IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBVIE INC. and ABBVIE DEUTSCHLAND GMBH & CO. KG, Plaintiffs, v. MYLAN PHARMACEUTICALS INC. and MYLAN LABORATORIES LTD., Defendants.	Civil Action No. 13-1072-RGA

MEMORANDUM OPINION

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ANDREWS, U.S. DISTRICT JUDGE:

Pending before the Court is the issue of claim construction for the disputed terms found in U.S. Patent Nos. 7,148,359 ("the '359 patent"); 7,364,752 ("the '752 patent"); 8,268,349 ("the '349 patent"); 8,399,015 ("the '015 patent"); 8,470,347 ("the '347 patent"); and 8,691,878 ("the '878 patent").

I. BACKGROUND

AbbVie initiated the present action against Mylan on June 14, 2013, alleging infringement of U.S. Patent Nos. 6,232,333 ("the '333 patent"); 7,432,294 ("the '294 patent"); and 7,141,593 ("the '593 patent"). (D.I. 1). On January 9, 2014, AbbVie filed its first amended complaint, adding infringement claims for the '359 patent, the '752 patent, the '349 patent, the '015 patent, and the '347 patent. (D.I. 36). On September 25, 2014, AbbVie filed a new lawsuit asserting infringement of the '878 patent (C.A. No. 14-1236, D.I. 1), which was consolidated into the present litigation. (D.I. 82). The parties filed a joint stipulation of dismissal for the '593 and '294 patents on January 22, 2015 (D.I. 128), and for the '333 patent on January 30, 2015. (D.I. 137). In the patents remaining, AbbVie has asserted the following claims: the '359 patent: claims 1, 2, and 4–7; the '752 patent: claims 11–13, 17, 18, 20–22, 26, and 27; the '015 patent: claims 18–22, 24–29, and 31; the '349 patent: 1–5 and 7; the '878 patent: 1–8 and 13–17; and the '347 patent: 1–3, 5, 6, 8–10, 20, 21, and 23. The Court has considered the parties' joint claim construction brief (D.I. 168), joint appendices (D.I. 169 & 170), and held oral argument on May 22, 2015. (D.I. 177).[1] Prior to oral argument, on May 20, 2015, the parties submitted a joint letter informing the Court that they had agreed upon constructions for the terms "solid

[1] During the *Markman* hearing, I ruled on the constructions of three of the disputed terms in open court. Any additional analysis in the present opinion is meant to supplement those rulings.

dispersion" and "composition." (D.I. 173). After the *Markman* hearing, the parties submitted letters with proposed alternative constructions for the term "self-emulsifying." (D.I. 178 & 179).

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). 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 and citations 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 (internal quotation marks and citations 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 (internal citations omitted).

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 (internal quotation marks and citations omitted). 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) (internal quotation marks and citation omitted).

III. AGREED-UPON CONSTRUCTIONS

1. "substantially pure" (as used in claims 1, 2, and 4 of the '359 patent)

a. *Agreed-upon construction*: Refers to amorphous ritonavir which is greater than about 90% pure, which means that the amorphous ritonavir does not contain more than about 10% of any other compound and, in particular, does not contain more than about 10% of any other form of ritonavir.

2. "amorphous ritonavir" (as used in claims 1, 2, and 4–7 of the '359 patent, and claims 1–5 and 7–9 of the '752 patent)

a. *Agreed-upon construction*: The solid physical form of ritonavir characterized by lack of crystal structure.

3. "solid dispersion" (as used in claims 1–5 and 7–9 of the '752 patent)

a. *Agreed-upon construction*: The dispersion of one or more active ingredients in an inert carrier or matrix at solid state.

4. "pharmaceutical composition" (as used in claims 1–5 and 7–9 of the '752 patent)

a. *Agreed-upon construction*: Product containing specific ingredient(s) suitable for pharmaceutical use.

5. "glassy solution" (as used in claims 19 and 29 of the '015 patent, and claim 2 of the '878 patent)

a. *Agreed-upon construction*: A homogeneous, glassy system in which a solute is dissolved in a glassy solvent.

6. "pharmaceutically acceptable surfactant" (as used in claims 1, 13, and 14 of the '878 patent)

a. *Agreed-upon construction*: A pharmaceutically acceptable non-ionic surfactant.

7. "binder component/binder" (as used in claims 1–3, 5, 6, 8–10, 20, 21, and 23 of the '347 patent)

a. *Agreed-upon construction*: A solid, meltable solvent that at least partly forms a matrix.

8. "essentially free of lipid and active pharmaceutical ingredient crystals" (as used in claims 1–3, 5, 6, 8–10, 20, 21, and 23 of the '347 patent)

a. *Agreed-upon construction*: Means the active ingredient and lipid components are essentially amorphous.

IV. CONSTRUCTION OF DISPUTED TERMS

1. "formulated as a solid dispersion of amorphous ritonavir in a matrix including a water soluble polymer" (claim 1 of the '752 patent)

a. *Plaintiffs' proposed construction*: Exists as a solid dispersion of amorphous ritonavir in a matrix including a water soluble polymer.

b. *Defendants' proposed construction*: A solid dispersion of amorphous ritonavir formulated by dissolving ritonavir in a solvent and dispersing the ritonavir-solvent mixture in a water soluble polymer, followed by evaporation of the solvent.

c. *Court's construction*: No construction is necessary.

I ruled on this term in open court, finding that no construction is necessary. (D.I. 177 at 57:24–59:12). The parties agree that the term "solid dispersion" in claim 1 of the '752 patent means "the dispersion of one or more active ingredients in an inert carrier or matrix at solid state." The parties also agree that the term "amorphous ritonavir" in claims 1–5 and 7–9 of the '752 patent means "the solid physical form of ritonavir characterized by lack of crystal structure." Thus, the dispute appears to be over the term "formulated." I disagree with Mylan that the '752 specification or prosecution history requires a specific solvent-evaporation process. The specification makes clear that "[a] solid (molecular) dispersion comprising an HIV protease inhibiting compound may be prepared by dissolving or dispersing the HIV protease inhibiting compound in a sufficient amount of an organic solvent followed by dispersion into a suitable

water soluble carrier. . . . The organic solvent (preferably ethanol) may then be evaporated away . . . ." (D.I. 167-1 at 6, 3:1–13). This language is permissive, not restrictive, and does not demonstrate the type of clear language necessary to import a limitation into the claims. On reexamination, the examiner stated, "The pharmaceutical composition as recited in [claim 1] encompasses its preparation by any process." (*Id.* at 67). Thus, Mylan's proposed construction attempts to import limitations that are not supported by the specification or the prosecution history. I find that the term is made of words that a person of ordinary skill in the art would understand. Therefore, no construction is necessary.

2. "solid dispersion" (claims 1–5 and 7 of the '349 patent; claims 18–22, 24–29, and 31 of the '015 patent; and claims 1–9, 13, and 14–17 of the '878 patent)

a. *Plaintiffs' proposed construction*: A system in a solid state (as opposed to a liquid or gaseous state) comprising at least two components, wherein at least one component exists in the system dispersed evenly throughout the other component or components.

b. *Defendants' proposed construction*: A system in a solid state (as opposed to a liquid or gaseous state) comprising at least two components, wherein one component is dispersed evenly throughout the other component or components.

c. *Court's construction*: A system in a solid state (as opposed to a liquid or gaseous state) comprising at least two components, wherein one component is dispersed evenly throughout the other component or components.

The parties have agreed that the term "solid dispersion" means "a system in a solid state (as opposed to a liquid or gaseous state) comprising at least two components, wherein one component is dispersed evenly throughout the other component or components." (D.I. 173 at 1). "The parties further agree that this construction is not limited to only one component being

evenly dispersed, and does not introduce any product-by-process limitation or process attribute to the claims." (*Id.*).

3. "solid solution" (claims 4 and 5 of the '349 patent; claims 19 and 29 of the '015 patent; and claim 2 of the '878 patent)

a. *Plaintiffs' proposed construction*: A solid dispersion that is chemically and physically uniform or homogenous throughout or consists of one phase (as defined in thermodynamics).

b. *Defendants' proposed construction*: A system in a solid state wherein the drug is molecularly dispersed throughout a matrix such that the system is chemically and physically uniform or homogenous throughout.

c. *Court's construction*: A system in a solid state wherein the drug is molecularly dispersed throughout a matrix such that the system is chemically and physically uniform or homogenous throughout.

I ruled on this term in open court, adopting Mylan's proposed construction. (D.I. 177 at 82:17–83:7). The patentees of the '349, '015, and '878 patents acted as lexicographers, defining the term "solid solution" as "a system in a solid state wherein the drug is molecularly dispersed throughout a matrix such that the system is chemically and physically uniform or homogenous throughout." (D.I. 167-3 at 24, 1:44–47). AbbVie argues that the '349 specification states, "When said dispersion of the components is such that the system is chemically and physically uniform or homogenous throughout or consists of one phase (as defined in thermodynamics), such a solid dispersion will be called a 'solid solution' or a 'glassy solution.'" (*Id.* at 24, 2:14–18). I adopt the lexicographical definition proposed by Mylan because it more explicitly defines the term, and only applies to the term "solid solution."

4. "molecular dispersion" (claims 1–3, 5, 6, 8–10, 20, 21, and 23 of the '347 patent)

a. *Plaintiffs' proposed construction*: A system in which a substance is homogeneously dispersed in a solvent.

b. *Defendants' proposed construction*: A system in which a substance is homogeneously dispersed in a solvent at a molecular level.

c. *Court's construction*: A system in which a substance is homogeneously dispersed in a solvent.

I ruled on this term in open court, adopting AbbVie's proposed construction. (D.I. 177 at 88:13–89:22). The inventors of the '347 patent expressly stated that "[t]he term 'molecular dispersion' is known to the skilled worker and essentially describes systems in which a substance, in the present case at least part and preferably the predominant part of the lipid or binder component, is homogeneously dispersed in a solvent." (D.I. 167-9 at 8, 7:56–60). I consider this a lexicographical definition. Mylan adds the phrase "at a molecular level," but this additional limitation is not supported by the intrinsic record. Therefore, I adopt the lexicographical definition provided in the '347 specification.

5. "self-emulsifying" (claims 1–3, 5, 6, 8–10, 20, 21, and 23 of the '347 patent)

a. *Plaintiffs' proposed construction*: A system that dissolves in an aqueous system to form an emulsion.

b. *Defendants' proposed construction*: Dissolves on contact with water or other aqueous media to spontaneously form an emulsion.

c. *Court's construction*: Dissolves upon contact with aqueous media to form an emulsion, with negligible input of mechanical energy, and without requiring the addition of further components in the aqueous media to form the emulsion.

I indicated at oral argument that I did not agree with either party's proposed construction, and gave both parties the opportunity to submit alternative proposals, based on the statements I made in open court. (D.I. 177 at 139:16–140:23). Mylan submitted the alternative construction: "capable of spontaneously forming an emulsion upon contact with aqueous media." (D.I. 178). This language mirrors the language in dependent claim 20 of the '347 patent, which states: "The formulation of claim 1, wherein the formulation is capable of spontaneously forming an emulsion upon contact with aqueous media which contains at least 50% by weight water." (D.I. 167-9 at 17, 26:45–48). AbbVie submitted the alternative construction: "dissolves upon contact with liquid aqueous media to form an emulsion, with no or mild agitation, and without requiring the addition of further components in the liquid aqueous media to form the emulsion." (D.I. 179). AbbVie's proposal reflects language from the '347 specification, which states that "[u]nder the conditions of use, the emulsions normally form spontaneously," noting that "negligible input of mechanical energy, e.g., stirring and/or shear energy, is necessary." (D.I. 167-9 at 15, 22:59–62). Thus, the specification implies that emulsions are not required to form "spontaneously," and that a "negligible" amount of energy is permitted. For this reason, I adopt AbbVie's alternative proposal, but replace the phrase "no or mild agitation" with "negligible input of mechanical energy" to mirror the language in the specification. I also remove the word "liquid" before "aqueous media" because it is not supported by the claims or the specification, and appears redundant.

6. "composition" (claims 4–7 of the '359 patent)

a. *Plaintiffs' proposed construction*: Product containing specified ingredient(s).

b. *Defendants' proposed construction*: A pharmaceutical composition.

c. *Court's construction*: No construction is necessary.

The parties have agreed that the term "composition" should be given its plain and ordinary meaning. (D.I. 173 at 1). Therefore, no construction is necessary.