**United States District Court**
**Southern District of New York**

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**DEY, INC., ET AL.,**
**Plaintiffs,**

**- against -**

**SEPRACOR, INC.,**
**Defendant.**

**07 Civ. 2353 (JGK)**

**MEMORANDUM OPINION AND ORDER**

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**JOHN G. KOELTL, District Judge:**

This patent infringement action involves formoterol-based pharmaceuticals that are used to treat chronic obstructive pulmonary disease, or COPD. The plaintiffs, Dey L.P., Dey, Inc., and Mylan, Inc., (collectively, "Dey"), and the defendant, Sunovion Pharmaceuticals, Inc. ("Sunovion"), are pharmaceutical companies. Dey alleges that Brovana, a pharmaceutical product made by Sunovion, infringes several of its patents. The Court now construes certain disputed claim terms from the patents in suit pursuant to Markman v. Westview Instruments, Inc., 517 U.S. 370 (1996) in preparation for the impending jury trial.

## I.

Claim construction is a matter of law. See Markman v. Westview Instruments, Inc., 52 F.3d 967, 970 (Fed. Cir. 1995) (en banc) (citation omitted), aff'd 517 U.S. 370 (1996). Courts determine the scope of a claim by applying well-known principles

of claim construction and examining three relevant sources: the language of the claim, the specification and the prosecution history. See Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996); see generally Phillips v. AWH Corp., 415 F.3d 1303, 1312–17 (Fed. Cir. 2005) (en banc); see also Hypoxico, Inc. v. Colo. Altitude Training, LLC, No. 02 Civ. 6191, 2008 WL 4129269, at *2 (S.D.N.Y. Sept. 4, 2008).

The language of a claim provides the starting point in a claim construction analysis. See Phonometrics, Inc. v. N. Telecom Inc., 133 F.3d 1459, 1464 (Fed. Cir. 1998). "Absent a special and particular definition created by the patent applicant, terms in a claim are to be given their ordinary and accustomed meaning." Renishaw PLC v. Marposs Societa' Per Azioni, 158 F.3d 1243, 1249 (Fed. Cir. 1998). "[T]he ordinary and customary meaning of a claim term 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 . . . ." Phillips, 415 F.3d at 1313.

The specification, however, is also highly relevant to the claim construction analysis, because it is the best guide to the meaning of a disputed term. Id. at 1315 (citing Markman, 52 F.3d at 978). While "it is the claims, not the written description, which define the scope of the patent right," Laitram Corp. v. NEC Corp., 163 F.3d 1342, 1347 (Fed. Cir.

1998), "[u]ltimately, the interpretation to be given a term can only be determined and confirmed with a full understanding of what the inventors actually invented and intended to envelop with the claim. 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." Phillips, 415 F.3d at 1316 (citation and internal quotation marks omitted).

A court in its discretion may also consider extrinsic evidence, including expert and inventor testimony, dictionaries, and learned treatises, in determining the meaning of claim terms; however, the Court of Appeals for the Federal Circuit has indicated that extrinsic evidence is less significant than the intrinsic record and that courts should discount expert testimony that is clearly inconsistent with the construction of the claim indicated by the written record. Phillips, 415 F.3d at 1317–19.

**II.**

The facts in this case, with which the parties are presumed to be familiar, are set forth in the Court's prior Opinion and Order, Dey, Inc. v. Sepracor, Inc., --- F. Supp. 2d ---, No. 07 Civ. 2353, 2012 WL 678175 (S.D.N.Y. Mar. 1, 2012), and need not be repeated here. In the previous Opinion and Order, the Court

granted partial summary judgment to Sunovion with respect to the second of the two families of patents at issue in this case pursuant to 35 U.S.C. § 102(b), based on the finding that those patents were invalid due to the prior public use of the claimed invention. Id. at *5-*9. The Court also granted partial summary judgment pursuant to 35 U.S.C. §§ 252 and 307 with respect to any claimed damages from any alleged infringement of Dey's first family of patents that occurred prior to the reexamination of those patents, because the independent claims in those patents had been substantively changed in the reexamination process. Id. at *12-*16. Thus, the Court need only construe the post-reexamination language of the disputed claims from Dey's first family of patents. Dey's first family of patents is composed of United States Patent Numbers 6,667,344 (the "'344 patent") and 6,814,953 (the "'953 patent"). The claims at issue are independent claim 1 ("Claim 1") of the '344 patent, and independent claim 74 ("Claim 74") of the '953 patent; dependent claim 2 ("Claim 2") of the '344 patent, and dependent claim 75 ("Claim 75") of the '953 patent, and dependent claim 65 ("Claim 65") of the '344 patent. Claims 1 and 74 were amended during reexamination. The other claims at issue were not.

## III.

### A.

Claim 1 claims:

> A pharmaceutical composition, comprising formoterol, or a derivative thereof, in a pharmacologically suitable aqueous solution, wherein the composition is stable during long term storage, the composition is formulated at a concentration effect[ive] for bronchodilation by nebulization, and the composition is suitable for direct administration to a subject in need thereof, without propellant and without dilution of the composition prior to administration.

See U.S. Patent No. 6,667,344, Reexamination Certificate C1 (8624th) (issued Oct. 11, 2011) ("'344 Patent Reexamination Certificate"), at col. 1, ll. 31-39.

Claim 74 claims:

> A method for the treatment, prevention, or amelioration of one or more symptoms of bronchoconstrictive disorders, comprising administering an effective amount of a pharmaceutical composition by nebulizer to a subject in need of such treatment, wherein the pharmaceutical composition comprises formoterol or a derivative thereof, formulated at a concentration suitable for direct administration to a subject in need of bronchodilation, without propellant and without dilution of the composition prior to administration, wherein said formoterol or derivative is present in a pharmacologically suitable aqueous solution, and wherein the composition is stable during long term storage.

See U.S. Patent No. 6,814,953, Reexamination Certificate C1 (8630th) (issued Oct. 18, 2011) ("'953 Patent Reexamination Certificate"), at col. 1, l. 66–col. 2, l. 11.

Claim 1 claims a pharmaceutical composition, while Claim 74 claims a method for administering the composition. However, the language used in both claims to describe the properties of the composition is the same, and it is that language which the parties dispute, and which the Court must construe. The parties dispute the following terms in the two independent claims:

- "pharmacologically suitable aqueous solution,"
- "stable during long term storage,"
- "formulated at a concentration effective for bronchodilation by nebulization," and
- "formulated at a concentration suitable for direct administration without propellant and without dilution of the composition prior to administration."[1]

Claim 2 claims:

> The pharmaceutical composition of [C]laim 1, wherein the composition has an estimated shelf-life of greater than one month usage time at 25° C. and greater than or equal to 1 year storage time at 5° C.

[1] The Court already construed much of the disputed language in the independent claims in its previous Opinion and Order, because it was necessary to construe the language from before and after the reexamination, during which the independent claims were amended, in order to determine whether the scope of the independent claims had substantively changed. See Dey, 2012 WL 678175, at *11.

See U.S. Patent No. 6,667,344 (issued Dec. 23, 2003; reexamination certificate issued Oct. 11, 2011) ("'344 Patent"), at col. 17, ll. 58-61.

Claim 75 claims:

> The method of [C]laim 74, wherein the composition has an estimated shelf-life of greater than one month usage time at 25° C. and greater than or equal to 1 year storage time at 5° C.

See U.S. Patent No. 6,814,953 (issued Nov. 9, 2004; reexamination certificate issued Oct. 18, 2011) ("'953 Patent"), at col. 21, ll. 59-62. With respect to Claims 2 and 75, the parties dispute the meaning of the term "shelf life."

Claim 65 claims:

> An article of manufacture, comprising packaging material, an aqueous composition comprising the composition of [C]laim 1 formulated for single dosage administration, which is useful for treatment, prevention or amelioration of one or more symptoms of diseases or disorders associated with undesired and/or uncontrolled bronchoconstriction, and a label that indicates that the composition is used for treatment, prevention or amelioration of one or more symptoms of diseases or disorders associated with undesired and/or uncontrolled bronchoconstriction.

'344 Patent at col. 21, ll. 27-36.

With respect to Claim 65, the parties dispute the following claim terms:

- "formulated for single dosage administration," and

- “a label that indicates that the composition is used for treatment, prevention or amelioration of one or more symptoms of diseases or disorders associated with undesired and/or uncontrolled bronchoconstriction.”

The Court will construe each of the disputed claim terms in turn.

**B.**

**1.**

The first issue is the meaning of the disputed term “pharmacologically suitable aqueous solution.” In its previous Opinion and Order, the Court held that the scope of the independent claims had substantively changed when the language of the claims was amended from a “pharmacologically suitable fluid” wherein “the fluid comprises water,” to a “pharmacologically suitable aqueous solution. See Dey, 2012 WL 678175, at *13-*14. The Court held that this change was substantive based in part on the prosecution history of the reexamination. During the reexamination, Dey distinguished its claim from a phospholipid-based fluid that comprised 1.5% water on the basis that the 1.5% water fluid was not “water-based.” See id. at *14 (“The difference, Dey explained, was that an aqueous solution is ‘water-based,’ and must contain more than

the 1.5% water found in a 'phospholipid-based fluid' such as Maesen's.").

Sunovion argues that the term "aqueous solution" is indefinite, because the solution must contain more than 1.5% water, but there is no way of knowing how much water it must contain in order to be "aqueous." This argument is unpersuasive, because, while Sunovion is correct that, based on the prosecution history, the solution must contain at least 1.5% water, it is not necessary to put an exact number on the amount of water required for a solution to be "aqueous." See Conoco, Inc. v. Energy & Envtl. Int'l, L.C., 460 F.3d 1349, 1355 (Fed. Cir. 2006) (affirming the district court's construction of a mixture described in the patent specification as "aqueous" as containing "more than negligible amounts of water"). Moreover, it is possible to arrive at a functional definition of a term based on the intrinsic record. A solution is a chemically and physically uniform mixture that contains at least one solvent and one solute, wherein the solute is dissolved into the solvent. See, e.g., Sears Petroleum & Transp. Corp. v. Archer Daniels Midland Co., No. 03 Civ. 1120, 2007 WL 2156251, at *13 (N.D.N.Y. 2007) (noting the dictionary definition of "solution" as a "homogeneous mixture of two or more substances, which may be solids, liquids, gases, or a combination of these." (quoting American Heritage Dictionary 1655 (4th ed. 2000)). An aqueous

solution, then, is a solution in which the solvent, or a primary solvent, is water. See, e.g., id. (noting that the "[u]se of the term 'aqueous' constricts the solution in issue . . . to a liquid with water as a component, or even the primary solvent" and construing the term to mean "a uniformly disbursed liquid mixture of two or more components, one of which is water, and which can contain incidental amounts of insoluble components"); accord McGraw-Hill Dictionary of Scientific and Technical Terms 120 (5th ed. 1994) (defining aqueous solution as "[a] solution in which the solvent is water"). Dey proposes that the Court construe the term as "a pharmacologically suitable solution in which the solvent is water-based," and the Court will adopt that construction, with a few modifications.

First, as explained in the previous Opinion and Order, the specifications, which were not amended during reexamination, no longer completely match up with the amended claim language. See Dey, 2012 WL 678175, at *14 ("The terms of the specifications indicate that some, but not all, of the fluids encompassed by the original claim terms were 'aqueous solutions' or 'aqueous mixtures', and therefore that some of the fluids encompassed by the original claim language were not aqueous solutions."). Nevertheless, the specifications plainly indicate that co-solvents, in addition to water, may be present in the solution, and the above-described plain meaning of "aqueous solution" is

consistent with that definition. See, e.g., '334 Patent at col. 9, ll. 6-14 ("Such solvents include, but are not limited to, water or alcohols . . . . Polar solvents also include protic solvents, including, but not limited to, water, aqueous saline solutions . . . , alcohols, glycols or a mixture thereof.").

Second, given the above-described prosecution of the patents during their reexamination, it is plain that an aqueous solution, as that term is used in the claims at issue, must be at least 1.5% water. See Dey, 2012 WL 678175, at *14. Indeed, it is difficult to conceive of how "a pharmacologically suitable solution in which the solvent is water-based," could use a solvent containing only negligible amounts of water. Water must be, if not the only solvent, then a primary or significant (rather than incidental or negligible) solvent in the solution for the solution to be "aqueous." However, the exact amount of water will depend on the co-solvents used in a given aqueous solution. In any event, water must be a non-negligible, or even primary, solvent. See, e.g., Conoco, 460 F.3d at 1355. The term "aqueous solution" as used in the claims at issue is not indefinite; it may be understood to require that water be a significant or primary co-solvent in the solution, which is consistent with the solvent being "water-based." This definition necessarily takes into account the fact that a

solvent that is 1.5% water will not be sufficient to form an aqueous solution within the meaning of the claim term.

The Court therefore adopts the following construction of the disputed term "pharmacologically suitable aqueous solution":

"A pharmacologically suitable fluid solution, where the solvent is water-based (water is the solvent or a primary co-solvent), and where the solution may include co-solvents, such as alcohols."

Dey argues that the court should also construe a "pharmacologically suitable aqueous solution" as one that is "not a liquified propellant gas," based on the language in the specifications. See, e.g., '334 Patent at col. 5, ll. 15-17. However, there is no basis for reading this additional limitation into the construction of the claim term "aqueous solution," especially when other terms in the claim already indicate that the method and composition claimed by the independent claims are "without propellant." See, e.g., Smartmetric Inc. v. Am. Express Co., 2012 WL 1367398, at *1 (Fed. Cir. 2012) (summary order) ("The claims are read in context with the specification, but limitations from the specification should not be read into the claims." (citing Phillips, 415 F.3d at 1315, 1323)).

**2.**

**a.**

The next issue is the parties' dispute over the term "stable during long term storage" in the independent claims. Dey argues that the Court should adopt the definition from the specifications, which state that:

> As used herein, the statement that a composition is stable during "long term storage" means that the composition is suitable for administration to a subject in need thereof when it has an estimated shelf-life of greater than 1, 2 or 3 months usage time at 25° C. and greater than or equal to 1, 2 or 3 years storage time at 5° C. In certain embodiments herein, using Arrhenius kinetics, >80% or >85% or >90% or >95% estimated bronchodilating agent remains after such storage.

See, e.g., '344 Patent at col. 6, l. 66 – col. 7, l. 6.

Sunovion argues that the Court should construe the term to mean: "The composition has an estimated shelf life of greater than 1 month usage time at 25° C. and greater than or equal to one year storage time at 5° C., where shelf-life indicates the length of time at a given temperature that greater than 80% of the initial amount of the active ingredient, formoterol, is present in the composition." The Court will adopt Sunovion's construction.

The parties have effectively admitted that there is no practical difference between these two constructions. See Apr. 12, 2012 Hr'g Tr. at 22 ("MR. HAUG: Right now I can't point to

any significant difference at all."). However, a construction which left multiple options for the percentages of formoterol remaining over multiple periods of time at a given temperature could confuse a jury, and force the jury impermissibly to construe the claim. Moreover, because there are dependent claims covering the composition, "wherein greater than 80% of the initial formoterol is present after 1 month usage time at 25° C. and one year storage time at 5° C," see, e.g., '344 Patent at col. 17, ll. 62-65, and the meaning of the independent claims must be broad enough to include these dependent claims, Dey, 2012 WL 678175, at *15 (citing AK Steel Corp. v. Sollac & Ugine, 344 F.3d 1234, 1242 (Fed. Cir. 2003)), it would make little sense to define the independent claim as potentially requiring 85%, or 90%, of the formoterol to remain after 2 or 3 months at room temperature. The independent claims must encompass as little as 80% formoterol retention.

Dey argues that the Court should not construe "stable during long term storage" as requiring at least 80% of the initial formoterol be present in the composition at a given time and temperature, because the specification says that "[i]n certain embodiments herein, . . . >80% or >85% or >90% or >95%" of the formoterol will remain. See, e.g., '344 Patent at col. 7, ll. 4-5. In other words, Dey argues that no specific amount of formoterol should be required to remain because the

specification only says that specific amounts of formoterol remain after a given period of time in "certain embodiments." However, nothing in the claim language, in the independent claims or the dependent claims, indicates any embodiment where less than 80% formoterol retention would still be considered "stable during long term storage." Nor does Dey point to any language in the claims or the specifications indicating how else, aside from the specification language indicating a minimum formoterol retention level of 80%, to tell if a sufficient amount of formoterol is left in the composition so that it has retained its properties and thus remains "suitable for administration to a subject in need thereof" after a period of storage. Dey's construction would thus invite the type of ambiguity to which courts routinely apply a narrowing construction.[2] See Halliburton Energy Servs., Inc. v. M-I LLC, 514 F.3d 1244, 1253 (Fed. Cir. 2008) ("We note that where a

[2] Moreover, to the extent that Dey presses the argument that the doctrine of claim differentiation requires that the independent claims include compositions that are "stable during long term storage" despite a lower level of formoterol retention than that described in the specifications and the dependent claims, the Court of Appeals for the Federal Circuit has recently reiterated that "claim differentiation is 'not a hard and fast rule and will be overcome by a contrary construction dictated by the written description or prosecution history.'" Marine Polymer Techs., Inc. v. HemCon, Inc., 672 F.3d 1350, 1359 (Fed. Cir. 2012) (en banc) (quoting Seachange Int'l, Inc. v. C–COR, Inc., 413 F.3d 1361, 1369 (Fed. Cir. 2005)).

claim is ambiguous as to its scope we have adopted a narrowing construction when doing so would still serve the notice function of the claims." (citing Athletic Alternatives, Inc. v. Prince Mfg., Inc., 73 F.3d 1573, 1581 (Fed. Cir. 1996)).

The Court thus adopts the following construction of the term "stable during long term storage":

"The composition has an estimated shelf life of greater than 1 month usage time at 25° C. and greater than or equal to one year storage time at 5° C., where shelf-life indicates the length of time at a given temperature that greater than 80% of the initial amount of active ingredient, formoterol, is present in the composition."

**b.**

The parties also dispute the meaning of the term "estimated shelf-life of greater than one month usage time at 25° C. and greater than or equal to 1 year storage time at 5° C." as it appears in Claims 2 and 75. The parties' dispute with respect to this term is largely the same as their dispute over the term "stable during long-term storage." In addition, Dey argues that "shelf-life" takes into account more than simply the "active ingredient and how much is left over time." Apr. 12, 2012 Hr'g Tr. at 32. However, Dey points to no other such factors, aside from the retention of formoterol, that are indicated in the

intrinsic record as being important to the definition of "shelf-life." By contrast, the specifications do indicate that formoterol retention over a given time period and temperature is a factor (indeed the only mentioned factor) in determining whether the composition has a sufficient "shelf-life" to be "suitable for long term storage." See, e.g., '344 Patent at col. 6, l. 66 – col. 7, l. 6. Dey argues that the Court should follow the District Court for the Northern District of West Virginia and construe the term shelf-life to mean "the period of time during which a drug may be stored and remains suitable for use." Dey, L.P. v. Teva Parenteral Meds., Inc., No. 09 Civ. 87, 2011 WL 2461888, at *12 (N.D.W.Va. June 17, 2011). However, as previously explained, this creates considerable ambiguity with respect to how a competitor (or a jury) would know whether the composition "remains suitable for use." A narrower construction, based on the minimum formoterol retention levels that the specifications and the claims indicate would render the composition suitable for use, is thus appropriate in this case. The Court therefore adopts the following construction of the disputed claim term:

"Greater than approximately 80% of the initial formoterol is present after more than 1 month usage time at 25° C. and after at least 1 year storage time at 5° C."

**3.**

The next issue is the parties' dispute over the term "formulated at a concentration effective for bronchodilation by nebulization" in the independent claims.[3] Dey argues that the term should be construed as having its plain meaning, and the scope of the claim is essentially functional, including any composition that is in fact effective for bronchodilation. It is true that a construction may properly be based on the function performed by the claimed invention. See Geneva Pharms., Inc. v. GlaxoSmithKline PLC, 349 F.3d 1373, 1384 (Fed. Cir. 2003) ("[A] functional limitation covers all embodiments performing the recited function."). However, Dey ignores the Court's previous ruling on Sunovion's motion for partial summary judgment. In that ruling this Court specifically explained that:

> As Dey explained during reexamination in distinguishing prior art that had disclosed formoterol compositions for an MDI inhaler, higher concentrations of formoterol, like the 120–400 µg/mL dose typically used with an inhaler, are 'far more

[3] Claim 74's language is slightly different, and claims a method for delivering "an effective amount of a pharmaceutical composition by nebulizer to a subject in need of such treatment, wherein the pharmaceutical composition comprises formoterol or a derivative thereof, formulated at a concentration suitable for direct administration to a subject in need of bronchodilation." '953 Patent Reexamination Certificate, at col. 1, l. 66–col. 2, l. 11. The parties have not argued that this claim language in the '953 Patent differs substantively from the language in the '344 Patent.

> concentrated than what is acceptable for nebulization' and 'far more concentrated than the concentrations specified in independent claim 1.' In other words, Dey explicitly disavowed during reexamination formoterol concentrations exceeding 120 µg/mL from the scope of the independent claims, despite the fact that the original independent claims must have included formoterol concentrations that greatly exceeded that amount.

Dey, 2012 WL 678175, at *16 (citations omitted). Sunovion argues that, based on the Court's prior ruling with respect to the prosecution history during the reexamination, Dey has disavowed concentrations of formoterol greater than 120 µg/mL from the scope of the independent claims because those concentrations are unsuitable for nebulization. Sunovion is correct. See Advanced Fiber Techs. (AFT) Trust v. J & L Fiber Servs., Inc., 674 F.3d 1365, 1372-73 (Fed. Cir. 2012) ("[I]f a patentee makes a clear and unambiguous disavowal of claim scope during prosecution, that disclaimer informs the claim construction analysis by 'narrow[ing] the ordinary meaning of the claim congruent with the scope of the surrender.'" (citation omitted)). Because Dey disavowed such higher concentrations of formoterol as ineffective for nebulization, the Court will construe the disputed term as meaning "formulated at a concentration of 120 µg/mL or less." This construction is consistent with the scope of the dependent claims, which claim

formoterol concentrations of between 5 and 118 micrograms per milliliter.

**4.**

The next issue is the parties' dispute over the term "formulated at a concentration suitable for direct administration without propellant and without dilution of the composition prior to administration."

The parties do not dispute that this claim language covers a composition that is not required to be diluted prior to administration, i.e. one that is "ready to use." See Dey, 2012 WL 678175, at *13 ("[A] person of ordinary skill in the art would understand the phrase 'formulated at a concentration suitable for direct administration' to mean that the compositions must be 'ready to use,' and that the compositions are 'ready to use' when they can be administered without diluting or mixing." (quoting Dey v. Teva, 2011 WL 2461888, at *7)). Moreover, there is no dispute that a composition remains within the claim even if it is in fact diluted prior to administration, so long as the composition was ready to administer without dilution prior to use. See Apr. 12, 2012 Hr'g Tr. at 28. Sunovion proposes that the Court construe the disputed language to include that the composition be suitable for direct administration without dilution "regardless of

whether or not the composition is actually diluted prior to administration." Dey admits that this language accurately describes the scope of the claim, but argues that it unnecessary.

While "[t]he Markman decisions, in ruling that claim construction is a matter of law for the court, do not hold that the trial judge in a patent case must repeat or restate every claim term in the court's jury instructions," "the district court normally will need to provide the jury in a patent case with instructions adequate to ensure that the jury fully understands the court's claim construction rulings and what the patentee covered by the claims." Sulzer Textil A.G. v. Picanol N.V., 358 F.3d 1356, 1366 (Fed. Cir. 2004). Thus, in patent cases, "[j]ury instructions are reviewed not only for accuracy, but for clarity, objectivity, and adequacy, taken as a whole." Id. at 1365. Because there is admittedly no substantive difference between the parties' proposed constructions of the disputed claim term, and because Sunovion's construction more clearly delineates the scope of the claim, the Court adopts the following construction for the disputed claim term:

"The composition is suitable (i.e., acceptable or appropriate) for administration without propellant and without dilution regardless of whether or not the composition is actually diluted prior to administration."

**5.**

The next issue is the parties' dispute over the term "formulated for single dosage administration" in Claim 65. Sunovion argues that the term means "designed for a single use, rather than multiple uses." Dey argues that the term means "formulated at a quantity that is taken or administered at one time." The Court will adopt Sunovion's construction.

There is no dispute that "formulated for single dosage administration" means that the composition is designed for use on a single-use dosage basis, that is, designed to be administered from a container with a single dose of the composition that an individual uses only once and cannot re-use. The issue is whether "formulated for single dosage administration" further requires that the composition be formulated in single dose quantities, such that doses that are formulated in a bulk solution and then divided into single dose containers for single-dose administration are outside the scope of the claim. In essence, Dey argues that "formulated for single dosage administration" should be read to mean "formulated in single dose quantities."

Nothing in the language of the claims or the specifications indicates that this additional limitation should be read into the claim. Dey refers to "Example 2" in the specification,

which discusses the "preparation of [2 mL] formoterol unit dose formulations," and contrasts this with Example 1, which discusses the "preparation of [2 liters of] formoterol inhalation solution." '344 Patent at col. 17, ll. 1-35. Dey argues that the "unit dose formulation" in Example 2 exemplifies how the composition would be "formulated for single dosage administration," and that the language in Example 2 and in Claim 65 is similar. However, this language is not particularly similar, and it makes little sense that the patentee would say "formulated for single dosage administration" in Claim 65 in order to indicate that the distinction between formulation in "unit dose" quantities, as in Example 2, and formulation in bulk quantities, as in Example 1, was somehow relevant to whether the composition fell within Claim 65. There is nothing in these examples that would justify reading a numerical limitation with respect to batch preparation size into Claim 65, see Smartmetric, 2012 WL 1367398, at *1, and Dey does not propose a specific limitation, such as 2 mL, or 5 mL, past which the volume of the formulation makes it unsuitable for "single dosage administration."

While Dey argues that the court in West Virginia adopted its proposed construction, the issue here—whether the composition may be "formulated for single dosage administration" when it is initially made in bulk—was not at issue in that case.

In the Teva case, the court held that "formulation 'for single dosage administration' turns on a solution quantity to be taken or administered at one time, and not a specific concentration of formoterol." Dey v. Teva, 2011 WL 2461888, at *15. There is no dispute here that "for single dosage administration" means that the composition is designed to be administered in the form of a single, nonreusable dose that is "administered at one time." The Teva Court did not address Dey's current argument, that the composition must be initially "formulated in single doses," rather than in bulk.

Dey's argument appears to be based on an anticipated prior art defense. See, e.g., Apr. 12, 2012 Hr'g Tr. at 34 ("THE COURT: I thought Brovana is also packaged in single little vials for -- . . . MR. HAUG: . . . It is for sure. It's a single dose as is called for in this claim, and in that sense is the same as Perforomist. But Sunovion in earlier work, much earlier work leading up to their final product maybe, they weren't making it in single doses. They were making a pot of coffee; not single shots of coffee."). This is an inappropriate basis upon which to construe the scope of a patent claim, because "[i]t is well settled that claims may not be construed by reference to the accused device." NeoMagic Corp. v. Trident Microsystems, Inc., 287 F.3d 1062, 1074 (Fed. Cir. 2002).

At bottom, Dey's proposed construction seeks to substitute "in single dose sizes" for the claim language "for single dosage administration." The basic language of the claim does not support that construction. While Dey's construction is unsupported, Sunovion's is uncontested. There is no dispute in this case that, in order for the composition to be "formulated for single dosage administration," it must be formulated such that it can be packed, stored and ultimately administered in a single dose, one-time use container. Indeed, it must be formulated "for" that type of administration. Accordingly, the Court adopts the following construction for the disputed claim term:

"Designed for a single use, rather than multiple uses."

**6.**

The final issue is the parties' dispute over the term "a label that indicates that the composition is used for treatment, prevention or amelioration of one or more symptoms of diseases or disorders associated with undesired and/or uncontrolled bronchoconstriction" in Claim 65.

The parties' dispute centers around the distinction between a label and labeling. Sunovion proposed that the Court construe a label as "a display of written, printed, or graphic matter upon the immediate container surrounding the pharmaceutical

product. To be distinguished from 'labeling,' which can include written, printed or graphic matter accompanying a pharmaceutical product, i.e., the package insert."[4] Dey proposes that the Court construe a "label" to mean "printed matter that states to a doctor or patient that the composition is used for treatment, prevention or amelioration."

As an initial matter, there is very little in the intrinsic record with which to resolve this dispute. However, the intrinsic record does support Sunovion's construction. Specifically, in describing "articles of manufacture" and "packaging materials" as claimed in Claim 65, the '344 Patent cites as an example U.S. Patent No. 5,033,252 (the "'252 Patent"). '344 Patent at col. 16, ll. 53-57. The '252 Patent shows a "label" affixed directly to the container. See U.S. Patent No. 5,033,252, figs. 1-2 (issued July 23, 1991).

More importantly, Sunovion points out that the label/labeling distinction is written into the Federal Food, Drug and Cosmetic Act, a source with which a person possessing ordinary skill in the art at the time would have been familiar. Compare 21 U.S.C. § 321(k) ("The term 'label' means a display of

[4] Sunovion additionally proposes: "That label must indicate that the undesired and/or uncontrolled reduction in the caliber of a bronchus or bronchi will be beneficially altered or lessened, whether permanent or temporary, lasting or transient, by administration of the composition." There is no explanation why this language is required for the label or is clearer than the language set out in the claim.

written, printed, or graphic matter upon the immediate container of any article."), and id. at § 321(l) ("The term 'immediate container' does not include package liners."), with id. at § 321(m) ("The term 'labeling' means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article."); accord United States Pharmacopeia 24th Revision 12 (2000)(attached as Ex. 25 to Hurd Claim Constr. Decl.) ("The term 'labeling' designates all labels and other written, printed or graphic matter upon an immediate container of an article or upon, or in, any package or wrapper in which it is enclosed . . . . The term 'label' designates that part of the labeling upon the immediate container.").

Dey argues that defining label as the labeling affixed to the immediate container makes no sense, because individual dosage vials are only two inches long, and thus it would be "impractical, if not impossible" to label each individual dose within the meaning of Claim 65. Apr. 12, 2012 Hr'g Tr. at 37. However, Dey admits that the vials are approximately two inches high, and have a circumference of somewhat less than two inches. There is no showing that the vial could not include the 24-word phrase "This composition is used for treatment, prevention or amelioration of one or more symptoms of diseases or disorders

associated with undesired and/or uncontrolled bronchoconstriction," on a two by two inch space.[5]

Because the Court concludes that a person of ordinary skill in the art would take the term "label" to comport with Sunovion's construction, and because that construction is consistent with the language of the claims and the specifications, the Court will adopt Sunovion's construction with respect to this disputed claim term. Accordingly, the Court adopts the following construction for the disputed claim term:

"A display of written, printed, or graphic matter upon the immediate container surrounding the pharmaceutical product that indicates that the composition is used for treatment, prevention or amelioration of one or more symptoms of diseases or disorders associated with undesired and/or uncontrolled bronchoconstriction."

[5] Dey also argues that extrinsic evidence, in the form of inventor testimony and various publications by entities such as the Food and Drug Administration and the National Cancer Institute, supports its argument that the label means the package insert. However, the extrinsic publications that Dey cites are far less authoritative than the definitions of pharmaceutical labeling provided by the Food, Drug and Cosmetics Act and the U.S. Pharmacopeia. Moreover, Dr. Chaudry's testimony is ambiguous, and Sunovion, too, cites Dr. Chaudry's deposition in support of its own position.

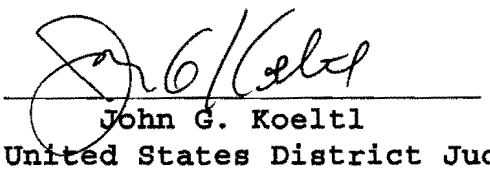
## CONCLUSION

The Court has considered all of the arguments raised by the parties. To the extent not specifically addressed above, the arguments are either moot or without merit.

For the reasons explained above, the Court construes the disputed claim terms as indicated in the text of this Opinion.

**SO ORDERED.**

**Dated: New York, New York**
**May 15, 2012**



**John G. Koeltl**
**United States District Judge**