IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA
Clarksburg

ASTRAZENECA AB and **ASTRAZENECA PHARMACEUTICALS LP,**

Plaintiffs,

v.

CIVIL ACTION NO. 1:22-CV-35
Judge Bailey

MYLAN PHARMACEUTICALS, INC. and **KINDEVA DRUG DELIVERY L.P.,**

Defendants.

MEMORANDUM OPINION AND ORDER

This patent infringement case involves one (1) United States Patent issued to AstraZeneca AB and sold and distributed by AstraZeneca Pharmaceuticals LP (collectively, "AstraZeneca"). Specifically, the patent at issue is U.S. Patent No. 11,311,558 ("the patent-in-suit"). AstraZeneca uses the pharmaceutical compositions and methods described in the patent to produce Symbicort®, a prescription drug approved for the treatment of inflammatory conditions/disorders, especially respiratory diseases such as asthma, chronic obstructive pulmonary disease ("COPD"), and rhinitis. The patent-in-suit shares a specification with U.S. Patent Nos. 7,759,328, 8,143,239, 8,575,137, and 10,166,247 that were the subject of two prior trials before Judge Keeley, but their claims have different scopes.

Pending before this Court is the parties' proposed competing claim construction of four (4) terms:

Claim Term	AstraZeneca's Proposed Construction	Mylan's Proposed Construction
"pharmaceutical composition"	"suspension for therapeutic administration"	Indefinite. Alternatively, "a formulation intended for therapeutic administration"
"formoterol"	"formoterol"	"Formoterol, including its enantiomers, mixtures of its enantiomers, the free base, salt or solvate, or a solvate of a salt"
"budesonide or an epimer thereof"	"budesonide or an epimer thereof"	"Budesonide, including epimers, esters, salts, and solvates thereof"
"about 0.001% w/w"	"approximately 0.001% w/w"	"0.001% ± 0.0002% w/w, i.e. within 0.0008%–0.0012% w/w"

I. Background

According to AstraZeneca, 3M Company, through its 3M Drug Delivery Systems division, submitted Abbreviated New Drug Application ("ANDA") No. 211699 to the United States Food and Drug Administration ("FDA") under 21 U.S.C. § 355(j), in order to obtain approval to engage in the commercial manufacture, use or sale of budesonide and formoterol fumarate dihydrate inhalation aerosol, 80 mcg/4.5 mcg and 160 mcg/4.5 mcg ("Mylan's ANDA Products"). *See* [Doc. 1 at 4]. On August 17, 2018, 3M transferred certain interests in ANDA No. 211699 to Mylan Pharmaceuticals Inc. [Id.]. Thereafter, on May 1, 2020, 3M closed on a transaction whereby 3M sold substantially all of its drug delivery systems business to an affiliate of Altaris Capital Partners, LLC ("Altaris"). [Id.]. Following this transaction, Altaris launched Kindeva as an independent company, and all of 3M's

activities relating to ANDA No. 21169 were transferred to Kindeva. [Id.]. Kindeva will manufacture Mylan's ANDA Products. [Id. At 4–5]. ANDA No. 21169 was approved on March 16, 2022.

In a letter dated August 30, 2018, Mylan notified AstraZeneca that it had filed ANDA No. 211699 seeking approval to market Mylan's ANDA Products prior to the expiration of the patents listed in FDA's Approved Drug Products with Therapeutic Equivalence Evaluations for Symbicort. [Id. at 5]. In its letter, Mylan asserted that the '328, '239, and '137 patents are invalid, unenforceable, and not infringed by the commercial manufacture, use, or sale of Mylan's ANDA Products. [Id. at 6].

In a second letter dated October 11, 2019, Mylan notified AstraZeneca that it had submitted a certification to the FDA to obtain approval to engage in the commercial manufacture, use, or sale of the product described in ANDA No. 211699 prior to the expiration of the '247 patent. [Id. at 5]. In its second letter, Mylan also asserted that the '247 patent was invalid, unenforceable, and not infringed by the commercial manufacture, use, or sale of Mylan's ANDA Products. [Id. at 6].

The parties proceeded to trial on the '328, '239, and '137 patents (the "Trial Patents") in October 2020. [Id.]. Prior to trial, Mylan stipulated to infringement of the asserted claims of the Trial Patents. [Id.]. After a five-day trial, Judge Keeley entered judgment of nonobviousness as to each asserted claim. *See* ***AstraZeneca AB v. Mylan Pharms. Inc.***, 522 F.Supp.3d 200 (N.D. W.Va. Mar. 2, 2021) (Keeley, J.). The Court held that a person of ordinary skill in the art ("POSA") "would not have been motivated to select the specific formulation claimed by the patents-in-suit." ***Id.*** at 219. The Court further found

that the prior art "teaches away and does not render the claims obvious" because it "cut against the very goal a POSA would have been trying to achieve–a stable product with a consistent dose." ***Id.*** at 220. Judge Keeley likewise found that "a POSA would not have had a reasonable expectation of success in creating a stable budesonide pMDI using HFA 227, PVP K25, and PEG-1000, much less when these ingredients were combined with formoterol." ***Id.***

Mylan appealed, and the Federal Circuit affirmed the Court's judgment of nonobviousness. ***AstraZeneca AB v. Mylan Pharms. Inc.***, 19 F.4th 1325, 1337–38 (Fed. Cir. 2021).[1]

In a letter dated March 8, 2022, AstraZeneca notified Mylan that the United States Patent and Trademark Office ("USPTO") allowed the pending claims of U.S. Patent Application No. 16/832,590 ("the '590 application"), which issued as the '558 patent on April 26, 2022. [Doc. 1 at 7]. In its letter, AstraZeneca notified Mylan of two items: (1) that its proposed generic Symbicort products infringe every limitation of the allowed claims and (2) that the allowed claims were substantially identical to the invention claimed in the U.S. Patent Application Publication No. 2021/0069215 ("the '215 publication"). [Id.].

II. Legal Standards

The construction of patent claims is a matter of law governed by federal statutes and the decisions of the Supreme Court of the United States and the United States Court

[1] The Federal Circuit disagreed with the Court's construction of a term not at issue in most claims of the patent-in-suit (0.001%). The Federal Circuit vacated for further proceedings. Judge Keeley issued a Memorandum Opinion and Order Following Bench Trial on November 9, 2022, holding Mylan carried its burden of proving that the asserted claims are invalid pursuant to 35 U.S.C. § 112 for lack of enablement and lack of written description. *See* Civ. Act. No. 1:18-CV-193 [Doc. 606].

of Appeals for the Federal Circuit. *See* ***Markman v. Westview Instruments, Inc.***, 52 F.3d 967, 979 (Fed. Cir. 1995). When interpreting the meaning of a claim, a court may consider the context, the specification, and the prosecution histories as intrinsic evidence. ***Id.*** (quoting ***Unique Concepts, Inc. v. Brown***, 939 F.2d 1558, 1561 (Fed. Cir. 1991)). "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) (internal quotation marks omitted). The description of an invention in the claims, therefore, limits the scope of the invention. ***Id.*** "[T]here is no magic formula or catechism for conducting claim construction." ***Id.*** at 1324. Instead, the Court is free to attach the appropriate weight to appropriate sources "in light of the statutes and policies that inform patent law." ***Id.***

"[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 (internal citations and quotation marks omitted). "[T]he ordinary meaning of a claim term is its meaning to the ordinary artisan after reading the entire patent." ***Id.*** at 1321 (internal quotation marks omitted).

When construing patent claims, then, a court must consider the context of the entire patent, including both asserted and unasserted claims. ***Id.*** Because a patent will ordinarily use patent terms consistently, "the usage of a term in one claim can often illuminate the meaning of the same term in other claims." ***Id.*** Accordingly, "[d]ifferences among claims" can provide insight into "understanding the meaning of particular claim terms," and "the

presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." ***Id.*** at 1314–15 (citing ***Liebel-Flarsheim Co. v. Medrad, Inc.***, 358 F.3d 898, 910 (Fed. Cir. 2004)).

Pursuant to 35 U.S.C. § 112(a), an inventor must use the patent specification to describe the claimed invention in "full, clear, concise, and exact terms." The patent specification therefore "is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." ***Vitronics Corp. v. Conceptronic, Inc.***, 90 F.3d 1576, 1582 (Fed. Cir. 1992).

"[T]he specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor's lexicography governs." ***Phillips***, 415 F.3d at 1316. "Even when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction." ***Hill-Rom Servs., Inc. v. Stryker Corp.***, 755 F.3d 1367, 1372 (Fed. Cir. 2014) (quoting ***Liebel-Flarsheim***, 358 F.3d at 906) (internal quotation marks omitted).

Nevertheless, a court may not import a limitation into the claims from the specification. ***Phillips***, 415 F.3d at 132. The Federal Circuit has "repeatedly warned" against limiting the claims to the embodiments specifically described in the specification. ***Id.*** In other words, a court should not construe the patent claims as being limited to a single embodiment simply because the patent describes only one embodiment. ***Id.*** (citing

Gemstar-TV Guide Int'l Inc. v. Int'l Trade Comm'n, 383 F.3d 1352, 1366 (Fed. Cir. 2004)).

A court "should also consider the patent's prosecution history, if it is in evidence." ***Markman***, 52 F.3d at 980. The prosecution history, which is "intrinsic evidence," "consists of the complete record of the proceedings before the PTO [Patent and Trademark Office] and includes the prior art cited during the examination of the patent." ***Phillips***, 415 F.3d at 1317. "[T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." ***Id***.

"The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." ***Renishaw PLC v. Marposs Societa' per Azioni***, 158 F.3d 1243, 1250 (Fed. Cir. 1998). It follows that "a claim interpretation that would exclude the inventor's device is rarely the correct interpretation." ***Osram GmbH v. Int'l Trade Comm'n***, 505 F.3d 1351, 1358 (Fed. Cir. 2007) (quoting ***Modine Mfg. Co. v. U.S. Int'l Trade Comm'n***, 75 F.3d 1545, 1550 (Fed. Cir. 1996)).

Finally, while a court may consider extrinsic evidence such as expert testimony, dictionaries, and learned treatises in defining the "ordinary and customary meaning" of a term, such evidence carries less legal significance than the intrinsic record. ***Id***. Reliable extrinsic evidence includes "those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean." ***Id***. at 1314

(quoting ***Innova/Pure Water, Inc. v. Safari Water Filtration Systems, Inc.***, 381 F.3d 1111, 1116 (Fed. Cir. 2004)). Extrinsic evidence "is to be used for the court's understanding of the patent, not for the purpose of varying or contradicting the terms of the claims." ***Markman***, 52 F.3d at 981.

The "ultimate issue of the proper construction of a claim" is a matter of law reviewed de novo, but a court's resolution of subsidiary factual issues during claim construction is reviewed for clear error. ***Teva Pharma. USA, Inc. v. Sandoz, Inc.***, 574 U.S. 318 (2015). When a judge reviews only intrinsic evidence, her "determination will amount solely to a determination of law, and the Court of Appeals will review that construction de novo." ***Id.*** at 841. When a judge needs to "look beyond the patent's intrinsic evidence" and consult extrinsic evidence to understand the background science, or the meaning of a term, she will "need to make subsidiary factual findings about that extrinsic evidence," which will be reviewed for clear error. ***Id.***

III. The Claims

The Court begins its analysis by looking to the "actual words of the claim," ***Becton, Dickinson and Co. v. Tyco Healthcare Group, LP***, 616 F.3d 1249, 1254 (Fed. Cir. 2010), as well as the context in which the disputed term appears. ***Phillips***, 415 F.3d at 1314. Patent claims come in two general forms: independent and dependent. 35 U.S.C. § 112(c). Independent claims do not refer to any other claim of the patent and are read separately to determine their scope. ***Inamin, Ltd. v. Magnetar Tech. Corp.***, 623 F.Supp.2d 1055, 1065 (C.D. Cal. 2009). Dependent claims, in contrast, refer to at least one other claim, include all of the limitations of the claim to which they refer, and specify

a further limitation on that claim. 30 U.S.C. § 112(d); *see also* ***Monsanto Co. v. Syngenta Seeds, Inc.***, 503 F.3d 1352, 1357 (Fed. Cir. 2007).

1. The '558 Patent

Independent claim 1 reads:

> 1. A pharmaceutical composition comprising formoterol, budesonide, or an epimer thereof, 1,1,1-2,3,3,3-heptafluoropropane (HFA 227), about 0.0005 to about 0.05% w/w polyvinyl pyrrolidone (PVP) K25, and about 0.05 to about 0.35% w/w polyethylene glycol (PEG) 1000 (PEG having an average molecular weight of 1000 Daltons).

'558 Patent, col. 8. Dependent claim 4 reads:

> 4. The pharmaceutical composition according to claim **1** wherein the formoterol is in the form of fumarate dihydrate salt.

Id. Dependent claim 7 reads:

> 7. The pharmaceutical composition according to claim **1**, wherein the pharmaceutical composition is in the form of a suspension.

Id. Dependent claim 12 reads:

> 12. The pharmaceutical composition according to claim **1** wherein the PVP K25 is present in an amount of about 0.001% w/w.

Id.

IV. Claim Construction

The task of the Court is to "define[ ] the claim[s] with whatever specificity and precision is warranted by the language of the claim and the evidence bearing on the proper

construction." ***PPG Indus. v. Guardian Indus. Corp.***, 156 F.3d 1351, 1355 (Fed. Cir. 1998).

A. "pharmaceutical composition"

Mylan's "pharmaceutical composition" construction recites "a formulation intended for therapeutic administration." AstraZeneca's proposes a narrower construction, "a suspension for therapeutic administration."

"'[C]laim differentiation' refers to the presumption that an independent claim should not be construed as requiring a limitation added by a dependent claim. *See* ***Nazomi Commc'ns, Inc. v. Arm Holdings, PLC.***, 403 F.3d 1364, 1370 (Fed. Cir. 2005) ('[C]laim differentiation "normally means that limitations stated in dependent claims are not to be read into the independent claim from which they depend."' (quoting ***Karlin Tech., Inc. v. Surgical Dynamics, Inc.***, 177 F.3d 968, 971–72 (Fed. Cir. 1999))); *see also* ***Phillips***, 415 F.3d at 1314–15 (explaining the presumption without invoking the 'claim differentiation' label). Thus, the claim differentiation tool works best in the relationship between independent and dependent claims. *See* ***Liebel-Flarsheim Co. v. Medrad, Inc.***, 358 F.3d 898, 910 (Fed. Cir. 2004) (citing ***SunRace Roots Enter. Co. v. SRAM Corp.***, 336 F.3d 1298, 1302–03 (Fed. Cir. 2003))." ***Curtiss-Wright Flow Control Corp. v. Velan, Inc.***, 438 F.3d 1374, 1380 (Fed. Cir. 2006).

35 U.S.C. § 112 stresses that a dependent claim must add a limitation to those recited in the independent claim. *See* 35. U.S.C. § 112 (2000) ("[A] claim in dependent form shall contain a reference to a claim previously set forth and then specify ***a further limitation of the subject matter claimed***." (emphasis added)). "Thus, reading an

additional limitation from a dependent claim into an independent claim would not only make the additional limitations superfluous, it might render the dependent claim invalid." ***Id.***

1. Suspension

The patent-in-suit includes independent claim 1 and dependent claims 2–13, which all depend from claim 1. Dependent claim 7 adds just a single limitation to independent claim 1: it requires that the "pharmaceutical composition according to claim 1" must be "in the form of a suspension." '558 Patent, col. 8. Claims 1 and 7 of the patent-in-suit thus trigger a strong presumption that the "suspension" limitation of dependent claim 7 should not be imported into the broader "pharmaceutical composition" of claim 1. Were it otherwise, claim 7 would be rendered meaningless.

The doctrine of claim differentiation is at its strongest in this case "where the limitation that is sought to be 'read into' an independent claim already appears in a dependent claim." ***InterDigital Communications, LLC v. International Trade Com'n***, 690 F.3d 1318, 1324 (Fed. Cir. 2012) (quoting ***Liebel-Flarsheim Co.***, 358 F.3d at 910)). Although the doctrine of claim differentiation creates only a presumption, which can be overcome by strong contrary evidence such as definitional language in the patent or a clear disavowal of claim scope, neither type of contrary evidence is present here. To the contrary, the presumption is "especially strong" in this case because "the limitation in dispute is the only meaningful difference between an independent and dependent claim, and one party is urging that the limitation in the dependent claim should be read into the independent claim." ***SunRace Roots Enter. Co.***, 336 F.3d at 1303.

Here, if the term "pharmaceutical composition" means "a suspension for therapeutic administration," then claim 7 would read: "A suspension for therapeutic administration according to claim **1**, wherein a suspension for therapeutic administration is in the form of a suspension." That would render claim 7 superfluous and redundant of claim 1. The term "pharmaceutical composition" must be construed as "a formulation for therapeutic composition," which includes other forms of compositions as well, including at least solutions.

2. Stability

Mylan seeks to read a functional stability requirement into "pharmaceutical composition" whereas AstraZeneca argues "pharmaceutical composition" does not include a functional stability requirement.

Because the claims–and not the specification–delineate the scope of exclusive rights, courts must not "improperly import[] a limitation from the specification into the claims." ***Cont'l Circuits LLC v. Intel Corp.***, 915 F.3d 788, 796–97 (Fed. Cir. 2019) (quotation omitted). Where, as here, multiple patents "derive from the same parent application and share many common terms," the court "must interpret the claims consistently across all asserted patents." ***SightSound Techs., LLC v. Apple Inc.***, 809 F.3d 1307, 1316 (Fed. Cir. 2015) (quoting ***NTP, Inc. v. Research in Motion, Ltd.***, 418 F.3d 1282, 1293 (Fed. Cir. 2005)).

The asserted claims of the patent-in-suit do not expressly recite a functional stability requirement. Reading a stability limitation into "pharmaceutical composition" violates the "well-established principle that a court may not import limitations from the written

description into the claims." ***Laitram Corp. v. NEC Corp.***, 163 F.3d 1342, 1347 (Fed. Cir. 1998); ***Phillips***, 415 F.3d at 1320, ***Cont'l Circuits***, 915 F.3d at 796–97.

An invention's purpose or property is not a claim limitation, unless it is recited explicitly in the claim. "[N]ot every benefit flowing from an invention is a claim limitation." ***i4i Ltd. P'ship v. Microsoft Corp.***, 598 F.3d 831, 843 (Fed. Cir. 2010). Even where a "claimed composition was designed to solve certain problems of the prior art" and "the patentee noted the functional import" in the specification, it "does not mean that we must attribute a function to [a] nonfunctional phrase." ***Ecolab, Inc. v. Envirochem, Inc.***, 264 F.3d 1358, 1367 (Fed. Cir. 2001). Simply put, "[w]here the function is not recited in the claim itself by the patentee, we do not import such a limitation." ***Id***. The "excellent physical suspension stability" of the compositions in the patent-in-suit was an important benefit of the invention, but that characteristic, unrecited in the claims, does not turn the physical suspension stability into a claim limitation.

"The fact that a patent asserts that an invention achieves several objectives does not require that each of the claims be construed as limited to structures that are capable of achieving all of the objectives." ***Phillips***, 415 F.3d at 1327. "An invention may possess a number of advantages or purposes, and there is no requirement that every claim directed to that invention be limited to encompass all of them." ***E-Pass Techs., Inc. v. 3Com Corp.***, 343 F.3d 1364, 1370 (Fed. Cir. 2003). Thus, the Federal Circuit's statement regarding the related patents that "the written description and prosecution history place considerable emphasis on the stability of the claimed formulations" does not support reading a stability limitation into the claims. ***AstraZeneca AB***, 19 F.4th at 1330.

"Even if 'all of the embodiments discussed in the patent' included a specific limitation, it would not be 'proper to import from the patent's written descriptions limitations that are not found in the claims themselves.'" ***Cadence Pharms. Inc. v. Exela PharmSci Inc.***, 780 F.3d 1364, 1369 (Fed. Cir. 2015) (quoting ***Flo Healthcare Solutions, Inc. v. Kappos***, 697 F.3d 1367, 1375 (Fed. Cir. 2012)).

The '247 patent claims recite a "*stable* pharmaceutical composition." As Judge Keeley's decision following the trial of the '247 patent explained, the claims of the '247 patent "contain an important behavioral limitation, that the formulation be 'stable.' This is a considerable change from the Previously Tried Claims which imposed even more specific structural limitations upon the formulation by requiring particular grades or concentrations of each of the five ingredients." Civ. Act. No. 1:18-CV-193 [Doc. 606 at 23]. This confirms that "pharmaceutical composition" does not require "stable" in the patent-in-suit. Importing a stability requirement into "pharmaceutical composition" here would render the term "stable" in the '247 patent superfluous. The Previously Tried Claims–*i.e.*, the claims of the '328, '237, and '139 patents asserted at the 2020 trial–like the patent-in-suit here, do not use the modifier "stable" with "pharmaceutical composition." The term "stable" in the '247 patent added a requirement that "pharmaceutical composition" did not carry: "'stable' further requires the applicable type of stability to be present." *See* [Doc. 158-25 at 22].

Because it is "highly disfavored to construe terms in a way that renders them void, meaningless, or superfluous," ***Wasica Fin. GMBH v. Cont'l Auto Sys., Inc.***, 853 F.3d 1272, 1288 n.10 (Fed. Cir. 2017), this Court declines to limit the term "pharmaceutical composition" to stable compositions. This Court notes that claims must be construed

consistently across all asserted patents. However, the patent-in-suit added a claim separate and distinct from other claims in the Previously Tried Patents. Thus, this Court will adopt "pharmaceutical composition" to mean "a formulation for therapeutic composition" so as to not include a functional stability requirement but also not render meaningless claim 7.

B. "formoterol" and "budesonide or an epimer thereof"

Although the parties in this case have litigated this patent family and specification for several years, neither has previously sought a construction of "formoterol" or "budesonide or an epimer thereof." In an attempt to preempt a hypothetical argument of its opponent, Mylan now asserts that construction of these terms is necessary. Specifically, it contends that AstraZeneca will improperly attempt to "limit the terms to particular forms of the chemicals described in the patent." *See* [Doc. 161 at 7]. But, as of yet, AstraZeneca has done no such thing and there appears to be no real dispute between the parties as to the scope of the terms. In fact, AstraZeneca agrees that the terms "do not exclude the drug forms in Mylan's construction" and Mylan concedes that it infringes these elements under either parties' construction. [Doc. 163 at 25].

"The ***Markman*** decisions do not hold that the trial judge must repeat or restate every claim term in order to comply with the ruling that claim construction is for the court. Claim construction is a matter of resolution of disputed meanings and technical scope, to clarify and when necessary to explain what the patentee covered by the claims, for use in the determination of infringement. It is not an obligatory exercise in redundancy." ***U.S. Surgical Corp. v. Ethicon, Inc.***, 103 F.3d 1554, 1568 (Fed. Cir. 1997).

Moreover, "although the claims are construed objectively and without reference to the accused device, only those terms need to be construed that are in controversy, and only to the extent necessary to resolve the controversy." ***Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.***, 200 F.3d 795, 803 (Fed. Cir. 1999).

Because the preference is to avoid needless constructions, this Court declines to construe "formoterol" and "budesonide or an epimer thereof." The parties have litigated claims with these terms for years without any further construction. The parties have fully participated in ***Markman*** proceedings both here and in Delaware, and have never previously sought construction of these terms. "The simple reason no party sought construction is that the meaning of these terms is not disputed–'formoterol' and 'budesonide or an epimer thereof' do not exclude the drug forms in Mylan's construction." *See* [Doc. 163 at 25].

Thus, this Court will adopt "formoterol" and "budesonide or an epimer thereof" to have their plain and ordinary meaning.

C. "about 0.001% w/w"

The term "about" appears in Claim 12 of the patent-in-suit. Specifically, Claim 12 states:

> 12. The pharmaceutical composition according to claim **1** wherein the PVP K25 is present in an amount of **about 0.001% w/w**.

'558 Patent, col. 8. AstraZeneca argues that "about" should be interpreted to mean "approximately." Mylan, on the other hand, contends that about should be ascribed a precise numerical range, i.e., "0.001 ± 0.0002% w/w, i.e. within 0.0008%-0.0012% w/w."

The claims and the specifications use the term "about" but never attempt to define it numerically. The Federal Circuit has made it clear that "about" is to be given its plain and ordinary meaning. *See also* ***Ferring B.V. v. Watson Labs., Inc.-Fla.***, 764 F.3d 1382, 1389 (Fed. Cir. 2014) ("We think that the district court did not err in giving the term 'about' its ordinary meaning and in refusing to give it a more specific construction."); ***Merck & Co., Inc. v. Teva Pharms. USA, Inc.***, 395 F.3d 1364, 1372 (Fed. Cir. 2005) ("Because the patentee did not clearly redefine 'about' in the specification, . . . [w]e thus hold that the term 'about' should be given its ordinary and accepted meaning of 'approximately.'"); ***Par Pharm. Inc. v. Hospira, Inc.***, 835 Fed.App'x. 578, 584 (Fed. Cir. 2020) ("The district court's analysis is consistent with our precedents. The parties agreed that 'about' should be construed to have its 'plain and ordinary meaning' of 'approximately' . . . with no further refinement as a claim-construction matter.").

"When 'about' is used as part of a numeric range, 'the use of the word "about[]" avoids a strict numerical boundary to the specified parameter. Its range must be interpreted in its technologic and stylistic context.' [***Pall Corp.***, 66 F.3d at 1217]. In determining how far beyond the claimed range the term 'about' extends the claim, '[w]e must focus ... on the criticality of the [numerical limitation] to the invention.' ***Ortho-McNeil Pharm., Inc. v. Caraco Pharm. Ltd.***, 476 F.3d 1321, 1327 (Fed. Cir. 2007). In other words, we must look to the purpose that the 'about 30 μm' limitation serves, to determine how much smaller than 30 μm the average particle diameter can be and still serve that purpose. To be clear, it is the purpose of the ***limitation*** in the claimed invention–not the

purpose of the invention itself–that is relevant." ***Cohesive Techs., Inc. v. Waters Corp.***, 543 F.3d 1351, 1368 (fed. Cir. 2008) (emphasis in original).

Here, the parties dispute the meaning of "about" in the context of a claim limitation that PVP K25 is present in an amount of "about 0.001% w/w." Mylan erroneously attempts to turn a dispute about infringement into a dispute about claim construction. The question of whether "about 0.001%" encompasses Mylan's concentration of PVP K25 is "a question of technologic fact whether an accused device meets a reasonable meaning of 'about' in the particular circumstances." ***Par Pharm., Inc. v. Hospira, Inc.***, 835 Fed.App'x 578, 584 (Fed. Cir. 2020). The "strict numerical boundary" Mylan currently seeks to engraft into the claim is the exact type of specificity for the claim term "about" the Federal Circuit proscribes. ***Cohesive Techs., Inc.***, 543 F.3d at 1368. Thus, this Court rules that "about" means "approximately" and will wait to hear the evidence presented at trial to determine what the word "approximately" means based on the stylistic and technological context of the '558 patent.

"[A] district court may engage in claim construction during various phases of litigation, not just in a ***Markman*** order." ***Conoco, Inc. v. Energy & Envtl Int'l, L.C.***, 460 F.3d 1349, 1359 (Fed. Cir. 2006). This Court may "engage in rolling claim construction, in which the court revisits and alters its interpretation of the claim terms as its understanding of the technology evolves." ***Id.*** (quoting ***Guttman, Inc. v. Kopykake Enters., Inc.***, 302 F.3d 1352, 1361 (Fed. Cir. 2002)).

V. Conclusion

For the foregoing reasons, this Court **CONSTRUES** the following terms and phrases as follows:

1. "pharmaceutical composition" means "a formulation for therapeutic administration";
2. "formoterol" means "formoterol";
3. "budesonide or an epimer thereof" means "budesonide or an epimer thereof"; and
4. "about 0.001% w/w" means "approximately 0.001% w/w".

It is so **ORDERED**.

The Clerk is directed to transmit copies of this Order to all counsel of record herein.

DATED: November 23, 2022.

JOHN PRESTON BAILEY
UNITED STATES DISTRICT JUDGE