F. App'x at 535-36; *Markem-Imaje Corp.*, 657 F.3d at 1300-01.

Like with the Inhaler Terms, Teva would need to show lexicography or disavowal to narrow the Dose Counter Terms to require a dose counter "used in connection with" an inhaler. *Thorner*, 669 F.3d at 1365-66. But no lexicography or disavowal exists here, either, and Teva does not contend otherwise.

C. The Court Should Reject Teva's Constructions for the Canister Terms. (Terms 2 and 7)

Teva's "plain and ordinary" meaning of the Canister Terms is not supported by its intrinsic or extrinsic evidence, for much of the same reasons as with the previous terms above. (Teva Br.

at 20-24, 38-40.) These claimed canisters do not necessarily "contain[ ] an active drug capable of being dispensed via the inhaler to the lungs" for the reasons provided below.

The table below repeats the competing proposed constructions of the Canister Terms (Terms 2 and 7).

No.	Claim Term	Teva's Proposed Construction	Amneal's Proposed Construction
2	*"medicament canister"* '289 patent, claims 1, 2 '587 patent, claims 1, 2, 12	Plain and ordinary meaning in view of the claims, specification, and prosecution history, which is: "a canister containing an active drug capable of being dispensed via the inhaler to the lungs"	No construction necessary. Plain and ordinary meaning, i.e., "a canister for medicament"
7	*"canister"* '889 patent, claim 1	Plain and ordinary meaning in view of the claims, specification, and prosecution history, which is: "a canister containing an active drug capable of being dispensed via the inhaler to the lungs"	No construction necessary. Plain and ordinary meaning, i.e., "canister"

(ECF No. 111-1, Joint Claim Construction and Prehearing Statement, Exhibit A at 16 and 43-44.)

The Court should reject Teva's constructions for "medicament canister" and canister," which do not reflect the plain and ordinary meaning and are inconsistent with the intrinsic and extrinsic record. (Teva Br. at 20-24, 38-40.)

1. The plain meaning of the Canister Terms does not require the presence of an active drug.

Teva's argument that the "medicament canister" and the "canister" necessarily contain an active drug does not reflect the plain meaning of these terms and is inconsistent with the intrinsic record. As described above, the same inventors in claim 1 of the related '156 patent included the

language a "***medicament*** canister ***containing an active drug***." (Amneal Ex. 8, '156 patent at claim 1 (AMN_PA0058084 at -8114) (emphases added).) If the term "medicament canister" itself necessarily contained an active drug, these same inventors would have no reason to include the "containing an active drug" language in the '156 patent. Teva's construction would make this language superfluous. *Versa Corp.*, 392 F.3d at 1330; *TMI Prods., Inc.*, 610 F. App'x at 972; *Wasica Fin. GmbH*, 853 F.3d at 1288 n.10. This language shows that the inventors knew how to claim "an active drug" as a component of a "medicament canister," but elected not to do so with the Asserted Patents. *Enzo Biochem, Inc.*, 599 F.3d at 1333; *Move, Inc.*, 413 F. App'x at 284-85. The Court should not permit Teva to rewrite its claims to add a phrase that the inventors included in a related patent in the same family, but elected not to do so here.

As Amneal explained in its opening brief, the terms "canister" and "medicament canister" are limitations directed to the canisters themselves, not their contents. (Amneal Br. at 18-19.) Tellingly, in its introduction Teva refers to metered dose inhalers as containing a "canister of medicament," rather than a "medicament canister." (Teva. Br. at 3.) This different wording is important. A "water bottle" has a different meaning than a "bottle of water." The former describes the purpose of the bottle, while the latter describes its contents. (Amneal Br. at 18.) Likewise, a "canister of medicament" (which is not claimed) is not the same as a "medicament canister" (which is claimed).

Even Teva uses the word "canister" according to Amneal's plain meaning, when arguing that an "empty canister" is not within the plain meaning of the term. (Teva Br. at 23.) The phrase "empty canister" itself demonstrates that the plain and ordinary meaning of "canister" is broader than Teva proposes. If the plain and ordinary meaning of "canister" required an active drug to be present, Teva's own phrase "empty canister" would be paradoxical.

2. Teva's constructions are not supported by its evidence.

Teva points to much of the same evidence as with the other terms, including the "inhaler" term itself, the claim language, the specification, and the prosecution history. But this evidence does not help Teva here, either. For the same reasons above in Section II.A.2., Teva's reliance on the "inhaler" term and agreed-upon constructions does not support Teva's constructions for the Canister Terms.

Other surrounding claim language does not support Teva's constructions. (Teva Br. at 21.) With respect to "medicament canister" in the '289 and '587 patents, the term "canister fire stem" again merely describes a structural component of the device found in the claim body. Similarly, the term "a dose counter . . . for operation by movement of the medicament canister" is describing a structural component of the device found in the claim body. Neither of these components taken alone or together somehow require that the canister contain anything, let alone that it contain an active drug. Furthermore, the "dose counter that counts the doses of the active drug that remain in the medicament canister" will reach zero at some point. (Teva Br. at 21.)

With respect to "canister" in the '889 patent, the claim context still does not help Teva. (Teva Br. at 38-39.) The preamble phrase "incremental dose counter" does not somehow define the contents of the "canister" in the body of the claim, and again the "doses of the active drug that remain in the canister" will eventually reach zero.

Teva's specification support is similarly unavailing. (Teva Br. at 21-22, 39.) Teva relies on the descriptions of Figs. 7A and 10D, for example, but these are merely embodiments. (*See, e.g.*, '289 patent at 11:6-10 (describing that "preferred embodiment[s] . . . will now be described with reference to the accompanying drawings").) It would be improper to limit the claims based on these select embodiments. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1323 (Fed. Cir. 2005) ("[A]lthough the specification often describes very specific embodiments of the invention, we have

repeatedly warned against confining the claims to those embodiments."); *Superguide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004) ("[A] particular embodiment appearing in the written description may not be read into a claim when the claim language is broader than the embodiment.").

Teva unsuccessfully resorts to more references in the specification. The "Background of the Invention" section does not support Teva. (Teva Br. at 22-23, 39-40.) Even Teva's quoted language—that "[m]etered dose inhalers ***can*** comprise a medicament-containing pressurised canister containing a mixture of active drug and propellant"—does not state that the inhaler "must" so comprise. (Teva Br. at 22 (quoting '289 patent at 1:25-29) (emphasis added).) And the inventors did not claim a "medicament-containing" canister, despite knowing how to do that with the related '156 patent as described above. Even the WO '552 reference in the specification states that "[s]uch metered-dose inhalers ***typically*** comprise a medicament containing vessel . . . ." (Teva Br. at 22 (quoting Teva Ex. 12 at 1:16-21) (emphasis added).)

The prosecution history does not help Teva for the same reasons as with the other terms. (Teva Br. at 23.) Again, the emphasis during prosecution was on the orientation of different structural parts of the inhaler, not on the contents of the canister itself. (Teva Ex. 8 at 6-7.)

Even if Teva were correct about the plain meaning of the Canister Terms, that still would not justify Teva's constructions because "the claims need not recite every component necessary to enable operation of a working device." *Rambus Inc.*, 318 F.3d at 1093; *Cadence Pharms. Inc.*, 780 F.3d at 1369; *Respironics, Inc.*, 656 F. App'x at 535-36; *Markem-Imaje Corp.*, 657 F.3d at 1300-01.

Like with other terms above, Teva would need to show lexicography or disavowal to narrow the Canister Terms to require "an active drug capable of being dispensed via the inhaler to

the lungs." *Thorner*, 669 F.3d at 1365-66. But no lexicography or disavowal exists here, either, and again Teva does not contend otherwise.

III. CONCLUSION

For the reasons above, Amneal respectfully requests that the Court find that the preambles of Terms 1 and 3-6 are not limiting and require no construction. Amneal also respectfully requests that the Court find that Terms 2 and 7 require no construction. Alternatively, Amneal respectfully requests that the Court adopt Amneal's proposed constructions for these terms.

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