IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

RECKITT BENCKISER PHARMACEUTICALS INC., RB PHARMACEUTICALS LIMITED, and MONOSOL RX, LLC, Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC., Defendant.	Civil Action No. 14-1451-RGA
RECKITT BENCKISER PHARMACEUTICALS INC., and MONOSOL RX, LLC, Plaintiffs, v. PAR PHARMACEUTICAL, INC. and INTELGENX TECHNOLOGIES CORP., Defendants.	Civil Action No. 14-1573-RGA
RECKITT BENCKISER PHARMACEUTICALS INC., and MONOSOL RX, LLC, Plaintiffs, v. WATSON LABORATORIES, INC. and ACTAVIS LABORATORIES UT INC., Defendants.	Civil Action No. 14-1574-RGA

MEMORANDUM OPINION

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June 29, 2016

Richard G. Andrews
ANDREWS, U.S. DISTRICT JUDGE:

Presently before the Court is the issue of claim construction of multiple terms in U.S. Patent Nos. 8,906, 277 ("the '277 patent"), 8,900,497 ("the '497 patent"), 8,603,514 ("the '514 patent"), 8,475,832 ("the '832 patent"), and 8,017,150 ("the '150 patent). The Court has considered the Parties' Joint Claim Construction Brief. (D.I. 108).[1] The Court heard oral argument on March 31, 2016. (D.I. 174).

I. BACKGROUND

The present claim construction dispute arises from Hatch-Waxman litigation involving Suboxone® sublingual film, Plaintiffs' pharmaceutical film product for the treatment of opioid dependence. The parties divide the five patents at issue into two groupings: the process patents and the Orange Book patents. The process patents, which include the '277 and '497 patents, claim processes for manufacturing pharmaceutical films. The process patents are asserted against the Defendants in all three of the present actions.

The Orange Book patents, which include the '150, '832, and '514 patents, claim various pharmaceutical film compositions. Plaintiffs' actions for infringement of the Orange Book patents against Defendants Watson and Par have already gone to trial and I have issued a final decision on the merits. (C.A. No. 13-1674-RGA, D.I. 446). Accordingly, the proposed claim constructions offered here for the '514, '832, and '150 patents only involve Civil Action No. 14-1451-RGA, Plaintiffs' action against Defendant Teva.

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

[1] Unless otherwise specifically noted, all references to the docket refer to Civil Action No. 14-1451-RGA.

(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 '277 and '497 Patents (the Process Patents)

The '277 and '497 patents both claim processes for making pharmaceutical films that contain substantially uniform amounts of the active ingredient. The two patents contain nearly identical specifications. Claim 1 of the '497 patent is representative and reads as follows:

> 1. 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).

1. "said [polymer] matrix having a substantially uniform distribution of [said/said pharmaceutical/at least one] active" ('277 patent claim 1; '497 patent, claims 1, 26, 27, 30)

    a. *Plaintiffs' proposed construction*: "[an active/a pharmaceutical active] is distributed in the [polymer] matrix such that individual dosage units do not vary by more than 10% from the intended amount of the active for that dosage unit."

    b. *Defendants' proposed construction*: Indefinite.

    c. *Court's construction*: "[an active/a pharmaceutical active] is distributed in the [polymer] matrix such that individual dosage units do not vary by more than 10% from the intended amount of the active for that dosage unit."

Plaintiffs argue that their proposed construction "employs the same measure of 'substantial uniformity' as is used consistently throughout the Process Patents." (D.I. 108 at p. 17). Plaintiffs further contend that the specifications support this construction because they "teach[] that uniformity is first created during the mixing of the matrix and then simply 'maintained' or 'locked-in' through subsequent steps of the process, [therefore] 'substantial uniformity' must mean the same thing at every step of the process." (*Id.* at p. 19). Plaintiffs also assert that their proposed construction is consistent with my claim construction in Plaintiffs' related Orange Book infringement actions against Defendants Par and Watson, construing the term "substantially uniformly stationed" in the '514 patent. (*Id.* at pp. 20–21 (citing C.A. No. 13-1674-RGA, D.I. 156 at 15–18)). Defendants assert that "Plaintiffs improperly conflate the required uniformity of the liquid matrix with the separate uniformity requirement of the final film product," which expressly requires less than 10% variation from the desired amount of the

active. (*Id.* at p. 11). While Defendants concede that the claims define substantial uniformity with regard to the final film, they contend that no intrinsic evidence provides an objective boundary for the required uniformity of the liquid matrix that precedes the final film. (*Id.* at p. 13). Thus, according to Defendants, the claim term is indefinite because "substantially uniform" is a term of degree and "neither the claim language, nor the specification, provides any objective boundaries to allow a [POSA] to determine when a flowable polymer matrix is 'substantially uniform' enough to fall within the claims." (*Id.* at p. 12).

The Court will adopt Plaintiffs' construction. The claims containing the disputed term describe a process that involves several steps, including (1) forming a flowable polymer matrix with a substantially uniform distribution of at least one active, (2) casting the matrix, (3) rapidly drying the matrix thereby evaporating some of the solvent in order to lock in or prevent migration of the active from the resulting visco-elastic film, and (4) further drying the film to create a final edible film product where the amount of the active does not vary by more than 10% from the desired amount of the active. (*See, e.g.*, '497 patent claim 1; '277 patent claim 1). The claims and the specifications clearly state the goal that the amount of the active in the final film product should not vary more than 10% from the desired dosage unit in order to comply with various world regulatory authorities. ('497 patent, col. 2, ll. 48–52; '277 patent, col. 2, ll. 45–49). The specifications and claims also both contemplate achieving this level of uniformity by locking-in or preventing migration of the active during the drying process. (*See, e.g.*, '497 patent, col. 12, ll. 41–42 ("Uniformity must be maintained as the flowable mass was formed into a film and dried."); *id.* col. 12, ll. 49–50 ("The films are controllably dried to prevent aggregation and migration of components . . . .").

In simpler terms, the patents describe a process that starts with a uniform liquid matrix and then seeks to maintain or lock-in uniformity when drying the liquid to form the resulting pharmaceutical films. Given the concern with losing uniformity during the drying process, discussed repeatedly in the specification, it seems fairly obvious that a POSA would understand that the distribution of the active in the liquid matrix should be as uniform as possible. ('497 patent, col. 12, ll. 40–42 ("[T]he flowable mixture is prepared to be uniform in content in accordance with the teachings of the present invention.")). The claims at issue clearly contemplate forming a final film product that has a substantially uniform distribution of the active, where substantial uniformity is assessed by whether or not the unit doses vary by more than 10% from the desired amount of the active. Accordingly, it logically follows that, with the patent's concern for losing uniformity, the initial polymer matrix must not vary by more than 10% from the intended amount of the active and ideally would be as uniform as possible. Plaintiffs' construction therefore provides a rather straightforward, precise meaning of the claim term read in light of the patents as a whole, and certainly does not leave a POSA contemplating an unbounded degree of possibilities. Accordingly, I conclude that the claim term is not indefinite. *See Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1370 (Fed. Cir. 2014) ("Claim language employing terms of degree has long been found definite where it provided enough certainty to one of skill in the art when read in the context of the invention.").

2. "to maintain said uniform distribution of said [pharmaceutical/at least one] active by locking-in or substantially preventing migration of said [pharmaceutical/at least one] active" ('277 patent, claim 1; '497 patent, claims 1, 26, 27, 30)

    a. *Plaintiffs' proposed construction*: "to maintain a distribution of [an active/a pharmaceutical active] by limiting its migration such that individual dosage units do not vary by more than 10% from the intended amount of the active for that dosage unit"

b. *Defendants' proposed construction*: The term "by locking-in or substantially preventing migration" should be construed as "dried to form a solid film." "Said [substantially] uniform distribution of said [pharmaceutical/at least one] active" is Indefinite.

c. *Court's construction*: "to maintain a distribution of [an active/a pharmaceutical active] by drying to form a viscoelastic solid film, thereby limiting its migration such that individual dosage units do not vary by more than 10% from the intended amount of the active for that dosage unit"

The parties address two disputes with regard to this claim term. First, Defendants renew their indefiniteness arguments, arguing that "said uniform distribution" of the active is indefinite. I conclude that it is not indefinite for the same reasons discussed above as to term one. The remaining dispute concerns whether the term "locking-in or substantially preventing migration" should be construed as "dried to form a solid film," or if that would be too narrow. Defendants argue that a POSA would understand a visco-elastic film to be solid and that "the specifications repeatedly describe the 'visco-elastic film' as a solid." (D.I. 108 at p. 24). Defendants also point to the declaration of their expert, Dr. Amiji, who opines that "'[a] visco-elastic solid would be understood to a [POSA] as a flexible, stretchable solid like Silly Putty.'" (*Id.* at p. 29 (alterations in original) (quoting D.I. 109-1 at ¶ 19)). Plaintiffs argue that the word "solid" never appears in the claims and that Defendants' proposed construction of a "solid film" effectively reads out the term "visco-elastic," which is actually used in the claims. (*Id.* at p. 27). Plaintiffs also cite extrinsic evidence that defines "'a viscoelastic material [as] one that possess both fluid and solid properties.'" (*Id.* (citing D.I. 109-3 at 2, N. Özkaya, et al., FUNDAMENTALS OF BIOMECHANICS: EQUILIBRIUM, MOTION AND DEFORMATION)). Plaintiffs also point out that the specification never uses the world "solid" alone, but instead always pairs it with the modifier "visco-elastic" or other terms of degree. (*Id.*).

I conclude that the proper construction is somewhere in between the two extremes proposed by the parties. Plaintiffs' proposed construction ignores the patents' repeated

disclosures that "locking in" occurs as a result of the liquid matrix attaining more solid properties after undergoing a drying process. Indeed, Plaintiffs' proposed construction is so broad as to not even necessarily require that drying actually occur, even though drying is the only method disclosed to achieve this locking in. For these reasons, Plaintiffs' construction is clearly at odds with the claims and specifications of the patents. ('277 patent, 8:65–9:1 (explaining that stability must be maintained "in the wet film stage until sufficient drying has occurred to lock-in the particles and matrix into a sufficiently solid form such that uniformity is maintained"); '497 patent, 8:65–9:1). However, Defendants' proposed construction seeks to characterize visco-elastic in absolute terms. It would require a 100% solid form where neither the claims nor the specifications require complete solidity at this particular stage of the claimed process. While the word solid is used in the specifications, it is always preceded by visco-elastic or other terms of degree. ('277 patent, col. 13, ll. 42–43 ("The resulting dried film 1 is a visco-elastic solid . . . ."); '497 patent, col. 13, ll. 55–56; '277 patent, col. 25, ll. 14–15 ("[During] its initial setting period . . . a solid, visco-elastic structure is formed."); '497 patent, col. 27, ll. 30–31; '277 patent, 8:67–9:1 ("a sufficiently solid form"); '497 patent, 8:67–9:1).

Indeed, the best way to describe the resulting film is to use the language actually employed throughout the specification—"a visco-elastic solid." This construction comports with the teachings of the specifications, which clearly contemplate that the liquid matrix substantially solidifies and thereby gains sufficient structure at this phase, while not requiring that no liquid remain at all. ('277 patent, col. 13, ll. 45–48 ("Although minor amounts of liquid carrier, i.e., water, may remain subsequent to formation of the visco-elastic, the film may be dried further without movement of the particles, if desired."); '497 patent, col. 13, ll. 58–61; '277 patent, col. 8, ll. 38–40 ("Formation of a viscoelastic or a highly structured fluid phase provides additional

resistive forces to particle sedimentation."); '497 patent, col. 8, ll. 38–40). This construction also comports with the extrinsic evidence submitted by each party: the Özkaya reference and the declaration of Dr. Amiji. (D.I. 109-3 at 2 ("[A] viscoelastic material is one that possess both fluid and solid properties."); D.I. 109-1 at ¶ 19 ("[A] [POSA] would understand that a solid film could contain water (or solvent) and could be subjected to further drying to remove water (or solvent).")).

Accordingly, I will construe "locking-in or substantially preventing migration" to mean "drying to form a visco-elastic solid film."

3. "film having a substantially uniform distribution of said at least one active component" ('497 patent, claims 1, 26, 27)

   a. *Plaintiffs' proposed construction*: "[an active/a pharmaceutical active] is distributed in the film such that individual dosage units do not vary by more than 10% from the intended amount of the active for that dosage unit."

   b. *Defendants' proposed construction*: Not disputed.

   c. *Court's construction*: "[an active/a pharmaceutical active] is distributed in the film such that individual dosage units do not vary by more than 10% from the intended amount of the active for that dosage unit."

Defendants appear to have dropped their initial contention that this term, directed toward the substantial uniformity of the final film, is indefinite, conceding that "the claim itself provides the objective boundary for the final film's uniformity." (D.I. 108 at p. 30). Because the 10% boundary is expressly stated in the relevant claim language, I will adopt Plaintiffs' construction.

4. "rapidly"[2] ('277 patent, claim 1; '497 patent, claims 1, 26, 27, 30)

   a. *Plaintiffs' proposed construction*: Plain and ordinary meaning.

   b. *Defendants' proposed construction*: "within about the first 4 minutes"

[2] The parties propose four different terms that present nearly identical variations of the same dispute. However, it is clear to the Court that these four proposed claim terms only reflect two fundamental disputes that can be assessed by construing two single-word terms: "rapidly" and "drying." Accordingly, the Court will construe those two terms instead of the four, paragraph-long terms proposed by the parties.

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

The parties dispute whether the term "rapidly"—when referring to drying, evaporating, or increasing viscosity—must mean "within about the first 4 minutes." In all of the claim limitations where the word rapidly appears, the claim expressly discloses that the visco-elastic film is formed or that the viscosity of the polymer matrix increases within about the first 4 minutes. For example, subpart (c) of claim 1 of the '497 patent reads as follows:

> (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 . . . .

('497 patent, claim 1). Plaintiffs argue that, because the claim limitations already expressly contain the temporal limitation advanced by Defendants (within the first 4 minutes), Defendants' proposed construction improperly renders the existing temporal claim limitation superfluous. (D.I. 108 at p. 35). Thus, Plaintiffs contend that the word rapidly must be read in the context of the claims in which it appears, and should merely be given its plain and ordinary meaning. (*Id.* at p. 36). Defendants argue that Plaintiffs are trying to hedge their infringement case by arguing that the claimed four-minute time periods can take longer than four minutes. (*Id.* at p. 42). Indeed, Defendants correctly point out that Plaintiffs appeared to argue that they are not limited by the four-minute time limitation by citing a passage of the specification that states "[d]esirably, the drying of the film will occur within about ten minutes or fewer." (*Id.* at p. 43). Defendants argue, however, that this passage "concerns the overall drying time needed to produce the final film, not the initial rapid drying period that creates the solid, visco-elastic film." (*Id.*).

I conclude that there is no need to construe "rapidly" in isolation and that the plain and ordinary meaning of the term should govern. When read in the context of the claim language as a whole, which includes a four minute temporal limitation, there is no need to read a second

four-minute temporal limitation into the word "rapidly." That being said, I do not view this construction as leaving Plaintiffs leeway to argue that they are not bound by the express claim language requiring that the visco-elastic film be formed or viscosity increase "within about the first 4 minutes" from the initiation of drying.[3] (*See, e.g.*, '277 patent, claim 1 ("by rapidly increasing the viscosity of said polymer matrix upon initiation of drying within about the first 4 minutes"); '497 patent, claim 1 ("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 . . . .")).

5. "drying" ('277 patent, claim 1; '497 patent, claims 1, 26, 27, 30)

   a. *Plaintiffs' proposed construction*: Plain and ordinary meaning.

   b. *Defendants' proposed construction*: "drying without solely employing conventional convection air drying from the top."

   c. *Court's construction*: "drying without solely employing conventional convection air drying from the top."

The parties dispute whether "drying" covers all means of drying or whether the specifications disavow certain methods of drying. Defendants argue that the specifications of both the '277 and '497 patents disavow and repeatedly disparage the prior art method of solely using conventional convection air drying from the top. (D.I. 108 at p. 37). Moreover, Defendants argue that the patentee distinguished the claimed processes from conventional convection air drying from the top, because the conventional method causes a ripple effect (a skin forming on the top of the film that repeatedly breaks), which results in an uneven, non-uniform film. (*Id.* at pp. 37–39). Defendants further assert that while the specifications contemplate the use of some top air drying, "in every instance that top air drying is disclosed, it is balanced with bottom air drying." (*Id.* at p. 41). Plaintiffs argue that the specifications only

[3] I agree with Defendants that the mention of drying "within ten minutes or fewer" in the specification relates only to the time it takes to dry the entire final film product, not the early step of forming the visco-elastic film.

warn that conventional air drying methods can cause a rippling effect but otherwise expressly disclose that embodiments of the invention may still use top air drying. (*Id.* at pp. 33–34, 44). Plaintiffs further contend that "neither statements about downsides of conventional drying nor the individual exemplary embodiments qualify as a 'clear and unmistakable' disavowal of employing only convection air drying from the top." (*Id.* at p. 34). Therefore, according to Plaintiffs, "The patent thus teaches to recognize the potential negative effects of uncontrolled drying using top air flow, not to negate entirely any top air flow or even top air flow by itself." (*Id.* at p. 45). Defendants respond by reiterating that their construction recognizes that the specification allows some top-air drying to be used, but only in conjunction with other drying methods and never alone. (*Id.* at p. 48).

"[T]he specification and prosecution history only compel departure from the plain meaning in two instances: lexicography and disavowal." *GE Lighting Solutions, LLC v. AgiLight, Inc.*, 750 F.3d 1304, 1309 (Fed. Cir. 2014). The standard for finding disavowal has been described as "exacting" and "requires that the specification [or prosecution history] make[] clear that the invention does not include a particular feature." *Id.* (alterations in original) (internal quotation marks omitted). However, "[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." *Chicago Bd. Options Exch., Inc. v. Int'l Sec. Exch., LLC*, 677 F.3d 1361, 1372 (Fed Cir. 2012) (alteration in original) (internal quotation marks omitted). Disavowal need not be explicitly stated as long as a POSA would understand—after reading the claims, specification, and prosecution history—that the invention does not encompass a particular feature. *See SciMed Life Sys., Inc. v.*

Advanced Cardiovascular Sys., Inc., 242 F.3d 1337, 1344 (Fed. Cir. 2001) ("[T]he written description can provide guidance as to the meaning of the claims, thereby dictating the manner in which the claims are to be construed, even if the guidance is not provided in explicit definitional format."). For instance, "repeated derogatory statements concerning one type of [feature can be] the equivalent of disavowal of that subject matter from the scope of the patent's claims." *Honeywell Int'l, Inc. v. ITT Indus., Inc.*, 452 F.3d 1312, 1320 (Fed. Cir. 2006).

After reviewing the specifications of the '497 and '277 patents, I conclude that the patentee disavowed using solely conventional convection air drying from the top, both through express statements of what the invention is and repeated disparagement of top drying methods. First, the specifications make clear that a key inventive aspect of the two patents is the claimed processes' ability to avoid a problem occurring in the prior art: "a ripple effect." According to the specifications, a ripple effect occurs during the process of drying a pharmaceutical film when surface water evaporates immediately, forming a top layer or skin that repeatedly rips and is reformed as water vapor under the skin heats up and escapes, a process that is repeated until the entire film is completely dried. ('497 patent, col. 3, ll. 43–63; '277 patent, col. 3, ll. 40–60). A ripple effect "produces an uneven, and therefore non-uniform film." ('497 patent, col. 3, ll. 59–60; '277 patent, col. 3, ll. 56–57). The specifications further explain that the prior art "conventional drying methods [] are unable to provide uniform films." ('497 patent, col. 3, ll. 20–22; '277 patent, col. 3, ll. 17–19). Accordingly, the patented processes achieve uniform distribution of the active ingredient through, among other features, "the use of a drying process that reduces aggregation or conglomeration of the components in the films as it forms into a solid structure." ('497 patent, col. 1, ll. 50–52; '277 patent, col. 1, ll. 45–47). This concern with

maintaining the uniform distribution of the active ingredient is discussed throughout the specifications and is covered by the claims.

Second, consistent with this goal of avoiding a ripple effect in order to maintain uniformity, the specifications expressly disavow using solely conventional convection air drying from the top:

> The wet film is then 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 as described herein. Controlled bottom drying or controlled microwave drying advantageously allows for vapor release from the film without the disadvantages of the prior art. *Conventional convection air drying from the top is not employed* because it initiates drying at the top uppermost portion of the film, thereby forming a barrier against fluid flow, such as the evaporative vapors, and thermal flow, such as the thermal energy for drying. Such dried upper portions serve as a barrier to further vapor release as the portions beneath are dried, which results in non-uniform films.

('497 patent, 10:58–11:3; '277 patent, 10:58–11:3 (emphasis added)). The specifications go on to qualify this statement by indicating that some top air flow can be employed in the drying process, but never alone, only when balanced out by bottom air:

> [S]ome top air flow can be used to aid the drying of the films of the present invention, but it must not create a condition that causes particle movement or a rippling effect in the film, both of which would result in non-uniformity. *If top air is employed, 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.*

('497 patent, col. 11, ll. 4–14; '277 patent, col. 11, ll. 4–14 (emphases added)). Tellingly, in the face of this clear, unmistakable disavowal of using solely top air, Plaintiffs are unable to point to single portion of the specification contemplating the use of top air drying alone.

Third, this clear disavowal is buttressed by repeated statements in the specifications that both tout the benefits of bottom drying over top drying and disparage methods of conventional convection air drying from the top:

> Desirably, the films are dried from the bottom. Controlled bottom drying . . . prevents the formation of a polymer film, or skin, on the top surface of the film. ('497 patent, col. 12, ll. 51–54; '277 patent, col. 12, ll. 51–54).
>
> [B]ottom drying also tends to result in a lower internal film temperature as compared to top drying. In bottom drying, the evaporating vapors more readily carry heat away from the film as compared to top drying which lowers the internal film temperature. ('497 patent, col. 11, ll. 37–41; '277 patent, col. 11, ll. 37–41).
>
> The objective of the drying process is to provide a method of drying the films that avoids complications, such as the noted "rippling" effect, that are associated with conventional drying methods and which initially dry the upper surface of the film, trapping moisture inside. In conventional oven drying methods, as the moisture trapped inside subsequently evaporates, the top surface is altered by being ripped open and then reformed. These complications are avoided by the present invention, and a uniform film is provided by drying the bottom surface of the film first or otherwise preventing the formation of polymer film formation (skin) on the top surface of the film prior to drying the depth of the film. This may be achieved by applying heat to the bottom surface of the film with substantially no top air flow, or alternatively by the introduction of controlled microwaves to evaporate the water or other polar solvent within the film, again with substantially no top air flow. ('497 patent, 6:64–7:13; '277 patent, 6:64–7:13).

It is difficult to discern how the patents' "repeated derogatory statements"—disparaging conventional top drying methods for causing the "ripple effect" that the claimed inventions expressly aim to avoid—could be taken as anything other than a disavowal. *See Openwave Sys., Inc. v. Apple Inc.*, 808 F.3d 509, 514–17 (Fed. Cir. 2015); *Honeywell,* 452 F.3d at 1320. Indeed, the '497 and '277 patents tout the use of bottom drying or controlled microwaves "for the express purpose of remedying the[] perceived deficiencies" with solely using top drying. *See Chicago Bd. Options Exch.*, 677 F.3d at 1372. Therefore, I conclude that the specifications of the '497 and '277 patents clearly teach that the drying step of the claimed processes does not involve solely using conventional convection air drying from the top. Thus, the "[c]laims are not correctly construed to cover what was expressly disclaimed." *SciMed Life*, 242 F.3d at 1341–42.

Accordingly, I will construe "drying" to mean "drying without solely employing conventional convection air drying from the top."

6. "wherein said drying apparatus uses air currents" ('277 patent, claim 1)

   a. *Plaintiffs' proposed construction*: Plain and ordinary meaning.

   b. *Defendants' proposed construction*: "wherein said drying apparatus uses bottom-drying air currents alone or in combination with nonconventional top air drying"

   c. *Court's construction*: "wherein said drying apparatus uses bottom-drying air currents alone or in combination with top-drying air currents."

Here, the parties briefly rehash their arguments as to whether the specifications disavow solely using conventional convection air drying from the top, in the context of a separate claim term that expressly requires air currents to be used in the drying process (as opposed to, for example, controlled microwaves). (D.I. 108 at pp. 48–50). The above analysis as to claim 5 will therefore govern. Plaintiffs do point out, however, that in only allowing "nonconventional top air drying," Defendants' construction for this term is more restrictive than what they offer for the previous term. (*Id.* at p. 49). I agree that Defendants do not adequately explain why here, unlike with the previous terms, they seek to require that any top air drying used be nonconventional, even when used in combination with bottom-drying air currents. For purposes of consistency, and because I see nothing in the specifications requiring that top air drying be nonconventional when used, I will not include nonconventional as part of the construction.

Accordingly, I will construe the term "wherein said drying apparatus uses air currents" to mean "wherein said drying apparatus uses bottom-drying air currents alone or in combination with top-drying air currents."

B. The Orange Book Patents—Teva Only

1. The '514 patent

The '514 patent "relates to rapid dissolve thin film drug delivery compositions for the oral administration of active components," which also incorporate taste-masking agents. ('514 patent, abstract). Claim 1 is representative and reads as follows:

> 1. A drug delivery composition comprising:
>
> (i) a cast film comprising a flowable water-soluble or water swellable film-forming matrix comprising one or more substantially water soluble or water swellable polymers; and a desired amount of at least one active;
>
> wherein said matrix has a viscosity sufficient to aid in substantially maintaining non-self-aggregating uniformity of the active in the matrix;
>
> (ii) a particulate active substantially uniformly stationed in the matrix; and
>
> (iii) a taste-masking agent coated or intimately associated with said particulate to provide taste-masking of the active;
>
> wherein the combined particulate and taste-masking agent have a particle size of 200 microns or less and said flowable water-soluble or water swellable film-forming matrix is capable of being dried without loss of substantial uniformity in the stationing of said particulate active therein; and
>
> wherein the uniformity subsequent to casting and drying of the matrix 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.

('514 patent, claim 1).

1. "a taste-masking agent coated or intimately associated with said particulate [active]" (claims 1 and 28)

    a. *Plaintiffs' proposed construction*: The Court previously construed "taste-masking of the active" as having its plain and ordinary meaning. Plaintiffs do not believe further, separate construction of this term by the Court is necessary in this case. If the Court determines to further construe the term, the plain and ordinary meaning is "a taste-masking agent sufficiently surrounding the particulate active, e.g., by being dissolved and homogenously distributed."

b. *Teva's proposed construction*: "The taste-masking agent is coated on, or in contact with, the particles of active ingredient."

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

The sole dispute over this claim term is whether "coated or intimately associated with" requires the taste-masking agent to be in contact with the active.[4] Plaintiffs argue that the plain and ordinary meaning of "'intimately associated with' [] requires only sufficient proximity between the agent and the active to provide taste-masking," and does not necessarily require contact. (D.I. 108 at p. 51). Plaintiffs further contend that "the '514 Patent specification discloses embodiments where an agent is used to 'provide taste-masking' without being 'coated on or in contract with' the active," for example, where all ingredients are combined into a uniform mixture before being cast into films. (*Id.*). Accordingly, Plaintiffs assert that Teva's proposed construction reads "intimately associated with" out of the claims and replaces it with "in contact with," without any clear demonstration that the patentee intended to do so. (*Id.* at pp. 51–52). Teva argues that "the specification describes only taste-masking techniques that involve coating the active agent or portions of the active agent with a taste-masking agent." (*Id.* at p. 53). Further, Teva points to arguments the applicant made during prosecution to overcome an indefiniteness rejection where the applicant argued that "'it is the combination of the particulate bioeffecting agent and the taste masking agent that has a particle size of 200 microns.'" (*Id.* at pp. 53–54 (quoting D.I. 91-5 at 11–12)). According to Teva, this makes clear that the claim term requires "forming a combined or coated particle." (*Id.* at p. 54).

I will construe "coated or intimately associated with" to have its plain and ordinary meaning, and I conclude that "intimately associated with" does not require direct contact. Teva

[4] Both parties acknowledge that I construed "taste-masking of the active" as having its plain and ordinary meaning in the previous litigation and do not argue that "taste-masking agent" needs to be construed any differently. (D.I. 108 at pp. 51–52; *see also* C.A. No. 13-1674-RGA, D.I. 156 at 16–17).

merely looks at disclosed embodiments that discuss coating and improperly seeks to limit the claim term to coating, but the claims purposefully employ broader language. Teva's construction ignores disclosed embodiments where a number of ingredients, beyond just the active and the taste-masking agent, are "combined by mixing until a uniform mixture [is] achieved and then cast into [two] films . . . ." ('514 patent at 53:39–54:2; *id.* at 61:35–62:3; *id.* at 65:1–67:21). These embodiments appear to be precisely what the "intimately associated" claim language seeks to capture, and it would be improper to read them out of the claims. *See Oatey Co. v. IPS Corp.*, 514 F.3d 1271, 1277 (Fed. Cir. 2008) ("[W]here claims can reasonably [be] interpreted to include a specific embodiment, it is incorrect to construe the claims to exclude that embodiment, absent probative evidence on the contrary."). The applicant's explanation during prosecution that the bioeffecting agent and the taste-masking agent have a specific particle size in combination is not inconsistent with this embodiment, because the combination often also contains other ingredients. In any event, it certainly does not inherently "make[] clear that the invention does not include a particular feature." *GE Lighting Solutions, LLC v. AgiLight, Inc.*, 750 F.3d 1304, 1308 (Fed. Cir. 2014) (alteration in original). Ultimately, Teva can point to nothing in the intrinsic record that surrenders the full claim scope of "intimately associated" or otherwise demonstrates an intent by the patentee to limit the term to require direct contact between the taste-masking agent and the active.

Accordingly, I will construe "coated or intimately associated with" to have its plain and ordinary meaning, which is not limited to being in direct contact with the active.

2. "said matrix has a viscosity sufficient to aid in substantially maintaining non-self-aggregating uniformity of the active in the matrix" (claims 1, 16, 28, 48, 58, and 62)

    a. *Plaintiffs' proposed construction*: The Court previously construed "viscosity sufficient to aid in substantially maintaining non-self-aggregating uniformity of the active in the matrix" as "viscosity sufficient to provide little to no aggregation

of the active within the film." Plaintiffs do not believe further construction of this term by the Court is necessary in this case.

b. *Teva's proposed construction*: Indefinite.

c. *Court's construction*: "viscosity sufficient to provide little to no aggregation of the active within the film"

Plaintiffs correctly point out that I construed this term in the prior litigation to mean "viscosity sufficient to provide little to no aggregation of the active within the film." (C.A. No. 13-1674, D.I. 156 at 15). Teva argues, however, that the previous Defendants did not make an indefiniteness challenge to this claim term and that because it employs a term of degree without an objective boundary, the Court should find it indefinite. (D.I. 108 at p. 60). Citing nothing, Teva contends that "[u]nder Plaintiffs' construction, a person of ordinary skill would be left to his or her own devices to adjust the viscosity of the matrix by trial and error, until arriving at a viscosity that resulted in a final film that had the required 10% uniformity." (*Id.*). The patent, however, does expressly disclose a desired range of viscosity for the liquid matrix phase. ('514 patent, col. 11, ll. 26–29 ("Generally the viscosity of the matrix will vary from about 400 cps to about 100,000 cps, preferably from about 800 cps to about 60,000 cps, and most preferably from about 1,000 cps to about 40,000 cps."). As with claim term 1 of the process patents discussed above, the "viscosity sufficient to aid" can be understood with reference to the expressly stated end goal of uniform distribution of the active that does not vary by more than 10% from the desired amount. (*See, e.g.*, '514 patent, claim 1). In any event, Teva's cursory argument does not prove by clear and convincing evidence that the claim term is indefinite. Accordingly, I will construe the term consistent with my previous ruling.

3. "dried without [the][5] loss of substantial uniformity" (claims 28 and 62)

a. *Plaintiffs' proposed construction*: The Court previously construed "capable of being dried without loss of substantial uniformity" as "the 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." Plaintiffs do not believe further, separate construction of this term by the Court is necessary in this case.

b. *Teva's proposed construction*: "dried without employing conventional convection air drying from the top"

c. *Court's construction*: "Without loss of substantial uniformity" will be construed to mean "such that individual dosage units do not vary by more than 10% from the intended amount of active for that dosage unit." "Dried" will be construed to mean "dried without solely employing conventional convection air drying from the top."

The parties are arguing about two different things in their initial briefing. Plaintiffs ask the Court to use its previous construction which more or less only construed what "without the loss of substantial uniformity" means. (D.I. 108 at p. 62). Teva does not actually dispute the previous construction of "without the loss of substantial uniformity." Instead, it proposes a construction of the word "dried" to reflect the patentee's alleged disavowal of using conventional convection air drying from the top. The argument is similar to the one Defendants made with regard to term five of the process patents. (*Id.* at pp. 63–65). Plaintiffs reiterate their argument, previously made above, that Teva seeks to improperly import a negative limitation from the specification. (*Id.* at pp. 63, 65). Plaintiffs also point out that, unlike Defendants' proposal for the process patents, Teva's proposed construction here "excludes all drying methods employing conventional convection air drying from the top—not just drying that "*solely*" employs conventional convection air drying from the top . . . ." (*Id.* at p. 63). Teva contends that "[t]he specification of the '514 patent is materially the same as that of the Process Patents when it

[5] The parties appear to dispute whether the word "the" should be included in the claim term. (D.I. 108 at p. 62). The parties, however, do not address this dispute in the briefing. The dispute appears not to have any significance. In any event, the claim language itself does not include the word "the," so there is no reason to include it in the claim term. ('514 patent, claims 28, 62).

comes to drying," and proceeds to cite language from the '514 patent that is identical to previously cited language from the process patents in order to support its disavowal argument. (*Id.* at p. 64). Teva also cites statements from the prosecution history of the '514 patent where the applicant distinguished the invention from pharmaceutical films prepared using conventional convection air drying from the top. (*Id.*).

I think the best course is to separately construe the two terms: "without loss of substantial uniformity" and "dried." Teva offers no argument as to why the previous construction of "without loss of substantial uniformity" was incorrect. Accordingly, I see no reason to depart from my prior decision, and will construe "without loss of substantial uniformity" to mean "such that individual dosage units do not vary by more than 10% from the intended amount of active for that dosage unit." (C.A. No. 13-1674-RGA, D.I. 156 at 17–18).

As to Teva's arguments that the applicant disavowed using conventional convection air drying from the top, it is correct that I did not previously address this question in the cases against Watson and Par. Teva is also correct that the '514 patent specification shares many identical statements about the drying process with the '497 and '277 process patents. In fact, the express statements I relied upon in finding that the applicant disavowed the full scope of "drying" in the context of the process patents also appear in the '514 patent's specification. ('514 patent, col. 28, ll. 52–64; *id.* col. 29, ll. 30–34; *id.* col. 30, ll. 46–49; *id.* col. 22, ll. 41–57). Accordingly, the analysis of the '497 and '277 patent specifications' disavowals applies equally to the '514 patent. Indeed, the case for disavowal in the '514 patent is even stronger, based on arguments the applicant made to the examiner during prosecution:

> As further evidence that Chen completely fails to appreciate uniformity, Chen merely disclosed conventional hot air oven drying. . . . Chen, however, does not disclose or even contemplate using *the specific controlled, bottom-drying methods presently claimed*. The only means of drying disclosed in the cited reference is the

method of drying that the present application specifically seeks to avoid (uncontrolled air drying).

(D.I. 91-6 at 18–19 (emphasis added)).

Plaintiffs are correct, however, that Teva's proposed construction drops the word "solely" from Defendants' proposed construction for the process patents. Teva did not respond to this point in both its answering and sur-reply briefs. As with the process patents, the '514 patent does contemplate the use of top drying, but only where balanced out by bottom drying. ('514 patent at 28:64–29:6; *id.* at col. 22, ll. 57–63). Thus, there is no reason to drop the word "solely" from the construction of this claim term, as doing so would read out a disclosed embodiment that uses bottom drying and top drying in combination.

Accordingly, I will construe "dried" to mean "dried without solely employing conventional convection air drying from the top."

2. The '832 Patent

The '832 patent relates to products and methods of treating narcotic dependence using pharmaceutical film formulations. ('832 patent, abstract). Claim 1 is representative and reads as follows:

1. A film dosage composition comprising:

   a. A polymeric carrier matrix;

   b. A therapeutically effective amount of buprenorphine or a pharmaceutically acceptable salt thereof;

   c. A therapeutically effective amount of naloxone or a pharmaceutically acceptable salt thereof; and

   d. A buffer in an amount to provide a local pH for said composition of a value sufficient to optimize absorption of said buprenorphine, where said local pH is from about 3 to about 3.5 in the presence of saliva.

('832 patent, claim 1).

1. "wherein said local pH is from about 3 to about 3.5" (claims 1 and 9)

   a. *Plaintiffs' proposed construction*: "wherein said local pH is above 2.5 and below 4.0"[6]

   b. *Teva's proposed construction*: "wherein said local pH is greater than 2.95 and less than 3.54"

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

The sole issue in dispute with regard to this term is what range of local pH levels the phrase "from about 3 to about 3.5" encompasses. Plaintiffs argue that the phrase should be construed to require a local pH above 2.5 and below 4.0, while Teva says it requires a local pH greater than 2.95 and less than 3.54. (D.I. 108 at pp. 67–68). The question is thus how a POSA would determine what constitutes a local pH level "from about 3 to about 3.5" in light of the intrinsic evidence and the specific "technologic and stylistic context." *Pall Corp. v. Micron Separations, Inc.*, 66 F.3d 1211, 1217 (Fed. Cir. 1995). Plaintiffs argue that the specification, prosecution history, and claim language only refer to pH levels in increments of 0.5. (D.I. 108 at pp. 68–69). Teva argues that a POSA would use the "standard scientific convention" of rounding to the nearest mathematically significant figure. (*Id.* at p. 70). Teva also argues that Plaintiffs are improperly trying to recapture claim scope that was surrendered during prosecution after the applicant narrowed the pH range down from 2 to 4 in response to the examiner's obviousness rejections. (*Id.* at p. 72). Both parties' arguments rely heavily on the testimony of their respective experts, Dr. Amiji and Dr. Davies. (*Id.* at pp. 70–78).

[6] Plaintiffs contend that I previously construed this term and need not construe it again. (D.I. 108 at p. 68). While this language was included in a previous claim term, it is abundantly clear that I did not construe or hear arguments concerning what "about 3 to about 3.5" means during the previous *Markman* proceedings. (C.A. No. 13-1674-RGA, D.I. 156 at 11–12). Accordingly, included above is only the alternative construction proposed by Plaintiffs that actually addresses the present dispute, rather than the page-long entry Plaintiffs included in their brief. (D.I. 108 at p. 67).

This is an issue where I would benefit from hearing live expert testimony and cross-examination. While I am dubious about construing the local pH ranges to extend as far as Plaintiffs propose, the record before me does not provide enough clarity to conclusively decide how a POSA would understand the word "about" in the context of pH levels in pharmaceutical formulations. Accordingly, I decline to resolve this dispute now and will let the experts testify live as to what a POSA would understand the term to mean.

3. The '150 patent

The '150 patent relates to pharmaceutical "film products and methods of their preparation that demonstrate a non-self-aggregating uniform heterogeneity." ('150 patent, abstract). Claim 1 is representative and reads as follows:

> 1. A mucosally-adhesive water-soluble film product comprising:
>
> an analgesic opiate pharmaceutical active; and
>
> at least one water-soluble polymer component consisting of polyethylene oxide in combination with a hydrophilic cellulosic polymer;
>
> wherein:
>
> the water-soluble polymer component comprises greater than 75% polyethylene oxide and up to 25% hydrophilic cellulosic polymer;
>
> the polyethylene oxide comprises one or more low molecular weight polyethylene oxides and one or more higher molecular weight polyethylene oxides, the molecular weight of the low molecular weight polyethylene oxide being in the range 100,000 to 300,000 and the molecular weight of the higher molecular weight polyethylene oxide being in the range 600,000 to 900,000; and
>
> the polyethylene oxide of low molecular weight comprises about 60% or more in the polymer component.

('150 patent, claim 1).

1. "at least one water-soluble polymer component consisting of polyethylene oxide in combination with a hydrophilic cellulosic polymer; wherein: the water-soluble polymer

component comprises greater than 75% polyethylene oxide and up to 25% hydrophilic cellulosic polymer." (claim 1)

a. *Plaintiffs' proposed construction*: "at least one water-soluble polymer component consisting of polyethylene oxide *and optionally* hydrophilic cellulosic polymer, wherein the polyethylene oxide is an amount of greater than 75% of the polymer component and *there may be* up to 25% hydrophilic cellulosic polymer in the polymer component"[7]

b. *Teva's proposed construction*: "at least one water-soluble polymer component consisting of polyethylene oxide in combination with a hydrophilic cellulosic polymer; wherein: the water-soluble polymer component comprises greater than 75% polyethylene oxide and up to 25% hydrophilic cellulosic polymer"

c. *Court's construction*: "at least one water-soluble polymer component consisting of polyethylene oxide in combination with a hydrophilic cellulosic polymer; wherein; the water-soluble polymer component comprises greater than 75% polyethylene oxide and up to 25% hydrophilic cellulosic polymer"

2. "at least one water-soluble polymer component consisting of polyethylene oxide in combination with a hydrophilic cellulosic polymer; wherein: the water-soluble polymer component comprises the hydrophilic cellulosic polymer in a ratio of up to about 4:1 with the polyethylene oxide." (claim 10)

a. *Plaintiffs' proposed construction*: "at least one water-soluble polymer component consisting of polyethylene oxide *and optionally* hydrophilic cellulosic polymer, wherein *the ratio of hydrophilic cellulosic polymer to polyethylene may be* up to about 4:1."

b. *Teva's proposed construction*: "at least one water-soluble polymer component consisting of polyethylene oxide in combination with a hydrophilic cellulosic polymer; wherein: the water-soluble polymer component comprises *greater than 75% polyethylene oxide and up to 25% hydrophilic cellulosic polymer*."

c. *Court's construction*: "at least one water-soluble polymer component consisting of polyethylene oxide in combination with a hydrophilic cellulosic polymer; wherein: the water-soluble polymer component comprises the hydrophilic cellulosic polymer in a ratio of up to about 4:1 with the polyethylene oxide."

The sole dispute regarding claim terms 5 and 6 is whether the claims allow for a water-soluble polymer component that contains polyethylene oxide ("PEO") without any hydrophilic

[7] Emphases were added by the Court to show how Plaintiffs' proposal differs from the actual claim language. Teva's proposal is simply to use the exact claim language.

cellulosic polymer ("HCP"). Plaintiffs argue that the plain and ordinary meaning of the "up to" claim language only imposes a limitation on the maximum amount of HCP that may be present and includes films that do not contain any HCP, making it an optional ingredient. (D.I. 108 at p. 79). According to Plaintiffs, the claims would encompass a water-soluble polymer component made of 100% PEO and 0% HCP. (*Id.*). Plaintiffs cite case law for the proposition that "up to" includes zero as a lower limit and portions of the specification which describe the presence of HCP as optional. (*Id.* at pp. 79–80). Plaintiffs also contend that Teva's construction excludes embodiments disclosed in the specification that do not contain any HCP. (*Id.* at p. 80). Teva argues that the actual claim language, "in combination with a [HCP]," expressly requires that both PEO and HPC be present in the water-soluble polymer component. (*Id.* at p. 81). Teva puts the claim language side-by-side with Plaintiffs' construction and notes that Plaintiffs essentially rewrote the claim language, replacing "in combination with" with "and optionally." (*Id.*). Teva further contends that the discussion in the specification of PEO, "when used alone or in combination with a [HCP]," demonstrates that the patentee knew how to properly write claim language that makes clear that it includes embodiments with no HCP. (*Id.* at p. 82).

The Court will adopt Teva's constructions, which propose the exact language of the claims, with one minor caveat.[8] To be clear, in doing so I am holding that these claim terms do not encompass water-soluble polymer components that do not contain any HCP. The language in the claims, "in combination," makes clear that both elements are required. I acknowledge that the phrase "up to," if used alone, could contemplate zero of the stated element, yet "up to" must

[8] Teva's proposed construction of claim term 6 uses the language "greater than 75% polyethylene oxide and up to 25% hydrophilic cellulosic polymer," the exact language that appears in claim 1 of the '150 patent, rather than the claim language actually employed in claim 10, "the water-soluble polymer component comprises the hydrophilic cellulosic polymer in a ratio of up to about 4:1 with the polyethylene oxide." (D.I. 108 at pp. 78–79). It is not clear to the Court whether this was intentional or merely a typo. In any event, this issue was not addressed in the parties' briefing or at the *Markman* hearing, and I see no reason to import the express claim language from claim 1 into claim 10.

be read in light of the fact that the claims expressly require a combination of two stated elements: PEO and HCP. The use of the phrase "up to" does not vitiate the explicitly stated requirement of a combination of two elements. While Plaintiffs are correct that the specification of the '150 patent discloses an embodiment not containing any HCP, this embodiment does not provide grounds for performing a wholesale rewrite of the claim language actually used by the patentee. *See, e.g.*, *TIP Sys., LLC v. Phillips & Brooks/Gladwin, Inc.*, 529 F.3d 1364, 1373 (Fed. Cir. 2008) ("[T]o construe the claim term to encompass the alternative embodiment in this case would contradict the language of the claims. . . . Our precedent is replete with examples of subject matter that is included in the specification, but is not claimed."). Accordingly, Plaintiffs' efforts to rewrite the express claim language based upon a disclosed embodiment are meritless.

IV. CONCLUSION

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