IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

INDIVIOR INC., INDIVIOR UK LIMITED, and AQUESTIVE THERAPEUTICS, INC., Plaintiffs, v. ACTAVIS LABORATORIES UT, INC., Defendant.	Civil Action No. 18-497-RGA

MEMORANDUM OPINION

Jack B. Blumenfeld and Jeremy A. Tigan, MORRIS, NICHOLS, ARSHT & TUNNEL LLP, Wilmington, DE; Jeffrey B. Elikan (argued), Erica Andersen (argued), Philip S. May, Jeffrey H. Lerner, R. Jason Fowler, and Ashley M. Kwon, COVINGTON & BURLING LLP, Washington, D.C., attorneys for Plaintiffs.

John C. Phillips, Jr. and Megan C. Haney, PHILLIPS, GOLDMAN, MCLAUGHLIN & HALL, P.A., Wilmington, DE; Michael Nutter, WINSTON & STRAWN LLP, Chicago, IL; Stephen R. Smerek (argued) and David P. Dalke, WINSTON & STRAWN LLP, Los Angeles, CA, attorneys for Defendant.

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ANDREWS, U.S. DISTRICT JUDGE:

Presently before the Court is the issue of claim construction of multiple terms in U.S. Patent Nos. 9,931,305 and 9,687,454. The Court has considered the Parties' Joint Claim Construction Brief. (D.I. 46). The Court heard oral argument on March 6, 2019. (D.I. 53).

I. BACKGROUND

On April 3, 2018, Indivior Inc., Indivior UK Limited, and Aquestive Therapeutics, Inc. (collectively, "Plaintiffs") filed suit against Actavis Laboratories UT, Inc. ("Defendant") alleging infringement of U.S. Patent Nos. 9,931,305 ("the '305 patent") and 9,687,454 ("the '454 patent"). (D.I. 1, 6). The '454 patent concerns "self-supporting dosage forms which provide an active agent for treating narcotic dependence while providing sufficient buccal adhesion of the dosage form." ('454 patent, abstract). The '305 patent concerns "rapid dissolve thin film drug delivery compositions for the oral administration of active components." ('305 patent, abstract).

The parties dispute a term in claims 1 and 26 of the '305 patent. Claim 1 is representative and reads as follows:

> 1. A drug delivery composition for making individual unit doses in a self-supporting film-dosage form, which individual unit doses cut from a self-supporting *continuously cast film* contain a desired amount of at least one active, said composition comprising:
>
> (i) said self-supporting *continuously cast film* having said active substantially uniformly stationed therein, said self-supporting continuously cast film formed from a flowable water-soluble or water swellable film-forming matrix comprising a polymer selected from the group consisting of cellulose, a cellulose derivative, polyethylene oxide (PEO), pullulan, hydroxypropylmethyl cellulose (HPMC), hydroxyethyl cellulose (HEC), hydroxypropyl cellulose, polyvinyl pyrrolidone, carboxymethyl cellulose, polyvinyl alcohol, polysaccharides, sodium alginate, xanthan gum, tragancanth gum, guar gum, acacia gum, arabic gum, polyacrylic acid, methylmethacrylate copolymer, carboxyvinyl copolymers, starch, gelatin, and combinations thereof;
>
> wherein said matrix has a viscosity sufficient to aid in substantially maintaining non-self-aggregating uniformity of said active substantially locked-in the matrix; and

(ii) a taste-masking agent selected from the group consisting of flavors, sweeteners, flavor enhancers, and combinations thereof to provide taste-masking of said active;

wherein said active has a particle size of 200 microns or less; and

wherein the uniformity of the self-supporting *continuously cast film* is measured by substantially equally sized individual unit doses cut from a self-supporting *continuously cast film* which do not vary by more than 10%, of said desired amount of said at least one active.

('305 patent, cl. 1) (disputed term italicized).

The parties also dispute terms in claim 1 of the '454 patent. Claim 1 reads as follows:

1. An oral, self-supporting, mucoadhesive film comprising:

(a) about 40 wt% to about 60 wt% of a water-soluble polymeric matrix;

(b) about 2 mg to about 16 mg of buprenorphine or a pharmaceutically acceptable salt thereof;

(c) about 0.5 mg to about 4 mg of naloxone or a pharmaceutically acceptable salt thereof; and

(d) an acidic buffer;

wherein the film is mucoadhesive to the sublingual mucosa or the buccal mucosa;

wherein the weight ratio of (b):(c) is about 4: 1;

wherein the weight ratio of (d):(b) is from 2:1 to 1:5; and

wherein application of the film on the sublingual mucosa or the buccal mucosa results in differing absorption between buprenorphine and naloxone, with a *buprenorphine* C_{max} *from about 0.624 ng/ml to about 5.638 ng/ml* and a *buprenorphine AUC from about 5.431 hr*ng/ml to about 56.238 hr*ng/ml*; and a naloxone C_{max} from about 41.04 pg/ml to about 323.75 pg/ml and a naloxone AUC from about 102.88 hr*pg/ml to about 812.00 hr*pg/ml.

('454 patent, cl. 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 (internal quotation marks 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) (citation and internal quotation marks omitted).

III. CONSTRUCTION OF DISPUTED TERMS

A. The '305 Patent

1. "continuously cast film" ('305 patent, cls. 1, 26)

a. *Plaintiffs' proposed construction*: plain and ordinary meaning, but if construction is necessary: "continuous sheet of cast film"

b. *Defendant's proposed construction*: "a film formed by combining components to form a matrix, depositing the matrix onto a substrate, and drying the matrix without solely employing conventional convection air drying from the top"

c. *Court's construction*: "a film formed by combining components to form a matrix, depositing the matrix onto a substrate, and drying the matrix without solely employing conventional air drying from the top"

Plaintiffs assert that this term should be given its plain and ordinary meaning because the claim language is clear. (D.I. 46 at 4). Plaintiffs also argue that Defendant's proposed construction improperly imports a process limitation into the apparatus claims. (*Id.* at 6, 10). Defendant argues that this claim term should be construed consistent with the Federal Circuit's decision in a preliminary injunction appeal. (*Id.* at 11-12). Defendant asserts that its proposed construction is

correct because a "continuously cast film" requires drying, and the specification specifically disclaims "solely employing conventional convection air drying from the top." (*Id.* at 12-13).

I agree with Defendant. While Plaintiffs are correct that ordinarily reading in a process limitation into an apparatus claim is disfavored (*id.* at 10 (citing *Baldwin Graphics Sys., Inc. v. Siebert, Inc.*, 512 F.3d 1338, 1344 (Fed. Cir. 2008)), here, the '305 patent is "rife with remarks that disparage, and therefore, disclaim" solely using conventional top air drying to form films. *Openwave Sys. Inc. v. Apple Inc.*, 808 F.3d 509, 514 (Fed. Cir. 2015). "Disavowal requires that 'the specification make clear that the invention does not include a particular feature.'" *Id.* at 513 (quoting *SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1341 (Fed. Cir. 2001)). Plaintiffs also argue that "continuously cast film" cannot provide textual support to import a drying limitation into the claim. (D.I. 46 at 8-9). Yet, as the Federal Circuit previously recognized when construing this term,

> [w]here the specification makes clear that the invention does not include a particular feature, that feature is deemed to be outside the reach of the claims of the patent, even though the language of the claims, read without reference to the specification, might be considered broad enough to encompass the feature in question. *Scimed,* 242 F.3d at 1341. Here, the specification makes clear that the invention does not include films that were dried using [solely] conventional top air drying.

Indivior Inc. v. Dr. Reddy's Laboratories, S.A., 752 F. App'x 1024, 1032 (Fed. Cir. 2018).[1] "[P]rocess steps can be treated as part of a product claim if the patentee has made clear that the process steps are an essential part of the claimed invention." *Anderson Corp. v. Fiber Composites, LLC*, 474 F.3d 1361, 1375 (Fed. Cir. 2007).

[1] I understand that this is neither a precedential opinion nor a decision on the merits after full claim construction briefing and hearing, and that therefore it is not controlling.

Plaintiffs point to a previous case[2] where I construed "cast film" to have its plain and ordinary meaning and argues that the addition of the word continuously should not result in Defendant's proposed construction. (D.I. 46 at 8). However, the word "continuously" was added in part to distinguish the invention in the '305 patent from prior art that involved creating dosage films through the use of a cast or mold. (D.I. 53 at 13:19-21). In that prior art, where single doses were created in molds, uniformity was not an issue. (*Id.* at 13:22-25). Here, however, the specification makes clear that uniformity throughout the film is crucial to the invention and that the wet-cast films must be dried to achieve the claims. *See* '305 patent, col. 26:55-56 ("The films of the present invention must be formed into a sheet prior to drying."). Thus, the previous construction of "cast film" where there was separate claim language addressing drying does not preclude the application of specification disclaimer to the '305 patent.

Throughout the '305 patent specification, the inventors expressly disclaim the sole use of conventional top air drying to produce films with the claimed content uniformity. As the Federal Circuit noted, "The patent distinguishes these conventional methods from the present invention and disparages their use, stating that these methods result in films that do not have content uniformity—a key feature of the invention." *Indivior*, 752 F. App'x at 1029. As the Court noted there, "the specification makes clear that a film produced using only conventional top air drying cannot satisfy the claim limitations . . . [because] one cannot obtain the claimed level of drug content uniformity in the final cast film." *Id.* (citing '305 patent, col. 3:29-31, 29:36-43, 48-50). The following passage of the specification is one such example:

> For the purposes of the present invention the term non-self-aggregating uniform heterogeneity refers to the ability of the films of the present invention to provide a substantially reduced occurrence of, i.e. little or no, aggregation or conglomeration of components within the film *as is normally experienced when films are formed*

[2] *Reckitt Benckiser Pharms. Inc. v. Dr. Reddy's Labs. S.A.*, 2017 WL 3837312 (D. Del. Aug. 31, 2017). This case is currently on appeal to the Federal Circuit. The Federal Circuit heard argument in this case on April 1, 2019.

> *by conventional drying methods* such as a high-temperature air-bath using a drying oven, drying tunnel, vacuum drier, or other such drying equipment.

'305 patent, col. 9:10–18 (emphasis added).

Additionally, the specification repeatedly clarifies that the drying step is important to ensure that the continuously cast film achieves the claimed uniformity and disparages the use of conventional drying techniques, and specifically, the sole use of top-air drying. For example, the specification states, "The present invention yields exceptionally uniform film products when attention is paid to reducing the aggregation of the compositional components . . . . [B]y drying the film in a rapid manner from the bottom up, such films result." ('305 patent, col. 23:50-56). A description of an embodiment states, "The wet film may be dried using controlled bottom drying or controlled microwave drying, desirably in the absence of external air currents or heat on the top (exposed) surface of the film. . . . Conventional convection air drying from the top is not employed because it . . . results in non-uniform films." ('305 patent, col. 29:30-33, 37-43). Later, the specification provides that, top-air drying may be employed if "it is balanced with the bottom air drying to avoid non-uniformity and prevent film lift-up on the carrier belt. A balance [sic] top and bottom air flow may be suitable where the bottom air flow functions as the major source of drying and the top air flow is the minor source of drying." ('305 patent, col. 29:48-53; *see also* '305 patent, col. 23:16-29).

"Process steps can be treated as part of a product claim if the patentee has made clear that the process steps are an essential part of the claimed invention." *Anderson*, 474 F.3d at 1375. The '305 patent specification makes clear that a continuously cast film must necessarily be dried, that the specific method of drying is crucial to achieving the claimed uniformity essential to the invention, and that conventional top air drying methods alone cannot achieve the claimed

invention. Therefore, I determine that a drying process limitation is properly read into the claims by specification disclaimer.

Thus, I construe the term "continuously cast film" to mean "a film formed by combining components to form a matrix, depositing the matrix onto a substrate, and drying the matrix without solely employing conventional air drying from the top."

B. The '454 Patent

2. "buprenorphine C_{max} from about 0.624 ng/ml to about 5.638 ng/ml" ('454 patent, cl. 1)

a. *Plaintiffs' proposed construction*: plain and ordinary meaning or alternatively, "buprenorphine C_{max} from approximately 0.624 ng/ml to approximately 5.638 ng/ml"

b. *Defendant's proposed construction*: "buprenorphine C_{max} values that are bioequivalent to a comparable one dose Suboxone® tablet, i.e., a film containing 8 mg buprenorphine compared to a tablet containing 8 mg buprenorphine"

c. *Court's construction*: plain and ordinary meaning

Plaintiffs assert that this term should be given its plain and ordinary meaning because the claim language is clear, and Defendant has identified no words that are unclear or require construction. (D.I. 46 at 45). Plaintiffs also argue that Defendant's "proposed construction reads the word 'about' out of the claim term" and excludes disclosed embodiments. (*Id.* at 46, 55). Defendant argues that the claim term should be construed in the context of bioequivalence to Suboxone® tablets of the same dosage strength because the '454 patent specification refers to the invention as a film dosage that has a bioequivalent effect to Suboxone® tablets. (*Id.* at 46-48).

I agree with Plaintiffs. First, the claim language is clear and unambiguous as to what it claims. *See Phillips*, 415 F.3d at 1314 ("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. . . ."). Second, Defendant's proposed construction improperly limits the claim scope by excluding

embodiments referenced in the specification. ('454 patent, col. 2:21-67 (describing several embodiments without reference to bioequivalence); *id.* col. 3:10-16 ("other embodiments of the present invention . . . provide[] an in-vivo plasma profile having a Cmax of between about 0.624 ng/ml and about 5.638 ng/ml for buprenorphine")). Moreover, many of the sections that Defendant points to in the specification do not support its claim construction. (*Id.* col. 3:32-39 ("The 'optimum' absorption *may be, for example*, a level that provides a bioequivalent absorption. . . . An 'optimum' Cmax of buprenorphine is about 0.67 to about 5.36 ng/ml") (emphasis added); *id.* col. 14:37-39 ("[T]he inventive film composition *preferably* provides an AUC value so as to provide a bioequivalent result. . . .") (emphasis added)).

Because the claim language is clear and unambiguous, I construe the term "buprenorphine C_{max} from about 0.624 ng/ml to about 5.638 ng/ml" to have its plain and ordinary meaning.

3. "buprenorphine AUC from about 5.431 hr*ng/ml to about 56.238 hr*ng/ml" ('454 patent, cl. 1)

a. *Plaintiffs' proposed construction*: plain and ordinary meaning or alternatively, "buprenorphine AUC from approximately 5.431 hr*ng/ml to approximately 56.238 hr*ng/ml"

b. *Defendant's proposed construction*: "buprenorphine AUC values that are bioequivalent to a comparable one dose Suboxone® tablet, i.e., a film containing 8 mg buprenorphine compared to a tablet containing 8 mg buprenorphine"

c. *Court's construction*: plain and ordinary meaning

The parties' arguments over claim construction for this term mirror the arguments on construction of the previous disputed term. I find that the claim language is clear and unambiguous to a person of ordinary skill in the art. Thus, I construe the term "buprenorphine AUC from about 5.431 hr*ng/ml to about 56.238 hr*ng/ml" to have its plain and ordinary meaning.