

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

INDIVIOR INC., INDIVIOR UK LIMITED,
and MONOSOL RX, LLC,

Plaintiffs,

v.

MYLAN TECHNOLOGIES INC., MYLAN
PHARMACEUTICALS INC., and MYLAN
N.V.,

Defendants.

Civil Action No. 15-1016-RGA

MEMORANDUM OPINION

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ANDREWS, U.S. DISTRICT JUDGE:

Presently before me is the issue of claim construction of multiple terms in U.S. Patent No. 8,603,514 (the “’514 Patent”), U.S. Patent No. 8,475,832 (the “’832 Patent”), U.S. Patent No. 8,017,150 (the “’150 Patent”), and U.S. Patent No. 8,900,497 (the “’497 Patent”). I have considered the parties’ Joint Claim Construction Brief. (D.I. 75). I have issued two relevant orders since the filing of that brief: the Stipulation Regarding Amended Joint Claim Constructions (D.I. 82) and the Consent Decree and Final Judgment Regarding the ’832 Patent (D.I. 83), which resolve disputes as to several terms. I held oral argument on December 16, 2016. (“Tr.”).

I. 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).

II. AGREED UPON CONSTRUCTIONS

The parties agree to, and I adopt, the following construction of “rapidly” (claim 1 of the ’497 patent): plain and ordinary meaning. (D.I. 75 at p. 2).

III. DISPUTED TERMS

1. “further drying said visco-elastic film to form a self-supporting edible film having a substantially uniform distribution of said at least one active component (claim 1 of the ’497 patent)”

- a. *Plaintiffs’ proposed construction*: the term should be given its plain and ordinary meaning
- b. *Defendants’ modified proposed construction*: further drying said visco-elastic film through a separate and distinct drying step to form a self-supporting edible film having a substantially uniform distribution of said at least one active component (D.I. 75 at 20–25, 29)
- c. *Court’s construction*: plain and ordinary meaning

Claim 1 provides:

A process for making a film having a substantially uniform distribution of components, comprising the steps of:

- (a) forming a flowable polymer matrix comprising an edible polymer, a solvent and a desired amount of at least one active, said matrix having a substantially uniform distribution of said at least one active;
- (b) casting said flowable polymer matrix;
- (c) rapidly evaporating at least a portion of said solvent upon initiation of drying to form a visco-elastic film within about the first 4.0 minutes to maintain said substantially uniform distribution of said at least one active by locking-in or substantially preventing migration of said at least one active within said visco-elastic film;
- (d) further drying said visco-elastic film to form a self-supporting edible film having a substantially uniform distribution of said at least one active component; and wherein said substantially uniform distribution of said at least one active component is measured by substantially equally sized individual unit doses which do not vary by more than 10% of said desired amount of said at least one active.

('497 patent, claim 1).

Defendants argue that their proposed construction clarifies the intention of the patentee to claim different drying steps. (D.I. 75 at p. 21).

I find it clear from the claim language that there are two phases of drying. In the first phase, within about the first 4.0 minutes, the solvent is rapidly evaporated to form a visco-elastic film. ('497 patent, claim 1 ¶ (c)). In the second phase, the film undergoes “further drying.” ('497 patent, claim 1 ¶ (d)). The first phase necessarily occurs before the second phase, a fact that Plaintiffs do not dispute. (D.I. 75 at p. 26). Defendants’ proposed construction is unnecessary and introduces terminology, such as “separate and distinct,” which is more confusing than helpful. I agree with the Plaintiffs that the term poses “no interpretative challenges.” (*Id.*). Thus, the term should be given its plain and ordinary meaning.

2. “capable of being dried without loss of substantial uniformity” (claims 1 and 62 of the '514 patent);

- a. *Court’s previous construction:* The Court construed this term to mean “[t]he film matrix is capable of being dried such that individual dosage units do not vary by more than 10% from the intended amount of active for that dosage unit.” (No. 13-1674, D.I. 156 at 18). The Court also further construed “dried” to mean “dried without solely employing conventional convection air drying from the top.” (No. 14-1451, D.I. 175 at 23).
- b. *Plaintiffs’ proposed construction:* Plain and ordinary meaning.
- c. *Plaintiffs’ alternate proposed construction:* If the Court’s previous construction is used, it should be “clarified” so that “solely employing conventional convection air drying from the top,” is interpreted to mean drying that (1) uses uncontrolled air currents, (2) only occurs without heating from the bottom, and (3) was commonly employed in the field at the time of the invention. (D.I. 75 at pp. 41, 43, 47).
- d. *Defendants’ proposed construction:* Defendants propose the Court’s previous constructions, with no further modification.
- e. *Court’s construction:* I adopt my previous constructions. To clarify my previous construction for “dried,” “dried without solely employing conventional convection air drying from the top” is meant to exclude drying techniques that are associated with the problem of the “rippling effect.” This problem takes place when the initial drying of the

upper surface of the film leads to the trapping of moisture inside the film, causing the top surface to be ripped open and reformed when the moisture trapped inside later evaporates. This does not necessarily exclude techniques where the only direct sources of air are from the top. This also should not be understood to require techniques to use direct sources of air from the bottom.

I adopt my previous construction for the reasons provided in my previous opinion. (No. 14-1451, D.I. 175). I will consider whether that construction needs to be further clarified.

Plaintiff argues that “conventional convection air drying from the top” refers to drying that uses “uncontrolled air currents.” (D.I. 75 at p. 41). The specification explains that “conventional film forming techniques” resulted in problems such as “particle self-aggregation and non-uniformity.” (’514 patent, 2:60–62). The specification further explains that “conventional drying methods” (which would be conventional film forming techniques) are associated with the problem of the “rippling effect.” (*Id.*, 3:33–54). This problem takes place when the initial drying of the upper surface of the film leads to the trapping of moisture inside the film, causing the top surface to be ripped open and reformed when the moisture trapped inside later evaporates. (*Id.*, 22:41–48; 28:57–29:1). To prevent this problem, the invention seeks to “dry[] the bottom surface of the film first” or to “otherwise prevent[] the formation of polymer film formation (skin) on the top surface of the film prior to drying the depth of the film.” (*Id.*, 22:49–52). The specification explains that the benefits of the invention can be achieved (1) “by applying heat to the bottom surface of the film with substantially no top air flow,” or (2) by “introduc[ing] . . . controlled microwaves to evaporate the water or other polar solvent within the film, again with substantially no top air flow,” or (3) “by using balanced fluid flow, such as balanced air flow, where the bottom and top air flows are controlled to provide a uniform film.” (*Id.*, 22:53–60). Essentially, the patent teaches that to avoid the rippling effect, “top air flow cannot break, distort or otherwise physically disturb the surface of the

composition.” (*Id.*, 29:14–15). Air speeds are ideally “below any force level that can move the liquids in the film-forming compositions.” (*Id.*, 29:16–18). These speeds should avoid “any lifting or other movement of the film formed from the compositions.” (*Id.*, 29:21–23). In light of the specification, I find that “conventional convection air drying” refers to drying techniques that are associated with the problem of the “rippling effect.”

Plaintiff’s proposed language that “conventional convection air drying” must “use[] uncontrolled air currents” is close but not entirely accurate. While I recognize that techniques that use “uncontrolled air currents” may very well be associated with the “rippling effect,” it is not necessary for one to show that a technique uses “uncontrolled air currents” to establish that a technique is a “conventional convection air drying” technique. It is more important to show that a technique is associated with the problem of the “rippling effect.” To be clear, for a drying technique to be “unconventional,” it must not be associated with the problem of the “rippling effect.”

Plaintiff further seeks to clarify that “conventional convection air drying from the top” does not require the air to originate from any particular location. (D.I. 75 at p. 43). Phrased differently, Plaintiff argues that a drying technique that is “unconventional” does not necessarily exclude techniques where the only direct sources of air are from the top. Thus, direct sources of air from the bottom are not required for a drying technique to be “unconventional.” I agree. There is evidence that the invention does not necessarily exclude techniques where the only direct sources of air are from the top. For example, the specification describes a technique of the invention (and, therefore, an unconventional technique) as one where “substantially no top air flow” was applied, while not mentioning the need for bottom-sourced air. (*See* ’514 patent, 22:49–60). This suggests that techniques which use a minimal amount of air directly sourced

from the top, and no air directly sourced from the bottom, could be unconventional. This clarification is not inconsistent with the specification's discussion about "conventional convection air drying" being air drying associated with the problem of the "rippling effect."

Plaintiffs lastly argues that "conventional convection air drying from the top" refers to techniques that were commonly employed in the field at the time of the invention. (D.I. 75 at p. 47). I do not find this clarification helpful as the commonality of the technique is implied in the plain meaning of the word "conventional."¹

3. "drying" (claim 1 of the '497 patent)

- a. *Court's previous construction*: The Court construed this term to mean "drying without solely employing conventional convection air drying from the top." (No. 14-1451, D.I. 175 at 13).
- b. *Plaintiffs' proposed construction*: Plain and ordinary meaning.
- c. *Plaintiffs' alternate proposed construction*: If the Court's previous construction is used, it should be "clarified" so that "solely employing conventional convection air drying from the top," is interpreted to mean drying that (1) uses uncontrolled air currents, (2) only occurs without heating from the bottom, and (3) was commonly employed in the field at the time of the invention. (D.I. 75 at pp. 41, 43, 47).
- d. *Defendants' proposed construction*: Defendants propose the Court's previous construction, with no further modification.
- e. *Court's construction*: I adopt my previous construction. To clarify my previous construction for "drying," "drying without solely employing conventional convection air drying from the top" is meant to exclude drying techniques that are associated with the problem of the "rippling effect." This problem takes place when the initial drying of the upper surface of the film leads to the trapping of moisture inside the film, causing the top surface to be ripped open and reformed when the moisture trapped inside later evaporates. This does not necessarily exclude techniques where the only direct sources of air are from the top. This also should not be understood to require techniques to use direct sources of air from the bottom.

¹ "Conventional" is defined as "ordinary, commonplace." *Conventional*, MERRIAM-WEBSTER (December 21, 2016), <https://www.merriam-webster.com/dictionary/conventional>; *Vitronics Corp. v. Conceptronc, Inc.*, 90 F.3d 1576, 1584 n.6 (Fed. Cir. 1996).

The analysis for this term mirrors the one provided above for “capable of being dried without loss of substantial uniformity.”

IV. CONCLUSION

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