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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

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

PLAINTIFFS' OPENING CLAIM CONSTRUCTION BRIEF

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I. INTRODUCTION

This is a Hatch-Waxman case. Plaintiff Teva holds patents listed in the Orange Book covering Teva's metered dose inhaler product ProAir® HFA (albuterol sulfate) Inhalation Aerosol. Defendants submitted Abbreviated New Drug Application ("ANDA") No. 211600 seeking to market a generic version of Teva's ProAir® HFA product prior to the expiration of Teva's Orange-Book-listed patents. On the basis of the ANDA filing, Teva sued Defendants for patent infringement and the parties dispute claim terms in four patents asserted against Defendants.

The claim construction dispute in this case concerns whether the asserted claims—which expressly recite an "inhaler," "medicament canister," or the like—require the presence of an active drug (as Teva argues) or claim only the device with no active drug (as Defendants argue). The claim language, specifications, and other intrinsic evidence compels the conclusion that an active drug is required. Indeed, without that requirement, the very premise of the inventions, which is based on accurately counting doses of the drug, would make no sense.

To avoid that ineluctable conclusion, Defendants argue that five of the seven disputed terms do not require construction because they are part of the preamble of the claims and not limiting. In the alternative, Defendants propose constructions for these terms that consist entirely of improperly rewriting the claims to add the word "device" to the disputed term. But Defendants' proposed constructions are directly

at odds with the intrinsic record and should be rejected. By contrast, Teva's proposed constructions stay true to the claim language and adhere to the tenets of claim construction. Accordingly, Teva respectfully requests the Court adopt Teva's proposed constructions.

II. BACKGROUND

The four Asserted Patents[1] cover Teva's metered dose inhaler ("MDI") product ProAir® HFA, which is approved by FDA to treat bronchospasm including asthma. ProAir® HFA was originally approved by FDA on October 29, 2004, as a "pressurized metered-dose aerosol unit for oral inhalation . . . contain[ing] . . . albuterol sulfate." *See* Ex. 5 (10/2004 ProAir® HFA Label). The original ProAir® HFA MDI approved in 2004 did not contain an integrated dose counter. *See id.* Based on the need in the art and FDA's recommendation to add a dose counter to the ProAir® HFA MDI, Teva invented an accurate and robust dose counter for integration with the albuterol sulfate MDI. Since 2012, Teva has marketed ProAir® HFA with a dose counter, including the branded and authorized generic products. *See* Ex. 6 (03/2012 ProAir® HFA Label).

[1] Teva is currently asserting claims of 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"). Each of the four Asserted Patents share the same specification. On February 28, 2024, Teva provided Defendants its Disclosure of Asserted Claims Pursuant to L. Pat. R. 3.6(b) and identified no claims from U.S. Patent No. 8,132,712.

In general, MDIs contain a pressurized canister of medicament (i.e., an active drug) that fits into a plastic body with a mouthpiece. In one configuration, when the patient pushes down on the medicament canister, it causes the canister to dispense a pre-determined amount of medicament, which the patient then inhales through the mouthpiece into the lungs. As an example, the patents' Fig. 1 depicts the inhaler body (10) with a mouthpiece (16), and Fig. 7A depicts a canister (20) inside the inhaler body (highlighting added).

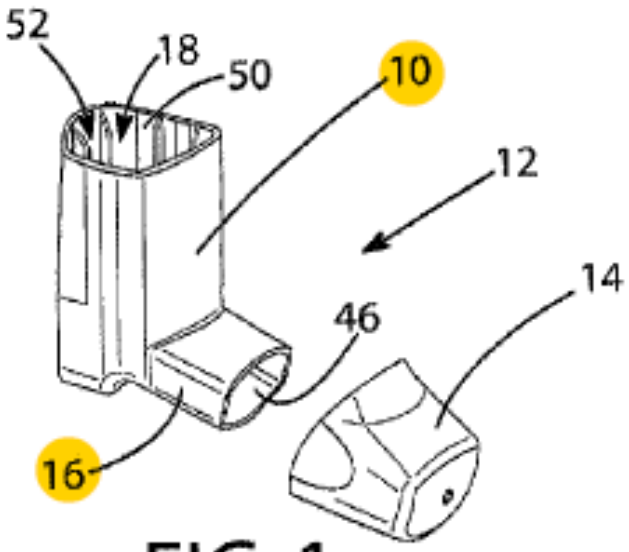

FIG. 1

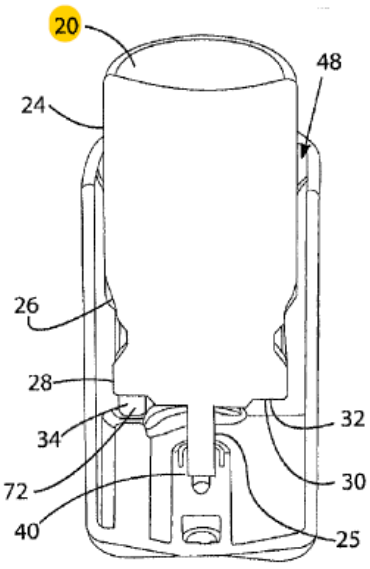

FIG. 7A

The canister in an MDI typically contains many doses of an inhalation medicament. For example, the ProAir® HFA MDI contains 200 doses per canister. Unlike patients taking tablets from a bottle, patients using MDIs cannot simply look at their inhaler and see how much drug remains. This presents a dilemma in which "patients must guess how many doses are left in their MDIs," leaving them with

"two practical options: (1) throw away an MDI that may still contain acceptable metered-doses or (2) use a product when it may be beyond the recommended number of doses and risk not receiving the correct drug dose." Ex. 7 (FDA Guidance for Industry: Integration of Dose-Counting Mechanisms into MDI Drug Products ("2003 FDA Guidance")) at 2. The former option is wasteful. As for the latter, the consequences of mistakenly believing that an inhaler contains additional doses is dangerous, as the patient believes they are receiving the necessary drug but in fact are not.

Recognizing this risky situation for patients, FDA issued guidance in 2003 recommending that "manufacturers with metered-dose inhalers under development for oral inhalation integrate a dose-counting device into the development of their MDI drug product." Ex. 7 (2003 FDA Guidance) at 3. FDA specified that "[t]he recommendations in this guidance address primarily MDI products designed to deliver drugs to the lungs for any indication," like Teva's ProAir® HFA product. *Id.* at 2. "This is because the consequences of not receiving an acceptable metered dose are more clinically important for oral inhalation drug products than for the current medications available in nasal MDIs. Medications delivered to the lungs often play a vital role in the treatment of airway diseases and are potentially life-saving." *Id.*

As such, dose counters must be scrupulously accurate. The force and

movement necessary to administer a dose of the drug must match the force and movement necessary to advance the dose counter. Moreover, the design must ensure that the dose counter does not "count" when no dose of the drug is delivered. An inaccurate dose counter is worse than no dose counter at all, since it provides the patient with a false sense of security. Thus it is critical to have a dose counter that records accurately every dose expended and does not increment inadvertently (e.g., when jostled). *See, e.g.*, '289 patent at 1:27-2:37.

As explained more below, the parties dispute the following seven claim terms from the four Asserted Patents:

- "An inhaler for metered dose inhalation" ('289 patent, claim 1; '587 patent, claims 1, 12)
- "medicament canister" ('289 patent, claims 1, 2; '587 patent, claims 1, 2, 12)
- "A dose counter for an inhaler" ('808 patent, claim 1)
- "an inhaler" ('808 patent, claim 1)
- "An incremental dose counter for a metered dose inhaler" ('889 patent, claim 1)
- "a metered dose inhaler" ('889 patent, claim 1)
- "canister" ('889 patent, claim 1)

The parties have also reached agreement with respect to the construction of fifteen claim terms. *See* D.E. 111-1 (Joint Claim Construction and Prehearing Statement ("JCCS")) at 3-5.

III. LEGAL STANDARDS

Claim construction is the process by which the Court gives legal effect to the meaning of the claims. *See Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 321-22 (2015). "It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (quotation marks and citation omitted). "[T]he words of a 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." *Id.* at 1312-13 (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)).

When construing the claims of a patent, courts consider a series of sources: the express language of the claims, the patent specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 977-80 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996); *Phillips*, 415 F.3d at 1314. Courts "should look first to the intrinsic evidence of record," which includes the claim language, the patent specification, and the prosecution history. *Vitronics*, 90 F.3d at 1582.

"[T]he claims themselves provide substantial guidance as to the meaning of

particular claim terms." *Phillips*, 415 F.3d at 1314. Indeed, "the context in which a term is used in the asserted claim can be highly instructive." *Id.*

"A [claim] preamble is generally construed to be limiting if it recites essential structure or steps, or if it is necessary to give life, meaning, and vitality to the claim." *Proveris Sci. Corp. v. Innovasystems, Inc.*, 739 F.3d 1367, 1372 (Fed. Cir. 2014) (quotation marks and citation omitted). The inquiry of whether the preamble is limiting involves "examination of the entire patent record to determine what invention the patentee intended to define and protect." *Rowe v. Dror*, 112 F.3d 473, 478 (Fed. Cir. 1997) (finding phrase in the claim preamble limiting because it provided "structural limitations" for the claimed invention). Other factors indicative of the preamble being limiting include (i) "when the preamble is essential to understand limitations or terms in the claim body," (ii) "dependence on a particular disputed preamble phrase for antecedent basis," and (iii) "clear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art." *Catalina Mktg. Int'l v. Coolsavings.com, Inc.*, 289 F.3d 801, 808-09 (Fed. Cir. 2002); *see also Lemoine v. Mossberg Corp.*, No. 2020-2140, 2021 WL 4199934, at *2 (Fed. Cir. Sept. 15, 2021) (affirming district court's determination finding preamble limiting, in part, "because it provides important context for the nature and structure of the invention being claimed, and that without the context provided by the preamble it is difficult to make sense of the claims").

After reviewing the words of the claim, the specification "is the single best guide to the meaning of a disputed term." *Phillips*, 415 F.3d at 1315 (quoting *Vitronics*, 90 F.3d at 1582). "[T]he specification is always highly relevant to the claim construction analysis" and "[u]sually, it is dispositive." *Id.* (quotes omitted). "In addition to consulting the specification, . . . a court 'should also consider the patent's prosecution history.'" *Id.* at 1317 (quoting *Markman*, 52 F.3d at 980). Furthermore, a "court will need to look beyond the patent's intrinsic evidence and to consult extrinsic evidence in order to understand, for example, the background science or the meaning of a term in the relevant art during the relevant time period." *Teva Pharms.*, 574 U.S. at 331.

IV. ARGUMENT

A. "An inhaler for metered dose inhalation" ('289 patent, claim 1; '587 patent, claims 1, 12)

Teva's Proposed Construction	Defendants' Proposed Construction
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"

The parties' dispute is two-fold. The parties dispute (1) whether this claim

phrase in the preamble is limiting (bold italics below) and (2) if so, the proper construction of this claim phrase. Claim 1 of the '289 patent and claim 1 of the '587 patent are representative for the disputed phrase and recite the following:

'289 Patent Claim 1

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.

'587 Patent Claim 1

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,
>
> 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.[2]

First, the disputed claim phrase is limiting for several reasons explained below, including because the phrase "recites essential structure" and "is necessary to give life, meaning, and vitality to the claim." *Proveris*, 739 F.3d at 1372 (citation omitted). Second, turning to the proper construction, consistent with the intrinsic and extrinsic record, an "inhaler for metered dose inhalation" would be understood to include an active medicine, and so this phrase should be construed as "An inhaler for metered dose inhalation containing an active drug capable of being dispensed via the inhaler to the lungs." Defendants' proposal to explicitly limit the inhaler to just

[2] Claim 12 of the '587 patent has the same language as claim 1, except the final clause which recites the following: "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."

the "device" (with no medicine) is inconsistent with both the intrinsic record and common meaning of the term. The Court should find this phrase in the preamble limiting and adopt Teva's proposed construction.

1. The disputed phrase in the preamble is limiting

The disputed claim phrase "An inhaler for metered dose inhalation" recites essential structure for the claimed invention and gives life, meaning, and vitality to the claims. *Proveris*, 739 F.3d at 1372. The preamble specifies that the claimed invention must be an inhaler for metered dose inhalation, which "provides important context for the nature and structure of the invention being claimed." *Lemoine*, 2021 WL 4199934, at *2. The preamble provides essential structure by requiring an inhaler. Indeed, the claimed invention is not a structurally complete invention without the preamble. *Rowe*, 112 F.3d at 478. If the preamble was not limiting, then these claims would require some (but not all) parts of an inhaler—e.g., "a medicament canister," "a dose counter," etc.—but not a complete inhaler or the inhaler itself. This would contravene Federal Circuit precedent and common sense. This holds true for the dependent claims as well. If these independent claims did not require the inhaler itself, the dependent claims would require some parts of an inhaler without the corresponding structure of the inhaler. *See, e.g.*, '289 patent, claim 2 ("The inhaler as claimed in claim 1 wherein the medicament canister is movable relative to the dose counter."). The preamble in the independent claims thus also

provides essential structure for the respective dependent claims.

Moreover, the specification emphasizes the importance of the essential structure of the inhaler, further supporting that the preamble (in which the term "inhaler" appears) is limiting.[3] *See Catalina*, 289 F.3d at 808 ("[W]hen reciting additional structure or steps underscored as important by the specification, the preamble may operate as a claim limitation."). The specification repeatedly discloses that the claimed invention ***is*** an "inhaler" incorporating a dose counter that provides accurate dose counting, which alleviates problems in the prior art concerning inhalers. *See, e.g.*, '289 patent at 1:25-2:37. For instance, the specification states that "[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." *Id.* at 1:49-54 (emphasis added). Additionally, the specification states that given problems with known "[i]nhalers incorporating dose counters . . . it has become desirable to improve dose counters further and, in particular, it is felt that it would be useful to provide extremely accurate dose counters for manually-operated canister-type metered dose inhalers." *Id.* at 1:59-60, 2:9-12. "If the preamble was

[3] For terms appearing in both the '289 and '587 patents, citations to the common specification of these patents refer to the '289 patent. Identical disclosures appear in the '587 patent.

not limiting, these disclosures would be rendered meaningless." *Lemoine*, 2021 WL 4199934, at *2.

The preamble is also limiting because it provides important context to understand the terms in the claim body. *Catalina*, 289 F.3d at 808 ("[W]hen the preamble is essential to understand limitations or terms in the claim body, the preamble limits claim scope."). The preamble makes clear that the claimed elements are incorporated into an "inhaler." If the preamble was not limiting, the claims would read as if the structural elements could be incorporated into ***any*** type of apparatus—not just an "inhaler"—which is contrary to the intrinsic record. Moreover, as explained below, the preamble provides important context that the "medicament canister" in the body of these claims contains active drug that is capable of being dispensed via the inhaler to the lungs. The preamble also provides important context that the "dose counter" in the body of these claims is counting doses of active drug remaining in the medicament canister after each use of the inhaler (i.e., after each time the medicament canister fires medicament).

Additionally, the preamble is limiting because it provides antecedent basis for the body of claim 1 of the '587 patent. *Catalina*, 289 F.3d at 808 ("[D]ependence on a particular disputed preamble phrase for antecedent basis may limit claim scope . . . ."). As noted above, the preamble is relied on to provide essential structure to the asserted claims of the '289 and '587 patents by requiring the inhaler itself. The

preamble in claim 1 of the '587 patent also provides antecedent basis for "the inhaler" referenced in the last clause of that claim. *See* '587 patent, claim 1 ("***An inhaler for metered dose inhalation***, ***the inhaler*** comprising . . . 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***." (emphasis added)). "[T]he" inhaler in the body of the claim is a reference to "[a]n" inhaler in the preamble, and demonstrates that the preamble provides antecedent basis. *See Catalina*, 289 F.3d at 808; *Proveris*, 739 F.3d at 1372-73 ("The phrase 'the image data' clearly derives antecedent basis from the 'image data' that is defined in greater detail in the preamble.").

Finally, the prosecution history further confirms that the preamble is limiting. In response to a Final Office Action, Teva emphasized that the claimed invention is functionally better than the examiner's suggestion because the examiner's suggestion "would increase the airflow resistance of the inhaler and could affect the ability of users with reduced lung function . . . to draw air through the inhaler and inhale medicament effectively." Ex. 8 (File History, U.S. Patent App. No. 14/103,324, Mar. 7, 2016 Resp.) at 6-7. Teva relied on the features and benefits of "the inhaler" in the preamble as patentably significant to distinguish the examiner's grounds for rejection. Accordingly, the preamble is limiting for this additional reason. *Catalina*, 289 F.3d at 808 ("[C]lear reliance on the preamble during

prosecution to distinguish the claimed invention from the prior art transforms the preamble into a claim limitation because such reliance indicates use of the preamble to define, in part, the claimed invention.").

2. Teva's proposed construction is consistent with the intrinsic and extrinsic record

As for the construction of the disputed phrase, the parties dispute whether "an inhaler for metered dose inhalation" requires an active drug. Defendants' proposal limits the term to just the "device," proposing to read that term into the construction. But the same record that confirms the preamble is limiting supports Teva's proposed construction, which requires an active drug.

The plain meaning of the claim language supports Teva's proposed construction. *See Phillips*, 415 F.3d at 1314. Starting with the disputed claim language itself, "An inhaler for metered dose inhalation" requires an active drug capable of being dispensed via the inhaler to the lungs. The common meaning of "inhaler" requires the presence of an active drug. The definitions of the terms "inhaler" and "inhalation" from a technical dictionary during the relevant time are illustrative. Merriam-Webster's Medical Desk Dictionary (2005) defines "inhaler" as "a device by means of which usu[ally] medicinal material is inhaled." Ex. 9 (Medical Desk Dictionary (2005)) at 397. This technical dictionary defines "inhalation" as "the action of drawing air into the lungs . . ." and "material (as medication) to be taken in by inhaling." *Id.* at 396. The common meaning, as

exemplified by these dictionary definitions, confirms Teva's proposed construction that the inhaler contains medicinal material that is drawn into the lungs through the inhaler.

So too do other terms in the claims. For example, the term "dose" indicates a measured quantity of active drug. Similarly, as discussed further below, a "medicament canister" is part of the inhaler, and contains a "medicament" or drug. The requirement of a "dose counter" would likewise make little sense if there were no drug to be dosed such that the number of doses can be counted. The same is true of the parties' agreed-upon constructions. The parties have agreed that the term "main surface of the inner wall" ('289 patent, claim 1; '587 patent, claims 1, 12) should be construed to mean "inside surface of the vertical cylindrical portion of the inhaler body, 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***." D.E. 111-1 (JCCS) at 3-4 (emphasis added). The inhaler must contain a medicament for it to be expelled when the inhaler is used. The parties have also agreed that the terms (i) "protects against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler" and (ii) "protects against dose count errors by reducing rocking of the medicament canister towards or away from the actuation member" should be construed to incorporate the concepts of "unwanted incrementing (or decrementing)

of the dose counter" or "fir[ing]" (or not) of the inhaler—concepts that make no sense unless the inhaler contains an active drug that is released when the inhaler is fired. *Id.* at 5. The words of the claims thus support Teva's proposed construction.

The specification further confirms Teva's proposed construction. The specification repeatedly describes the "inhaler" as containing an active drug. "Metered dose inhalers can comprise a medicament-containing pressurised canister containing a mixture of active drug and propellant." '289 patent at 1:27-29. The specification describes that a feature of such inhalers is that they are "manually operable" in that "the user applies by hand a compressive force to a closed end of the canister," which must be "sufficient to actuate the metering valve and cause a metered quantity of the drug and the propellant to be expelled through the valve stem." *Id.* at 1:34-45. This design is "potentially hazardous" because if the user cannot determine how much "active drug" is "left," "dosing becomes unreliable." *Id.* at 1:49-54. The specification goes on to describe that the claimed invention is an inhaler incorporating a dose counter that provides extremely accurate dose counting, which alleviates problems in the prior art concerning inhalers. *See, e.g.*, '289 patent at 1:25-2:37. In particular, the claimed inhaler addressed the difficulty of accurately determining how much active drug remains in the inhaler. *Id.* Simply put, an "inhaler" without an active drug is not an "inhaler."

Consistent with the common meaning of the terms, the specification explains

that the inhaler contains an active drug capable of being dispensed via the inhaler to the lungs. The specification refers to inhalers incorporating dose counters that are known in the art, including EP-A-1486227 ("EP '227").[4] These cited references also support construing the claimed inhaler to require the presence of an active drug for administration by inhalation to the lungs. For example, in the "Background of the Disclosure," the cited EP '227 refers to dispensing the drug to the lungs: "[m]etered dose medicament inhalers are well known for dispensing medicament to the lungs of a patient, for treating asthma for example." Ex. 10 (EP '227) at 1:24-26. The specification also explains that the inhaler dispenses the drug for inhalation. For instance, the specification states that "[t]he user can, when readying the inhaler 12 for first use, prime the inhaler by depressing the canister . . . [to] indicat[e] that 200 doses are remaining to be dispensed from the canister 20 and inhaler 12." '289 patent at 17:4-10; *see also id.* 20:14-17 (referring to "dispensing" the "medicament in metered doses for patient inhalation").

The prosecution history likewise supports Teva's proposed construction. As noted above, during prosecution, Teva distinguished its claimed design over the examiner's suggestion by highlighting how the claimed inhaler improved the ability of users "to draw air through the inhaler and inhale medicament effectively." Ex. 8

[4] These cited references were also submitted to the PTO during the prosecution of these patents. *See, e.g.*, Ex. 11 (File History, U.S. Patent App. No. 14/103,324, Dec. 11, 2013 Information Disclosure Statement).

(File History, U.S. Patent App. No. 14/103,324, Mar. 7, 2016 Resp.) at 6-7. This statement evidences that the claimed inhaler contains active drug that is effectively inhaled through the inhaler by the user.

The meaning of the disputed claim term from the intrinsic evidence is in accordance with the extrinsic evidence. *Teva Pharms.*, 574 U.S. at 331 (sometimes, a "court will . . . consult extrinsic evidence in order to understand, for example, the background science or the meaning of a term in the relevant art during the relevant time period"). For example, the FDA Guidance on dose counters makes clear that an inhaler contains a drug for inhalation into the lungs: "MDIs [Metered Dose Inhalers] represent a reliable, convenient dosing device for delivery of medications to the lungs." Ex. 7 (2003 FDA Guidance) at 2. As noted above, dictionaries similarly provide definitions requiring the presence of an active ingredient in an inhaler. Accordingly, a POSA would understand the claim term "An inhaler for metered dose inhalation" to require an active drug capable of being dispensed via the inhaler to the lungs in view of the intrinsic and extrinsic record.

B. "medicament canister" ('289 patent, claims 1, 2; '587 patent, claims 1, 2, 12)

Teva's Proposed Construction	Defendants' Proposed Construction
Plain and ordinary meaning in view of the claims, specification, and prosecution history, which is:	No construction necessary. Plain and ordinary meaning, i.e., "a canister for medicament"

Teva's Proposed Construction	Defendants' Proposed Construction
"a canister containing an active drug capable of being dispensed via the inhaler to the lungs"	

The parties dispute the plain and ordinary meaning of the term "medicament canister." Defendants contend that no construction is necessary and that the term should be construed to essentially mean the disputed phrase itself but by changing the claim language (i.e., "a canister for medicament"). Teva's proposed construction construes this term according to its plain terms as understood by a POSA in view of the claims, specification, and prosecution history, and thus should be adopted.

Teva's construction reflects the plain meaning of the claim language. The disputed term "medicament canister" itself indicates that the canister contains a medicament (i.e., an active drug). The surrounding claim language further supports Teva's proposed construction. *See Phillips*, 415 F.3d at 1314 ("[T]he context in which a term is used in the asserted claim can be highly instructive."). The preamble to these claims requires "An inhaler for metered dose inhalation." Teva's proposed construction reflects that the active drug is capable of being dispensed via the inhaler and that it is inhaled to the lungs. Indeed, Defendants have agreed that other claim terms require the medicament canister to contain a medicament. As noted above, the parties have agreed on the construction of the claim term "main surface of the inner wall" as meaning "inside surface of the vertical cylindrical portion of the

inhaler body, 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***." D.E. 111-1 (JCCS) at 3-4 (emphasis added). Defendants' agreement that the medicament canister will "expel medicament" necessarily requires that the canister contains a medicament.

The other surrounding claim language also supports Teva's proposed construction. For instance, these independent claims specify that the medicament canister has a "canister fire stem"—a stem for firing active drug from the canister. These claims further require "a dose counter . . . for operation by movement of the medicament canister"—a dose counter that counts the doses of the active drug that remain in the medicament canister. These other claim terms confirm Teva's construction.

The specification likewise supports the plain meaning of the claims. *See Phillips*, 415 F.3d at 1315. The specification repeatedly refers to the claimed medicament canister as containing an active drug capable of being dispensed via the inhaler to the lungs. *See, e.g.*, '289 patent at 1:25-2:37, 4:59, 7:26-35, 7:61-8:4, 8:28-31, 12:13-37, 14:50-59, Fig. 7A, Fig 10D. For instance, with respect to Fig. 7A (pictured above), the specification describes that "[t]he valve stem block 40 has a passageway 42 leading to a nozzle 44 for directing ***the contents of the canister 20, namely active drug and propellant***, towards an air outlet 46 of the inhaler main body

12." *Id.* at 12:13-37, Fig. 7A (emphasis added). With respect to Fig. 10D, the specification describes that "the metered dose valve . . . inside the canister has at this very position fired in order to eject active drug and propellant through the nozzle." *Id.* at 14:50-53, Fig. 10D.

The specification's description of the "Background of the Invention" provides additional support for Teva's proposed construction. The specification states that "[m]etered dose inhalers can comprise a medicament-containing pressurised canister containing a mixture of active drug and propellant." '289 patent at 1:25-29. That description is consistent with the disclosures of the references cited in that section of the specification. As noted above, the specification refers to inhalers incorporating dose counters that are known in the art, including EP '227 and WO 2008/119552 ("WO '552").[5] These cited references further support construing the claimed medicament canister to require the presence of an active drug for administration by inhalation to the lungs. For example, the cited WO '552 states that "Such metered-dose inhalers typically comprise a medicament-containing vessel and an actuator body having a drug delivery outlet. The medicament-containing vessel may be a pressurised canister containing a mixture of active drug and propellant." Ex. 12 (WO '552) at 1:16-21; *see also id.* at 13:28-29 ("The medicament may be any medicament that is suitable to be delivered to a patient via

[5] As noted above, these references were submitted to the PTO during prosecution.

a metered-dose inhaler.").

Finally, Teva's construction is also consistent with the prosecution history. The active drug in the inhaler will necessarily be in the medicament canister. As explained above, Teva emphasized during prosecution that the design of its claimed inhaler improved the ability of users "to draw air through the inhaler and inhale medicament effectively." Ex. 8 (File History, U.S. Patent App. No. 14/103,324, Mar. 7, 2016 Resp.) at 6-7. Improving the ability of users to inhale medicament effectively is particularly important for users with reduced lung function. *Id.* For the users to inhale medicament effectively, the medicament canister in the inhaler must contain an active drug capable of being dispensed via the inhaler to the lungs.

While Defendants suggest that "no construction is necessary," they then propose a construction of "a canister for a medicament." Defendants appear to be suggesting that the canister is appropriate for a medicament, but need not necessarily have a drug within the canister. There is no support for such a construction. As outlined above, the words of the claims, the specification, and the prosecution history all make plain that the claimed medicament canister contains an active ingredient—and it is one that can be administered to the lungs through inhalation. Defendants' attempt to construe the term "medicament canister" to include an empty canister that could, but need not, be filled with a drug should be rejected.

In view of the claims, specification, and prosecution history as a whole, a

POSA would understand the plain and ordinary meaning of the term "medicament canister" to mean a canister containing an active drug capable of being dispensed via the inhaler to the lungs.

C. "A dose counter for an inhaler" ('808 patent, claim 1)

"an inhaler" ('808 patent, claim 1)

Teva's Proposed Construction	Defendants' Proposed Construction
"A dose counter for an inhaler" 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"	"A dose counter for 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"
"an inhaler" 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"	"an inhaler" 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"

The parties dispute two phrases from the preamble of claim 1 of the '808 patent: (i) "A dose counter for an inhaler" (bold italics below) and (ii) "an inhaler"

(underlined below). As with the first disputed term, the parties dispute (1) whether these claim phrases in the preamble are limiting and (2) if so, the proper construction of each. Claim 1 of the '808 patent recites the following:

> 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.

The Court should find these phrases in the preamble limiting for several reasons, including because the preamble "recites essential structure" and "is necessary to give life, meaning, and vitality, to the claim." *Proveris,* 739 F.3d at 1372 (citation omitted). As for the proper constructions of these phrases, Defendants' proposal is to improperly add the word "device" to both disputed claim phrases (like they have done for three other disputed terms). Teva's proposed constructions are consistent with the intrinsic and extrinsic record, and therefore should be adopted.

1. The disputed phrases in the preamble of the '808 patent are limiting

The disputed claim phrases in the preamble are limiting for several separate reasons. These phrases recite essential structure for the claimed invention and give life, meaning, and vitality to the claims. *Proveris,* 739 F.3d at 1372. The preamble—"A dose counter for an inhaler"—specifies that the claimed dose counter

requires an inhaler. This provides important context for the nature of the invention being claimed. *See Lemoine*, 2021 WL 4199934, at *2. Indeed, the claimed invention is a dose counter for an inhaler, not a dose counter for anything else. For example, the claimed invention does not cover a dose counter for an autoinjector. As such, the preamble gives essential structure and meaning to the claims.

Moreover, the preamble is limiting because the preamble "recit[es] additional structure . . . underscored as important by the specification." *Catalina*, 289 F.3d at 809. The specification repeatedly discloses that the claimed invention is a dose counter for an inhaler, which addressed problems in determining how much active drug was left in the inhaler. *See, e.g.*, '808 patent at 1:30-2:40. For instance, in the "Field of the Invention," the specification states that "[t]he present invention relates to dose counters for inhalers" and that the invention is particularly applicable to several types of inhalers. *Id.* at 1:23-27; *see also id.* at 2:44-53; 10:48-58. The specification further states that given problems with known "[i]nhalers incorporating dose counters . . . it has become desirable to improve dose counters further and, in particular, it is felt that it would be useful to provide extremely accurate dose counters for manually-operated canister-type metered dose inhalers." *Id.* at 1:59-60, 2:9-13. If the preamble was not found limiting, "these disclosures would be rendered meaningless." *Lemoine*, 2021 WL 4199934, at *2.

The preamble is also "essential to understand limitations [and] terms in the

claim body." *Catalina*, 289 F.3d at 808. The preamble is essential to understanding that the dose-counter elements claimed in the claim body are to be used in connection with an inhaler. For example, the preamble provides important context that the "counter display arranged to indicate dosage information" in the body of the claim is counting and indicating the doses of active drug remaining in the inhaler after each use (i.e., after each time the inhaler fires medicament). Similarly, the preamble is essential to understanding that the "drive system arranged to move the counter display . . . in response to actuation input" in the claim body moves the counter display in response to input from the patient using the inhaler to fire active drug. Because the preamble adds structure to the claims and is necessary to understand the body of the claims, it is limiting.

2. Teva's proposed constructions are consistent with the intrinsic and extrinsic record

Turning to the disputed constructions, as with the other patents, Defendants dispute whether these terms require the presence of an active drug. Teva's proposed constructions reflect the plain meaning of these terms and should be adopted.

a. "A dose counter for an inhaler"

As for the term "A dose counter for an inhaler," Defendants have not proposed a construction that contests that the claimed dose counter is "for"—or, requires the presence of—an inhaler. Instead, Defendants propose to explicitly limit the "inhaler" portion the preamble to an "inhaler device" (with no medicine). Teva's

proposed construction for this term is consistent with the intrinsic and extrinsic record—the plain meaning of "for" in the preamble means "used in connection with." In other words, the claim phrase "A dose counter for an inhaler" requires the presence of an inhaler.

The plain meaning of the claim language requires an inhaler to be present. *See Phillips*, 415 F.3d at 1314. The preamble itself states that the claimed invention is "A dose counter ***for*** an inhaler." The preamble limits the claimed dose counter to be used in connection with an inhaler, not any other drug delivery mechanism. The specification further confirms the plain meaning of this claim phrase. The same record from the specification that confirms the preamble is limiting supports Teva's proposed construction. For instance, the specification discloses that the claimed invention is a dose counter to be used in connection with an inhaler. *See, e.g.*, '808 patent at 1:23-27 ("The present invention relates to dose counters for inhalers . . . ."). *id.* at 2:44-53 ("According to a first aspect of the present invention there is provided a dose counter for an inhaler . . . ."); *id.* at Title ("Dose Counter for Inhaler Having an Anti-Reverse Rotation Actuator."). The specification does not disclose the claimed dose counter being used in connection with anything other than an inhaler.

Dictionary definitions of the word "for" further confirm the plain meaning from the intrinsic record. For instance, Webster's Third New International Dictionary of the English Language Unabridged ("Webster's Unabridged 2002")

defines "for" as "used as a function word to indicate the person or thing that something is to be . . . used by or in connection with." Ex. 13 (Webster's Unabridged 2002) at 886; *see also* Ex. 14 (Merriam-Webster's Collegiate Dictionary (11th ed. 2007)) at 488 (defining "for" as "used as a function word to indicate purpose"). The common meaning of "for" demonstrated by these dictionary definitions confirms Teva's proposed construction that the claimed dose counter requires an inhaler.

b. "an inhaler"

Turning to the construction of "an inhaler," Defendants take the same approach as they did for the disputed phrase of the preamble for the '289 and '587 patents. Defendants propose limiting the inhaler to "an inhaler device" without drug. Defendants' proposal is contrary to the intrinsic and extrinsic record. Teva's proposed construction—"an inhaler containing an active drug capable of being dispensed via the inhaler to the lungs"—reflects the plain meaning of this term.

The plain meaning of the claim language supports Teva's proposed construction. As explained above with respect to the disputed preamble phrase from the '289 and '587 patents, the common meaning of "inhaler" requires the presence of an active drug. *See supra* pp. 15-16 (discussing Merriam-Webster's Medical Desk Dictionary (Ex. 9) at 396-97). The other claim terms in the '808 patent likewise support Teva's proposed construction. The term "a counter display arranged to indicate dosage information" refers to the display indicating the number

of doses of active drug remaining in the inhaler. Without active drug to be dosed, the term "indicat[ing] dosage information" would make little sense. So too with the phrase "regulate motion of the counter display"—which makes no sense unless the counter display indicates the number of doses remaining.

The specification further confirms the plain meaning of this claim term. The '808 and '289 patents share a common specification. Accordingly, the same support from the specification supporting Teva's proposed construction for "An inhaler for metered dose inhalation" in the '289 patent applies equally here with respect to the same proposed construction for "an inhaler" in the '808 patent. *See supra* pp. 15-19. For instance, the specification of the '808 patent repeatedly refers to the inhaler as containing an active drug. *See, e.g.*, '808 patent at 1:31-33, 1:53-55, 12:28-31. The specification further describes that the claimed invention improved dose counters for inhalers to address the difficulty of accurately determining how much active drug remains in the inhaler. *Id.* at 1:53-2:40.

Lastly, the meaning of the disputed term "an inhaler" from the intrinsic evidence is in accordance with the extrinsic evidence. *See Teva Pharms.*, 574 U.S. at 331. For example, the FDA Guidance on dose counters makes clear that an inhaler contains a drug for inhalation into the lungs. *See* Ex. 7 (2003 FDA Guidance) at 2. As described above, dictionaries similarly provide definitions requiring the presence of an active ingredient in an inhaler. In view of the intrinsic and extrinsic evidence,

a POSA would understand the claim term "an inhaler" to require an active drug capable of being dispensed via the inhaler to the lungs.

D. "An incremental dose counter for a metered dose inhaler" ('889 patent, claim 1)

"a metered dose inhaler" ('889 patent, claim 1)

Teva's Proposed Construction	Defendants' Proposed Construction
"An incremental dose counter for a metered dose inhaler" 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"	"An incremental dose counter for 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"
"a metered dose inhaler" 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"	"a metered dose inhaler" 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"

The parties have a similar dispute concerning the '889 patent. The parties dispute two phrases from the preamble of claim 1 of the '889 patent: (i) "An incremental dose counter for a metered dose inhaler" (bold italics below) and (ii) "a metered dose inhaler" (underlined below). Like the other disputed terms found in the preamble, the parties dispute (1) whether these claim phrases in the preamble are limiting and (2) if so, the proper construction of each. Claim 1 of the '889 patent recites the following:

> 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.

The disputed claim phrase is limiting for the same reasons as the other terms discussed, including because the phrase "recites essential structure" and "is necessary to give life, meaning, and vitality to the claim." *Proveris,* 739 F.3d at 1372. As for the proper constructions of these phrases, the same arguments as in the other patents support adopting Teva's proposed constructions.

1. The disputed phrases in the preamble of the '889 patent are limiting

The disputed claim phrases in the preamble are limiting for multiple reasons. These phrases recite essential structure for the claimed invention and give life, meaning, and vitality to the claims. *Proveris,* 739 F.3d at 1372. The preamble—"An incremental dose counter for a metered dose inhaler"—specifies that the claimed dose counter requires a metered dose inhaler. This provides important context for the nature of the invention being claimed. *See Lemoine*, 2021 WL 4199934, at *2. As in the '808 patent, which shares a specification with the '889 patent, the dose counter is described and exemplified with an inhaler.

The preamble is also limiting because the preamble "recit[es] additional structure . . . underscored as important by the specification." *Catalina*, 289 F.3d at 809. The specification repeatedly discloses that the claimed invention is a dose counter for a metered dose inhaler, which addressed issues in determining how much active drug was left in the inhaler. *See, e.g.*, '889 patent at 1:30-2:40, 2:44-53, 10:48-58. The specification further states that given problems with known "[i]nhalers incorporating dose counters . . . it has become desirable to improve dose counters further and, in particular, it is felt that it would be useful to provide extremely accurate dose counters for manually-operated canister-type metered dose inhalers." *Id.* at 1:59-60, 2:9-13. "[T]hese disclosures would be rendered meaningless" if the preamble was not limiting. *Lemoine*, 2021 WL 4199934, at *2.

Furthermore, the preamble is limiting because it "is essential to understand limitations [and] terms in the claim body." *Catalina*, 289 F.3d at 808. The preamble is essential to understanding that the dose-counter elements claimed in the claim body are to be used in connection with a metered dose inhaler. As explained more below, the preamble further provides essential context for the claim term "canister" in this claim as containing an active drug that is capable of being dispensed via the inhaler to the lungs. Lastly, the preamble provides important 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" in the body of the claim. The preamble is essential to understanding that the dose counting mechanism moving in response to canister motion is counting doses of active drug remaining in the canister after each use of the inhaler (i.e., after each time the canister fires active drug). As with the other, similar terms, the preamble should be construed as limiting.

2. Teva's proposed constructions are consistent with the intrinsic and extrinsic record

As with the parties' other disputed constructions, the parties dispute whether these terms require the presence of an active drug. Teva's proposed constructions reflect the plain meaning of these terms in view of the intrinsic and extrinsic record and should be adopted.

a. "An incremental dose counter for a metered dose inhaler"

Like the disputed construction for the preamble of the '808 patent, Defendants do not appear to dispute that the claimed dose counter requires the presence of a metered dose inhaler. Rather, Defendants again propose to limit the "metered dose inhaler" portion the preamble to a "metered dose inhaler device" (with no medicine). Teva's proposed construction reflects the plain meaning of "for" in the preamble—i.e., meaning "used in connection with." The claim phrase "An incremental dose counter for a metered dose inhaler" requires the presence of a metered dose inhaler. Because Teva's proposed construction is consistent with the intrinsic and extrinsic record, it should be adopted.

The plain meaning of the claim language requires the presence of a metered dose inhaler. *See Phillips*, 415 F.3d at 1314. The preamble itself states that the claimed invention is "An incremental dose counter ***for*** a metered dose inhaler." The preamble thus limits the claimed dose counter to be used in connection with a metered dose inhaler, not any other apparatus. The specification further supports the plain meaning of this claim phrase. By way of example, the specification discloses that the claimed invention is a dose counter to be used in connection with a metered dose inhaler. *See, e.g.*, '889 patent at 1:23-27 ("The present invention relates to dose counters for inhalers . . . ."); *id.* at 2:13-16 ("[I]t would be useful to provide extremely accurate dose counters for manually-operated canister-type metered dose

inhalers."); *id.* at 10:48-58 ("According to a further aspect of the invention, an incremental dose counter for a metered dose inhaler has . . . .").

As explained above with respect to the disputed preamble term for the '808 patent, dictionary definitions of the word "for" further confirm the plain meaning from the intrinsic record. *See supra* pp. 28-29 (quoting Ex. 13 (Webster's Unabridged 2002) at 886; Ex. 14 (Merriam-Webster's Collegiate Dictionary (11th ed. 2007)) at 488). The common meaning of "for" exemplified by these dictionary definitions further confirms that Teva's proposed construction is the plain meaning—the claimed incremental dose counter requires a metered dose inhaler.

b. "a metered dose inhaler"

The parties' main dispute regarding the construction of the preamble of the '889 patent is the term "a metered dose inhaler." Defendants again improperly attempt to limit the claimed invention to a "device" without medicine. Teva's proposed construction should be adopted because it reflects the plain meaning of the claim term.

The plain meaning of the claim language again supports Teva's proposed construction. As explained above with respect to the disputed preamble phrases from the other three patents, the common meaning of "inhaler" requires the presence of an active drug. That common meaning, as illustrated by these dictionary definitions, confirms Teva's proposed construction that the metered dose inhaler

contains an active drug that is drawn into the lungs via the inhaler. Ex. 9 (Medical Desk Dictionary (2005)) at 396-97. The surrounding claim language further supports Teva's construction. As explained more below, the claimed "canister" is part of the inhaler and contains active drug. The words of the claim support Teva's proposed construction.

The specification also supports that Teva's construction reflects the plain meaning of this claim term. The '889, '808, and '289 patents share a common specification. Accordingly, the same support from the specification supporting Teva's proposed construction for "An inhaler for metered dose inhalation" in the '289 patent and "an inhaler" in the '808 patent applies equally here with respect to the same proposed construction for "a metered dose inhaler" in the '889 patent. *See, e.g.*, '889 patent at 1:31-33, 1:53-55. The specification also states that "[m]etered dose inhalers can comprise a medicament-containing pressurised canister containing a mixture of active drug and propellant." '889 patent at 1:31-33. Additionally, the cited references in the specification confirm the same. *See* Ex. 10 (EP '227) at 2:24-26.

Lastly, the meaning of the disputed term "an inhaler" from the intrinsic evidence is in accordance with the extrinsic evidence. *See Teva Pharms.*, 574 U.S. at 331; *see also supra* p. 19 (discussing FDA Guidance (Ex. 7) at 2). In view of the intrinsic and extrinsic evidence, a POSA would understand the term "a metered dose

inhaler" to require an active drug capable of being dispensed via the inhaler to the lungs.

E. "canister" ('889 patent, claim 1)

Teva's Proposed Construction	Defendants' Proposed Construction
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"

Similar to the parties' dispute regarding the term "medicament canister" for the '289 and '587 patents, the parties dispute the plain and ordinary meaning of the term "canister" for claim 1 of the '889 patent. Defendants contend that no construction is necessary and that the term should be construed as the term itself (i.e., "canister"). Like with the term "medicament canister," the Court should adopt Teva's proposed construction: "a canister containing an active drug capable of being dispensed via the inhaler to the lungs."

Teva's construction reflects the plain meaning of the claim language. The context in which the term "canister" appears in claim 1 is "highly instructive." *Phillips*, 415 F.3d at 1314. As discussed above, the preamble to this claim requires "An incremental dose counter used in connection with a metered dose inhaler." The claimed "incremental dose counter" counts the doses of the active drug that remain

in the canister. The claim language reflects that the active drug is contained within the claimed canister.

The specification further confirms the plain meaning of this claim term. As noted above, the '889 and '289 patents share a common specification. Accordingly, the same support from the specification supporting Teva's proposed construction for "medicament canister" in the '289 patent applies equally here with respect to the same proposed construction for "canister" in the '889 patent. The specification of the '889 patent repeatedly refers to the claimed canister as containing an active drug capable of being dispensed via the inhaler to the lungs. *See, e.g.*, '889 patent at 1:29-2:40, 4:51-5:3, 12:15-38, Fig. 7A. Even without the term "medicament" in the claim, the specification makes clear that the "canister" contains a medicament in the context of these claims. For instance, the specification describes that "[t]he valve stem block 40 has a passageway 42 leading to a nozzle 44 for directing ***the contents of the canister 20, namely active drug and propellant***, towards an air outlet 46 of the inhaler main body 12." *Id.* at 12:15-38, Fig. 7A (emphasis added).

Additionally, as explained above in more detail, the specification's description of the "Background of the Invention" supports Teva's proposed construction. *See supra* p. 22. That section of the specification states that "[m]etered dose inhalers can comprise a medicament-containing pressurised canister containing a mixture of active drug and propellant." *Id.* at 1:31-33. The references cited in the

specification referring to inhalers incorporating dose counters are consistent with the specification's descriptions. For instance, the cited WO '552 states that "[s]uch metered-dose inhalers typically comprise a medicament-containing vessel and an actuator body having a drug delivery outlet. The medicament-containing vessel may be a pressurised canister containing a mixture of active drug and propellant." Ex. 12 (WO '552) at 1:16-21; *see id.* at 13:28-29 ("The medicament may be any medicament that is suitable to be delivered to a patient via a metered-dose inhaler.").

In view of the intrinsic record as a whole, a POSA would understand the plain and ordinary meaning of the term "canister" to mean a canister containing an active drug capable of being dispensed via the inhaler to the lungs.

V. CONCLUSION

For the foregoing reasons, Teva respectfully requests that the Court adopt its proposed constructions for each of the disputed terms and reject Defendants' proposals.

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