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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 OPENING 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"*
Conroy Decl.	Declaration of Rebekah Conroy, submitted herewith
Ex. __	Exhibit number __ attached to the Conroy Decl.

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 Opening Claim Construction Brief to address the seven disputed claim terms (Terms 1-7). The seven disputed terms appear in four asserted patents, U.S. Patent Nos. 9,463,289 ("the '289 patent") (Ex. 1), 9,808,587 ("the '587 patent") (Ex. 2), 10,561,808 ("the '808 patent") (Ex. 3), and 11,395,889 ("the '889 patent") (Ex. 4) (collectively, the "Asserted Patents").

The Court may be familiar with the Asserted Patents from the parties' previous Rule 12 motions, where the Court granted Amneal's Rule 12(c) motion for judgment on the pleadings. In particular, the Court found that the Asserted Patents "do not claim 'the drug for which the applicant submitted the application," and therefore were not properly listed in the Orange Book. (D.I. 88 at 16-17.) That decision is currently on appeal.

The instant claim construction dispute is merely Teva's attempt to rewrite the claims of the Asserted Patents to make them "listable" in the Orange Book. Teva's proposed constructions do not salvage the Asserted Patents, but the Court should nevertheless reject those constructions.

Although there are seven disputed terms, each term fits into one of three distinct groups. The first group (Terms 1, 4, and 6) concerns the "inhaler" term in all of the claim preambles. Amneal maintains that these preambles are not limiting, and require no construction. The Court should reject Teva's attempt to import "an active drug" requirement into the "inhaler" preambles. No support for such a construction exists in the intrinsic record. If anything, the Court should construe the "inhaler" preambles as Amneal proposes to clarify that the claimed inhaler is a "device," which is a word the inventors repeatedly used when referring to the claimed inhaler.

The second group (Terms 3 and 5) concerns the word "for" in two of the same preambles (e.g., "[a] dose counter *for* an inhaler"). Again, these preambles are not limiting and require no construction. Teva's constructions would mutate the composition claims into method claims by adding a use requirement (e.g., "[a] dose counter *used in connection with* an inhaler"). The Court should reject Teva's constructions and, if anything, construe the terms as Amneal proposes to clarify that the claimed inhaler is a "device."

The third group (Terms 2 and 7) concerns "canister" terms in three of the Asserted Patents. These terms need no further construction. Indeed, both parties repeat the word "canister" in their constructions. Teva, however, again attempts to import "an active drug" requirement into the "medicament canister" and "canister" terms. But a claim limitation to a canister—even a specific type of canister—is not also a claim limitation to its contents. Teva's constructions would exclude empty (e.g., depleted) canisters and should be rejected.

II. LEGAL STANDARDS

The words of a patent claim "are generally given their ordinary and customary meaning," which "is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005).

There are "two exceptions" to depart from a term's ordinary meaning: lexicography and disavowal. *Thorner v. Sony Comput. Ent. Am. LLC*, 669 F.3d 1362, 1365-66 (Fed. Cir. 2012). "To act as its own lexicographer, a patentee must 'clearly set forth a definition of the disputed claim term' other than its plain and ordinary meaning[,]" and "must 'clearly express an intent' to redefine the term." *Id.* at 1365 (quoting *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002) and *Helmsderfer v. Bobrick Washroom Equip, Inc.*, 527 F.3d 1379, 1381 (Fed. Cir. 2008)). For disavowal, the intrinsic record must "make[ ] clear that the invention does

not include a particular feature." *Thorner*, 669 F.3d at 1366 (quoting *SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1341 (Fed. Cir. 2001)).

The patent specification "is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Phillips*, 415 F.3d at 1315 (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). The prosecution history also may be considered because it can show "how the PTO and the inventor understood the patent." *Phillips*, 415 F.3d at 1317. But "because the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes." *Id.* Extrinsic evidence may be considered, but is "less reliable than the patent and its prosecution history in determining how to read claim terms." *Id*. at 1318.

III. ARGUMENT

A. The Court Should Find That the Preambles of the Inhaler Terms Are Not Limiting and Require No Construction or, Alternatively, Adopt Amneal's Constructions. (Terms 1, 4, and 6)

Terms 1, 4, and 6 are present in the preambles of the independent claims of each Asserted Patent. These preambles are reproduced below with the disputed terms emphasized.

> ***An inhaler for metered dose inhalation***, the inhaler comprising:
> . . . .
> [Term 1: '289 patent, claim 1 and '587 patent, claims 1 and 12]
>
> A dose counter for ***an inhaler***, the dose counter having . . . .
> [Term 4: '808 patent, claim 1]
>
> An incremental dose counter for ***a metered dose inhaler*** having a body arranged to retain a canister for movement of the canister relative thereto, the incremental dose counter having. . . .
> [Term 6: '889 patent, claim 1]

(Ex. 1, '289 patent at claim 1 (emphasis added); Ex. 2, '587 patent at claims 1 and 12 (emphasis added); Ex. 3, '808 patent at claim 1 (emphasis added); Ex. 4, '889 patent at claim 1 (emphasis added).)

The table below has the competing proposed constructions of these terms.

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.)

The same dispute exists for Terms 1, 4, and 6 (referred to herein as the "Inhaler Terms"). Specifically, the parties dispute (1) whether the preambles of the Inhaler Terms are limiting and need construction, and (2) if limiting and in need of construction, whether the preambles merely describe the inhaler as a device (Amneal's construction), or whether the preambles require an inhaler containing an active drug with specific capabilities (Teva's construction).

1. The preambles are not limiting.

The preamble is the "introductory words of a claim," *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257 (Fed. Cir. 1989), often appearing before a transitional term such as "comprising," *Gillette Co. v. Energizer Holdings, Inc.*, 405 F.3d 1367, 1371 (Fed. Cir. 2005).[1] The language after "comprising" is the body of the claim. *Id.* (referring to "comprising" as "transitioning from the preamble to the body").

"[A]s a general rule preamble language is not treated as limiting." *Aspex Eyewear, Inc. v. Marchon Eyewear, Inc.*, 672 F.3d 1335, 1347 (Fed. Cir. 2012). A preamble may "limit[ ] the invention if it recites essential structure or steps, or if it is 'necessary to give life, meaning, and vitality' to the claim." *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002) (quoting *Pitney Bowes, Inc. v. HewlettPackard Co.*, 182 F.3d 1298, 1305 (Fed. Cir. 1999)). A preamble also may be limiting if it is "necessary to provide antecedent basis for the body of the claim." *Symantec Corp. v. Computer Assoc. Int'l, Inc.*, 522 F.3d 1279, 1288 (Fed. Cir. 2008).

But "the preamble has no separate limiting effect if, for example, 'the preamble merely gives a descriptive name to the set of limitations in the body of the claim that completely set forth

[1] The '808 and '889 patents recite "having" instead of "comprising." (*See, e.g.*, Ex. 3, '808 patent at claim 1 ("[a] dose counter for an inhaler, the dose counter ***having***").) The term "having" is also a transitional term. *See Crystal Semiconductor Corp. v. TriTech Microelectronics Int'l, Inc.*, 246 F.3d 1336, 1348 (Fed. Cir. 2001).

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)). Moreover, "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." *Catalina*, 289 F.3d at 809. In addition, "a preamble is not limiting 'where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention.'" *Id.* at 808 (quoting *Rowe v. Dror*, 112 F.3d 473, 478 (Fed. Cir. 1997)). "If the preamble 'is reasonably susceptible to being construed to be merely duplicative of the limitations in the body of the claim (and was not clearly added to overcome a [prior art] rejection), we do not construe it to be a separate limitation.'" *Am. Med. Sys.*, 618 F.3d at 1359 (quoting *Symantec*, 522 F.3d at 1288-89).

Here, there is no reason for the Court to depart from the general rule that the preamble is not limiting.

As explained further below, the alleged inventions of the Asserted Patents are dose counters for inhalers, and the bodies of the claims—not the preambles—provide the "essential structure" for these mechanical features. *Catalina*, 289 F.3d at 808. The preambles of Terms 1, 4, and 6, in contrast, are not "necessary to give life, meaning, and vitality" to the claims. *Id.* Rather, the preambles merely provide a descriptive name (e.g., "an inhaler") or a use ("metered dose inhalation") for the set of limitations each body. *Am. Med. Sys.*, 618 F.3d at 1359.

a. The preambles are not necessary to provide antecedent basis to the claim bodies.

The preambles do not provide antecedent basis to the body of the claim, and should not be found limiting on this basis. Claim 1 of the '289 patent, for example, is reproduced below with Term 1 emphasized.

> ’289 patent, claim 1:
> ***An inhaler for metered dose inhalation***, the inhaler comprising:
> a main body having a canister housing,
> a medicament canister, which is moveable relative to the canister housing and retained in a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister, and
> a dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister,
> wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall, and
> wherein the canister housing has a longitudinal axis X which passes through the center of the central outlet port,
> the inner wall canister support formation, the actuation member, and the central outlet port lying in a common plane coincident with the longitudinal axis X.

(Ex. 1, ’289 patent, claim 1.) Here, the body of the claim does not derive antecedent basis support from the claimed preamble. The term “an inhaler for metered dose inhalation” is found nowhere in the body of the claim. The same is true of the of claims 1 and 12 of the ’587 patent, which are the other claims where Term 1 appears. (*See* Ex. 2, ’587 patent, claims 1 and 12.)

Similarly, Terms 4 and 6 are not repeated in the body of the claims of the ’808 and ’889 patents, respectively. Claim 1 of each of these patents is reproduced below with Terms 4 and 6 emphasized.

> ’808 patent, claim 1:
> A dose counter for ***an inhaler***, the dose counter having a counter display arranged to indicate dosage information, a drive system arranged to move the counter display incrementally in a first direction from a first station to a second station in response to actuation input, wherein a regulator is provided which is arranged to act upon the counter display at the first station to regulate motion of the counter display at the first station to incremental movements.

> ’889 patent, claim 1:
> An incremental dose counter for ***a metered dose inhaler*** having a body arranged to retain a canister for movement of the canister relative thereto, the incremental dose counter having a main body,

> an actuator arranged to be driven and to drive an incremental output member in a count direction in response to canister motion, the actuator being configured to restrict motion of the output member in a direction opposite to the count direction, such that the actuator acts as an anti-back drive member when the actuator is in a non-depressed position, and wherein the incremental dose counter further comprises a second anti-back member configured to restrict motion of the output member in a direction opposite to the count direction when the actuator is disengaged from the output member by a bump surface.

(Ex. 3, '808 patent, claim 1; Ex. 4, '889 patent, claim 1.) Again, the bodies of these claims do not derive antecedent basis support from the claimed preamble. The same is true of the dependent claims of all four Asserted Patents. (*See* Ex. 1, '289 patent, claims 2-10; Ex. 2, '587 patent, claims 2-11 and 13-22; Ex. 3, '808 patent, claims 2-29; Ex. 4, '889 patent, claims 2-6.)

Thus, the preambles of Terms 1, 4, and 6 are not "necessary to provide antecedent basis for the body of the claim." *Symantec*, 522 F.3d at 1288.

b. The preambles are not patentably significant.

The preambles are also not limiting for the additional reason that their language is not patentably significant. As illustrated in the previous section, the preambles of Terms 1, 4, and 6 merely introduce the claimed structures, with the structural details coming after the "comprising" or "having" transition language.

Furthermore, the preambles here merely describe features that were already known in the art. Inhalers, including those for metered dose inhalation and those with dose counters, were known in the art. (*See, e.g.*, Ex. 1, '289 patent at 1:55-56 ("Inhalers incorporating dose counters have therefore become known."); Ex. 2, '587 patent at 1:57-58 (same); Ex. 3, '808 patent at 1:59-60 (same); Ex. 4, '889 patent at 1:59-60 (same).) There is no evidence that the preambles are patentably significant due to the patentee's reliance on preamble language to overcome prior art. *Catalina*, 289 F.3d at 809 ("[P]reamble 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."); *Am. Med. Sys.*, 618 F.3d at 1359 ("If the preamble 'is reasonably susceptible to being construed to be merely duplicative of the limitations in the body of the claim (and was not clearly added to overcome a [prior art] rejection), we do not construe it to be a separate limitation.'") (quoting *Symantec*, 522 F.3d at 1288-89).

The Term 1 preamble also describes an inhaler "for metered dose inhalation." But that language merely recites an intended use of the inhaler, which is not limiting. *Arctic Cat Inc. v. GEP Power Prod., Inc.*, 919 F.3d 1320, 1328 (Fed. Cir. 2019) ("We have long ruled that 'a preamble is not limiting where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention.") (quoting *Catalina*, 289 F.3d at 808).

Thus, for each of Terms 1, 4, and 6, the Court should find that the preambles are not limiting and do not require construction.

2. If limiting and in need of construction, the Court should adopt Amneal's proposed constructions.

To the extent the Court finds that the preamble is limiting and does require construction, it should adopt Amneal's constructions. These constructions recognize that the inventors considered the claimed inhaler to be a "device."

The specification supports Amneal's constructions. For example, when describing the state of the art of inhalers, the specification[2] repeatedly refers to inhalers as "devices":

> "It has also been found to be fairly difficult to assembly [*sic*] some known ***inhaler devices*** and the dose counters therefor." (Ex. 1, '289 patent at 2:31-33 (emphasis added).)

[2] The four Asserted Patents are in the same family and contain the same specification disclosure. For convenience, Amneal has quoted the '289 patent unless otherwise noted.

> The dose counter must not count a dose when the canister has not fired since this might wrongly indicate to the user that a dose has been applied and if done repeatedly the user would throw away the canister or ***whole device*** before it is really time to change ***the device*** due to the active drug and propellant reaching a set minimum. (Ex. 1, '289 patent at 2:20-25 (emphases added).)
>
> "In order ***to actuate a manually operable inhaler***, the user applies by hand a compressive force to a closed end of the canister and the internal components of the metering valve assembly are spring loaded so that a compressive force of approximately 15 to 30N is required ***to activate the device*** in some typical circumstances." (Ex. 1, '289 patent at 1:34-40 (emphasis added).)
>
> "Additionally, the canister must not fire without the dose counter counting because the user may then apply another dose thinking that the canister has not fired, and if this is done repeatedly the active drug and/or propellant may run out while the user thinks ***the device*** is still suitable for use according to the counter." (Ex. 1, '289 patent at 2:25-31 (emphasis added).)
>
> "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." (Ex. 1, '289 patent at 1:49-54 (emphasis added).)

(*See also* Ex. 2, '587 patent at 1:36-42, 1:51-56, 2:22-35; Ex. 3, '808 patent at 1:38-44, 1:53-58, 2:23-36; Ex. 4, '889 patent at 1:38-44, 1:53-58, 2:23-36.) From the excerpts above, it is clear that the inventors considered inhalers to be "devices."

The prosecution history provides additional support for Amneal's constructions. During prosecution, the inventors referred both to prior art inhalers and to the claimed invention as "devices." With the '289 patent, in response to an Examiner's rejection based on a prior art reference (Davies), the Applicant stated: "Accordingly, Davies' neither discloses all of the features recited in amended claim 1, nor does ***Davies' device*** confer the same benefits as ***the device that is recited in amended claim 1***." (Ex. 5, '289 patent File History Amendment under 37 C.F.R. § 1.116 at 6 (Mar. 7, 2016) (TEVAPRO_00000574 at -01580) (emphases added).) Similarly, with

the '808 patent, in response to an Examiner's rejection based on another prior art reference (O'Leary), the Applicant stated: "Applicant respectfully submits that O'Leary does not disclose ***the device of claim 1***." (Ex. 6, '808 patent File History Response to the Office Action (Mar. 15, 2017) (TEVAPRO_00001907 at -02040) (emphasis added).) Finally, with the '889 patent, in response to an Examiner's rejection based on a third prior art reference (Bowman), the Applicant stated: "[T]here would have been no motivation for ***the device of Bowman*** to be modified in such a way as to arrive at the claimed subject matter." (Ex. 7, '889 patent File History Amendment under 37 C.F.R. § 1.111 (Oct. 21, 2021) (TEVAPRO_000006442 at -06623) (emphasis added).) Again, the inventors repeatedly refer to inhalers—both in the prior art and in the claims—as "devices."

3. The Court should reject Teva's proposed constructions.

The Court should reject Teva's constructions because they are a blatant, yet unsuccessful, attempt to rewrite its claims to make "listable" patents in the Orange Book. But, just as "it is well settled that no matter how great the temptations of fairness or policy making, courts do not redraft claims" to salvage validity, *Quantum Corp. v. Rodime, PLC*, 65 F.3d 1577, 1584 (Fed. Cir. 1995), this Court should not permit Teva to redraft its claims in an attempt to salvage those patents in the Orange Book.

Teva's constructions improperly add an affirmative limitation for "an active drug" into the preamble of every claim. Teva points to no lexicography or disavowal demonstrating a "clear intention to limit the claim scope using 'words or expressions of manifest exclusion or restriction.'" *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906-07 (Fed. Cir. 2004) (quoting *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1327 (Fed. Cir. 2002)). Instead, Teva attempts to recast these constructions as "plain and ordinary" meaning. But this purported

"plain and ordinary meaning" cannot be used to import such extensive limitations into the claim preambles.

Furthermore, Teva's constructions would exclude embodiments from the specification. The specification makes clear that "an active drug" is not a necessary component of an inhaler. For example, the specification states that "[m]etered dose inhalers ***can*** comprise a medicament-containing pressurised canister containing a mixture of active drug and propellant." (Ex. 1, '289 patent at 1:27-29 (emphasis added); *see also* Ex. 2, '587 patent at 1:29-31; Ex. 3, '808 patent at 1:31-33; Ex. 4, '889 patent at 1:31-33.) The word "can" here signifies that the active drug is not required, but Teva's constructions ignore that. The specification also recognizes that the inhaler can contain an active drug or not (i.e., it can be empty):

> 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 not always available.

(Ex. 1, '289 patent at 1:49-54 (emphasis added); *see also id.* at 2:25-31 ("***the active drug and/or propellant may run out*** while the user thinks the device is still suitable for use") (emphasis added); Ex. 2, '587 patent at 1:51-56 and 2:27-33; Ex. 3, '808 patent at 1:53-58 and 2:28-34; Ex. 4, '889 patent at 1:53-58 and 2:28-34.) As illustrated above, the use of "if any" or "run out" indicates that the inventors understood that an inhaler could be empty. But under Teva's construction, once an inhaler is empty, it ceases to be an "inhaler" at all. That cannot be correct.

Teva's additional requirement that the active drug is "capable of being dispensed via the inhaler to the lungs" is found nowhere in the intrinsic record. There is no evidence in the claims, specification, or prosecution history that the inventors had actually performed the steps necessary to assess such capability with the claimed subject matter. A claim construction that embraces capabilities without support in the written description cannot be correct.

B. The Court Should Find That the Preambles of the Dose Counter Terms Are Not Limiting and Require No Construction or, Alternatively, Adopt Amneal's Constructions. (Terms 3 and 5)

Terms 3 and 5 are present in the preambles of the independent claims of the '808 and '889 patents. The table below has the competing proposed constructions of these terms.

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. Plain and ordinary meaning in view of the claims, specification, and prosecution history, which is: "A dose counter used in connection with an inhaler"	The phrase "A dose counter for 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 "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.)

The same dispute exists for both of Terms 3 and 5 (referred to herein as the "Dose Counter Terms"). This dispute is whether the word "for" in the preamble should be construed as "used in connection with" (Teva's construction) or simply remain "for," as with Term 1 (Amneal's construction).

1. The preambles are not limiting.

Terms 3 and 5 appear in the preambles of claim 1 of the '808 and '889 patents, below.

> '808 patent, claim 1:
> ***A dose counter for an inhaler***, the dose counter having a counter display arranged to indicate dosage information, a drive system arranged to move the counter display incrementally in a first direction from a first station to a second station in response to actuation input, wherein a regulator is provided which is arranged to act upon the counter display at the first station to regulate motion of the counter display at the first station to incremental movements.
>
> '889 patent, claim 1:
> ***An incremental dose counter for a metered dose inhaler*** having a body arranged to retain a canister for movement of the canister relative thereto, the incremental dose counter having a main body, an actuator arranged to be driven and to drive an incremental output member in a count direction in response to canister motion, the actuator being configured to restrict motion of the output member in a direction opposite to the count direction, such that the actuator acts as an anti-back drive member when the actuator is in a non-depressed position, and wherein the incremental dose counter further comprises a second anti-back member configured to restrict motion of the output member in a direction opposite to the count direction when the actuator is disengaged from the output member by a bump surface.

(Ex. 3, '808 patent, claim 1; Ex. 4, '889 patent, claim 1.)

Terms 3 and 5 involve the same preambles as Terms 4 and 6, discussed in Section III.A. For the same reasons discussed above with respect to Terms 4 and 6, these same preambles of Terms 3 and 5 are not limiting and do not require construction. To the extent the Court finds the preambles limiting and in need of construction, however, Amneal maintains that the same construction of an inhaler as a "device" from Terms 4 and 6 should apply to Terms 3 and 5 here.

2. The Court should reject Teva's proposed constructions.

The Court should reject Teva's construction because it improperly adds a use limitation to the claims. Specifically, by construing "for" as "used in connection with," Teva's construction

would require a specific use of the dose counter in the claims themselves. Such a construction cannot be correct because the "composition claims would mutate into method claims." *Union Oil Co. of California v. Atlantic Richfield Co.*, 208 F.3d 989, 995 (Fed. Cir. 2000) (refusing to narrow a claim to "[a]n unleaded gasoline suitable for combustion in an automotive engine" to specific uses).

C. The Court Should Find that the Canister Terms Need No Construction, or Adopt Amneal's Proposed Constructions. (Terms 2 and 7)

Terms 2 and 7 are present in claims 1 and 2 of the '289 patent (Term 2), claims 1, 2, and 12 of the '587 patent (Term 2), and claim 1 of the '889 patent (Term 7). These claims are reproduced below with the disputed terms emphasized.

> '289 patent, claim 1 (Term 2):
> An inhaler for metered dose inhalation, the inhaler comprising:
> a main body having a canister housing,
> a ***medicament canister***, which is moveable relative to the canister housing and retained in a central outlet port of the canister housing arranged to mate with a canister fire stem of the ***medicament canister***, and
> a dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the ***medicament canister***,
> wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall, and
> wherein the canister housing has a longitudinal axis X which passes through the center of the central outlet port,
> the inner wall canister support formation, the actuation member, and the central outlet port lying in a common plane coincident with the longitudinal axis X.
>
> '289 patent, claim 2 (Term 2):
> The inhaler as claimed in claim 1 wherein the ***medicament canister*** is movable relative to the dose counter.
>
> '587 patent, claim 1 (Term 2):
> An inhaler for metered dose inhalation, the inhaler comprising:
> a main body having a canister housing,
> a ***medicament canister***, which is moveable relative to the canister housing and retained in a central outlet port of the canister housing

arranged to mate with a canister fire stem of the ***medicament canister***, and
a dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the ***medicament canister***,
wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall,
wherein the canister housing has a longitudinal axis X which passes through the center of the central outlet port, and
wherein the first inner wall canister support formation, the actuation member, and the central outlet port lie in a common plane coincident with the longitudinal axis X such that the first inner wall canister support formation protects against unwanted actuation of the dose counter by reducing rocking of the ***medicament canister*** relative to the main body of the inhaler.

'587 patent, claim 2 (Term 2):
The inhaler as claimed in claim 1 wherein the ***medicament canister*** is movable relative to the dose counter.

'587 patent, claim 12 (Term 2):
An inhaler for metered dose inhalation, the inhaler comprising:
a main body having a canister housing,
a ***medicament canister***, which is moveable relative to the canister housing and retained in a central outlet port of the canister housing arranged to mate with a canister fire stem of the ***medicament canister***, and
a dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the ***medicament canister***,
wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall,
wherein the canister housing has a longitudinal axis X which passes through the center of the central outlet port, and
wherein the first inner wall canister support formation, the actuation member, and the central outlet port lie in a common plane coincident with the longitudinal axis X such that the first inner wall canister support formation protects against dose count errors by reducing rocking of the ***medicament canister*** towards or away from the actuation member.

'889 patent, claim 1 (Term 7):
An incremental dose counter for a metered dose inhaler having a body arranged to retain a ***canister*** for movement of the ***canister***

> relative thereto, the incremental dose counter having a main body, an actuator arranged to be driven and to drive an incremental output member in a count direction in response to ***canister*** motion, the actuator being configured to restrict motion of the output member in a direction opposite to the count direction, such that the actuator acts as an anti-back drive member when the actuator is in a non-depressed position, and wherein the incremental dose counter further comprises a second anti-back member configured to restrict motion of the output member in a direction opposite to the count direction when the actuator is disengaged from the output member by a bump surface.

(Ex. 1, '289 patent at claims 1 and 2 (emphases added); Ex. 2, '587 patent at claims 1, 2, and 12 (emphases added); Ex. 4, '889 patent at claim 1 (emphases added).)

The table below has the competing proposed constructions of these terms.

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 same dispute exists for both of Terms 2 and 7 (referred to herein as the "Canister Terms"). Specifically, the parties dispute whether the claimed canister must contain an active drug

with specific capabilities (Teva's construction), or whether that is optional (Amneal's construction).

Teva's proposed construction is yet another attempt to inject an "active drug" requirement somewhere into the in the claims. The Court should reject this attempt as well.

1. If construed, the Court should adopt Amneal's construction.

Terms 2 and 7 are directed to the "medicament canister" and the "canister" themselves, not their contents. Thus, the Court need not construe these terms to define the contents of the canisters. Indeed, both parties' proposed constructions repeat the word "canister" in them. Accordingly, Amneal submits that these terms do not require construction.

A "medicament" canister merely describes a purpose of how the container can be used. It does not necessitate the presence of "medicament." A claim limitation to a "water bottle" would be directed to the bottle itself, not its contents. Likewise, the claims here are directed to the "medicament canister" itself. In other words, the word "medicament" merely describes the type of "canister." Indeed, Teva's constructions for both "medicament canister" and "canister" are identical, indicating that the word "medicament" itself does no more than describe a type of "canister" here.

The intrinsic record makes clear that the contents inside the canister are not part of the claimed invention. The claims do not describe the contents of the canister, but they do describe how the canister interacts with the other structural components in the claims. For example, claim 12 of the '587 patent describes a structural configuration where "the first inner wall canister support formation protects against dose count errors by ***reducing rocking of the medicament canister towards or away from the actuation member***." ('587 patent, claim 12.) This "reduc[ed] rocking" of the medicament canister has nothing to do with the contents of the canister. Indeed,

neither the claims nor the specifications give a single example of "an active drug" to be used in the canister.

The specification further recognizes that an inhaler can be empty, where no active drug or propellant is left in the canister. As discussed above with respect to Terms 1, 4, and 6, the specification states:

> 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 not always available.

(Ex. 1, '289 patent at 1:49-54 (emphasis added); *see also id.* at 2:25-31 ("***the active drug and/or propellant may run out*** while the user thinks the device is still suitable for use") (emphasis added); Ex. 2, '587 patent at 1:51-56 and 2:27-33; Ex. 4, '889 patent at 1:53-58 and 2:28-34.) From the above passages, it is clear that an inhaler—and therefore its canister—need not always contain an active drug.

2. The Court should reject Teva's proposed constructions.

Yet again, Teva improperly tries to import several limitations into the claims under the guise of claim construction. The plain and ordinary meaning of a "canister" cannot depend on its contents. Teva's construction, however, would do just that. Under Teva's construction, if a canister is or becomes empty, that structure would cease to exist as a "canister." Such a construction makes little sense. Furthermore, Teva's additional requirement that the active drug is "capable of being dispensed via the inhaler to the lungs" also presents the same problems discussed above with respect to Terms 1, 4, and 6 in Section III.A.3.

IV. 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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