IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

VECTURA LIMITED,

Plaintiff,

v.

GLAXOSMITHKLINE LLC and GLAXO GROUP LIMITED,

Defendants.

Civil Action No. 1:16-cv-00638-RGA

MEMORANDUM OPINION

Kelly E. Farnan, Christine D. Haynes, RICHARDS, LAYTON & FINGER, P.A., Wilmington, DE; Dominick A. Conde, Christopher B. Borello (argued), Brendan M. O'Malley (argued), Michael P. McGraw, Damien N. Dombrowski, FITZPATRICK, CELLA, HARPER & SCINTO, New York, NY.

Attorneys for Plaintiff.

Jack B. Blumenfeld, MORRIS, NICHOLS, ARSHT & TUNNELL LLP, Wilmington, DE; Martin J. Black, Kevin M. Flannery (argued), Robert Ashbrook, Sharon K. Gagliardi, DECHERT, LLP, Philadelphia, PA; Blake B. Greene (argued), DECHERT LLP, Austin, TX.

Attorneys for Defendants.

October 1, 2018

ANDREWS, U.S. DISTRICT JUDGE:

Presently before the Court is the issue of claim construction of multiple terms in U.S. Patent Nos. 8,303,991 ("the '991 patent") and 8,435,567 ("the '567 patent"). The Court has considered the Parties' Joint Claim Construction Brief. (D.I. 82). The Court heard oral argument on May 21, 2018. (D.I. 106 ("Tr.")). The Court heard expert testimony on September 10, 2018. ("Exp. Tr." (transcript not yet docketed)).

I. BACKGROUND

The patents-in-suit "relate to pharmaceutical compositions for inhalation and methods of making them." (D.I. 82 at 1).

The parties originally presented claim construction disputes for U.S. Patent No. 8,956,661 ("the '661 patent"). (D.I. 82 at 1 n.1). However, Plaintiff has since stated that it will not assert the '661 patent. (D.I. 117 at 1). Plaintiff nonetheless indicates that several terms which appear in the '661 patent "may remain in the case depending on the Court's construction of the claim terms in" the '991 and '567 patents. (*Id.* at 2).

The '991 and '661 patents share a specification, and derive from the same parent application. (D.I. 82 at 1 n.1). The '567 patent contains a distinct specification, and derives from a different parent application. (*Id.*).

Independent claim 1 of the '991 patent is representative, and reads as follows:

> 1. *Composite active particles* for use in a pharmaceutical composition for pulmonary administration, *each composite active particle comprising a particle of active material and particulate additive material on the surface of that particle of active material*, wherein the composite active particles have a mass median aerodynamic diameter of not more than 10 μm, and *wherein the additive material promotes the dispersion of the composite active particles upon actuation of a delivery device*.

('991 patent, claim 1) (disputed terms italicized). Claim 1 of the '567 patent is representative:

1. *Microparticles* for use in a pharmaceutical composition for pulmonary administration, *comprising particles of an active substance having, on their surfaces, particles of a hydrophobic material suitable for promoting the dispersal of the active particles on actuation of an inhaler* and *suitable for delaying the dissolution of the active substance*, wherein the hydrophobic material comprises one or more materials selected from the group consisting of hydrophobic amino acids, metal stearates, a C_{10} to C_{22} carboxylic acid, phospholipids, and derivatives thereof.

('567 patent, claim 1) (disputed terms italicized).

II. LEGAL STANDARD

"It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (internal quotation marks omitted). "'[T]here is no magic formula or catechism for conducting claim construction.' Instead, the court is free to attach the appropriate weight to appropriate sources 'in light of the statutes and policies that inform patent law.'" *SoftView LLC v. Apple Inc.*, 2013 WL 4758195, at *1 (D. Del. Sept. 4, 2013) (quoting *Phillips*, 415 F.3d at 1324) (alteration in original). When construing patent claims, a court considers the literal language of the claim, the patent specification, and the prosecution history. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 977-80 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). Of these sources, "the specification is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Phillips*, 415 F.3d at 1315 (internal quotation marks omitted).

"[T]he words of a claim are generally given their ordinary and customary meaning. . . . [Which is] the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Id.* at 1312-13 (citations and internal quotation marks omitted). "[T]he ordinary meaning of a claim term is its meaning to [an] ordinary artisan after reading the entire patent." *Id.* at 1321

(internal quotation marks omitted). "In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words." *Id.* at 1314.

When a court relies solely upon the intrinsic evidence—the patent claims, the specification, and the prosecution history—the court's construction is a determination of law. *See Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 841 (2015). The court may also make factual findings based upon consideration of extrinsic evidence, which "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Phillips*, 415 F.3d at 1317-19. Extrinsic evidence may assist the court in understanding the underlying technology, the meaning of terms to one skilled in the art, and how the invention works. *Id.* Extrinsic evidence, however, is less reliable and less useful in claim construction than the patent and its prosecution history. *Id.*

"A claim construction is persuasive, not because it follows a certain rule, but because it defines terms in the context of the whole patent." *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) (citation omitted).

III. TERMS FOR CONSTRUCTION

A. "composite active particle(s)" ('991) and "microparticles" ('567); "on the surface (of)" ('991) and "on their surfaces" ('567); "each composite active particle comprising a particle of active material and particulate additive material on the surface of that particle of active material" ('991) and "comprising particles of an active substance having, on their surfaces, particles of a hydrophobic material" ('567)[1]

[1] The parties represent that some disputed terms are "subsumed within [other] terms and proposed constructions." (D.I. 82 at 5, n.6).

1. *Plaintiff's proposed construction ("composite active particles")*: "[a] single particulate entit[y/ies] made up of a particle of active material to which one or more particles of additive material are fused"

2. *Plaintiff's proposed construction ("each composite active particle comprising a particle of active material and particulate additive material on the surface of that particle of active material")*: "where a composite active material is a single particulate entity made up of a particle of active material to which one or more particles of additive material are fused"[2]

3. *Defendants' proposed construction ("composite active particle(s)")*: "particulate entities formed by milling a uniform blend of only additive particles and active particles (with or without liquid) using sufficient energy and duration to ensure sufficient break-up of agglomerates of both constituents, dispersal, and even distribution of additive over the active particles"

4. *Defendants' proposed construction ("each composite active particle comprising a particle of active material and particulate additive material on the surface of that particle of active material")*: "each composite active particle comprising a particle of active material and particles of additive material irreversibly bound by fusing to the surface of the active particle, thereby forming a continuous coating or a discontinuous coating covering, on average, at least 50% of the total surface area of the active particles"

5. *Court's construction ("composite active particles")*: "[a] single particulate entit[y/ies] made up of a particle of active material to which one or more particles of additive material are fixed such that the active and additive particles do not separate in the airstream"

6. *Court's construction ("each composite active particle comprising a particle of active material and particulate additive material on the surface of that particle of active material")*: "where a composite active material is a single particulate entity made up of a particle of active material to which one or more particles of additive material are fixed such that the active and additive particles do not separate in the airstream"

The parties agree that a "composite active particle" is "made up of a particle of active material to which one or more particles of additive material are fused." (D.I. 82 at 5). However, Defendants seek to read several additional limitations into the disputed limitations and seek to define the term "fused." (*Id.*).

[2] For the '567 patent, Plaintiff proposes using "securely attached" in lieu of "fused." (D.I. 82 at 6).

First, Defendants argue that the intrinsic record establishes that Plaintiff clearly injected a "milling" requirement into the "composite active particles" limitation. (D.I. 82 at 11). Ordinarily, courts should not read process steps such as "milling" into composition claims. However, "process steps can be treated as part of a product claim if the patentee has made clear that process steps are an essential part of the claimed invention." *Andersen Corp. v. Fiber Composites, LLC*, 474 F.3d 1361, 1375 (Fed. Cir. 2007).

Here, Defendants argue that Plaintiff made "milling" an essential part of the claimed invention by disclaiming non-milling processes for making "composite active particles" in both the patent specification and prosecution history. (D.I. 82 at 11-13).

Plaintiff stated in the '991 patent Abstract, "The invention relates to a method for making composite active particles . . . , the method comprising a milling step . . . . The invention also relates to compositions for inhalation prepared by the method." (*See, e.g.*, '991 patent at 1:9-12, 2:3-12, 2:35-44). But the disputed claims do not include a milling requirement. Rather, the milling method is separately claimed in the '661 patent, which shares a specification with the '991 patent. ('661 patent, claim 1). Defendants analogize Plaintiff's statements in the Abstract to statements made in *Medicines Co. v. Mylan, Inc.*, 853 F.3d 1296 (Fed. Cir. 2017). (D.I. 82 at 13). There, the Federal Circuit concluded that a product claim requires the use of a process "because the specification's definition of [the claim term] by itself injects a . . . process as a limitation in the asserted claims." *Medicines*, 853 F.3d at 1304. Here, on the other hand, the Abstract does not provide a "definition" of "composite active particles" that includes "milling." Rather, the patent plainly establishes that the relevant "invention" is a composition: "composite active particles for use in a pharmaceutical composition." ('991 patent at 11:44-55). Given that this specification enables both composition and method claims, the specification's references to

"the invention" are ambiguous. Just because the specification describes a single known way to make the claimed composition does not mean that I must read that method into the claims. Thus, I do not find disclaimer based on the specification.

During prosecution of the '991 patent, Plaintiff stated, "As described in the . . . specification, the additive particles are fused to the active particle in a manner only possible using an aggressive milling procedure." (D.I. 61-1, Exh. 10 at 4). This statement came in response to an anticipation rejection and explained why the patentee added the word "particulate" to describe additive material. (*Id.*). The patentee explained, "[T]he . . . reference cannot possibly teach, or suggest, particles comprising particulate surface modifier material . . . ." (*Id.* at 5). Separately, the patentee stated, "[The claimed composite particles] can only be produced using high energy milling processes . . . ." (*Id.* at 8). This statement came in response to an obviousness rejection over the same reference. (*Id.*). Again, the patentee emphasized, "[T]he advantages of the claimed composite particles arise as a consequence of the specific structure, in which additive material is present on the surface of the active particles." (*Id.*). Although the patentee did state that "[t]hese particles can only be produced using high energy milling processes," the patentee never defined the "particles" on the basis of their formation by "milling," nor did the patentee exclude "particles" formed by other processes. Instead, the patentee distinguished the claimed invention on the basis of structure, or "particulate" additive material. Thus, I do not find a clear and unambiguous disclaimer. I will not read the milling process into the disputed claim limitations.

Second, Defendants argue that "composite active particles" must be formed by a "uniform" blend of "only additive particles and active particles," and no carrier particles. (D.I. 82 at 14-17, 34-35). This limitation appears in a "comprising" claim. "'Comprising' is a term of

art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim." *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501 (Fed. Cir. 1997). Thus, the claimed "composite active particles" may contain carrier particles, absent a teaching or disclaimer to the contrary.

Defendants argue that the patentee disclaimed formation of "composite active particles" using anything other than "additive" and "active" particles. During prosecution of the '991 patent, the patentee stated, "[C]o-milling of active and additive material . . . is the only method that can produce the claimed composite particles." (D.I. 61-1, Exh. 10 at 9) (underlining in original). The patentee also stated that the milling process "involves firstly obtaining a uniform blend of active and additive particles . . . ." (*Id.*). Plaintiff avers it was "only emphasizing that the claimed invention involves blending 'particles' rather than the liquid-phase additive material as disclosed in" the prior art. (D.I. 82 at 44). The patentee's statements do not necessarily exclude the presence of other particles in the milling process. Accordingly, they do not constitute disclaimer. Furthermore, Plaintiff's arguments ultimately provide specific details about the "milling" process. I am not reading a "milling" limitation into the claim. I will not read these limitations into the claim for that additional reason.

Defendants also argue, "[I]n all of the examples directed to making composite active particles . . . , only active . . . and additive . . . were milled together (with or without liquid)."[3] (D.I. 82 at 14). However, neither the specification nor any embodiment includes any words or expression of manifest restriction. *See Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367,

[3] The patent teaches that "milling" may occur with or without liquid. ('991 patent at 6:56-57) ("The milling may be wet milling, that is, the milling step may be carried out in the presence of liquid."). However, because I am not reading a "milling" limitation into the claim, I need not specify whether milling may occur with or without liquid.

1372 (Fed. Cir. 2014) (noting that disclaimer applies when, for example, the patentee makes statements such as "all embodiments of the present invention are…" or "the present invention requires…," or the specification indicates that a feature of a preferred embodiment is a "very important feature"). Thus, because the claim language does not restrict "composite active particles" to formation by a "uniform" blend of "only additive particles and active particles," and no carrier particles, I will not read those limitations into the claims.

Third, Defendants argue that milling must ensure dispersal and even distribution of the additive over the active particles. (D.I. 82 at 18-19). "[P]rocess steps can be treated as part of a product claim if the patentee has made clear that process steps are an essential part of the claimed invention." *Andersen Corp.*, 474 F.3d at 1375. However, I am not reading a "milling" process limitation into the claim. Accordingly, I will not read details about a "milling" process limitation into the claim. Even if I were to interpret "even distribution of the additive over the active particles" to be a structural limitation, rather than a process limitation, Defendants' argument falls short. (D.I. 82 at 18-19). Defendants' argument depends on a statement in the '991 patent specification that "a degree of intensive mixing is required to ensure . . . even distribution of additive over the host active particles" and on a reference to "coat[ing] the active particle" in the '991 patent's prosecution history. ('991 patent, 3:9-14; D.I. 61-1, Exh. 10 at 4-5). Defendants argue, Plaintiff "repeatedly referenced these limitations through the specification" to define "[t]he method," meaning Plaintiff defined the claimed particles as including "dispersal and even distribution of the additive over the active particles." (D.I. 82 at 18-19). However, this is not lexicography for the claimed particles. The patent never expressly defines the claimed particles as including "dispersal and even distribution of the additive over the active particles." Likewise, Defendants have not identified a "clear and unambiguous

disclaimer" that supports its construction. Accordingly, I will not read that limitation into the claims.

Fourth, although the parties agree that "fused" is the proper term to describe the interaction between the active and additive particles, they disagree on the correct definition of "fusion." (D.I. 82 at 21). Defendants argue that the fusion between the active and additive particles must be "irreversible." (*Id.* at 21-22). Plaintiffs aver that "fused" merely means "securely attached . . . so that they remain associated during aerosolization and movement through the air." (*Id.* at 6).

The intrinsic record on this point is not especially enlightening.

The concept of "fusion" appears in the patents' specifications, which distinguish fusion from weaker contact adhesion. (*See* '991 patent at 3:31-34 ("In some cases a simple contact adhesion may be insufficient and a stronger embedding or fusion of additive particles onto active particles is required to prevent segregation, or to enhance the structure and functionality of the coating.")).

During prosecution of the '991 patent, Applicant addressed fusion, arguing,

> [T]he additive particles are fused to the active particle in a manner only possible using an aggressive milling procedure. The additive particles thereby coat the active particle, forming a single entity, a composite particle, which does not dissociate upon, for example, incorporation into a formulation for inhalation or upon actuation of the inhaler in which it is contained.

('991 patent File History: Response to Office Action (April 26, 2010) at 4-5 (D.I. 61-1, Exh. 10 at 4-5) (citations omitted)).

These two intrinsic references to "fusion" clarify only that the relevant fusion is stronger than "simple contact adhesion" and strong enough to prevent dissociation of the particles in formula or upon actuation.

Defendants point primarily to extrinsic evidence to support their "irreversibly bound" interpretation of "fusion." (D.I. 82 at 20-21). Specifically, Defendants cite the prosecution history of an unrelated Vectura patent, Patent No. 9,351,928 ("the '928 patent"). During prosecution of the '928 patent, Applicant argued,

> As one of ordinary skill in the art [] is aware, . . . a composite particle is a particle which is a composite of two different materials, wherein the two materials are inseparable. The claimed composite particles can only be produced by a high energy process in which additive particles are pressed and smeared together with the excipient particles. The result is a fine structure of composite particles comprising small daubs of additive material randomly and irreversibly bound to the surface of the excipient particles.

('928 patent file history: Response to Office Action (April 13, 2015) at 6 (D.I. 83-1, Exh. 23 at 6). Defendants advocate that this statement is unambiguous evidence of Vectura's position on a POSA's understanding of a composite particle. (D.I. 82 at 21). Defendants also argue that Plaintiff clearly defined "fusion" as "permanently attached" in a European patent, European Pat. No. 1337239. (D.I. 82 at 20-21 (citing D.I. 83-1, Exh. 26 at 8)). I do not find these unrelated patents, addressing a somewhat different type of particle, compelling.

To clarify the "fusion" dispute, I heard expert testimony on the concept of "fusion" on September 10, 2018. The parties' experts agreed that fusion in the pharmaceutical context would not involve strong chemical bonds. (*See* Exp. Tr. at 13-14, 71-72). Rather, surface interactions cause the fusion between the two particles and they remain chemically separate. (*Id.* at 72, 75-76). However, the experts disagreed on the necessary strength of the surface interactions between the active and additive particles.

Plaintiff's expert, Dr. John Koleng, testified that "fused" means "put on the surface with sufficient energy in order to ensure that the particles do not disassociate or come apart during that inhalation or actuation process from the inhalant." (*Id.* at 8). This construction is not based

on a POSA's understanding, because Dr. Koleng's position is that there was no accepted meaning of "fused" at the relevant time. (*Id.* at 18-19). In contrast, Defendants' expert, Dr. Paolo Colombo, testified that a POSA at the relevant time would understand, "Fusion is an inseparable combination of an additive over an active particle. The result[] of this combination is [the] creation of [a] single particulate entity, and this present[s] new physical chemical properties." (*Id.* at 34). In support of his construction, Dr. Colombo cited contemporary sources that indicate "fusion" meant particles are "fixed" or "imbedded." (*See id.* at 36-50). The numerous sources presented by Dr. Colombo strongly indicate that a POSA would have had an understanding of "fusion" at the relevant time.

I agree with Defendants that the "fusion" contemplated by the patents is something more than a "secure attachment," but I doubt that the construction presented by Defendants' expert would assist a jury in understanding the claims. Specifically, I am hesitant to include "inseparable" or "irreversible." Dr. Colombo admitted during his testimony that covalent or ionic bonds between the additive and active particles are not desirable in this field. (*Id.* at 71-72). Moreover, Defendants acknowledged that the particles do separate in the lungs. (*Id.* at 84). This is consistent with the '991 patent's specification and file history, which indicate that the relevant time period for fusion is until the particles exit the airstream.[4] "Irreversible" and "inseparable" do not capture the timing-specific nature of the fusion. Therefore, the construction will reflect that "fusion" means "fixed such that the active and additive particles do not separate in the airstream."

[4] Plaintiff agreed at the hearing that the active and additive particles do not separate in the airstream and admitted that the particles are inseparably fused at that time. (Exp. Tr. at 85-86).

Fifth, Defendants argue that the "microparticles" limitation of the '567 patent has the same meaning as the "composite active particles" limitation of the '991 patent in the context of the claims. (D.I. 82 at 19-21). Defendants aver, "[Plaintiff] points to nothing in the specification where microparticles are defined in terms of 'attachment,' nor does it explain why a POSA would have necessarily interpreted the hydrophobic and active particles within microparticles as being attached in view of this [spray drying] embodiment." (*Id.* at 20). Plaintiff, however, argues that the construction of the "microparticles" limitation of the '567 patent should use "securely attached" instead of "fused." (*Id.* at 10-11, 33). Plaintiff asserts that using "fusion" for the '567 patent would read out that patent's "non-mechanical" milling method, "spray drying." (*Id.* at 10).

I agree with Defendants. The '567 patent's specification does not discuss microparticles in terms of attachment. Additionally, Plaintiff sought to define "fused" as "securely attached" in the '991 patent's construction and then to use the term "securely attached" in the '567 patent's claim construction. (*See id.* at 6, 33). This is circular. If "fused" means "securely attached," and microparticles are "securely attached," then it follows that microparticles are properly described as "fused." I will construe the '991 and '567 patents consistently.

Sixth, Defendants argue that "additive material" must form "a continuous coating or a discontinuous coating covering, on average, at least 50% of the total surface area of the active particles." (D.I. 82 at 23-26).

The patents teach only that there must be "an amount of an added material." ('991 patent, 2:12-19). The patents characterize a coating as a preferred embodiment for this "amount" of additive, stating, "The additive material is preferably in the form of a coating on the surfaces of the particles of active material." ('991 patent, 2:12-19, 6:38-42).

However, Defendants argue that "[r]egardless [of] whether the patents-in-suit characterize the coating as a preferred embodiment," Plaintiff's disclaimer requires a coating limitation. (D.I. 82 at 24). During prosecution of the '991 patent, Plaintiff stated, "[T]he additive particles are fused to the active particle . . . , thereby coat[ing] the active particle, forming a single particulate entity, a composite particle."[5] (D.I. 61-1, Exh. 10 at 4-5). However, this statement is not inconsistent with the proposition that fusion can sometimes result in the preferred embodiment of a coating of additive.

I cannot read a preferred embodiment into the claims. *Phillips*, 415 F.3d at 1323 ("[W]e have expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment."). Accordingly, I will not read the coating limitation into the claims.[6]

---

[5] Defendants point to two other disclaimers. First, Defendants note that during prosecution of the '567 parent patent, the applicant stated, "[S]uch a controlled coating process results, inter alia, in a consistent coating of hydrophobic particles on individual active particles." (D.I. 82 at 23 (citing D.I. 61-1, Exh. 15 at 6)). Second, Defendants note that during prosecution of a "related foreign patent," the applicant stated, "[F]orming composite particles by fusing one material to another will result in a different distribution of the materials, with one material forming a coating on the surface of the other." (D.I. 82 at 23-24 (citing D.I. 83-1, Exh. 24 at 4)). However, Defendants do not argue that the milling process described in those patents is identical to the milling process described in these patents. Furthermore, these statements are not inconsistent with a coating being a preferred embodiment, as fusion and milling can result in a coating. Thus, I do not find disclaimer.

[6] Defendants further request that the coating limitation be specified as covering "at least 50% of the total surface area of the active particles." Defendants obtain this number from the specification, which stated, "Where the coating is discontinuous, it preferably covers, on average, at least 50% (that is, at least 50% of the total surface area of the active particles will be covered by additive material)." ('991 patent, 6:38-49). However, this is merely a preferred embodiment. Even if I found that a coating limitation should be present, I could not read this 50% requirement into the claims. *Phillips*, 415 F.3d at 1323. As discussed at oral argument, ladybugs can "coat" a soccer ball, even when covering less than 50% of the soccer ball's surface area. (Tr. 39:13-23).

Taken together, I construe "composite active particle[s]" to mean "[a] single particulate entit[y/ies] made up of a particle of active material to which one or more particles of additive material are fixed such that the active and additive particles do not separate in the airstream" and "each composite active particle comprising a particle of active material and particulate additive material on the surface of that particle of active material" to mean "where a composite active material is a single particulate entity made up of a particle of active material to which one or more particles of additive material are fixed such that the active and additive particles do not separate in the airstream."

B. "milled" and "a milling step in which particles of active material are milled in the presence of particles of an additive material" ('661)

1. *Plaintiff's proposed construction ("a milling step in which particle of active material are milled in the presence of particles of an additive material")*: "a step in which particles of active material are processed in the presence of particles of additive material using any mechanical process that applies sufficient force such that one of more particles of additive material become fused to a particle of active material"

2. *Plaintiff's proposed construction ("milled")*: "processed using any mechanical process that applies sufficient force such that one of more particles of additive material become fused to a particle of active material"

3. *Defendants' proposed construction ("a milling step in which particle of active material are milled in the presence of particles of an additive material")*:

   "milling a uniform blend of only additive particles and active particles (with or without liquid) using sufficient energy and duration to ensure sufficient break-up of agglomerates of both constituents, dispersal, and even distribution of additive over the active particles"

   The milling step does not comprise blending

4. *Defendants' updated construction ("milling")*: "subjected to a mechanical process which applies sufficient force to the particles of active material that it is capable of breaking coarse particles (for example, particles of mass medium aerodynamic diameter greater than 100 μg) down to fine particles of mass medium aerodynamic diameter not more than 50 μg or which applies a relatively controlled compressive force such as in the Mechano-Fusion or Cyclomix methods, wherein said process uses sufficient energy and duration to ensure sufficient break-up of agglomerates of both additive particles and active particles, dispersal, and even distribution of additive over the active particles"

Plaintiff noted that these disputed terms, which appear in the'661 patent, "may remain in the case depending on the Court's construction of the claim terms in" the '991 and '567 patents. (D.I. 117 at 2). In Section III.A, I decline to read the milling process into the claims. Accordingly, I need not construe these terms.

C. "wherein the additive material promotes the dispersion of the composite active particles upon actuation of a delivery device" ('991), "suitable for promoting the dispersal of the active particles on actuation of an inhaler" ('567)

1. *Plaintiff's proposed construction ("wherein the additive material promotes the dispersion of the composite active particles upon actuation of a delivery device")*: "wherein a composition that contains one or more composite active particles has increased dispersion of the active material upon activating a delivery device for inhalation into the lungs by a patient, as compared to the active material without the additive material"

2. *Plaintiff's proposed construction ("suitable for promoting the dispersal of the active particles on actuation of an inhaler")*: "suitable for increasing dispersal of an active material upon activating an inhaler, as compared to the active material without the additive material"

3. *Defendants' proposed construction (both terms)*: This term is indefinite.

4. *Court's construction ("wherein the additive material promotes the dispersion of the composite active particles upon actuation of a delivery device")*: "wherein a composition that contains one or more composite active particles has increased dispersion of the active material upon activating a delivery device for inhalation into the lungs by a patient, as compared to the same composition wherein unmodified active particles are substituted for the composite active particles"

5. *Court's construction ("suitable for promoting the dispersal of the active particles on actuation of an inhaler")*: "suitable for increasing dispersal of an active material upon activating an inhaler, as compared to the same composition wherein unmodified active particles are substituted for the microparticles"

The parties agree that efficiency of dispersal can be measured using a twin stage impinger (TSI), a device that simulates the respiratory tract and is used in the assessment of inhalers. (D.I. 82 at 57). Plaintiff argues that the claims require measuring the efficiency of dispersal of the claimed composition absent additive material, measuring the efficiency of the claimed

composition with additive material, and looking for "increasing dispersal." (*Id.*). Plaintiff further argues, "[A] POSA would have understood from the patents-in-suit that if a composition comprising additive material fused to active material has improved dispersal compared to the same composition without additive material, then the increased dispersal of the active particles is in part attributed to the additive material that is fused to the active particles." (D.I. 82 at 66).

Defendants, however, argue that these claim terms are indefinite. (D.I. 82 at 56). "[A] patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2124 (2014). Specifically, Defendants argue that there is no objective way for a skilled artisan to know whether an additive "promotes" dispersion. (D.I. 83 at 59-61). They continue, "The Dispersion Limitations are concerned solely with improved dispersibility resulting from a single particle-particle interaction—fusion—between additive and active particles." (*Id.* at 59). Thus, for a composition having both the claimed composite active particles and other particles, like carrier particles, Defendants say "single fusion interaction . . . must be isolated from those of all other particle interactions." (*Id.* at 60). Defendants argue, "[A] POSA would have known that there was no scientifically established means for isolating any one of myriad particle-to-particle interactions," meaning the claims cannot possibly be fulfilled. (*Id.*).

Plaintiff responds that the claims do not have an "isolation" of fusion requirement. (D.I. 82 at 65). Rather, Plaintiff says, Defendants' reading is "untenable," because a skilled artisan would not read the claims as requiring isolating the fusion interaction, and would know that such an analysis is scientifically impossible. (*Id.* at 67).

I agree with Plaintiff that the claims are not indefinite. The claim language requires measuring the efficiency of dispersal of a composition with unmodified active particles, measuring the efficiency of the composition with composite active particles, and looking for increased dispersal. The claims do not require isolating the fusion interaction as the sole source of the increased dispersion. This is indicated in Example 4, which compares the dispersal of composite active particles to the dispersal of unmodified active particles. ('991 patent, 14:31-15:48).[7] Example 4 reports the results of a test of a fairly simple composition, so it must be viewed as merely illustrative of how a POSA would approach testing the efficacy of the patented particles. However, it highlights that a POSA would understand that, to test whether the additive[8] is promoting or suitable to promote dispersion in a given composition, she would need to control for all variables that may contribute to dispersion. Therefore, isolating the impact of the composite active particles on the overall dispersion of the composition is the relevant inquiry.[9] I find that Example 4, in the context of the patent, sufficiently informs a POSA of how to approach this testing. Accordingly, I reject Defendants' assertion that the claims are indefinite.

Because Defendants did not propose an alternative construction, I will adopt a construction mirroring the construction proposed by Plaintiff. However, I disagree with Plaintiff's characterization of Example 4. Example 4 does not teach that the relevant inquiry is

---

[7] Notably, the composition tested in Example 4 does not contain carrier particles or other particles extraneous to the composite active particles. ('991 patent, 14:31-15:48). However, the specification teaches that the compositions "may comprise additional ingredients such as carrier particles." (*Id.* at 12:8-11).

[8] Additive in this context refers to the material fused to the active to form a composite active particle or microparticle

[9] If a POSA wanted to determine whether composite active particle C_2 increased dispersion compared to active particle C_1 in a composition also containing particles A and B, she would not vary A and B during testing.

the presence or absence of additive material. This cannot be the case because the patent teaches that additive materials, as a general matter, were known in the prior art to promote dispersion. ('991 patent, 1:55-58). Rather, Example 4 teaches that testing compositions with composite active particles and comparing those results to compositions with unmodified active particles is the proper approach for determining whether the additive material of the claimed invention is promoting dispersion. Accordingly, I construe "wherein the additive material promotes the dispersion of the composite active particles upon actuation of a delivery device" to mean "wherein a composition that contains one or more composite active particles has increased dispersion of the active material upon activating a delivery device for inhalation into the lungs by a patient, as compared to the same composition wherein unmodified active particles are substituted for the composite active particles" and "suitable for promoting the dispersal of the active particles on actuation of an inhaler" as "suitable for increasing dispersal of an active material upon activating an inhaler, as compared to the same composition wherein unmodified active particles are substituted for the microparticles."

D. "suitable for delaying the dissolution of the active substance" ('567)

1. *Plaintiff's proposed construction*: "suitable for delaying the dissolution of an active substance, as compared to the active substance without the hydrophobic material"
2. *Defendants' proposed construction*: This term is indefinite.
3. *Court's construction*: "suitable for delaying the dissolution of an active substance, as compared to the active substance without the hydrophobic material"

The parties agree that a composition's "dissolution" is testable. (D.I. 82 at 77, 80). Plaintiff argues, "[D]issolution testing is performed on the composition containing

microparticles, which is compared to the composition without the hydrophobic material."[10,11] (*Id.* at 79).

Defendants argue that this term is indefinite. (*Id.* at 76). Defendants argue that the claims require that delayed dissolution "result[s] from a single particle-to-particle interaction—fusion—between hydrophobic and active particles." (*Id.*). Defendants argue that the intrinsic record teaches that "the samples to be tested are the microparticles themselves," rather than "the full composition at issue," which might include carrier particles. (*Id.* at 76-77). Defendants point to several parts of the specification, which provide that "microparticles [are] tested." (*Id.* at 77 (citing '567 patent, 17:7-12)).

However, the intrinsic record makes clear that dissolution testing can be performed on entire formulations. (*See, e.g.,* '567 patent at 16:16-30 ("Standard Dissolution Test . . . 1mg of the formulation to be tested is placed on the sinter and a timer is started."); *Id.* at 17:30-35 ("if the concentration of the active substance in the dissolution test on the formulation reached . . ."). In fact, the quote relied on by Defendants is merely inclusive of testing on microparticles alone. It states that measuring the "delayed release performance of a particular formulation . . . can be done by carrying out the standard dissolution test given above on a sample of the microparticles to be tested." (*Id.* at 17:7-12). Furthermore, Defendants do not point to any part of the specification which requires only testing microparticles in isolation. Rather, the specification

---

[10] The '567 patent claims provide that the "hydrophobic" and "active particles" form a "microparticle." ('567 patent, claim 1).

[11] Defendants argue that this statement represents Plaintiff's effort to "vastly expand the scope of these limitations," as compared to Plaintiff's original construction. (Tr. 112:3-113:9). I disagree. In making this statement, Plaintiff merely clarifies the scope of its proposed construction.

provides that "compositions . . . may comprise additional ingredients such as carriers . . . . Preferably, the carrier particles are of lactose." (*Id.* at 6:62-7:25).

Accordingly, I find the claim terms not indefinite. I adopt Plaintiff's proposed construction. Defendants do not substantively dispute Plaintiff's proposed construction, aside from its indefiniteness argument. (D.I. 82 at 76-79).

E. Other terms

In their briefing, the parties argue constructions for various other terms. They do not seriously dispute the meaning of these terms, but rather argue that they will enhance the jury's understanding. (D.I. 82 at 73-75). As discussed at oral argument, these clarifications are unnecessary. (Tr. 110:12-111:19). Accordingly, I will not construe the terms.

IV. CONCLUSION

Within five days the parties shall submit a proposed order consistent with this Memorandum Opinion.