NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC., and NORTON (WATERFORD) LTD., Plaintiffs, v. CIPLA LTD., AUROBINDO PHARMA LLC, AUROBINDO PHARMA USA, INC., and AUROLIFE PHARMA LLC, Defendants.	**Civil Action No. 20-10172 (JXN) (MAH)** (Consolidated with Civil Action Nos. 20-14833 and 20-14890) **MARKMAN OPINION**

NEALS, District Judge:

Before this Court are the briefs and supporting materials of Plaintiffs Teva Branded Pharmaceutical Products R&D, Inc. and Norton (Waterford) Ltd. (collectively, "Plaintiffs" or "Teva") and Defendants Cipla Ltd., Aurobindo Pharma Ltd., Aurobindo Pharma USA, Inc., and Aurolife Pharma LLC (collectively, "Defendants") regarding their request for patent claim construction pursuant to Local Patent Rule 4.5(a). This Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202. Venue is proper under 28 U.S.C. §§ 1391(b) and 1400(b). This Court held a *Markman*[1] hearing on November 30, 2021 regarding patent claims in Plaintiffs' U.S. Patent Nos. 9,463,289 ("the '289 Patent"); 9,808,587 ("the '587 Patent"); 10,086,156 ("the '156 Patent"); 10,561,808 ("the '808 Patent"); and 10,695,512 ("the '512 Patent"). After carefully considering the parties' written and oral arguments, this Court construes the nineteen disputed claim terms as discussed below.[2]

[1] *Markman v. Westview Instruments Inc.*, 52 F.3d 967 (Fed. Cir. 1995).
[2] For sake of clarity, the Court notes that some of the terms have been grouped together by the parties. The Court also notes that since the parties submitted their *Markman* disputes, the Court has entered several stipulations and orders

I. BACKGROUND

The five Asserted Patents relate to Teva's Qvar® product, which was U.S. Food and Drug Administration ("FDA") approved for maintenance treatment of asthma as prophylactic therapy in patients 5 years of age and older. Teva Br. at 2, ECF No. 110; Compl. ¶ 15. Teva asserts that Defendants infringed the patents in suit by filing an Abbreviated New Drug Application ("ANDA") No. 211434 to the FDA seeking approval to commercially manufacture, use, offer for sale, sell, and/or import generic versions of Teva's Qvar®. *Id.* Teva commenced this lawsuit on August 7, 2020, and the case was later consolidated with Civil Action Nos. 20-14833 and 20-14890. Compl.; *see* ECF No. 40. The parties filed their opening *Markman* briefs on August 6, 2021 [ECF Nos. 109, 110] and their responsive briefs on September 24, 2021 [ECF Nos. 115, 116]. The Court held oral argument on the parties *Markman* dispute on November 30, 2021. The dispute is now ripe for the Court to decide.

II. LEGAL STANDARD

Patent claim construction is a matter of law for the court. *Markman*, 52 F.3d 967, 979 (Fed. Cir. 1995). During interpretation of a claim, courts should initially look to intrinsic evidence, namely "the patent claims, the specification and the prosecution history if in evidence." *Bristol-Myers Squibb Co. v. Immunex Corp.*, 86 F. Supp. 2d 447, 448 (D.N.J. 2000). "[I]ntrinsic evidence is the most significant source of the legally operative meaning of disputed claim language." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). "The court should presume that the terms in the claim mean what they say, and, unless otherwise compelled, give full effect to the ordinary and accustomed meaning of claim terms." *Bristol-Myers Squibb Co.*, 86 F. Supp. 2d at 448. A person of ordinary skill in the art "is deemed to read the claim term . . . in

dismissing certain patents from this case. *See* ECF Nos. 144, 150, and 173. Thus, some of the terms construed herein may longer be relevant to this case.

the context of the entire patent." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005); *see Medrad, Inc. v. MRI Devices Corp.*, 401 F.3d 1313, 1319 (Fed. Cir. 2005) ("We cannot look at the ordinary meaning of the term . . . in a vacuum. Rather, we must look at the ordinary meaning in the context of the written description and the prosecution history." (citation omitted)); *see also Markman*, 52 F.3d at 979.

If the intrinsic evidence alone will not resolve the ambiguity, the Court may rely on extrinsic evidence, which includes expert testimony, treatises, dictionaries, and articles. *Bristol-Myers Squibb Co.*, 86 F. Supp. 2d at 448–49. Extrinsic evidence may not be used to vary or contradict the meaning established by the intrinsic evidence. *Phillips*, 415 F.3d at 1318–19, 1324. "The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be . . . the correct construction." *Id.* at 1316. A key aspect of claim construction is to assist the jury in understanding complicated language and concepts. *See Encap LLC v. Oldcastle Retail, Inc.*, Civ. No. 11-808, 2012 WL 2339095, at *9 (E.D. Wis. June 19, 2012) ("Claim construction is not intended to allow for needless substitution of more complicated language for terms easily understood by a lay jury."); *AFG Indus., Inc. v. Cardinal IG Co., Inc.*, 239 F.3d 1239, 1247 (Fed. Cir. 2001) ("It is critical for trial courts to set forth an express construction of the material claim terms in dispute, in part because the claim construction becomes the basis of the jury instructions, should the case go to trial. It is also the necessary foundation of meaningful appellate review." (Citation omitted)).

III. ANALYSIS

1. "actuation member"

Term	Teva's Proposed Construction	Defendants' Proposed Construction	Court's Construction
"actuation member"	"a component of the dose counter's actuator that transmits motion from the canister to the actuator"	"pin arranged to engage with a medicament canister and effect movement causing the dose counter to record a count"	"a component of the dose counter's actuator that transmits motion from the canister to the actuator"

The parties dispute whether the term "actuation member" must be a pin and whether its construction should recite the purpose of the movement of the actuation member. Defendants point to the specification, Applicants' argument during prosecution, and the Examiner's reason for allowance, and argue that the term "actuation member" is limited to a pin and that their construction should recite the purpose of the movement of the actuation member. Def.'s Br. at 13-15, ECF No. 109. Defendants assert that its construction most accurately captures the structure disclosed in the specification and the purpose of the "actuation member" in view of the intrinsic record. *Id.* In support of their argument, Defendants note that the "actuation member" and "the central outlet port are arranged in a particular configuration to prevent canister rocking 'towards the position of the dose counter actuation member, which rocking can change the height of the actuation member and thereby undesirably alter the accuracy of the dose counter.'" *See* Def.'s Br. at 16 (citing '289 Patent Prosecution History, March 7, 2016 Office Action Response (Ex. 6) at 5). Moreover, Defendants note that applicants repeatedly refer to the actuation member as a pin and use the terms "actuation member" and "actuation pin" interchangeably. *Id.* As a result, Defendants contend that "it is clear from the intrinsic record that the 'actuation member' is a 'pin.'" *Id.* at 14.

Teva argues that the term "actuation member" should be construed to mean "a component of the dose counter's actuator that transmits motion from the canister to the actuator." Teva Br. at 11, ECF No. 110. Teva contends that Defendants' proposed construction inappropriately limits the claim to a preferred embodiment and seeks to import the purpose of the actuation member into its construction. Moreover, Teva argues that the specification's description of the actuation member in a particular embodiment as "comprising" a pin does not prohibit the actuation member from taking a different form in other embodiments. *Id.* at 14. According to Teva, the patentee used the narrower term "actuation pin" when describing figures depicting an embodiment with a pin shaped actuation member but used the broader term "actuation member" in elsewhere in the specification. *Id.* at 16 (citing '289 Patent, 6:31-62). Teva notes that the patentee clearly used two terms that had two different meanings and selected the broader term for use in the claims. *Augme Techs., Inc. v. Yahoo! Inc*., 755 F.3d 1326, 1333 (Fed. Cir. 2014) ("[D]ifferent claim terms are presumed to have different meanings." (quoting *Helmsderfer v. Bobrick Washroom Equip., Inc.*, 527 F.3d 1379, 1382 (Fed. Cir. 2008)). As a result, Teva argues that Defendants may not undo the patentee's selection by equating the broad term the patentee chose with the narrower one that they prefer. Teva Br. at 16. The Court agrees.

Teva's construction comports with the claim and specification. Defendants' construction, on the other hand, seeks to import the purpose of the term into its construction, a practice the Federal Circuit routinely rejects. *See e.g., Toshiba Corp. v. Imation Corp*., 681 F.3d 1358, 1368 (Fed. Cir. 2012); *Powell v. Home Depot U.S.A., Inc.*, 663 F.3d 1221, 1233 (Fed. Cir. 2011). Defendants also seek to import limitations from the preferred embodiments into the claim. Teva is correct that limiting "actuation member" in this way would be inconsistent with the patents' specification, which makes "clear that the figures illustrate only embodiments of the invention,

rather than defining the invention as a whole." Teva Br. at 15. Teva "did not need to include a drawing" of a non-pin actuation member in order to claim one. *CCS Fitness, Inc. v. Brunswick Corp*., 288 F.3d 1359, 1367 (Fed. Cir. 2002). Accordingly, the Court will adopt Teva's construction.

2. "[lying or lie] in a common plane coincident with the longitudinal axis X"

Term	**Teva's Proposed Construction**	**Defendants' Proposed Construction**	**Court's Construction**
"[lying or lie] in a common plane coincident with the longitudinal axis X"	"Features lie on a common plane coincident with the longitudinal axis X if it is possible to draw a straight line connecting those features that passes through the center of the stem block."	"aligned in a single plane such that a straight line can be drawn through the center of the central outlet port, a canister support formation located directly adjacent to the actuation member, and the actuation member"	"aligned in a single plane such that a straight line can be drawn through the center of the central outlet port, the canister support formation, and the actuation member"

The parties sole dispute with respect to this term is whether the canister support formation in the configuration must be located directly adjacent to the actuation member. Teva argues that Defendants improperly import an additional requirement: that a canister support formation cannot "lie in a common plane" with the other specified features unless that canister support formation is also "located directly adjacent to the actuation member." Teva Br. at 17, ECF No. 110. Teva contends that Defendants' construction is utterly divorced from the language of the claims, finds no support in the specification, and directly contradicts the prosecution history, in which Teva removed such an "adjacency" requirement from its claims. The Court agrees.

Urging the Court to adopt their construction, Defendants contend that the canister support formation must be located directly adjacent to the actuation member to accomplish its stated purpose—preventing rocking in the direction of the actuation member. Defendants argue that

during prosecution, the Applicants highlighted the particularly claimed arrangement of the actuation member, canister support formation, and central outlet port as an allegedly novel feature. In support of their argument, Defendants point to the following excerpt from the prosecution history:

> . . . [T]he claimed arrangement has the advantage of ***preventing the canister from rocking towards the position of the dose counter actuation member***, which rocking can change the height of the actuation member and thereby undesirably alter the accuracy of the dose counter. . . .
>
> Applicant has discovered that by minimizing and/or eliminating the described rocking of the canister ***in the direction of the actuation member***, by way of the ***specific positioning of a canister support formation relative to the actuator*** and outlet port, the present invention improves accuracy of such dose counters. Neither the problem of canister rocking, nor the solution of ***specific placement of the canister support formation*** are taught or suggestion by the prior art. . . .

Def.'s Br. at 15, ECF No. 109. Defendants assert that "the Applicants argued the importance of the function of the claimed arrangement—a function that only Defendants' construction captures." *Id.* at 16. Contrary to Defendants' assertions, nothing in this excerpt, including the sections emphasized by Defendants, suggests that the Applicants argued that the canister support formation must be adjacent to the actuation member.

Moreover, Defendants argue that their proposed construction is consistent with the Examiner's reasons for allowance. Def.'s Br. at 16. In support of this argument, Defendants note that "[i]n the Notice of Allowance, the Examiner explained that '[t]he examiner ***is persuaded*** that rocking by the canister about its central axis ***in the direction of the actuation member*** could risk triggering false counting, and that a ***canister support formation directly in line with the actuation member*** and the central canister axis ***could prevent rocking in this direction*** and thus reduce false counts.'" *See id.* (citing '289 Patent Prosecution History, May 20, 2016, Notice of Allowance (Ex. 7) at 3 (emphasis in original)). Defendants argue that to prevent rocking in the direction of the

actuation member, the canister support formation must be located directly adjacent to the actuation member. *Id.* While that may be true, the Examiner did not reach the same conclusion. The Examiner merely stated that the "***canister support formation directly in line with the actuation member*** and the central canister axis ***could prevent rocking in this direction*** and thus reduce false counts." *Id.* Contrary to Defendants' assertions, the canister support formation can be directly in line with the actuation member without being adjacent to the actuation member.

Finally, the language that Defendants seek to include in this term—canister support formation located directly adjacent to the actuation member—was removed from the claim during prosecution. Teva Br. at 20. The Court will not construe this term to include language that the Examiner allowed the Applicants to remove during prosecution. *Laryngeal Mask Co. v. Ambu*, 618 F.3d 1367, 1372-73 (Fed. Cir. 2010). The plain language of claim 1 of the '289 and '587 Patents require that "the inner wall canister support formation, the actuation member, and the central outlet port l[ie] in a common plane coincident with the longitudinal axis X." '289 Patent, claim 1, 22:9-13. The Patents do not require that the canister support formation and the actuation member be adjacent. Therefore, the Court will construe the term to mean the following: "aligned in a single plane such that a straight line can be drawn through the center of the central outlet port, the canister support formation, and the actuation member."

3. "positioned at opposite ends of the inside surface of the main body to face each other"

Term	Teva's Proposed Construction	Defendants' Proposed Construction	Court's Construction
"positioned at opposite ends of the inside surface of the main body to face each other"	"located on opposite sides from one another on the inside surface of the main body, and extending outwardly from the inner wall towards each other"	"positioned directly across from one another such that a straight line can be drawn from one support rail through the center of the longitudinal axis X to the facing support rail"	"positioned at opposite ends of the inside surface of the main body to face each other"

At issue here is what does "opposite ends" mean in the context of the phrase "positioned at opposite ends of the inside surface of the main body to face each other." Teva contends that "opposite ends" needs no construction and should not be interpreted so narrowly as Defendants suggest. Teva Br. at 21. Teva doesn't necessarily explain what "opposite ends" means, but it does provide multiple examples for the Court to consider. *See id.* at 22. For example, Teva states "that Los Angeles and Washington, D.C. are at 'opposite ends' of the country, even though the line that connects them does not pass through the center of the U.S." *Id.* Teva also contends that the patentee's choice to use "opposite ends" rather than "diametrically opposed" in the Asserted Claims must be credited. *Id.* at 23.

Defendants argue that for rails to be positioned at "opposite ends," the rails must be "diametrically opposed" from one another, such that a straight line can be drawn from one support rail through the center of the longitudinal axis X to the facing support rail. Def. Br. 38. For support, Defendants point the Court to the language of the specification, which provides:

> As shown in FIGS. 7C and 7D, the inner wall **50** of the main body **10** is provided with a two-step support rail **144** which extends longitudinally along inside the main body and is located directly adjacent the aperture **74**. As shown in FIG. **7B** a ***diametrically opposed*** two step support rail **146** is also provided and this ***diametrically opposed*** in the sense that a vertical plane (not shown) can pass

> substantially directly through the first rail **144**, the aperture **74**, a central aperture **148** of the valve stem block **40** (in which cannister stem **25** is located) and the second two-step support rail **146**.

See Def. Br. 38 (citing ECF No. 110-2, Ex. 1, at 15:33-43 (emphasis in original)). In its response, Teva contends that this passage does not define "opposite ends"—or even use those words. Instead, it uses the distinct term "diametrically opposed" to convey the concept Defendants wrongly seek to import via "opposite ends." Teva Resp. Br. at 13.

Here, the parties request that court construe a term that has a plain meaning. "When claim language has a plain meaning on an issue as the language does here, leaving no genuine uncertainties on interpretive questions relevant to the case, it is particularly difficult to conclude that the specification reasonably supports a different meaning." *Straight Path IP Grp., Inc. v. Sipnet EU S.R.O.*, 806 F.3d 1356, 1361 (Fed. Cir. 2015). This Court therefore concludes that no construction is necessary and declines to adopt the parties' proposed constructions.

4. "step formed thereon"

Term	Teva's Proposed Construction	Defendants' Proposed Construction	Court's Construction
"step formed thereon"	"a location of changing width dimension thereon"	"A stepwise increase in the extent to which the support rail extends inwardly"	"a location of changing width dimension thereon"

The dispute between the parties centers on how to define the term "step" in the phrase "step formed thereon." Defendants contend that the terms should be construed to mean "a stepwise increase in the extent to which the support rail extends inwardly." Def.'s Br. at 39, ECF No. 109. In support of their construction, Defendants point the Court to the specification in the '289 Patent. *Id.* at 40. Defendants argue that the specification describes the rails in terms of the extent that the rail extends inwardly (width) at a particular portion of the rail. According to Defendants, for the

rail to have a step, the rail must have a portion that extends inwardly to one extent, and another portion that extends inwardly to a different extent from the first portion. *Id.*

Teva argues that Defendants' construction seeks to exclude very specific embodiments from the scope of the Asserted Claims. Teva Br. at 24. Teva contends that the "preferred embodiment of Figure 7C plainly shows that step 164 is both the end of a support rail, and reflects a gradual change in support rail width." *Id.* at 25. In response, Defendants argue that under Teva's proposed construction, the support rail can literally have no steps (such as a gradual slope down the entire rail) and still include "a step formed thereon." Def.'s Resp. Br at 29, ECF No. 115.

The Court's construction is supported by the specification. *See* '289 Patent, 7:1-7, ECF No. 109-2 ("Each said rail may be stepped, in that it may have a first portion located towards a medicine outlet end or stem block of the canister housing which extends inwardly a first distance from a main surface of the inner wall . . ."). Although Defendants argue that this construction would include a support rail with no steps, the construction is consistent with the specification and description of the embodiments from the scope of the asserted claims.

5. "aperture"

Term	**Teva's Proposed Construction**	**Defendants' Proposed Construction**	**Court's Construction**
"aperture"	"an opening or open space: hole"	"hole"	"an opening or open space: hole"

The parties propose similar constructions for this disputed term. Teva's construction is defined more broadly and includes "an opening or open space." Defendants contend that aperture should be construed as a "hole" because Teva's construction is "so vague as to create more issues than it resolves." Def. Br. at 41. Teva counters that Defendants' construction reflects a truncated version of the plain and ordinary meaning of the word "aperture," and is flatly inconsistent with the term's broader use in the specification. Teva Br. at 26. Teva claims that its construction comes

from the Merriam Webster's Collegiate Dictionary and is consistent with the Asserted Patents claims.

Notwithstanding the above, Defendants admit that the Patent does not "explicitly define" the term "aperture" to mean "hole." Def.'s Br. 41. The term "aperture" was not limited in the Asserted Patents, so the Court will stay true to the claim language and not limit its construction as Defendants suggest. The Court will adopt Teva's construction, which is consistent with the plain meaning of aperture, the descriptions in the specification and supported by extrinsic evidence.

6. "count pawl"

Term	**Teva's Proposed Construction**	**Defendants' Proposed Construction**	**Court's Construction**
"count pawl"	"a pawl that is a component of the dose counter that is capable of engaging with a second tooth of the rachet wheel"	"a pawl that is part of the dose counter, separate from an actuator pawl, that is arranged to engage with a second tooth different from the first tooth of the ratchet wheel"	"a pawl that is part of the dose counter, separate from an actuator pawl, that is arranged to engage with a second tooth of the rachet wheel"

The primary disputes between the parties are whether the construction must structurally differentiate "the count pawl" from the actuator pawl, and whether the count pawl need only be "capable of" engaging with a second tooth of the rachet wheel. The Court's construction is consistent with the intrinsic evidence. Claim 1 of the '156 Patent recites "the dose counter" comprises the "actuator comprising an actuator pawl" and "a count pawl arranged to engage with a second tooth of the ratchet wheel[.]" '156 Patent, Claim 1, ECF No. 109-4 at 32. This claim makes it clear that the actuator pawl is part of the actuator, and the actuator and the count pawl are both parts of the dose counter. Thus, the actuator pawl and count pawl are separate components on the same structure—the dose counter.

Moreover, claim 1 recites "a count pawl arranged to engage with a **second tooth** of the ratchet wheel[.]" *Id.* (emphasis added). The claim expressly limits the count pawl to engaging with the second tooth. The claim is silent as to whether the count pawl may engage the first tooth or any other tooth. Thus, the Court will stay true to the claim and construe the term "count pawl" to mean the following: "a pawl that is part of the dose counter, separate from an actuator pawl, that is arranged to engage with a second tooth of the rachet wheel."

7. "canister fire sequence"

Term	Teva's Proposed Construction	Defendants' Proposed Construction	Court's Construction
"canister fire sequence"	"a sequence of configurations and positions that occur before, while, and after the medicament canister fires medicament"	"process of ejecting medicament from an inhaler where the actuator pawl follows a particular sequence of movement from the start configuration to the reset configuration, to the fire configuration, to the count configuration, before returning to the start configuration upon release of pressure on the canister, where in the start configuration, prior to depression of the canister, the count pawl is engaged with a tooth of the ratchet wheel and the actuator pawl is spaced from the ratchet wheel"	"a series of configurations or positions that occur during the process of ejecting medicament from an inhaler where the actuator pawl follows a particular sequence of movement from the first reset position, to the canister fire configuration, and then to the count configuration"

Defendants argue that it is undisputed that the "canister fire sequence" refers to a series of configurations or positions that occur during "the process of ejecting medicament from an inhaler." Def.'s Br. at 19. The parties dispute, however, whether the sequence of configurations must occur in a particular order. *Id.* In support of their position, Defendants point to the specification and Applicants' prosecution history. *Id.* Defendants note that the patent describes the sequence of configurations in the following order: "'start configuration' followed by the 'first reset position' followed by the 'canister fire configuration' followed by the 'count configuration.'" *Id.* (citing '289 Patent (Ex. 1) at 14:9-15:12). In further support of their proposed construction, Defendants contend that the Applicants highlighted the necessity of this particular order during prosecution. *Id.* Defendants note that during prosecution the Applicants argued that "the prior art Bowman reference did not disclose a first reset position, a canister fires configuration, which is after the first reset position, and a count configuration, which is after the canister fire configuration." *Id.* (citing '156 Patent, Prosecution History, April 20, 2017 Office Action Response (Ex. 11) at 7). Finally, Defendants argue that the configurations must be located in the datum plane.

In response, Teva contends that it does not dispute that claim 1 requires the "first reset position," "canister fire configuration," and "count configuration" to "occur" in that "particular order." Teva Resp. Br. at 16. Teva disputes that Defendants cannot import the following limitations into the term:

- "from the start configuration to the reset configuration";
- "before returning to the start configuration upon release of pressure on the canister";
- "where in the start configuration, prior to depression of the canister, the count pawl is engaged with a tooth of the ratchet wheel and the actuator pawl is spaced from the ratchet wheel."

Id. The Court agrees.

Defendants' proposed construction imposes limitations that are not supported by the intrinsic record. For example, Defendants' proposed construction requires that "in the start configuration, prior to depression of the canister, the count pawl is engaged with a tooth of the ratchet wheel" and that the "actuator pawl" return "to the start configuration upon release of pressure on the canister, where . . . the actuator pawl is spaced from the ratchet wheel." Def.'s Br. at 19. These limitations are not supported by the claims or specification. Although Teva's proposed construction does not include inappropriate limitations, the Court will construct "canister fire sequence" to include the order which claim 1 requires. "Canister fire sequence" means "a series of configurations or positions that occur during the process of ejecting medicament from an inhaler where the actuator pawl follows a particular sequence of movement from the first reset position, to the canister fire configuration, and then to the count configuration."

8. "first reset position"

Term	**Teva's Proposed Construction**	**Defendants' Proposed Construction**	**Court's Construction**
"first reset position"	"a position of the actuator in which the actuator pawl is brought into engagement with the first tooth of the ratchet wheel and which is before the fire configuration"	"configuration in which the actuator pawl is above the datum plane, but closer to the datum plane than in the start configuration, and is just engaged with one of a tooth of the ratchet wheel"	"a position of the actuator in which the actuator pawl is brought into engagement with the first tooth of the ratchet wheel and which is before the fire configuration"

The parties dispute whether "first reset position" should include location limitations. Claim 1 of the '156 Patent provides that "the actuator is arranged to define a first reset position in which the actuator pawl is brought into engagement with the first tooth[.]" '156 Patent, Claim 1, ECF No. 110-2, Ex. 3. The parties agree that in this configuration, the actuator pawl is just engaged

with a tooth of the ratchet wheel. Def.'s Br. at 20; Teva Br. at 31. Nevertheless, Defendants point to the specification and argue that the patent makes clear that this configuration has a specific location with respect to the datum plane, and the other configurations in the claimed "canister fire sequence." Def.'s Br. at 20. The Court disagrees. Nothing in the plain and ordinary meaning of claim 1's language imposes such limitations. Absent such language, the proper construction of the claim language must stay true to the claim language to avoid giving invention-defining effect to specification language included for other descriptive and enablement purposes. *See Straight Path*, 806 F.3d at 1361.

Teva's proposed construction is consistent with the language of the claim. Accordingly, the Court will adopt Teva's proposed construction, which is consistent with the intrinsic record.

9. "canister fire configuration"

Term	**Teva's Proposed Construction**	**Defendants' Proposed Construction**	**Court's Construction**
"canister fire configuration"	"a configuration of the dose counter in which the medicament canister fires medicament"	"configuration in which the actuator pawl is lower than in the first reset position and below the datum plane and the medicament is ejected"	"a configuration of the dose counter in which the medicament canister fires medicament"

The parties dispute whether "canister fire configuration" should include location limitations. Claim 1 of the '156 Patent provides that "at a canister fire configuration, the medicament canister fires medicament before the dose counter reaches a count configuration[.]" '156 Patent, Claim 1, ECF No. 110-2, Ex. 3. The parties agree that in this configuration, the medicament canister fires. Def.'s Br. at 21; Teva Br. at 31. Nevertheless, Defendants argue that the patent, makes clear that this configuration has a specific location with respect to the datum

plane, and the other configurations in the claimed "canister fire sequence." Def.'s Br. at 21. In support of their argument, Defendants point the Court to Figures in the Patent, which Defendants argue explains actuator pawl is lower than in the first reset position and below the datum plane. *Id.* The Court disagrees. Nothing in the plain and ordinary meaning of claim 1's language imposes a location limitation. Teva's proposed construction is consistent with the language of the claim. Accordingly, the Court will adopt Teva's proposed construction, which is consistent with the intrinsic record.

10. "count configuration"

Term	**Teva's Proposed Construction**	**Defendants' Proposed Construction**	**Court's Construction**
"count configuration"	"a configuration of the dose counter whereby the dosage indicator has indicated a count"	"configuration in which the actuator pawl is further below the datum plane than when in the canister fire position and the dose counter has counted one dose"	"a configuration of the dose counter whereby the dosage indicator has indicated a count"

The parties dispute whether "count configuration" must occur in a specific location. Claim 1 of the '156 Patent provides that "the count pawl resiliently jumps over the second tooth and the dose counter reaches the count configuration, whereby the dosage indicator has indicated a count[.]" '156 Patent, Claim 1, ECF No. 110-2, Ex. 3. The parties agree that in this configuration, the dose counter counts a dose. Def.'s Br. at 22; Teva Br. at 31. Nevertheless, Defendants again argue that the patent, makes clear that this configuration has a specific location with respect to the datum plane, and the other configurations in the sequence. Def.'s Br. at 22. In support of their argument, Defendants point the Court to Figures in the Patent, which Defendants argue explains actuator pawl is below the datum plane and lower than in the fire configuration. *Id.* The Court

disagrees. Nothing in the plain and ordinary meaning of claim 1's language imposes a location limitation. Teva's proposed construction is consistent with the language of the claim. Accordingly, the Court will adopt Teva's proposed construction, which is consistent with the intrinsic record.

11. "datum plane which passes through a shoulder of a valve stem block configured to receive the medicament canister"

Term	**Teva's Proposed Construction**	**Defendants' Proposed Construction**	**Court's Construction**
"datum plane which passes through a shoulder of a valve stem block configured to receive the medicament canister"	"a plane that passes through a shoulder of the portion of the inhaler body that engages the valve stem and is perpendicular to the direction of movement of the medicament canister"	"plane or line passing through the bottom surface of a structure into which the valve stem of a medicament canister is inserted, wherein the bottom surface is where the valve stem block meets a passageway to a nozzle for directing the canister contents towards an air outlet"	"datum plane which passes through a shoulder of a valve stem block configured to receive the medicament canister"

Claim 1 of the '156 Patent provides that "in the canister fire configuration, the actuator pawl is below a datum plane which passes through a shoulder of a valve stem block configured to receive the medicament canister." 156 Patent, Claim 1, ECF No. 109-4 at 32. The parties dispute centers on the construction of "a shoulder of a valve stem block." Defendants contend that there needs to be clarity on "what a shoulder is" and how to identify "a plane passing through a shoulder." Def.'s Br. at 23. In construing the phrase, Defendants point to the specification and Figures 9 and 3A to identify the structures surrounding the valve stem block. *See id.* at 24. Defendants note that "**the only passage in the entire patent** that describes the location of the datum plane states that it 'passes through [a/the] bottom surface or shoulder **42** of valve stem block

40.'" Def.'s Resp. Br. at 13 (citing ECF No. 109-2, Ex. 1 at 14:17-19) (emphasis in original). As a result, Defendants contend that "a shoulder is a bottom of the valve stem block" and that their construction clearly describes how to identify the "shoulder" or "bottom surface" of the valve stem block. *Id.*

Teva contends that Defendants' proposal imports extraneous limitations that run contrary to bedrock principles of claim construction. Teva argues that Defendants seek to rewrite the claim such that the "datum plane" need not pass through "a shoulder" of the valve stem block, as the claims provide, but instead must pass through the "bottom surface" of the valve stem block, which according to Defendants, is the location "where the valve stem block meets a passageway to a nozzle for directing the canister contents towards an air outlet." Teva Br. at 39. "Given that the language surrounding 'datum plane' in claim 1 clearly defines the term," Teva argues that no construction of the term is necessary. Teva Br. at 38-39. The Court agrees.

Defendants' construction which seeks to limit the meaning of "shoulder" to one specific location in the "valve stem block" is not supported by extrinsic or intrinsic evidence. In arguing that the specification uses the term "shoulder" to refer to "the bottom surface of the valve stem block," Defendants ignore the claim language itself, which is part of the specification and defines the scope of the claimed inventions. *Phillips*, 415 F.3d at 1312. The claim requires that a datum plane pass through "a shoulder" of "a valve stem block." "***A*** shoulder"—rather than "***the*** shoulder"—obviously means that there can be more than one shoulder, which the claim does not limit to any particular area of the valve stem block as Defendants suggest. Thus, Defendants' construction which limits the "shoulder" to the "bottom surface" is not consistent with the claim.

Here, the parties do not dispute the meaning of "datum plane" or "a valve stem block." In the context of this claim, POSA would be able to identify a "datum plane which passes through a

shoulder of a valve stem block configured to receive the medicament canister." Accordingly, the Court finds that no construction of the term is necessary.

12. "counter display arranged to indicate dosage information"

Term	Teva's Proposed Construction	Defendants' Proposed Construction	Court's Construction
"counter display arranged to indicate dosage information"	"a component of the dose counter that displays information regarding the number of doses remaining"	"structure displaying the number of doses remaining"	"counter display arranged to indicate dosage information"

The parties dispute whether the phrase "counter display arranged to indicate dosage information," which appears in '808 Patent, requires further construction. *See* '808 Patent, Claim 1, ECF No. 110-2. Teva argues that the term requires no construction; but if construction is necessary, the Court should define "counter display arranged to indicate dosage information" as "a component of the dose counter that displays information regarding the number of doses remaining." Teva Br. at 50-51. In contrast, Defendants assert that the proper construction is "structure displaying the number of doses remaining." Def.'s Br. at 25.

The Court finds that no construction is necessary here because the terms are not technical but rather reflect common usage. *Green Pet Shop Enters., LLC*, 2021 WL 5450185, at *5. In any event, Defendants' proposed construction is undercut by the caselaw. Defendants' proposed construction is based on Figures included in the '289 Patent, which they argue "properly identifies the 'counter display' as 'a structure.'" Def.'s Br. at 26. But claims and patents must be viewed in their entirety and not cherry-picked in a vacuum; further, "[c]laims, not the specification embodiments, define the scope of protection." *Dow Chem. Co. v. Sumitomo Chem. Co.*, 257 F.3d 1364, 1378 (Fed. Cir. 2001) (emphasis omitted); *see also Medrad, Inc.*, 401 F.3d at 1319 ("We cannot look at the ordinary meaning of the term . . . in a vacuum. Rather, we must look at the

ordinary meaning in the context of the written description and the prosecution history."). The Court finds that the plain and ordinary meaning of the claim language controls, and no further claim construction is needed.

13. "first station" / "second station"

Term	Teva's Proposed Construction	Defendants' Proposed Construction	Court's Construction
"first station"	"a first region"	"first structure on which the counter display is located"	"a first region"
"second station"	"a second region"	"second structure, separate from the first structure, on which the counter display is located"	"a second region"

The parties dispute whether a "first" and "second" station of the dose counter must be physically separate structures on which the counter display is located. Teva argues if the construction is necessary the Court should construe the terms as "a first region" and "a second region." Teva Br. at 53. Defendants, on the other hand, argue that the proper construction is the "first structure on which the counter display is located" and "second structure, separate from the first structure, on which the counter display is located." Def.'s Br. at 28.

In opposition to Defendants' proposed construction, Teva argues that the claims do not require that the first and second station be separate structures. *Id.* Teva points to the "Summary of Invention," which provides that "first station may comprise a region of the dose counter," and that region may be located before a display location, such as a display window, for the counter indicia. '808 Patent, 2:65-67. Teva argues that this "language makes it clear that a 'station' of the dose counter is a location or region, not an independent structure." *Id.*

In further opposition of Defendants' proposed construction, Teva argues that the claims also support Teva's proposed construction. *Id.* at 54. Teva points to claim 23 of the '808 Patent, which provides that the "second shaft . . . is located at the second station." *Id.* (citing '808 Patent, Claim 23, ECF No. 110-2 at 133. According to Teva, "Claim 23 thus refers to a structure ("second shaft") located at a region ("second station"), in the same way that one might say the house (a structure) is located at the corner (a location)." Teva Br. at 54.

Defendants counter that the specification supports their construction because it "repeatedly explains that **the tape is held on a structure**." Def.'s Resp. Br. at 18. Defendants then point to various examples throughout the Patent that identifies "stock bobbin" and "tape." *Id*. Based on these examples, Defendants argue that the "first station" is a structure on which the counter display is located. *Id.* at 19. Defendants further argue that the claims and specification similarly make clear that the second station is a separate structure. Defendants note, for example, that the specification provides that the **second shaft** may be . . . **spaced from and parallel to** the **first shaft**." *Id.* (citing '808 Patent at 13:3-8). Finally, Defendants argue that their proposed construction is consistent with the plain meaning in view of the specification and the scope of the actual invention and should be adopted.

The Court disagrees with Defendants' argument that the claims and specifications require that the first and second stations be separate structures. The Court is persuaded by Teva's argument which is consistent with the intrinsic record. As Teva noted, the specification and claims make clear that "first station" and "second station" are a "location or region, not an independent structure." Claim 23 of the '808 Patent provides that the "second shaft . . . is located at the second station, the second shaft being rotatable to wind the tape onto the second shaft." '808 Patent, Claim 23, ECF No. 110-2 at 133. This language makes clear that the shaft is a structure, and the second

station is where the structure is located. Accordingly, the Court finds Teva's construction to be appropriate and will adopt Teva's construction.

14. "separate counter chamber" / "dose counter chamber"

Term	Teva's Proposed Construction	Defendants' Proposed Construction	Court's Construction
"separate counter chamber"	"a separate chamber of the inhaler in which the dose counter is located"	"discrete space or cavity defined by the main surface of the inner walls and the inner wall through which a portion of the actuation member extends in which the dose counter is located"	"a separate chamber of the inhaler in which the dose counter is located"
"dose counter chamber"	"a chamber of the inhaler in which the dose counter is located"	"space or cavity defined by the main surface of the inner walls and the inner wall through which a portion of the actuation member extends in which the dose counter is located"	"a chamber of the inhaler in which the dose counter is located"

As Defendants note, these two claim phrases are grouped together because the dispute for both centers on the term "chamber." In more specific terms, Teva contends that the parties' dispute is limited to a simple issue:

> whether the recitation of a "counter chamber" in claims 2 and 3 of the '512 Patent and claim 12 of the '156 Patent require that the claimed system include such a chamber, or whether it requires that the chamber be created by two particular walls of the inhaler body.

Teva Br. at 43. Teva claims that the clear answer is the former and argues that the relevant claims of the '512 and '156 Patents do *not* impose any requirements as to how the counter chamber is formed. *Id.* Teva further argues that Defendants' constructions seek to import extraneous

limitations that the law does not allow courts to introduce. *Id.* at 43-44. Defendants counter that their proposed construction provides the structural requirements of the chambers and its relation to the other components of the inhaler. *See* Def.'s Br. at 30.

In opposition to Teva's proposed construction, Defendants contend that claim 2 specifies that "a dose counter chamber" is "formed in the body" and that this "wording indicates that the 'chamber' is not simply an area or open space in where the dose counter is positioned. Rather, the phrase 'formed in the body' indicates that the dose counter 'chamber' must have some structural definition in the body." *Id.* Moreover, Defendants note that "claim 3 recites a cover that conceals the dose counter chamber indicating the dose counter chamber is defined space within the body." *See id.* (citing '512 Patent (Ex. 5) at claim 3 ("a cover . . . to conceal the dose counter chamber")). In further support of their argument, Defendants point the Court to the '289 Patent, which provides:

> The inhaler main body may include a canister receiving portion and a separate counter chamber, the dose counter being located within the main body thereof, the incremental output member and actuator thereof inside the counter chamber, ***the main body of the inhaler having wall surfaces separating the canister-receiving portion and the counter chamber***, the wall surfaces being provided with a communication aperture, an actuation member extending through the communication aperture to transmit canister motion to the actuator.

Def.'s Br. at 31 (citing '289 Patent (Ex. 1) at 6:24-37 (emphasis added)). Defendants argue that the specification makes clear that there are two separate chambers within the inhaler main body. *Id.*

In response, Teva argues that nothing in the claims or specification provides that a "counter chamber" must be defined or created by the walls of the inhaler body. Teva Resp. Br. at 39. Teva notes that Claim 2 of the '512 Patent, for example, merely sets out the spatial relationship between the dose counter chamber, medicament canister, and body of the inhaler by providing that the dose counter chamber is located within the inhaler body at "a location beneath the medicament

canister." Teva further notes that claim 12 of the '156 Patent is similar and provides that the body of the inhaler "includes a canister-receiving portion and a separate counter chamber." *Id.* That claim also provides that the body of the inhaler has "wall surfaces separating the canister-receiving portion and the counter chamber." But as Teva correctly notes, the claim does not require, or even suggest, that the counter chamber is formed exclusively by these "wall surfaces." Thus, the Court finds that the claim language requires only that the counter chamber be located in the inhaler body and be separate from the medicament receiving portion. Accordingly, the Court will adopt Teva's proposed constructions.

15. "the body"

Term	**Teva's Proposed Construction**	**Defendants' Proposed Construction**	**Court's Construction**
"the body"	"inhaler body" - '156 Patent, 22:64, 67 "dose counter body" - '156 Patent, 22:66	Indefinite	

Defendants advance an indefinite challenge with respect to "the body." Defendants argue this term is indefinite because a POSA would not understand the meaning of the term "body" in claim 12. Def.'s Br. at 33-34. Defendants argue that when claims 1 and 11 are read together there is only one element that is "the body:" the inhaler body. *Id.* at 33. Claim 12, however, recites "the body, ratchet wheel and actuator being located inside the counter chamber." *Id.* Defendants argue that the claim as written is indefinite because the only body for which there is antecedent basis is "the body of the inhaler." *Id.* at 34. According to Defendants, the claim recites: "An inhaler as claimed in claim 11 in which [the body of the inhaler] includes a canister receiving portion and a separate counter chamber; [the body of the inhaler], ratchet wheel and actuator being located inside

the counter chamber . . . ." *Id.* Defendants argue that "[t]he counter chamber cannot simultaneously include a separate counter chamber and be located inside the counter chamber." *Id.* Thus, Defendants contend that "[w]hen read with the only antecedent basis available, the claim is non-sensical, impossible to understand, and insolubly indefinite." *Id.*

In response, Teva argues that intrinsic record makes clear, however, that the POSA would understand "body" to refer to either the inhaler body or the dose counter body, depending on the context in which the term is used. Teva Resp. at 24. Teva also argues that Defendants' indefiniteness argument is premature. Teva Br. at 46. Citing to various courts in this district, Teva argues that indefiniteness arguments are best reserved for trial, because of the "high burden of proof on a party challenging the patent based on indefiniteness," the dispositive nature of the ruling, and the lack of expert testimony at claim construction. *Id.* (citing *Adapt Pharma Operations Ltd. v. Teva Pharm. USA, Inc.*, No. 16-7721-JLL, 2019 WL 1789463, at *4 (D.N.J. Apr. 24, 2019); *Int'l Dev. LLC v. Richmond*, No. 9-2495-GEB, 2010 WL 4703779, at *6 (D.N.J. Nov. 12, 2010)). The Court agrees. It is not uncommon for courts to defer ruling on an indefiniteness challenge at the claim construction stage where such a ruling would be better suited for trial. *See Adapt Pharma Operations*, No. CV 16-7721, 2019 WL 1789463, at *4 (citing *Alcon Research, Ltd. v. Barr Labs. Inc.*, No. 09-0318, 2011 WL 3901878, at *16 (D. Del. Sept. 6, 2011) (collecting cases)). Because the indefiniteness argument in this claim construction is "potentially dispositive, require[s] a high burden of proof, and may more profitably be considered in connection with patent validity," the Court declines to rule on the indefiniteness of "the body" at the claim construction stage. *See Adapt Pharma Operations*, No. CV 16-7721, 2019 WL 1789463, at *4 (citing *Fresenius Kabi USA, LLC v. Fera Pharm., LLC*, No. 15-3654, 2016 WL 5109142, at *9 (D.N.J. Sept. 20, 2016)).

16. "different sides"

Term	Teva's Proposed Construction	Defendants' Proposed Construction	Court's Construction
"different sides"	"not the same side"	"distinct surfaces where each pin/aperture of the chassis connects to a different face of the body"	"different sides"

The parties dispute whether the term "different sides" requires that the pin/aperture connections are on different surfaces. There is no such requirement in the language of the claim. Claim 1 of the '512 Patent provides that "either the pins or the apertures on the chassis are positioned on different sides of the chassis for stabilizing the chassis on the body[.]" '512 Patent, Claim 1 (Ex. 5). Teva argues that "different sides" does not require any construction. Teva Br. at 54. Defendants, on the other hand, argue that the proper construction is the "distinct surfaces where each pin/aperture of the chassis connects to a different face of the body." Def.'s Br. at 34.

In support of their proposed construction, Defendants point the Court to the prosecution history of a related application that is not at issue. In so doing, Defendants ignore the claim language, which, in general terms, provides that the pins or apertures are not positioned on the same side of the chassis. *See* '512 Patent, Claim 1 (Ex. 5). Defendants also point the Court to various Figures, which they claim support their proposed construction. Def.'s Br. at 35. Teva counters arguing that "several figures in the specification undercut Defendants' position." Teva Br. at 55. For example, the preferred embodiment illustrated in Figures 6B and 6C show that apertures 188, 190, 192 are formed on three different sides of the chassis and Figures 8B and 8C show two pins on the inhaler that are located on the same face of the body. *Id.* Under Defendants' proposed construction, Teva's preferred embodiments would be excluded. *See, e.g.*, *Epos Techs.*

Ltd. v. Pegasus Techs. Ltd., 766 F.3d 1338, 1347 (Fed. Cir. 2004) ("[A] claim construction that excludes a preferred embodiment . . . is rarely, if ever correct and would require highly persuasive support."). Accordingly, the Court declines to adopt Defendants' proposed construction, finds that the plain and ordinary meaning of the claim language controls, and no further claim construction is needed.

17. "formed in the body"

Term	**Teva's Proposed Construction**	**Defendants' Proposed Construction**	**Court's Construction**
"formed in the body"	"located in the body"	"an integrated part of the body"	"formed in the body"

The main dispute between the parties is whether the structure that forms the dose counter chamber in the body is an integrated part of the body, or not necessarily part of the body but located in the body. Defendants contend that the specification and figures make plain that the dose counter chamber is formed by walls of the body and is therefore "an integrated part of the body." Def.'s Br. at 37. In contrast, Teva argues that the term requires no construction; but if construction is necessary, the Court should define "formed in the body" as "located in the body." Teva Br. 56-57.

In support of their proposed construction, Defendants point to claim 2 of the '512 Patent. Def.'s Br. at 37. Defendants argue that in claim 2 the "'dose counter chamber' is defined by the inner walls of the main body and the inner wall separating the dose counter chamber from the canister chamber, i.e., the separator wall **76**." *Id.* (emphasis in original). Based on this, Defendants argue that "[t]he inner walls of the main body are obviously an 'integrated' part of the body." *Id.* Finally, Defendants contend that "the separator wall is depicted in the figures as integrated with the inner walls of the main body." *Id.*

Teva argues that Defendants' proposal, in effect, rewrites the claim by changing the locational requirement "***formed in*** the body" to the compositional requirement "***created by*** the body." Teva Br. at 57 (emphasis in original). Teva notes that "formed in the body" merely indicates that the dose counter chamber has to be located inside, rather than outside of the body of the inhaler. *Id.* Teva argues that "[i]t does not impose any additional restrictions on how the dose counter chamber was made, what structures form the boundaries of the chamber, etc." *Id.*

Claim 2 of the '512 Patent, expressly provides that "[t]he inhaler as claimed in claim 1, wherein the dose counter is positioned in a dose counter chamber that is formed in the body at a location beneath the medicament canister." '512 Patent, Claim 2, ECF No. 109-6. Contrary to Defendants assertion, nothing in claim 2 of the '512 Patent requires that "the dose counter chamber is formed ***by walls of the body***." Def.'s Br. 37 (emphasis in original). Based on the plain language of the claim, the dose counter chamber is "formed ***in the body*** at a location beneath the medicament canister." '512 Patent, Claim 2, ECF No. 109-6. As Teva correctly notes, "[t]hat language limits the dose counter's location, not which surfaces must create it." Teva Resp. Br. at 38. When reading the term "formed in the body" in context with the entire claim, the Court finds that "formed in the body" is a term that a POSA would understand. Accordingly, the Court finds that the plain and ordinary meaning of the claim language controls, and no further claim construction is needed.

IV. CONCLUSION

For the reasons stated above, this Court construes the disputed claims as set forth in this Opinion. An appropriate order follows.

s/ Julien Xavier Neals

DATED: November 11, 2022

JULIEN XAVIER NEALS
United States District Judge