IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

RECKITT BENCKISER PHARMACEUTICALS, INC., RB PHARMACEUTICALS LIMITED, and MONOSOL RX, LLC, Plaintiffs, v. WATSON LABORATORIES, INC., Defendant.	C.A. No. 13-1674-RGA Consolidated
RECKITT BENCKISER PHARMACEUTICALS INC., RB PHARMACEUTICALS LIMITED, and MONOSOL RX, LLC, Plaintiffs, v. PAR PHARMACEUTICAL, INC., and INTELGENX TECHNOLOGIES CORP. Defendants.	C.A. No. 14-0422-RGA

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I. INTRODUCTION

In these patent infringement cases, consolidated for all pretrial proceedings including the *Markman* hearing (D.I. 85), Plaintiffs assert that the products proposed in Defendants' ANDAs infringe U.S. Patent Nos. 8,475,832 ("the '832 patent"), 8,017,150 ("the '150 patent"), and 8,603,514 ("the '514 patent") (collectively, "the patents-in-suit").

II. AGREED-UPON CONSTRUCTIONS

The parties have met and conferred and agree that the following claim terms have their plain and ordinary meaning and do not require further construction:

Patent	Term/Phrase	Agreed-Upon Construction
'514 patent	"coated or intimately associated [with said particulate]" (claims 1, 28)	plain and ordinary meaning
'514 patent	"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" (claims 1, 28, 62)	plain and ordinary meaning

III. DISPUTED CONSTRUCTIONS

A. '150 Patent—Term 1

Term	Plaintiffs' Proposed Construction[1]	Defendants' Proposed Construction
"the polyethylene oxide comprises one or more low molecular weight polyethylene oxides and one or more higher molecular weight polyethylene	The polyethylene oxide comprises	The polyethylene oxide comprises

[1]The format of Plaintiffs' proposed construction is different than in the chart in the Joint Claim Construction Statement (JCCS) (D.I. 75) to more closely align with the format of Defendants' construction and reduce the dispute between the parties. The substance of Plaintiffs' construction is the same as in the JCCS.

Term	Plaintiffs' Proposed Construction[1]	Defendants' Proposed Construction
oxides, the molecular weight of the low molecular weight polyethylene oxide being in the range of 100,000 to 300,000 and the molecular weight of the higher molecular weight polyethylene oxide being in the range of 600,000 to 900,000; and the polyethylene oxide of low molecular weight comprises about 60% or more in the polymer component" (claims 1, 10)	(i) one or more polyethylene oxides having a low molecular weight in the range of 100,000 to 300,000 Daltons; and (ii) one or more polyethylene oxides having a higher molecular weight in the range of 600,000 to 900,000 Daltons; and (iii) the polyethylene oxides having low molecular weight comprise about 60% or more in the polymer component.	(i) one or more polyethylene oxides having a lower average molecular weight, calculated from the molecular weights of all the chains in the sample, in the range of 100,000 to 300,000; and (ii) one or more polyethylene oxides having a higher average molecular weight, calculated from the molecular weights of all the chains in the sample, in the range of 600,000 to 900,000, and (iii) the polyethylene oxide having the lower average molecular weight comprises about 60% or more by weight but less than 100% by weight in the polymer component. Alternatively, the term "molecular weight" is indefinite.

1. Plaintiffs' Opening Position

The '150 patent is directed to the use of certain excipients to make an orally dissolvable pharmaceutical film that contains an opioid as an active ingredient. More specifically, the invention claimed in the '150 patent is a film product comprising, among other things, certain amounts of specific polymers, including polyethylene oxides (PEOs). All the claims require the presence of both low molecular weight PEOs and higher molecular weight PEOs in the film product. As specified in the claims, low molecular weight PEOs have a molecular weight in the range of 100,000 to 300,000 while higher molecular weight PEOs have a molecular weight in the range of 600,000 to 900,000. Furthermore, the claims require at least about 60% of the PEO

combination to be within the low molecular weight range.

Thus, the plain language of the claims requires a certain amount of PEOs having molecular weights that fall within certain ranges; the claims do not recite "***average***" molecular weight. As further discussed below, Defendants improperly seek to import the term "average" into the claims and thereby improperly re-define them in a way that is inconsistent with their plain and ordinary meaning.

The dispute between the parties is whether "molecular weight" should be given its plain and ordinary meaning as used in the specification and claims, as Plaintiffs believe. Defendants' proposed construction of "***average*** molecular weight" has no explicit or implicit support in the '150 patent. At Defendants' request, "molecular weight" is construed separately below.

2. Defendants' Answering Position[2]

The parties dispute two different limitations: (a) whether the PEO portion of the claimed "polymer component" comes from the same or different sources; and (b) whether there is an upper limit to the "60% or more" limitation. Plaintiffs' proposed construction violates fundamental canons of claim construction by flatly contradicting statements made during prosecution or rendering the resulting claims indefinite. Defendants' proposed construction, however, reflects the plain and ordinary meaning, is consistent with the intrinsic evidence, and provides adequate guidance for a skilled artisan to make and use the purported invention. Accordingly, Plaintiffs' construction should be rejected in favor of Defendants' construction.

a. The "water-soluble polymer component" of the claimed film product requires two different sources of polyethylene oxide.

Independent claims 1 and 10 are directed to a film product that includes "an opiate

[2] With respect to the '150 patent, Defendants believe that the logical flow of the brief is enhanced by first presenting arguments for "molecular weight" (Term 2) before the arguments for Term 1—a disputed term that includes "molecular weight.

pharmaceutical active" and "at least one water-soluble polymer component consisting of polyethylene oxide in combination with a hydrophilic cellulosic polymer." (Ex. A[3], Claims 1, 10.) The "polyethylene oxide" phrase in those claims is at issue in the proposed constructions. As required by the claims, the PEO component of the film product "comprises one or more low molecular weight polyethylene oxides and one or more higher molecular weight polyethylene oxides." (*Id.*) In dispute is whether these low molecular weight PEOs and the higher molecular weight PEOs can come from the same source or must come from different sources. A plain reading of the specification and ***all*** of the intrinsic evidence confirms that a person of ordinary skill in the art would understand that the claims require two different sources of PEO. In other words, a skilled artisan attempting to replicate the claimed films would select two different sources of PEO—one low molecular weight source containing polymers having an average molecular weight ranging from 100,000 to 300,000 daltons, and one higher molecular weight source containing polymers having an average molecular weight ranging from 600,000 to 900,000 daltons. Defendants' construction comports with the skilled artisan's understanding and is consistent with the intrinsic evidence.

During prosecution, the Examiner rejected the pending claims, relying on the Schiraldi reference, which disclosed polymers having molecular weights "above 100,000 and preferably above 3,000,000." (Ex. G, at 3.). Applicants distinguished Schiraldi, asserting that it failed to lead one of skill in the art "to us[e] the ***claimed combination*** of molecular weights." (*Id*. (emphasis added).) Applicants argued that Schiraldi provided "no disclosure or guidance to select low MW polymers, and particularly there is no disclosure to select ***a particular combination*** of MW polymers." (*Id*. (emphasis added).) Further, Applicants argued that "an

[3] All citations herein are to the Joint Claim Construction Chart unless otherwise indicated.

opiate . . . has a significantly different solubility and release profile than other analgesics, such as those listed in Schiraldi. The Applicant has discovered that ***the particular combination of molecular weights and polymers*** claimed provides a suitable release profile for an opiate." (*Id*., at 4 (emphasis added).) Further, "the claims recite ***a particular combination*** of polymers, having a particular molecular weight, in a particular ratio. This is not a matter of simply testing different molecular weights, or simply testing different ratios." (*Id*. (emphasis added).) Notably, Applicants never asserted that the claimed PEOs represented any distribution of molecular weights within a given sample—they expressly relied upon a combination of separate samples.

Thus, throughout prosecution, Applicants continually argued that the claimed compositions require particular combinations of low and higher molecular weight PEOs. By allowing for only a single source of PEO, Plaintiffs' proposed construction would obviate the need for the film product to include the very combination of low and higher molecular weight polymers that was critical to overcome the Examiner's rejections. Indeed, under Plaintiffs' proposed construction, there would be no low and higher molecular weight PEO sources to combine. Because of the way PEOs are synthesized, a single source of PEO may randomly include some finite number of individual PEO molecules that happen to fall within each of the claimed molecular weight ranges. (*See* JA Ex. 5, ¶ 29-31; *see also infra* III.B.2.) But, the films of the prior art that Plaintiffs purported to distinguish during prosecution would likewise have a distribution in which individual PEO molecules could happen to fall within each of the claimed molecular weight ranges, and thus Plaintiffs' construction for the term cannot be correct

Plaintiffs' proposal glosses over the distinctions that were critical to allowance of the claims, thereby improperly broadening the scope of the claims. Claims must be construed the

same way during litigation and prosecution. *Hockerson-Halberstadt, Inc. v. Avia Group Int'l, Inc.*, 222 F.3d 951, 956 (Fed. Cir. 2000). Plaintiffs' proposed construction contradicts this fundamental canon of claim construction and, therefore, should be rejected.

Additionally, Plaintiffs misunderstand Defendants' proposed construction. They read the phrase "average molecular weight ***calculated from the molecular weights of all the chains in the sample***" as requiring a skilled artisan to mathematically calculate the average molecular weight. (*See, e.g., infra* at 24.) This understanding ignores the methods readily available to a skilled artisan to determine average molecular weight of a polymer. (*See* JA Ex. 5, ¶¶ 32-44.) Rather than requiring a skilled artisan to conduct any type of statistical analysis, a person of ordinary skill in the art would readily understand from Defendants' proposed construction how the value for the average molecular weight is to be obtained.[4] (*See id.* ¶ 39.)

b. The "60% or more" limitation must be less than 100%.

Plaintiffs' proposed construction flatly contradicts arguments made to get the claims allowed and should be rejected. Defendants' proposed construction is consistent with the intrinsic evidence. In addition to arguing that the claimed film product requires a combination of low and higher molecular weight PEOs, Applicants also relied on the claimed ratio of low to higher molecular weight polymers to overcome the prior art. (Ex. G, at 3).

During prosecution, the examiner asked, "What is unobvious about combining two polymers of different molecular weight to obtain a polymer mixture of the median molecular weight?" (Ex. AA, at 11.) In response, Applicants stated:

[4] There are several methods available to calculate molecular weight, and because the intrinsic evidence contains no guidance as to which method should be utilized, Defendants contend that the term "molecular weight" is indefinite. However, Defendants' alternate proposal uses the "weight average molecular weight"—one of the most common measurement methods.

> [g]iven the numerous possible combinations of film forming materials available, and in particular given the wide number of molecular weights available to choose from, one of ordinary skill in the art simply would not be able to predict which particular combination of polymers having which particular molecular weights would be useful to form the claimed invention…***The claims recite a particular combination of polymers, having a particular molecular weight, in a particular ratio***.

(Ex. H, at 3 (emphasis added).) Applicants also noted that "[g]iven the vast number of polymers and wide disparity of molecular weights to choose from, there is a significantly high degree of experimentation necessary to arrive at ***the narrow ranges claimed***." (*Id*. at 4 (emphasis added).)

Thus, the claims not only require the film product to have a combination of two different sources of PEO; they also require that the final polymer component as a whole comprise about 60% by weight—but less than 100% by weight—of the low molecular weight source of PEO. Plaintiffs' proposed construction places no upper limit on the amount of low molecular weight PEO that must be present in the final film product. Under Plaintiffs' proposed construction, a final film product could contain 100% of low molecular weight PEO and 0% of high molecular weight PEO and still fall within the scope of the claims. Adopting Plaintiffs' construction would read out the two features—the combination of low and higher molecular weight polymers in a particular ratio—that were critical to allowance. Plaintiffs cannot now broaden the scope of the claims by allowing one source of PEO (*e.g.*, with an average weight of 600,000 daltons) to meet the "three specific numerical limitations" that were necessary to distinguish the claimed film product from the prior art. (Ex. G, at 5.) Plaintiffs cannot use claim construction to recapture non-infringing embodiments abandoned during prosecution. *Norian Corp. v. Stryker Corp*., 432 F.3d 1356, 1363 (Fed. Cir. 2005) (narrowing claim amendment presumptively surrenders all scope between the broader and narrower claims).

On the other hand, Defendants' proposed construction is consistent with the specification and the prosecution history because it properly requires that ***both*** low and higher molecular weight PEOs be present in the final film product in the required ratios, allowing a person of ordinary skill in the art to make and use the claimed invention. Defendants' proposed construction is supported by the intrinsic evidence and reflects the plain and ordinary meaning of the term. Therefore, Defendants' proposed construction should be adopted.

3. Plaintiffs' Reply Position

a. The Claim Term "Molecular Weight" Refers To Actual Molecular Weight

The claim construction issues relating to the '150 patent generally turn on the construction of the term "molecular weight." As explained in Plaintiffs' Opening position above, the proper construction of that term is actual molecular weight, i.e., the sum of the atomic weights of all the atoms in a molecule. Defendants contend, largely based not on the intrinsic evidence but on the Declaration of their expert, Dr. Amiji, that all references to "molecular weight" refer to an average (a term that appears nowhere in the patent). Defendants also argue that the polyethylene oxide ("PEO") polymers referred to in the claims must come from two separate sources, in effect two bottles (another groundless limitation).

Defendants' strained positions on this issue—generated to buttress their contentions of indefiniteness and noninfringement—fall into three categories: i) a complete mischaracterization of the Federal Circuit's decision in *Teva v. Sandoz*; ii) plainly wrong interpretations of the specification and claim language that attempt to import limitations found nowhere in the patent into the claims, ignoring the objectives of the invention and that the language used only makes sense if understood as referring to actual molecular weight; and iii) scientifically false statements by their expert, Dr. Amiji, including the false assertions that the molecular weight of a PEO *must*

be expressed as an average (it is also commonly expressed as a distribution of actual molecular weights), that the actual molecular weight of a PEO molecule is a multiple of 44 daltons (it is not, as this figure ignores the end groups on these polymers), and that it would be "impossible" to determine if 60% of the polymer component consists of low molecular weight PEO (in fact, size exclusion chromatography has been used for decades to measure molecular weight distribution).

b. The *Teva* Case Supports Plaintiffs' Construction

Contrary to Defendants' assertions, Plaintiffs' proposed construction for "molecular weight" is consistent with and supported by the *Teva* Federal Circuit decision. *See Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 723 F.3d 1363 (Fed. Cir. 2013). The Federal Circuit certainly did not state that "molecular weight" in the context of polymers necessarily refers to an average molecular weight, as Defendants contend. The *Teva* district court expressly held that the plain and ordinary meaning (*i.e.*, the sum of the atomic weights of all the atoms in a molecule) could apply to polymers, and does indeed apply in the context of individual polymer molecules. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 810 F. Supp. 2d 578, 587 (S.D.N.Y. 2011). On appeal, the Federal Circuit also found that certain molecular weight values for "copolymer–1" referred to "exact values" (*i.e.*, actual molecular weight) rather than "statistical measures" (*i.e.*, average molecular weight). *Teva*, 723 F.3d at 1370.

In *Teva*, the Federal Circuit considered claims that include nearly identical language to the claims asserted here, and found that "molecular weight" in the context of those claims should be construed as precise points on a molecular weight distribution curve (*i.e.*, actual molecular weight values), and not as a "statistical propert[y] of the polymer molecular weight [distribution] curve" (*i.e.*, average molecular weight). *Id.* at 1370. The Federal Circuit concluded that these

claims, as construed, were not indefinite, a holding which governs here.

The Federal Circuit distinguished two sets of claims: Group I claims which recite a "Copolymer–1 having *a molecular weight of about 5 to 9 kilodaltons . . .*," and Group II claims which recite a "Copolymer–1 having over *75% of its mole fraction within the molecular weight range from about 2 kDa to about 20 kDa . . . .*" *Id.* at 1367 (emphasis in original). The Federal Circuit found that the Group I claims correspond to an average molecular weight and are indefinite because "the plain language [of the claims] does not indicate which average molecular weight measure is intended." *See id.* at 1369.

The *Teva* court concluded that the Group II claims were not indefinite because the claims did not recite average molecular weight values but rather, as is the case here, boundaries of a molecular weight range corresponding to precise points on the molecular weight axis of a distribution curve (*i.e.*, actual molecular weight values). *See id.* at 1370. The following illustration used in *Teva* and the precise language of *Teva*, are instructive:

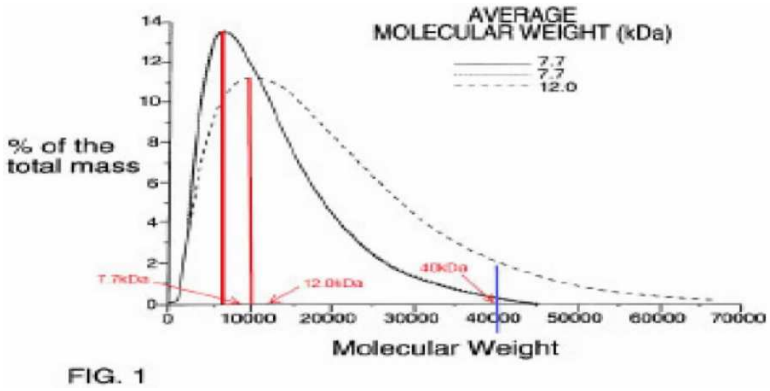


FIG. 1

> Group II claims, by contrast, do not recite average molecular weight values. Instead of describing copolymer–1 in terms of a statistical measure, such as M_w, Group II claims recite the **percentage of copolymer–1 molecules in a sample falling within an arbitrarily set molecular weight range**. The numbers that set the boundaries of that range, such as "2 kDa" and "20 kDa" in the '430 patent claim 1, refer to **precise points on the "Molecular Weight" axis**, rather than to statistical properties [(e.g. average molecular weight)] of the polymer molecular

> weight curves. Like the numbers 10,000 (*i.e.*, 10 kDa) and 20,000 (*i.e.*, 20 kDa) in the figure above, "2 kDa" and "20 kDa" refer to exact values rather than statistical measures. The scope of Group II claims is thus readily ascertainable. We hold that Group II claims are not invalid for indefiniteness.

Id. at 1369-70 (emphasis added).

Like the Group II claims, the asserted claims here recite molecular weight ***ranges*** and ***boundaries*** for those ranges (100,000 to 300,000 and 600,000 to 900,000), as well as the ***percentage*** falling within the claimed range (60% low molecular weight PEOs). *Compare Teva*, 723 F.3d at 1367, 1370.

Per *Teva*, the claimed boundaries of the molecular weight ranges in the asserted claims of the '150 patent should not be construed as average molecular weights, but rather as actual molecular weights (*i.e.*, under the plain and ordinary meaning, the sum of the atomic weights of all the atoms in a molecule), as proposed by Plaintiffs. As confirmed by the Federal Circuit, the claim term "molecular weight" is not indefinite under Plaintiffs' proposed construction. *See Teva*, 723 F.3d at 1370.

c. Molecular Weight In The Specification And Claims Of The '150 Patent

Nowhere in the patent is there a reference to "average" molecular weight—all references to molecular weight are unqualified without "average" or any other similar term. Defendants, through their expert, assert that, nevertheless, the term molecular weight must, somehow, necessarily mean average molecular weight, as a matter of general principle in polymer science. This overreaching assertion is rebutted by Plaintiffs' expert Dr. Mathias (*see e.g.*, JA Ex. 6, Mathias Dec. ¶¶ 14-18, 24-25) and nothing in the specification supports it. Defendants ignore the functional objectives of the invention as described in the specification in regard to PEO molecular weight and why that term must be understood to refer to actual weight and not to some

undefined average.

The main discussion in the specification of PEO and molecular weight is found in columns 17 to 18 and 50 to 51 of the patent. That discussion makes it unmistakably clear that the purpose of including a certain amount of PEO having a low molecular weight and a certain amount having a high molecular weight is so that the resulting pharmaceutical film will have certain functional attributes. The specification makes clear (*see, e.g.*, JCCS Ex. B, 17:43-51 and 18:6-2) that the references to, and use of, low molecular weight and high molecular weight PEO, as defined by the molecular weight ranges of 100,000 to 300,000 for low and 600,000 to 900,000 for high, have a crucial functional significance, as PEOs within these weight ranges strongly impact various film properties. This is further confirmed in column 51:23-45, where the results of various experiments are discussed (the "molecular weight of PEO in the polymer component [was] varied to achieve different film properties . . . . In those films containing combinations of varying molecular weight PEOs, those with about 60% or higher of the lower molecular weight PEOs (100,000 to 300,000) in the PEO combination dissolved faster."). These passages in the specification make clear to one of ordinary skill in the art that the use of low and high molecular weight PEOs, within certain defined ranges, is very important for the significant film properties discussed, including dissolution time, adhesion, and tear resistance.[5]

Because the term "average" is never used to qualify the term "molecular weight," there is also no discussion of which average, such as viscosity average, weight average, or number

[5] Defendants assert Plaintiffs' construction fails to include an upper limit to the required amount of low molecular weight PEO, supposedly allowing the PEO to be 100% low molecular weight (100,000 to 300,000). However, Plaintiffs construction also requires the presence of higher molecular weight PEO in the range of 600,000 to 900,000, and therefore excludes the possibility of 100% low molecular weight PEO.

average (all of which may be and are likely different for a given polymer, *see, e.g., Teva*, 723 F.3d at 1367; JA Ex. 6, Mathias Dec. ¶ 18). Rightly so, a person of ordinary skill in the art would readily grasp that these functional teachings about the use of low and high molecular weight PEOs refer, not to any average, but to actual molecular weights as would be plotted on a molecular weight distribution curve.

Understanding these ranges as referencing actual molecular weight plainly provides a much more precise teaching that matches the functional objectives of using PEOs within the defined low and high ranges. It does not make sense, nor have Defendants or their expert proffered any legitimate reason, to think that the inventors meant to convey these functionally important, molecular weight range-based teachings by using some concept of averages. If the ranges were understood as referring to averages and not to actual molecular weight, the use of any average (since it can contain even drastically different actual weights and can be calculated different ways and produce significantly different results) is necessarily far less precise for attempting to achieve a functional objective.

Defendants and their expert argue that the patent's failure to identify which average is supposedly implicitly referred to by the unmodified term, "molecular weight," renders the patent indefinite. But that argument is not plausible in the face of the careful passages from the specification discussed above. Defendants' baseless indefiniteness contentions only serve to prove further that the only reasonable way to read the patent, to give a reasonable meaning to the molecular weight ranges discussed and defined in the specification, is to understand them as referring to actual molecular weights (precise points on the "molecular weight" axis, as in *Teva*). It follows then that none of Defendants' strained speculations about which "average" was purportedly meant need arise and that the claims are, therefore, not indefinite.

Finally, Defendants' contention that these recited molecular weight ranges should be read as averages and that the PEOs in the two ranges must come from separate sources (e.g., two bottles) seeks to import limitations into the claims that do not appear there.[6] The claims do not use the term "average" or any similar term. Nor is there anything in the claims (or the specification) that requires that the PEOs be obtained from two separate sources. There is no reason to believe that, instead of providing actual weight ranges readily comprehended and implemented by one of ordinary skill in the art, the inventors were intending to use undefined, much less precise averages of some kind that would be less likely to convey the intended functional teachings or achieve the intended functional properties.

d. Defendants' Misplaced Reliance On Their Expert Dr. Amiji

Defendants' position that the term molecular weight necessarily refers to an average largely rests on incorrect assertions made by their expert, Dr. Amiji. The section above shows why the specification and claims of the '150 patent affirmatively support Plaintiffs' position on this issue and serve as an intrinsic evidence rebuttal to Defendants' and Dr. Amiji's contentions. The following further refutes several of those contentions relying in particular on the rebuttal declaration of Plaintiffs' expert Dr. Lon Mathias.

Defendants' expert, Dr. Amiji, makes the sweeping assertion (*see e.g.*, Amiji Dec., JA Ex. 5, ¶ 23) that when the term "molecular weight" is used to describe a polymer, the person of ordinary skill in the art thinks that it must mean "average molecular weight." This, as Dr. Mathias explains, is clearly wrong. There is no dispute that the molecular weight of a polymer

[6] Defendants assert the claimed molecular weight ranges of PEO cannot be derived from one source of PEO because applicants allegedly "expressly relied upon a combination of separate samples" to distinguish prior art during prosecution. However, the file history statements simply refer to the claimed combination of polymer molecules having different molecular weights and present in a particular ratio. They say nothing about the source of the PEO or how to accomplish the combination. They certainly make no mention of separate samples.

can be, and often is, specifically referred to as a type of average, including weight average, number average, viscosity average, and "z" average. But it is also true, and has been for decades, that the molecular weight of a polymer, including PEO, is also, and often, referred to as meaning the actual weight, as shown in a molecular weight distribution ("MWD"). JA Ex. 6, Mathias Dec. ¶¶ 15-17. An example of an analytical technique for determining such actual molecular weight has been available since the 1970s. *Id.* ¶¶ 19-20, fn. 6. That technique is called size exclusion chromatography ("SEC"). *Id*. Over the last 30 years, SEC has increasingly become the preferred way to determine the molecular weight of polymers, including PEO, and the molecular weight distribution information from SEC is also used to determine weight average and number average molecular weight. *Id.*[7]

Defendants and Dr. Amiji assert that it would be impossible to separate PEO molecules and determine the actual molecular weight of a percentage thereof and that, consequently, the 60% low molecular weight PEO claim limitation must refer to an average. This is scientifically false given the long-established routine use of SEC, precisely to determine the MWD, which shows actual molecular weights of polymers, including PEO. *Id.* ¶ 26.

Defendants and Dr. Amiji assert that the molecular weight of PEO is expressed as a multiple of 44 (Daltons) and that the inventors of the '150 patent could not be referring to actual molecular weight because the molecular weight ranges referred to in the patent, such as 100,000-300,000, are not multiples of 44. First, this is wrong because, while the molecular weight of the individual ethylene oxide monomer is 44, the weight of the end groups on each PEO chain must also be taken into account. *Id.* ¶ 26, fn. 6. Furthermore, actual molecular weights of PEO are

[7] Dr. Amiji's reference to certain discussions of average molecular weight takes them out context and seeks to use them for a purpose for which they were not intended, while ignoring the standard expression of molecular weight distribution values for polymers examined by the appropriate analytical techniques. *See* JA Ex. 6, ¶ 16.

generally expressed with no more than 2 or 3 significant digits and not as a multiple of anything. *Id.* ¶¶ 29-30. This is so, in part, due to the inherent error in the measurement methods. Therefore, as one of ordinary skill in the art would appreciate, necessarily rounded number is not indicative of an average molecular weight but can equally apply to an actual molecular weight. *Id.*[8]

For these reasons, it is incorrect to assert as Dr. Amiji does, that a rounded number such as 100,000 as used in the '150 patent to refer to molecular weight somehow must refer to an average and not to actual weight. In fact, some of the standards used for determining the MWD of PEO correspond with the kind of round numbers that appear in the molecular weight ranges provided in the patent. *Id.* Thus, contrary to Dr. Amiji's assertions, one of ordinary skill in the art would not view the rounded figures used in the patent for the molecular weight ranges as being in any way inconsistent with an intention to convey ranges of actual molecular weights. *Id.*

Further contrary to Dr. Amiji's assertions, one of ordinary skill in the art would understand that low and high molecular weight PEOs can be derived from one source because that is a typical consequence of the methods by which they are synthesized. *Id.* ¶¶ 31-36. Nor is there anything in the patent, including the claims, that somehow restricts the claims to requiring that the PEOs be obtained from two different sources (two bottles). The functional objective of using low and high molecular weight PEO makes clear that what is important is the presence of PEOs required by the claims—how they got there (from one bottle or two) is completely irrelevant. *Id.*

[8] Nor do references in the patent to the use of Dow's product Polyox as a source of PEO require any other conclusion. A person of ordinary skill in the art would understand that Dow's Polyox, as is typical for many commercial polymers, contains a number of molecules having differing actual molecular weights (referred to as dispersity) while also reasonably assuming that, for example, Polyox 200,000 would consist substantially of PEOs having an actual molecular weight between the ranges of 100,000 and 300,000. *Id.* ¶ 37.

4. Defendants' Sur-Reply Position[9]

The Parties disagree whether the claims contemplate: (1) two separate PEOs of different average molecular weight (as Defendants propose); or (2) a single PEO with a distribution of individual molecules of particular molecular weights (as Plaintiffs propose).

a. Plaintiffs' Reliance on *Teva*'s "Group II" Claims Is Misplaced

Plaintiffs contend that the court in *Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc.*, 723 F.3d 1363 (Fed. Cir. 2013), considered claims with "nearly identical language to the claims asserted here," and on that basis, contend that the claims of the '150 patent cover a distribution of molecular weights. (*Supra* at 9.) But the intrinsic evidence demonstrates that Plaintiffs' "nearly identical" argument is incorrect. A direct comparison of the representative claim limitations follows:

***Teva* "Group II" Claim Limitation**	**'150 Patent Claim Limitation**
"Co-polymer-1 having over 75% of its mole fraction within the molecular weight range from about 2 kDa to about 20 kDa…" 723 F.3d at 1367.	"the polyethylene oxide component 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 polymer 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."

First, Plaintiffs' proposed analogy to *Teva* improperly relies on the construction of an unrelated patent, relating to different subject matter, without any regard for the differences

[9] Because Plaintiffs have presented this argument in the context of Term 1, Defendants address all of Plaintiffs' arguments here. However, Plaintiffs' arguments are also responsive to Defendants' arguments regarding Term 2. Accordingly, Defendants respectfully refer the Court to the arguments pertaining to Term 2 in conjunction with this Section.

between the specifications and prosecution histories of those patents. *See Apple, Inc. v. Motorola, Inc.*, 757 F.3d 1286, 1312 (Fed. Cir. 2014) ("S]tatements made in unrelated applications are not relevant to claim construction."). A brief examination of the claims reveals several significant differences. For example, the *Teva* claim recites only a single Co-polymer-1, whereas the '150 patent claims require multiple PEOs: "***one or more*** low molecular weight polyethylene oxide***s***" ***and*** "***one or more*** higher molecular weight polyethyelene oxide***s***." Additionally, the *Teva* claim recites only a singular range of molecular weights, while the '150 patent requires two separate and distinct molecular weight ranges. Further, unlike in *Teva*, the '150 patent claims require that the low molecular weight PEO make up 60% of not just PEO but of the ***polymer component*** (which also includes HPC—a fact Plaintiffs do not dispute).

As Defendants' expert Dr. Amiji explains, unlike the *Teva* "Group II" claims, the '150 patent claims do not recite a distribution of molecular weights. (JA Ex. 7, Amiji Supp. Decl., ¶¶ 6, 18-28 .) For example, the claims do not state that 60% of the PEO molecules fall within the low molecular weight range—they say one PEO comprises 60% of a component containing at least two PEOs and HPC. (*Id.* ¶ 18.) Further, the claims recite two separate molecular weight ranges—not one range, as one would expect if the claims were describing a unimodal PEO distribution. (*Id.* ¶ 22.) Thus, the plain language does not describe a distribution of polymer molecules having particular molecular weights.

b. The Intrinsic Record Contemplates Using Multiple PEOs

Defendants' proposed construction is based on the straightforward and plain claim language, which requires one or more polyethylene oxides of one molecular weight, and one or more polyethylene oxides of a different molecular weight. Remarkably, Plaintiffs contend that there is no support for Defendants' argument that the claimed invention must contain two

separate PEOs. (*Supra* at 14 & n.6.) Indeed, Plaintiffs assert that the claimed polymer component simply has a "certain amount" of PEO from the low molecular weight range and a "certain amount" from the high molecular weight range. (*Supra* at 12.) Plaintiffs' argument is inconsistent with the actual claim language**,** which plainly requires that the film contain ***multiple*** PEOs, such as from two separate sources, not a single PEO component with a single distribution of molecular weights that happens to have a "certain amount" of molecules falling within a given range.

Plaintiffs' logic interprets "one or more polyethylene oxides" to mean "one or more polyethylene oxide ***molecules***." This is entirely inconsistent with how a person of ordinary skill in the art would understand the plain and ordinary meaning of the term. Indeed, a skilled artisan would understand that a reference to "one or more PEOs" means one or more sources, not one or more polymer molecules. (JA Ex. 7, Amiji Supp. Decl., ¶ 20.) Moreover, a person of ordinary skill in the art would not discuss a film product by the makeup of its individual molecules—he would understand it to refer to the ***components*** of that film. (*Id.*) Thus, the claim language demonstrates that the film must contain more than one PEO component. (*Id.*)

The specification confirms Defendants' position. For example, the '150 patent identifies by weight percentage certain polymers of different molecular weights that are ***combined*** into the film. (*Id.* ¶ 24.) In other words, the patent describes the makeup of the film by its components—not by a distribution. Moreover, the specification describes varying the level and molecular weights of these PEOs, and it only describes varying the relative amount of each component—not varying the distribution of a single PEO. (*Id.* ¶ 25.)

Further, Plaintiffs' construction ignores the prosecution history where the applicants repeatedly pointed to the ***combination of polymers*** as a purportedly novel aspect of the claimed

film. (*Supra* at 4-5.) In other words, Defendants agree that the combination of molecular weights was critical to allowance of the claims, but the applicants were referring to a combination of different sources of PEOs having ***different average molecular weights***—not merely a single source of PEO having a particular molecular weight distribution. (Ex. G, at 2-3.)

c. Plaintiffs' Attacks On Dr. Amiji's Analysis Are Misguided

Dr. Amiji does ***not*** assert that polymers are always described in terms of average molecular weight—he states that polymer molecular weight can be described as either an average ***or*** a distribution, but never by reference to the sum of atomic weights of ***individual polymer molecules***. Nothing in Plaintiffs' reply alters that conclusion. Since the '150 patent does ***not*** pertain to a molecular weight distribution, a person of ordinary skill in the art would readily understand that the molecular weights described in the '150 patents refer to an average value. (JA Ex. 7, Amiji Supp. Decl., ¶¶ 3, 6.)

Plaintiffs' heavy reliance on size exclusion chromatography is misplaced. Contrary to Plaintiffs' assertion, that technique is not used to determine the actual molecular weight of individual polymer molecules, and it cannot be used to determine "the sum of the atomic weights of all the atoms in a molecule," as Plaintiffs' construction requires. (*Id.* ¶¶ 11-12.) Instead, SEC is used to determine the ***distribution*** of ***approximate*** molecular weights by reference to a standard, and to calculate average molecular weight. (*Id.* ¶¶ 10-14.) Moreover, SEC is frequently used to calculate either the weight average molecular weight or the number average molecular weight. (*Id.* ¶ 14; *supra* at 15.)

Additionally, Plaintiffs assert that the molecular weight distribution must be measured in the final film product. (*Infra* at 27-28.) If that were true, it would be impossible to use SEC to measure the molecular weight of the ***polyethylene oxide*** molecules alone, *i.e.* separated from the

other components of the film, including HPC, the actives, taste-masking agents, etc. (JA Ex. 7, Amiji Supp. Decl., ¶¶ 15-16.) Even if one could determine that 60% of the molecules in the polymer component fell within the range of 100,000-300,000 daltons, there is no plausible way to determine whether all of those molecules are ***PEO*** molecules, as required by the claims.

Finally, Plaintiffs' and their expert's assertions that the molecular weights recited in the specification describe actual molecular weights are mistaken. First, even if the end groups of the PEO chains are considered, the sum of the atoms in a molecule ***still*** does not add up to the precise numbers disclosed in the patent. (*Id.* ¶ 29.) Second, Plaintiffs assert that molecular weights are generally expressed with no more than two or three significant digits because polymer molecular weight cannot be described any more accurately due to inherent measurement error. (*Supra* at 16.) But that is exactly the point—***Plaintiffs*** propose construing "molecular weight" to be the sum of the atomic weights of the molecules, which does not contemplate any measurement error because it merely involves adding atomic weights in a molecule. Aside from the fact that this cannot be determined for a polymer, if Plaintiffs' proposal were correct, a person of skill in the art would expect to see precise molecular weights in the specification—not figures rounded to any particular number of significant digits. (JA Ex. 7, Amiji Supp. Decl., ¶ 30.) Thus, Plaintiffs' statements that "measurement error" is inherent in a determination of molecular weight underscores why their proposed construction cannot be correct.[10]

B. '150 Patent—Term 2

Term	Plaintiffs' Proposed Construction	Defendants' Proposed Construction
"molecular weight" (claims 1, 10)	The plain and ordinary meaning is the sum of the atomic weights of	Average molecular weight calculated from the molecular

[10] Plaintiffs' construction is also indefinite for the same reasons as stated in Defendants' opening brief.

Term	Plaintiffs' Proposed Construction	Defendants' Proposed Construction
	all the atoms in a molecule.	weights of all the chains in the sample Alternatively, the term "molecular weight" is indefinite.

1. Plaintiffs' Opening Position

Plaintiffs propose that "molecular weight," which is used throughout the specification as it is in the claims (without the significant modifier "average"), be construed to have its plain and ordinary meaning as universally known and confirmed by technical dictionaries: "molecular weight" means the weight of a molecule or chain, i.e., the sum of the atomic weights of all the atoms in a molecule. JA Ex. 1, MCGRAW-HILL DICTIONARY OF SCIENTIFIC AND TECHNICAL TERMS, 5th Ed., McGraw-Hill (1994); JA Ex. 2, MCGRAW-HILL DICTIONARY OF SCIENTIFIC AND TECHNICAL TERMS, 6th Ed., McGraw-Hill (2002); JA Ex. 3, CHAMBERS DICTIONARY OF SCIENCE AND TECHNOLOGY, Chambers (2007).[11] *See also Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 810 F. Supp. 2d 578, 587 (S.D.N.Y. 2011) ("Outside the context of copolymer-1 mixtures, there is virtually no dispute that 'molecular weight' means the sum of the atomic weights of the atoms making up a molecule.").

The language of the claims requires a certain amount of PEOs having actual, individual, molecular weights that fall within certain ranges—PEOs that have actual molecular weights in the range of 100,000-300,000 and in the range of 600,000-900,000. The claims do not recite the term "***average***" molecular weight nor do the claims require "***average***" molecular weights that fall within certain ranges. In construing disputed terms, Courts should first look at the language of

[11]Copies of the patents-in-suit, as well as other portions of the intrinsic record relied upon by the parties, were attached as Exhibits B through Z to the parties' Joint Claim Construction Statement. Additional exhibits are included as a Joint Appendix (JA) to this submission.

the claims themselves, because "[i]t 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). Here, the plain meaning of the disputed terms and the claim language itself, however, make clear that the claimed composition comprises PEOs having molecular weights within certain ranges and not an average molecular weight within a certain range. In fact, not only does the term "***average*** molecular weight" appear nowhere in the claims, but, as further discussed below, it is also entirely absent from specification and the file history, which similarly lack any calculation of an "average" molecular weight.

Furthermore, insofar as Defendants' proposed construction is asserted to entail the mixing of ***two*** batches or grades of PEOs where each has a certain ***average*** molecular weight, such a construction constitutes an unsupported and improper narrowing of the claims since what the claims expressly require is not ***average*** molecular weights at all, let alone ***two sets of PEOs with different average molecular weights,*** but simply the presence (whatever the source) of one or more PEOs having an actual, individual molecular weight between 600,000 and 900,000 and one or more PEO's having an actual, individual molecular weight between 100,000 and 300,000 where the molecules that fall within the latter range comprise 60% of the polymer component. JCCS Ex. B, 18:6-21; 51:39-45.

a. The Intrinsic Evidence Mandates Plaintiffs' Construction

The term "molecular weight" appears throughout the specification and claims, without modification. There is no suggestion in the intrinsic record that the term has anything but its ordinary meaning. Contrary to Defendants' proposed construction, there is no mention of "***average*** molecular weight" anywhere in the patent or in its file history. Indeed, the statistical

concept of an "average" molecular weight appears nowhere in the claims, the specification or the file history.

Instead the specification makes clear that the inventors were specifying PEOs having different weights and the amounts thereof that would impart certain desirable qualities to the film when combined. For instance, in describing embodiments corresponding to the claimed film products which use PEO combinations, the specification states:

> In some embodiments, it may be desirable to combine high molecular weight (600,000 to 900,000) with low molecular weight (100,000 to 300,000) PEOs in the polymer component. For instance, certain film properties, such as fast dissolution rates and high tear resistance, may be attained by combining small amounts of high molecular weight PEOs with larger amounts of lower molecular weight PEOs. Desirably, such compositions contain about 60% or greater levels of the lower molecular weight PEO in the PEO-blend polymer component.

JCCS Ex. B, '150 patent, 18:11-21. Similarly: "In those films containing combinations of varying molecular weight PEOs, those with about 60% or higher of the lower molecular weight PEOs (100,000 to 300,000) in the PEO combination dissolved faster." *Id*. at 51:41-45.

The specification thus emphasizes combining two or more PEOs of different molecular weights, to utilize their different characteristics. This is antithetical to calculating a single average molecular weight, as Defendants' construction requires. The invention utilizes the actual characteristics of PEO molecules or chains of different weights, not the hypothetical characteristics of a calculated average.

Defendants' proposed construction would actually encompass scenarios where no PEOs are within the claimed molecular weight ranges. A calculated average molecular weight within the range of for example 100,000 to 300,000 Daltons, on the other hand, does not necessarily mean that a single molecule with a molecular weight within that range is present. For example, in a mixture comprising a PEO molecule having a molecular weight of 50,000 and a PEO molecule having a molecular weight of 350,000, the average molecular weight is 200,000. In

other words, the specification and the claims make clear that the PEOs need to comprise PEOs having an actual atomic mass (which is measured in Daltons[12]) of 100,000 to 300,000 as well as PEOs having an actual atomic mass of 600,00 to 900,000, as opposed to some calculated average mass within those ranges.

This is also made clear in the file history. There the applicants explained during prosecution that "median molecular weight," a statistical concept introduced by the examiner, is misplaced in an interpretation of the '150 patent:

> Appellants respectfully submit that the Examiner's statement that combining two polymers having different molecular weights to arrive at a median molecular weight is misplaced. One of skill would appreciate that the low MW PEO would release at different time than the high MW PEO. Accordingly, combining these two different types of PEO would not provide a new polymer having a "median molecular weight", which would release at the same time.

JCCS Ex. F, Statement in Support of Pre-Appeal Brief Request For Review, at 4 (MSL_0001213).

Thus, when the '150 patent uses the term "molecular weight" in reference to PEOs, it consistently uses that term to have a precise, well-understood, literal meaning, namely, the weight of a molecule (which is determined by the sum of the atomic weights of the atoms in a molecule). And the low and high molecular weight ranges referred to in the claims and in the specification refer, in turn, to actual weights of individual PEOs that fall within certain ranges as PEOs within those ranges were found to impart certain desirable properties to the film composition. This is very different from the statistical concept of an average molecular weight – a concept or limitation found nowhere in the '150 patent and which, therefore, should not be imported into the claims as Defendants propose.

[12] *See* JA Ex. 4, McGraw-Hill Dictionary of Scientific and Technical Terms, 5th Ed., McGraw-Hill (1994).

b. The Inventors Said "Average Molecular Weight" (In A Related Patent) When That Is What They Meant

There is no reference anywhere in the '150 patent to ***average*** molecular weight, whether of PEOs or any other compounds. The related '514 patent-in-suit names the same inventors as the '150 patent and shares much of its specification. In a passage present only in the '514 patent, however, the specification speaks of using, as taste-masking agents, water-soluble polymers which desirably have "an average molecular weight of equal to or greater than" a certain value. JCCS Ex. D, '514 patent, 6:14-16. In two dependent claims of the '514 patent (7 and 34), such water-soluble polymers are specified using this "average molecular weight" characteristic from the specification.

This plainly demonstrates that these inventors knew how to specify average molecular weight, instead of ranges of molecular weights of actual molecules or chains, when they so desired. Furthermore, the passage in the '150 patent specification describing combining different molecular weight PEOs, without mentioning average molecular weights (Ex. B, 18:6-21), a portion of which is quoted above, is found verbatim also in the '514 specification (Ex. D, 12:48-63). That is, in the '514 patent the inventors refer to certain water-soluble polymers by their average molecular weight but still describe the same low and high molecular weight PEOs as in the '150 patent without any reference to average molecular weights. It would be improper to construe the disputed "molecular weight" of the different PEOs to actually mean "average molecular weight," a different term the inventors used when that is what they intended.*See, e.g., BigBand Networks, Inc. v. Imagine Communs., Inc*., No. 07-351, 2011 U.S. Dist. LEXIS 30578, at *13 (D. Del. Mar. 24, 2011) ("Generally, different terms are presumed to have different meanings.").

c. The Federal Circuit Has Refused To Import "Average" Into Molecular Weight Claims Like Those In The '150 Patent

The Federal Circuit recently dealt with the interplay between actual polymer molecular weights and average molecular weights in *Teva Pharms. USA, Inc. v. Sandoz, Inc*., 723 F.3d 1363 (Fed. Cir. 2013).[13] In that case, it was undisputed that one group of claims recited average molecular weights. *Id*. at 1369. Defendants contended that a second group of claims also "necessarily refer to a . . . certain average molecular weight." *Id*. at 1368. The Federal Circuit disagreed:

> Group II claims, by contrast, ***do not recite average molecular weight values***. . . . . Group II claims ***recite the percentage of*** copolymer-1 ***molecules*** in a sample ***falling within an arbitrarily set molecular weight range***. The numbers that set the boundaries of that range, such as "2 kDa" and "20 kDa" in the '430 patent claim 1, refer to precise points on the "Molecular Weight" axis, rather than to statistical properties of the polymer molecular weight curves. . . . The scope of Group II claims is thus readily ascertainable.[14]

Id. at 1370 (emphasis added). Just as in the *Teva* Group II claims, the claims of Plaintiffs' '150 patent do not recite ***average molecular weights*** (the concept is nowhere found in the patent) but instead recite ***molecular weight ranges***, i.e., precise points on the molecular weight axis of a polymer molecular weight distribution curve.

d. Defendants' Construction Makes No Sense In A Product Claim

The claims of the '150 patent are all directed to a "film product." Controlling Federal

[13]Certiorari has been granted on the question whether a district court's fact finding in support of its claim construction may be reviewed *de novo*, as the Federal Circuit does, or only for clear error. 134 S. Ct. 1761, 2014 U.S. LEXIS 2312.

[14]The Federal Circuit held that this second group of claims (which did not involve average molecular weights) was not indefinite but held the first group of claims invalid as indefinite for reciting average molecular weights without specifying which of the several customary kinds of average molecular weight was intended. *Id.* at 1369. As indicated in the claim chart, Defendants here have also raised an indefiniteness issue relating to the term "molecular weight" in the '150 patent, if it is not construed as they propose. As the Federal Circuit held in *Teva*, though, there is nothing indefinite about the term "molecular weight" in the '150 patent when correctly construed as ***not*** referring to average molecular weights.

Circuit law holds that such a claim "claims a product, not merely a recipe for making whatever product results from the use of the recipe ingredients." *Exxon Chem. Patents, Inc. v. Lubrizol Corp*., 64 F.3d 1553, 1557 (Fed. Cir. 1995). "The chemical composition exists at the moment the ingredients are mixed together. Before creation of the mixture, the ingredients exist independently. The particular proportions specified in the claims simply define the characteristics of the claimed composition." *Id*. at 1558.

Plaintiffs' construction makes perfect sense when the claims of the '150 patent are viewed as product claims (***and*** if viewed as a recipe). In the film product, there are high molecular weight PEOs and low molecular weight PEOs, as the claims require. Mixing the different PEOs together to form the product has not changed the claimed characteristics, i.e., the molecular weights of the PEO molecules.

Defendants' construction, on the other hand, falls apart when the claims are properly viewed as product claims, i.e., claims directed to a mixture of components. Calculating the average PEO molecular weight "from the molecular weights of all the chains in the sample" will necessarily yield a single value. There cannot be two average molecular weights of all the PEOs in the single mixed-together product. The concept of two separate ***average*** molecular weights, reflecting the two different kinds of PEOs required by the claims, makes no sense once all the PEOs are mixed together, which is the way the Federal Circuit requires that product claims be read. This further demonstrates that Defendants' redefinition of "molecular weight" as "average molecular weight" cannot be correct in the context of the '150 patent.

2. Defendants' Answering Position

It is well established that the plain and ordinary meaning of a term must be considered ***in the context of the invention***. *See Golden Bridge Tech., Inc. v. Apple Inc.*, 758 F.3d 1362, 1365 (Fed. Cir. 2014); *Medrad, Inc. v. MRI Devices Corp.*, 401 F.3d 1313, 1319 (Fed. Cir. 2005)

("We cannot look at the ordinary meaning of the term in a vacuum. Rather, we must look at the ordinary meaning in the context of the written description and the prosecution history." (quotations and citations omitted)). Yet Plaintiffs' assertion that the plain and ordinary meaning of the term "molecular weight" is simply "the sum of the atomic weights of all of the atoms in a molecule" takes the phrase out of the context of the patent, which relates to the molecular weight of ***polymers***. Because a polymer is a heterogeneous mix of chains of varying lengths and molecular weights, a person of ordinary skill in the art would understand that the term "molecular weight" in the context of polymers cannot simply refer to the molecular weight of any individual chain—it must refer to some average value. Thus, as Defendants' polymer expert Dr. Amiji explains, the plain and ordinary meaning of molecular weight ***in the context of the claimed invention*** is not, as Plaintiffs contend, merely a sum of atomic weights.

While a person of ordinary skill in the art would readily understand that molecular weight of a polymer must be an average value, he would also understand that there are multiple methods of calculating that average value (with results varying depending on the method used), such that it is necessary to specify ***which type*** of molecular weight is applicable to a given polymer sample. But, the '150 patent provides no guidance as to which method should be used to calculate the molecular weight of the claimed polyethylene oxide polymers, rendering the term "molecular weight" indefinite.

a. Plaintiffs' Proposed Plain and Ordinary Meaning Is Incorrect In The Context Of Polymers

A polymer is a long chain of repeating units called monomers. (JA Ex. 5, ¶ 25.) Polyethylene oxide (PEO) is a type of polymer made by a process resulting in a random, heterogeneous mix of polymer chains of varying lengths and molecular weights. (*Id.* ¶¶ 28-30.) A typical polymer sample—including the commercially-available polymers described in the

patent—contains thousands of chains, and it is impossible to identify the length of each individual chain within that sample. (*Id.* ¶¶ 28-31, 35.) As a result, a person of ordinary skill in the art, when working with polymers, understands that it is inappropriate to speak in terms of molecular weight of individual molecules. (*Id.* ¶¶ 32-35, Ex. 5-D ("The existence of a distribution of molecular weights in a polymer sample implies that any experimental measurement of molecular weight in the given sample gives only an average value.").) Instead, polymer molecular weight is expressed as an average value, or by the distribution of molecular weights within a given sample. (*Id.* ¶¶ 32-36.) The average molecular weight of polymers can be expressed in a variety of ways, including weight average molecular weight, number average molecular weight, and viscosity average molecular weight. (*Id.* ¶¶ 38-40.) No matter the method used, one of ordinary skill of the art would readily understand that polymer molecular weight cannot be determined by simple addition of the atoms contained within any particular chain. (*Id.* ¶ 35.) For this reason alone, Plaintiffs' proposed construction should be rejected.

The intrinsic record further confirms that the applicants understood molecular weight to refer to some average molecular weight. For example, Table 22 purports to describe various film compositions, listing the compositions by the weight percent of the polymer component. (Ex. B, at 50:5-33.) Yet Table 22 lists only four molecular weights of PEO: 100,000 PEO, 200,000 PEO, 300,000 PEO, and 900,000 PEO. Some compositions contain 100% of just one type of PEO—for example, Composition DO contains 100% 200,000 PEO. If Plaintiffs' proposed construction were adopted, one of ordinary skill would understand this composition to require that the sum of the atomic weight of the atoms making up ***every molecule*** in that sample to be exactly 200,000 daltons. Such a result is technologically impossible for two reasons. First, because each individual PEO molecule is a chain of ethylene oxide molecules, the molecular

weight of each individual molecule must be a multiple of the molecular weight of ethylene oxide, which is 44 daltons. (JA Ex. 5, ¶ 36.) Because none of the molecular weights listed in Table 22 is a multiple of 44, they cannot plausibly be understood to refer to the weight of an individual PEO molecule. Second, the commercially-available polymers described in the '150 patent that could be used to make the claimed films (Ex. B, at 48:35-60; JA Ex. 5, ¶ 42, Ex. C) are not homogenous mixtures of molecules with identical molecular weights. (JA Ex. 5, ¶ 42.) Thus, the only plausible interpretation of the use of the term "molecular weight" in the specification must refer to an average value.

Plaintiffs' cited references, which purportedly support the "plain and ordinary meaning" of the term molecular weight, ignore the random and heterogeneous nature of polymers. (*Id.* ¶ 37.) In fact, Plaintiffs cite *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 810 F. Supp. 2d 578, 587 (S.D.N.Y. 2011) ("*Teva I*") for the notion that "[***o***]***utside the context of copolymer-1 mixtures***, there is virtually no dispute that 'molecular weight' means the sum of the atomic weights making up a molecule." (*See supra* III.B.1 (emphasis added).) But in that case, the court was distinguishing polymers ***versus small molecules*** and noted that the plaintiff's proposed construction "may be an acceptable definition for molecular weight when referring to a small molecules, such as water, in which every molecule has the same molecular weight." *Id.* The court explained:

> Because complex non-uniform mixtures, such as copolymer-1, often include molecules of varying weights, however, the molecular weight of such mixtures cannot be characterized by the molecular weight of any single species. The most precise way of describing the molecular weight of such mixtures, according to Dr. Grant, is a complete molecular weight distribution. For practical purposes, *the* ***molecular weight of a polymer is often expressed in a single, average molecular weight****.*

(*Id.* (quotations and citations omitted) (emphasis added).) Thus, the court acknowledged that for polymers, molecular weight is appropriately expressed as an average. (*Id.*[15]) The case does not support Plaintiffs' proposed construction; it undermines it.

As the *Teva I* court acknowledged, the molecular weight of a ***small molecule*** can be readily calculated by calculating the sum of the atomic weights of all the atoms in a molecule because the exact chemical composition of a small molecule is readily known and invariable. (JA Ex. 5, ¶ 32.) By contrast, because a sample of polymers is heterogeneous in length, the sum of weights of the atoms in each molecule is not known and varies from molecule to molecule. (*Id.* ¶¶ 32-33.) For that reason, Plaintiffs' cited references do not reflect the understanding of a person of ordinary skill ***in the context of polymers***. (*Id.* ¶ 37.) Thus, contrary to Plaintiffs' assertions, the plain and ordinary meaning of "molecular weight" *in the context of polymers* means the average molecular weight, and a person of ordinary skill in the art would understand that this average can be calculated by a variety of methods.

Finally, Plaintiffs' assertion that under Defendants' proposal it would be possible for none of the molecules to fall within the claimed molecular weight range is contrary to the science. A polymer sample contains a unimodal distribution of molecular weights. (*Id.* ¶ 31.) In other words, a graph of the distribution of the lengths of the polymer chains within a particular sample would contain a single peak, like a bell curve, for example. Thus, if the average molecular weight of a given PEO is between 100,000 to 300,000 daltons, it is scientifically

[15] The *Teva* court adopted a construction that referred to average molecular weight calculated using the peak molecular weight method. The Federal Circuit ultimately agreed that polymer molecular weight is expressed as an average and can be calculated by three methods, but reversed the district court's decision, holding that the claims reciting average molecular weight were indefinite. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 723 F.3d 1363, 1369 (Fed. Cir. 2013) ("*Teva II*") ("It is undisputed that Group I claims contain an ambiguity because their plain language does not indicate which average molecular weight measure is intended.")

implausible that such a PEO sample would contain no molecules having a molecular weight falling within that range. (*Id.*)

b. The Federal Circuit Has Defined "Molecular Weight" To Mean An Average

Plaintiffs assert that the claims of the '150 patent are similar to the "Group II" claims in *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 723 F.3d 1363 (Fed. Cir. 2013) ("*Teva II*"), which recite the percentage of copolymer-1 molecules that fall within a set molecular weight range. But Plaintiffs' argument that the Federal Circuit "refused to import 'average' into molecular weight claims" is mistaken. In fact, the *Teva II* decision supports Defendants' construction here.

In *Teva II*, the Court construed "molecular weight" in the "Group I" claims to mean "average molecular weight." As here, the representative "Group I" claim identified by the Federal Circuit *did not* expressly recite average molecular weight—it recited "copolymer-1 having a ***molecular weight*** of about 5 to 9 kilodaltons." (*Id.* at 1367 (emphasis added).) Like the "Group I" claims at issue in *Teva II*, the claims of the '150 patent here specify that the claimed invention contains a PEO with a ***molecular weight*** of 100,000 to 300,000, and a PEO with a molecular weight of 600,000 to 900,000—just as in *Teva II*, the "molecular weight" referred to in these claims must necessarily be understood to be an average.

Plaintiffs appear to suggest that because the claims contain a limitation that the low molecular weight polymer must comprise 60% or more of the polymer component, the claims refer to a distribution of molecular weights, as with the "Group II" claims in *Teva II*. But here the claim language makes clear that the molecular weights expressed are not a distribution. Instead, the specification and prosecution indicate that there are two ***separate and distinct*** PEO components, each with a specified molecular weight, as well as a hydrophilic cellulosic polymer component. Moreover, the claims expressly define the "polymer component" to include not only

the PEO, but also the hydrophilic cellulosic polymer, and the low molecular weight PEO portion of "polymer component" must comprise 60% or more by weight of the whole polymer component. Thus, the plain language of the claims demonstrates that the claimed molecular weights do not describe a distribution within a single sample, but pertains to two separate samples. (*See* JA Ex. 5, ¶¶ 45-46.)

c. The Term "Molecular Weight" Is Indefinite

As in *Teva II*, the "molecular weight" term here is indefinite. The *Teva II* court acknowledged that there were at least three different methods for calculating polymer molecular weight—peak average molecular weight (M_p), number average molecular weight (M_n), and weight average molecular weight (M_w). 723 F.3d at 1369. But (as here) the claims in *Teva* did not specify any particular calculation, claiming simply "molecular weight." The court acknowledged that each molecular weight measurement would differ and noted that the specification and prosecution history did not resolve the ambiguity as to which calculation applied to the claims. As a result, the court held that the claims reciting molecular weight were indefinite. (*Id.*)

Here, as in *Teva*, a person of ordinary skill in the art has no guidance from the patent or the prosecution history describing which measure of molecular weight is applicable to the claimed invention. As noted above, these different methods of calculating molecular weight often lead to different measurements, and while one may fall within a given range, another may not. (JA Ex. 5, ¶ 41.) Thus, the patent is not "precise enough to afford clear notice of what is claimed," resulting in a "zone of uncertainty" as to whether an accused product will infringe the

claimed invention, thereby rendering the term "molecular weight" indefinite. *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2129 (2014).[16]

Defendants' proposed construction defines "molecular weight" as the weight average molecular weight.[17] Should the Court determine that the claims are not indefinite, Defendants would accept an alternative construction that utilizes another accepted method of measuring molecular weight of polymers. However, absent any guidance in the intrinsic evidence to adopt one definition over another, Defendants respectfully submit that "molecular weight" is indefinite.

d. Plaintiffs' Arguments Concerning The Final Product Composition Underscore the Indefiniteness of This Claim Term

It is not correct, as Plaintiffs argue, that Defendants' proposed constructions "make no sense" in a product claim because the infringement inquiry must consider the final product and not the "ingredients" or "recipe." This assertion is directly contrary to the intrinsic evidence, which repeatedly explains that two separate PEO components—low molecular weight and higher molecular weight—must both be included in the final film product. Under Plaintiffs' logic, any film product would necessarily have only a single PEO component, contrary to the arguments Plaintiffs made to distinguish the claimed product from the prior art. (Ex. G, at 2-5.)

Moreover, Plaintiffs' proposed construction further renders the claims indefinite, because a person of ordinary skill in the art could not determine whether 60% of the polymer component consists of low molecular weight PEO. While it is possible to obtain an approximate distribution

[16] Defendants raise the issue of indefiniteness of this claim term at this stage to explain the basis for their proposed construction and to address the flaws in Plaintiffs' alleged "plain and ordinary meaning." Defendants reserve the right to present additional indefiniteness arguments regarding this and other claim terms at a later date.

[17] During the prosecution of the '150 patent, the applicant occasionally used the abbreviation "MW." However, one of skill in the art would understand this to be a generic abbreviation for molecular weight, as the weight average molecular weight utilizes subscript in the abbreviation (M_w).

of the molecular weights of those molecules, it is not possible to ascertain with any reasonable certainty whether 60% by weight of a polymer falls within a precise range. (JA Ex. 5, ¶ 35.) This is particularly true here because the claimed polymer component includes not only PEO molecules, but HPC as well. Accordingly, particularly under Plaintiffs' proposed construction, the term "molecular weight" is indefinite.

3. Plaintiffs' Reply Position

Plaintiffs Reply Position is presented under Term 1 above.

4. Defendants' Sur-Reply Position

Defendants' Sur-Reply position responds to Plaintiffs' Reply position and is therefore presented under Term 1 above.

C. '832 Patent—Term 1

Term	Plaintiffs' Proposed Construction	Defendants' Proposed Construction
"provide a local pH for said composition of a value sufficient to optimize absorption of said buprenorphine wherein said local pH is from about 3 to about 3.5 in the presence of saliva" (claim 1)	The composition contains one or more components that provide a local pH sufficient to optimize absorption of said buprenorphine wherein said local pH is about 3 to 3.5 in the presence of saliva, where local pH refers to the pH of the region of the carrier matrix immediately surrounding the active agent as the matrix hydrates and/or dissolves, for example, in the mouth of the user. The term "sufficient to optimize absorption of said buprenorphine" means sufficient to reach an optimum level of buprenorphine absorption that includes a bioequivalent absorption as compared to the absorption after administration of Suboxone® tablets.	Control the pH of the region of the carrier matrix immediately surrounding the active agent as the matrix hydrates and/or dissolves such that said pH is about 3 to about 3.5 in the mouth

1. Plaintiffs' Opening Position

The filing of the '832 patent in August 2009 marked the first disclosure of an actual embodiment of, and the first specific teaching how to make, a pharmaceutical film containing buprenorphine and naloxone. The patent describes the need the invention is meant to satisfy: "There is currently a need for an orally dissolvable film dosage form that provides the desired absorption levels of the agonist and antagonist, while providing an adhesive effect in the mouth, rendering it difficult to remove once placed in the mouth, thereby making abuse of the agonist difficult." JCCS Ex. C, '832 patent, 1:65 to 2:2. More specifically, the patent states that "the present invention provides a method of treating narcotic dependence by providing an orally dissolvable film dosage, which provides a bioequivalent effect to Suboxone®" tablets. *Id.* at 4:55-58. And the entirety of the specification, including but not limited to the specific ingredients, their amounts and ratios as disclosed in Table 1, and the inventors' discovery that the oral mucosal absorption of buprenorphine (and naloxone) is bioequivalent to Suboxone® tablets when the local pH that the film provides in the presence of saliva is lowered to about 3.0 to 3.5 (*see, e.g., id*. at 23:1-7 and 11:50-61), constitutes the first teaching in the art how to make such a film formulation.

Disputed term 1 of the '832 patent is found in the last element of claim 1, which reads:

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

The disputed term contains two phrases which are expressly defined in column 3 of the specification. Plaintiffs' construction incorporates the specification definitions of "local pH" and "optimize absorption" and otherwise retains the readily understandable claim language. Defendants propose to read the element "sufficient to optimize absorption of said buprenorphine" out of the claims for reasons that are not clear to Plaintiffs. Defendants also

want to replace the function of the buffer ("to ***provide*** a local pH") with "to ***control*** the pH . . . ." The specification uses both verbs repeatedly ("provide" is used in relation to the pH at least in lines 2:12, 2:40, 2:50-51, 12:65, and 13:26), but the applicants chose to use "provide" in the claims. There is no reason to switch to "control" in construing those claims. Finally, Defendants want to replace "in the presence of saliva" with "in the mouth," which is unnecessary and unjustified. For example, tests involving simulated saliva outside the mouth should clearly be encompassed by the claim and not potentially excluded. Plaintiffs' construction remains true to the claim language and the specification and should be adopted.

2. Defendants' Answering Position

Three issues are disputed for this claim term: (a) the proper meaning of "provide a local pH;" (b) whether "in the presence of saliva" is limited to saliva in the mouth of a user; and (c) whether "…a value sufficient to optimize absorption of said buprenorphine, wherein said local pH is…" has any meaning after Applicants' narrowing amendments.

As a whole, Plaintiffs' proposed construction lacks clarity and unnecessarily adds confusion to what a skilled artisan would understand the disputed term to mean. Plaintiffs' construction also fails to explain the plain meaning of the term in the context of the intrinsic record and should be rejected. *Phillips*, 415 F.3d at 1312, 1314 (citation omitted).

a. The phrase "provide a local pH" means "control the pH of the carrier matrix immediately surrounding the active agent in the mouth"

There is no dispute that the term "local pH" refers to "the pH of the region of the carrier matrix immediately surrounding the active agent as the matrix hydrates and/or dissolves." Indeed, that term is defined in the specification. (*See* Ex. C, at 3:35-38.) The parties do, however, dispute the meaning of the phrase "to provide a local pH." Plaintiffs offer no construction for this term. Defendants' construction, on the other hand, reflects the plain and

ordinary meaning of the term as it is used in the patent. According to the specification, dosage release of buprenorphine and/or naloxone is accomplished in "the film [by] including an agonist and an antagonist [that] is desirably pH-controlled through the inclusion of a buffer." (*Id*. at 12:26-28.) In other words, "[c]ontrolling of the local pH allows for the desired release and/or absorption of the components, and thus provides a more useful and effective dosage." (*Id*. at 13:17-20.) It is the presence of the buffer that enables "controlling the local pH of the dosage" to "reduce the absorption of the antagonist by chemical means." (*Id.* at 11:19-20.) Accordingly, a skilled artisan reading the specification would understand that "to provide a local pH" means "to control the pH of the region of the carrier matrix immediately surrounding the active agent."

The prosecution history supports Defendants' proposed construction. To overcome rejections, Applicants argued that "the application as filed and in the Examples, controlling the local pH by providing a buffer having a specific buffer capacity in the film composition of the present invention provides a system in which the desired release and/or absorption of the components is achieved." (Ex. M, at 9.) Defendants' proposed construction accomplishes the required "desired release" by describing the buffer as "control[ling] the pH of the region of the carrier matrix immediately surrounding the active agent."

b. The phrase "in the presence of saliva" means "in the mouth."

Plaintiffs concede that the point of the claimed film composition is to deliver an optimal amount of active—the opiate buprenorphine—into the mouth of a patient where it can be absorbed into the patient's bloodstream. To accomplish this goal, the local pH in the area immediately around the film must be controlled with an appropriate buffer. (*See, e.g.*, Ex. C at 3:9-38.) Plaintiffs' proposed construction is so broad that it would allow absorption of buprenorphine not only in the mouth of a user, but also somehow, inexplicably, in a test tube.

But it is impossible to measure absorption in an *in vitro* setting; Plaintiffs provide no explanation for this paradox. And, in fact, the patent and the prosecution history only contemplate absorption in terms of *in vivo* bioequivalence metrics, including "AUC"[18] and "Cmax"[19] values. Indeed, each example in the patent refers to AUC and Cmax values. Applicants expressly defined these values to ***require*** administration to a human. Additionally, certain dependent claims require "bioequivalent absorption" of buprenorphine. (*See e.g.*, *id.* claim 2.) The patent defines "bioequivalent" as "obtaining 80% to 120% of the Cmax and AUC values for a given active in a different product." (*Id.* at 3:48-50.) The theoretical ability of a buffer to control a pH outside the mouth is wholly irrelevant and outside the intended scope of the invention. Therefore, consistent with the stated goals of the patent, the "local pH" must be established in the presence of saliva in the mouth of a user.

Plaintiffs cite nothing to support the proposition that the alleged invention was intended to encompass *in vitro* analyses; nor do Plaintiffs explain how a skilled artisan would actually determine the "optimal absorption" of a drug without first administering it to an animal and then measuring blood plasma levels of the drug. (*See, e.g.*, *id.*at 14:28-43). Thus, consistent with the specification and the claims, the film composition must be able to control the local pH from about 3 to about 3.5 in the mouth of a user—the conditions that allow optimal absorption of buprenorphine, while simultaneously inhibiting absorption of naloxone. (*See id.* at 11:50-60) ("[I]t has been surprisingly discovered by the Applicants that by buffering the dosage to a particular pH level, the optimum levels of absorption of the agonist and antagonist may be

[18] AUC refers to the "mean area under the plasma concentration-time curve value after administration of the compositions formed herein." (3:12-14). This allows one to determine how long it takes a drug, at a certain concentration to reach the blood stream.

[19] Cmax refers to "the mean maximum plasma concentration after administration to a human subject." (3:9-11).

achieved…[a]t this local pH level, the optimum absorption of the agonist and the antagonist is achieved."). *In vitro* tests of the film composition cannot and do not meet a fundamental requirement of the claims—establishing optimal buprenorphine absorption. Again, Plaintiffs cannot reconcile their proposed construction with claims that necessarily require administration of the film composition "in the mouth." While Plaintiffs may seek to divorce the stated goals of the alleged invention from this claim term in an attempt to create an infringement position, Plaintiffs' position is in direct contradiction to the intrinsic evidence and should be rejected.

c. The phrase "a value sufficient to optimize absorption of said buprenorphine wherein said local pH" expresses the intended result of the claimed invention.

Plaintiffs argue that Defendants' construction reads out the element "sufficient to optimize absorption of said buprenorphine" from the claims. But, the prosecution history makes clear that this phrase expresses the intended results of the claimed pH range, and therefore Defendants' proposed construction is proper. As initially drafted, independent claim 1 recited no pH range whatsoever. (*See* Ex. K, at 33.) To overcome a series of rejections, however, Applicants first amended the claims to recite a broad range—"about 2 to about 3.5" —then systematically narrowed the claim eventually settling on the range of "from about 3 to about 3.5." Without a recited pH range—and even when the broader range was first added—the claims required a skilled artisan to determine whether a particular pH value was "sufficient to optimize absorption of said buprenorphine." But, after the pH range was narrowed, a skilled artisan no longer needs to make this determination because the allowed claims define the pH range—"from about 3 to about 3.5" —in which buprenorphine absorption is optimized. (*See, e.g.,* Example 8; *see also* Ex. BB, at 5, ("Independent claims 1 and 17 have been amended to recite a local pH range of about 3 to about 3.5…the claimed pH ranges achieves the goals of optimizing the

absorption of one component (buprenorphine) and minimizing the absorption of a second component (naloxone).")

Thus, the claims, as amended, define the optimal pH range for buprenorphine absorption. In *Bristol-Myers Squibb Co. v. Ben Venue Labs*., the Federal Circuit held that construing claims based on the plain language's internal "duplication" was appropriate. 246 F.3d 1368, 1375 (Fed. Cir. 2001). There, the claim read "[a] method…comprising…administering…an antineoplastically effective amount of about 135-175 mg/m^2 taxol over a period of about three hours." The court held that the "expression of intended result essentially duplicates the dosage amounts recited in the claims…" Further, "[t]he express dosage amounts are material claim limitations; the statement of the intended result of administering those amounts does not change those amounts or otherwise limit the claim." *Id*., at 1375. Here, as in *Bristol-Myers*, the pH is the "material claim limitation[]" while the "optimal absorption" phrase is merely a "statement of the intended result" that "does not change…or otherwise limit the claim." *Id*. Accordingly, Defendants' proposed construction, which is consistent with the prosecution history and comports with the plain and ordinary meaning, should be adopted.

3. Plaintiffs' Reply Position

a. No Reason To Replace The Claim Term "provide" With "control"

The parties agree that the claim term "local pH" should be construed to have the meaning the specification gives it, i.e., "the pH of the region of the carrier matrix immediately surrounding the active agent as the matrix hydrates and/or dissolves." The claims use "local pH" in the recitation "a buffer in an amount to provide a local pH." The specification also talks of the buffer "controlling" the pH. Defendants insist that the claim term "provide" a local pH

should be rewritten to say "control" a local pH.[20] Defendants have provided no rationale for rewriting the claims and no explanation of how the claims would be better understood using "control" instead of the actual claim language.

b. No Reason To Add "in the mouth" To Certain Claims

Defendants attempt to impose a requirement that the "local pH" in claims 1 and 9 must be determined "in the mouth." As to Term 1, which occurs in its entirety only in claim 1, Defendants allege that "in the presence of saliva" means "in the mouth." Since the other independent claim reciting a local pH, claim 9, does not include the phrase "in the presence of saliva," Defendants (in Term 2 below) propose to also construe "local pH" itself as necessarily referring to the pH of the mouth.

Defendants try to characterize "local pH" as a necessarily *in vivo* parameter that is necessarily determined only in the mouth of a person, but Defendants confuse absorption with pH. Defendants correctly state that the purpose of the film is to deliver buprenorphine to a human through absorption in the mouth, and absorption of a drug is determined "in terms of *in vivo* bioequivalence metrics." Because absorption is measured *in vivo* by blood plasma levels of the drug, Defendants suggest that the patent does not "encompass *in vitro* analyses" and assert that pH must therefore also be measured *in vivo*. But absorption pharmacokinetics and chemical pH are very different things. The patent presents the results of *in vivo* measurements of absorption in detail but makes no mention of any *in vivo* pH measurements. There is no

[20] Defendants point to instances in the specification and prosecution history that speak of "controlling the local pH" as the function performed by the buffer in the film composition. But the specification also talks of the buffer "providing" the local pH: "Any desired level of buffer may be incorporated into the film composition so as to provide the desired local pH level." '832 patent, 12:63-65; *see also id*. at 2:12, 2:40, 2:50-51, and 13:26. Of the two verbs used in the specification, "provide" was chosen for the claims. Defendants present no reason to override the patentee's choice.

indication anywhere in the intrinsic evidence that any of the local pH values in the specification must be determined *in vivo* in the mouth. Defendants' attempt to impose a requirement that pH be measured in the mouth should be rejected.

c. The Element "sufficient to optimize absorption of said buprenorphine" Should Not Be Read Out Of The Claims

Defendants admit their proposed construction reads the element "sufficient to optimize absorption of said buprenorphine" out of the claims, because the phrase purportedly only "expresses the intended result of the claimed invention." According to Defendants, because the claims specify a pH range, there is no need to require optimal buprenorphine absorption, i.e., an absorption bioequivalent to that of Suboxone® tablets. However, Defendants themselves, only a few sentences before their section on this "optimize absorption" element, point out "a fundamental requirement of the claims—establishing optimal buprenorphine absorption." Plaintiffs agree that optimized buprenorphine absorption is a requirement of the claims and not just the intended result of the film dosage composition providing a local pH as the film dissolves within the recited pH range from about 3 to about 3.5. The specification defines "optimizing the absorption" as including "a bioequivalent absorption as administration of the currently commercially available Suboxone® tablet" (3:15-21); indeed, the thrust of the whole patent is to provide a film that is bioequivalent to Suboxone® tablets. Hence, the claims require bioequivalence to Suboxone® tablets in addition to providing a specified local pH. Plaintiffs' construction properly accounts for this element, including giving it its specification definition. Defendants instead improperly read out of the claims what Defendants themselves characterize as a "fundamental requirement." *See, e.g., Gemalto S.A. v. HTC Corp.*, 754 F.3d 1364, 1372 (Fed. Cir. 2014) (improper to read express limitations out of claim).

4. Defendants' Sur-Reply Position

a. The Claim Language Requires That The Buffer Optimize The Absorption Of Buprenorphine

According to the intrinsic record, the term "to provide a local pH" means "to control the pH of the carrier matrix immediately surrounding the active agent in the mouth." Plaintiffs have offered no cogent reason for this Court to adopt a different construction. Indeed, Plaintiffs' proposed alternative ignores the claim language, which requires that a buffer provide a local pH "sufficient to optimize absorption of said buprenorphine"—in other words, a pH of about 3 to about 3.5. Of course, absorption cannot be "optimize[d]" if the local pH is only held for a moment. Rather, the buffer must able to ***control*** the pH around the film long enough for the buprenorphine to be absorbed. But under Plaintiffs' construction, a fleeting moment is all that the claim requires. Accordingly, this is a situation where "claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words." *Phillips*, 415 F.3d at 1314. Plaintiffs' construction is at odds with the rest of the claim language, and should be rejected.

b. Plaintiffs' Proposed Construction Ignores The Specification, Which Only Describes *in vivo* Measurements

Plaintiffs' construction would improperly expand the scope of "provide a local pH" to include *in vitro* pH measurements as well as *in vivo* pH measurements. But nothing in the patent supports such an overly broad construction. Indeed, Plaintiffs concede that the purpose of this alleged invention is to ***deliver buprenorphine to a human through oral absorption***. (Supra at 37.) All the examples in the specification reflect this purpose. But *in vitro* measurements simply have nothing to do with the delivery of buprenorphine in the mouth. Accordingly, Defendants' construction is consistent with the specification.

c. Plaintiffs' Proposed Construction Ignores The Prosecution History

Plaintiffs incorrectly argue that Defendants' construction reads out an express claim limitation: "sufficient to optimize absorption of said buprenorphine." (*Supra* at 37.) But this argument ignores the prosecution history, which makes clear that the "sufficient to optimize" phrase is simply the intended ***result*** of a ***different*** limitation: a local pH "from about 3 to about 3.5." To overcome prior art, the applicants amended the claims to specifically recite this pH range because at this range, buprenorphine absorption in a user's mouth is optimized. (*Supra* at 41.) "[T]he statement of the intended result of [certain dosage amounts] does not change those amounts or otherwise limit the claim." *Bristol-Myers Squibb Co. v. Ben Venue Labs*., 246 F.3d 1368, 1375 (Fed. Cir. 2001). Similarly here, "the statement of the intended result" by providing a certain local pH "does not change [that requirement] or otherwise limit the claim."

D. '832 Patent—Term 2

Term	Plaintiffs' Proposed Construction	Defendants' Proposed Construction
"provide a local pH" (claims 1, 9)	*Plaintiffs propose to construe as part of the longer phrase (see claim term 1 above).*	To control the pH of the region of the carrier matrix immediately surrounding the active agent as the matrix hydrates and/or dissolves in the mouth Alternatively, the term "provide a local pH" is indefinite.

1. Plaintiffs' Opening Position

The parties have proposed constructions for this term, which is recited in both claim 1 and claim 9, within the above constructions of term 1. Plaintiffs do not believe it needs to be construed a second time. Plaintiffs' construction of "provide a local pH," as it appears above within term 1, is "provide a local pH . . . where local pH refers to the pH of the region of the carrier matrix immediately surrounding the active agent as the matrix hydrates and/or dissolves,

for example, in the mouth of the user." The definition of "local pH" is taken verbatim from the specification (at lines 3:35-38), including the non-limiting words "***for example***, in the mouth of the user." Defendants' construction would instead limit "local pH" to "in the mouth." It appears Defendants are reacting to the fact that "in the presence of saliva" is recited in claim 1 but not in claim 9. However, that difference between the claims is no reason to import the limitation "in the mouth" into the term "provide a local pH."

2. Defendants' Answering Position

Contrary to Plaintiffs' assertion, Defendants propose construing this term separately from Term 1 simply because the entire phrase in Term 1 does not appear in claim 9. The term "provide a local pH" should be construed as "to control the pH of the region of the carrier matrix immediately surrounding the active agent as the matrix hydrates and/or dissolves in the mouth."

a. The "local pH" must refer to the pH of the mouth

The '832 specification and file history evince a clear requirement that the local pH must refer to the pH of the user's mouth, and cannot extend to the pH measured in simulated saliva. A finding otherwise would eviscerate the purpose of the invention disclosed in the '832 patent.

Plaintiffs rely on the purported definition of "local pH" in the specification as support for their assertion that the local pH is not limited to the mouth of the user. While the specification does note that the term "local pH" "refers to the pH of the region of the carrier matrix immediately surrounding the active agent as the matrix hydrates and/or dissolves, for example, in the mouth of the user," (Ex. C, at 3:35-38) the term must be construed in the context of the claims first, then the specification and the prosecution history. *Vitronics Corp. v. Conceptronic*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). Proper context requires an understanding of the purpose of the '832 patent and the roles that the buffer and local pH have.

The ’832 patent is directed to treating narcotic dependence by co-administering an agonist (buprenorphine), which satisfies the body’s urge for a narcotic, with an antagonist (naloxone), which helps lower the body’s dependence. (Ex. C, at 1:30-52.) According to the patent, the agonist and antagonist must be absorbed in different parts of the user’s body—the agonist in the mouth, and the antagonist in the stomach: “In a dosage form that is to be placed in the oral cavity, it is desired to absorb the agonist buccally, so as to provide rapid integration of the agonist into the body of the user. At the same time, it may be desired to prevent or reduce absorption of any antagonist buccally, thereby allowing the antagonist to be swallowed and destroyed in the stomach.” (*Id.* at 11:10-16.) The patent discloses that “by controlling the local pH of the dosage form, the release and/or absorption of the actives therein may be controlled.” (*Id.* at 11:21-23.) Specifically, “the local pH of a composition including an agonist and an antagonist is between about 2 to about 4, and most desirably is from 3 to 4.” (*Id.* at 11:53-55.) In other words, a local pH from 3 to 4 allows buprenorphine to be absorbed in the mouth and naloxone to be absorbed in the stomach, which is the intent of the patented invention.

Against this backdrop, the local pH must be construed as the pH in the mouth, and cannot be construed to refer to the pH of simulated saliva. The patent’s references to the local pH are made explicitly with respect to either the user’s mouth or body. (*See, e.g.*, Ex. C, at 11:23-26 (“For example, in a dosage that includes an amount of an agonist, the local pH may be controlled to a level that maximizes its release and/or absorption into the ***oral cavity*** of the user.”); 13:28-31 (“In addition to a desired local pH level, the buffer preferably has a buffer capacity sufficient to maintain the ionization of the optional antagonist during the time that the composition is in the ***oral cavity*** of a user.”) (emphases added)). In addition, Examples 5-8 in the patent, which provide support for a preferred local pH of about 3 to about 3.5, are all *in vivo* studies.

Furthermore, the surrounding claim language of claims 1 and 9 refer to placing the composition in the user's mouth, which mandates that the local pH be measured in the mouth. Claim 1 describes a "film dosage composition," which is defined repeatedly in the specification as an *orally* dissolvable film composition. (*See, e.g.*, Ex. C, at 4:61-67.) Similarly, claim 9 concludes that the composition must be administered to "the oral cavity of a user."

During the prosecution of the '832 patent, the Examiner rejected the application for anticipation and obviousness over the Oksche reference (WO2008/025791), explaining that Oksche described films containing buprenorphine and naloxone and it would have been obvious to identify the optimal pH and dosage. (*See, e.g.*, Ex. CC, at 2, 4-5.) Applicants' Request for Continued Examination argued that nothing in Oksche taught adjusting the pH to "optimize the adsorption [sic] of buprenorphine and minimize the adsorption [sic] of naloxone," and noted that the patent's divergence from pH partition theory "allows the Applicant to ***produce a film which delivers buprenorphine to the bloodstream and passes the naloxone to the gut*** where it is ineffective, thus providing a treatment regime for buprenorphine." (Ex. N, at 7 (emphasis added)) Because Oksche "never identifies nor understands the criticality of pH," Applicants argued that modifying the pH was not merely a results effective variable that can be modified. (*Id.* at 8.) These arguments underscore the need to measure pH in the mouth.

b. The Term Is Indefinite Under Plaintiffs' Proposed Construction.

The term "provide a local pH" is indefinite under Plaintiffs' proposed construction. Under the standard set forth in *Nautilus*, 134 S.Ct. at 2129, Plaintiffs' proposed construction for the term "provide a local pH" is indefinite because the intrinsic record provides no direction as to how one of skill in the art would determine absorption of buprenorphine or naloxone without measuring AUC and C_{max} values, which require measurement of the levels in

human blood or plasma. The patented subject matter is a film composition that, when administered orally, optimizes buprenorphine absorption in the ***mouth*** and naloxone absorption in the ***stomach***. The specification and prosecution history solely pertain to the release of drugs *in vivo* and provide no guidance showing how one of skill in the art could correlate *in vitro* data with location of release *in vivo*, which necessarily creates an insurmountable zone of uncertainty with respect to at least infringement. *See Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1215-16 (Fed. Cir. 1991) (holding that district court did not err in construing claims to require *in vivo* measure); *Alza Corp. v. Mylan Labs., Inc.*, 464 F.3d 1286, 1295-96 (Fed. Cir. 2006) (holding that a Plaintiff failed to establish infringement of an *in vivo* claim where the evidence pertained only to *in vitro* characteristics). Plaintiffs concede this point by proposing a construction of "bioequivalent absorption of buprenorphine" that hinges on C_{max} and AUC values. (*See e.g.*, "'832 Patent – Term 3" *infra* at 53.) If the local pH could be measured outside the body, including in "tests involving simulated saliva," as Plaintiffs propose, then the term is indefinite because it fails to inform those skilled in the art about the scope of the invention with reasonable certainty. *See Nautilus*, 134 S. Ct. at 2129.

3. Plaintiffs' Reply Position

a. Local pH Need Not Be Determined "in the mouth"

This is the main dispute before the Court in both Terms 1 and 2 of the '832 patent. Defendants contend that the intrinsic evidence "underscore[s] the need to measure pH in the mouth." However, Defendants do not and ***cannot cite a single mention or suggestion of any measurement of pH in the mouth anywhere in the intrinsic evidence***. The examples in the specification describe comparing the pharmacokinetics (*in vivo* measures of absorption after administration to a human subject) of test film formulations which vary in their "local pH," but there is no mention anywhere of determining that local pH *in vivo*. *See, e.g.*, 18:25-42 (Example

5 (Preparation of Films for In Vivo Study)). Defendants' attempts to impose a requirement of *in vivo* measurements of local pH in both Claim Terms 1 and 2 should be rejected.

b. The Term Is Definite Under Either Construction

Defendants argue that the term "provide a local pH" is indefinite under Plaintiffs' construction because there is "no direction as to how one of skill in the art would determine absorption of buprenorphine or naloxone ***without measuring*** AUC and Cmax values" *in vivo*. But Plaintiffs have never said that absorption can be determined without *in vivo* pharmacokinetic values. Indeed, Plaintiffs' construction of Term 1 expressly requires "bioequivalent absorption," i.e., as confirmed in both parties' constructions of Term 3, certain Cmax and AUC values ***as measured*** *in vivo*. Thus, there is no indefiniteness.

Defendants assert that if "provide a local pH" is construed (narrowly) as the local pH in the mouth, such an *in vivo* limitation cannot be met with evidence of *in vitro* pH testing, for instance in simulated or actual saliva, misleadingly citing *Alza*, 464 F.3d at 1295-96. However, as the Federal Circuit specifically explained, "[t]he critical deficiency in the evidence presented by Alza was not that it was 'indirect' rather than 'direct,' but rather that it failed to credibly link these pieces of [*in vitro*] evidence with the relevant" *in vivo* claim limitation. *Id*. at 1296. Interpreting *Alza*, this Court has agreed that the case "conclud[es] that infringement can be found based on *in vitro* data where the evidence before the court demonstrates that the *in vitro* system adequately modeled the results that would be derived from *in vivo* conditions." *Allergan, Inc. v. Watson Labs, Inc*., 869 F. Supp. 2d 456, 500-01, 506 (D. Del. 2012) (Sleet, C.J.). Even if Defendants' construction is adopted and "in the mouth" is read into the claims—and "local pH" is considered an *in vivo* limitation—Defendants' own *Alza* case, as confirmed by this Court in

Allergan, sets out the framework for ascertaining, through *in vitro* testing, whether the local pH limitation is infringed.[21]

4. Defendants' Sur-Reply Position

a. The Purpose Of The Invention And The Context Of The Claims Requires That "Local pH" Be Determined In The Mouth

Plaintiffs' proposed construction would encompass *in vitro* measurements, and thus is at odds with the purpose of the alleged invention. Further, as Plaintiffs concede, "optim[al] absorption of said buprenorphine" can only be measured *in vivo*. (*Supra* at 51.) If the specification and the prosecution history provide no support for determining pH either in the mouth or in a test tube, then the inquiry focuses on what the proper construction of the term should be in the context of the claims. *See Epos Techs., Ltd. v. Pegasus Techs., Ltd.*, 766 F.3d 1338, 1341 (Fed. Cir. 2014). For the reasons described in Defendants' opening brief, Defendants' construction accurately reflects the correct meaning of the term when properly considered in the context of the claims, specification, and prosecution history, and should be adopted.

b. Plaintiffs' Construction Is Indefinite

In an attempt to support their argument based on *in vitro* data, Plaintiffs rely on *Allergan, Inc. v. Watson Labs., Inc.*, 869 F. Supp. 2d 456, 500-01, 506 (D. Del. 2012). But *Allergan* cannot bear the weight Plaintiffs assign to it. Although the *Allergan* court did find infringement based on *in vitro* data that adequately modeled *in vivo* conditions (*Supra* at 51), that holding does not apply here. The '832 patent provides ***no*** information describing any "*in vitro*

[21] Defendants also allege that, under Plaintiffs' construction, "[i]f the local pH could be measured outside the body, including in 'tests involving simulated saliva,' as Plaintiffs propose, then the term is indefinite because it fails to inform those skilled in the art about the scope of the invention with reasonable certainty." Not so. That is a routine method used, including by Defendants, to determine local pH.

system," and there is no indication ***anywhere*** in the intrinsic record that the applicants ever contemplated, much less utilized, an "*in vitro* system" in the context of the alleged invention. Nor is there any other evidence that, like the expert testimony in *Allergan*, would support a conclusion that *in vitro* data could adequately replicate the conditions of a human mouth. Thus, adopting Plaintiffs' construction would fail to provide any reasonable clarity to a person of ordinary skill in the art as to the scope of these claims.

E. '832 Patent—Term 3

Term	Plaintiffs' Proposed Construction	Defendants' Proposed Construction
"bioequivalent absorption of buprenorphine to that of a tablet having an equivalent amount of buprenorphine" (claims 2, 10)	80% to 125% of the Cmax and AUC values for buprenorphine in a tablet having an equivalent amount of buprenorphine.	80% to 125% of the Cmax and AUC values for buprenorphine in a Suboxone® tablet having the same amount of buprenorphine

1. Plaintiffs' Opening Position

This term is only recited in dependent claims 2 and 10. "Bioequivalent" is defined in the specification as meaning "obtaining 80% to 125% of the Cmax and AUC values for a given active in a different product." *Id*. at 3:48-50. The parties agree that this definition should be implemented in the construction and the remainder of Plaintiffs' construction then simply tracks the claim language. Defendants want to replace "***an equivalent*** amount" with the obviously narrower "***the same*** amount." But there is no basis or support for limiting the concept of bioequivalent dosages to dosages having the same amount of active. As long as they achieve the required Cmax and AUC values, two dosage units are bioequivalent even if they do not have the same amount of active. Defendants' improper narrowing construction should be rejected.

2. Defendants' Answering Position

Plaintiffs argue that "[a]s long as two [dosages] achieve the required C_{max} and AUC values, [those] dosages are bioequivalent even if they do not have the same amount of active." (*Supra* at 53.) Under this construction, Plaintiffs contend the concentration of the active itself is irrelevant, and the only critical metric is the bioequivalence of the two dosage forms. This reads the phrase "having an equivalent amount of buprenorphine" out of the claim entirely. It also conflicts with intrinsic evidence. On its own, the term "equivalent" provides no guidance to a person of ordinary skill in the art to identify which concentrations of buprenorphine fall within the scope of this claim. For example, different tablets may have different C_{max} and AUC, leaving no guidance to one of ordinary skill in the art as to what is "equivalent." But the intrinsic evidence provides no guidance, and it is contrary to Plaintiffs' construction: all demonstrate that the amount of buprenorphine claimed is equal to the amount found in Suboxone® tablets having the same buprenorphine concentration.

Limiting the scope of this term to only Suboxone® tablets is appropriate because the patentees have "demonstrated a clear intention to limit the claim scope using words or expression of manifest exclusion or restriction." *Aria Diagnostics, Inc. v. Sequenom, Inc*., 726 F.3d 1296, 1301 (Fed. Cir. 2013) (citations and quotations omitted). Specifically, the patent states that:

> Currently, treatment of opioid dependence is aided by administration of Suboxone®, which is an orally dissolvable tablets. This tablet which provides a combination of buprenorphine (an opioid agonist) and naloxone (an opioid antagonist)(sic). Therefore, the present invention provides a method of treating narcotic dependence by providing an orally dissolvable film dosage, which provides a bioequivalent effect to Suboxone®.

(Ex. C, at 4:47-58). Every example in the '832 patent is also limited to a Suboxone® tablet.

Further, Plaintiffs' contentions that "the same amount" is "obviously narrower" than equivalent amount demonstrates that Plaintiffs are taking an improperly broad view of the

meaning of "equivalent." For example, Federal Regulations define a "pharmaceutical equivalent" to mean "identical dosage forms that contain ***identical amounts***" of the identical active drug ingredient. 21 C.F.R. § 320.1 (emphasis added). Defendants would not oppose a construction that uses the word "equivalent" so long as it means "identical amount," but a broader definition of "equivalent" is inconsistent with the intrinsic evidence.

Because the patent is clearly intended to be restricted to Suboxone® tablets containing the same amount of buprenorphine, Defendants' construction should be adopted. Because Plaintiffs' construction effectively reads out a claim limitation and provides no instruction or assistance to understanding the plain and ordinary meaning of this term (and in fact is contrary to the intrinsic evidence), it should be rejected.

3. Plaintiffs' Reply Position

There is no difference between the parties as to the tablets referred to, but Plaintiffs' construction of Term 1 already requires bioequivalence with Suboxone® tablets so it is unnecessary to specify Suboxone® again in Term 3. Defendants insist that "equivalent" should be rewritten as "the same," yet they point to no intrinsic evidence in support. Instead they cite Federal Regulations defining a "pharmaceutical equivalent" to mean "***identical dosage forms*** that contain identical amounts" of the identical active ingredient. This definition is clearly inapposite as the claim term (and indeed the whole patent) specifically is about achieving bioequivalence between ***different dosage forms***—a film and a tablet. There is no justification for rewriting this claim term and Plaintiffs' construction should be adopted.

4. Defendants' Sur-Reply Position

The parties' proposed constructions are similar, but only Defendants' construction reflects the undisputed facts. The parties agree that the word "tablet" in the disputed term refers to a Suboxone® tablet. (*Supra* at 54.) Defendants' construction simply makes this undisputed

fact clear, and states that the amount of buprenorphine in the claimed film is the same as the amount of buprenorphine in the Suboxone® tablet. This is consistent with the specification, which discloses examples where bioequivalence is determined based on these ***same amounts*** of buprenorphine. (*See, e.g.*, Ex. C at 17:15-23:55.). Because Defendants' proposed construction reflects the undisputed fact that the word "tablet" refers to a Suboxone® tablet, it should be adopted.

F. '514 Patent—Term 1

Term	Plaintiffs' Proposed Construction	Defendants' Proposed Construction
"flowable" (claims 1, 28, 62)	The term should be given its plain and ordinary meaning.	Capable of being formed into a film and dried

1. Plaintiffs' Opening Position

The '514 patent is directed to producing prescription pharmaceutical film compositions that have sufficient uniformity of active ingredient content (such that it does not vary by more than 10% from the desired amount) to obtain FDA approval. The parties dispute five claim terms which all occur in each of the three asserted independent claims of the '514 patent; the terms are highlighted and numbered below in representative claim 62:

> 62. A drug delivery composition comprising:
>
> (i) a cast film comprising a [1]***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 [2]***viscosity sufficient to aid in substantially maintaining non-self-aggregating uniformity of the active in the matrix***;
>
> (ii) a particulate active [3]***substantially uniformly stationed*** in the matrix; and
>
> (iii) a taste-masking agent selected from the group consisting of flavors, sweeteners, flavor enhancers, and combinations thereof to provide [4]***taste-masking of the active***;
>
> wherein the particulate active has a particle size of 200 microns or less and said flowable water-soluble or water swellable film-forming matrix is [5]***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.

Plaintiffs believe that terms 1 and 4, "flowable" and "taste-masking of the active," have their plain and ordinary meaning, while Defendants propose to redefine them and add limitations to them. The remaining three disputed claim terms concern aspects of the central feature of the claimed invention: substantial uniformity of active ingredient content in pharmaceutical films.

The simple term "flowable" is readily understood and should be given its plain and ordinary meaning. Defendants instead propose that the term be interpreted to mean something different and very narrow: "capable of being formed into a film and dried." Nothing in the claims, specification or file history indicates that "flowable" has anything but its plain and ordinary meaning, much less that it should be given Defendants' narrow interpretation. To deviate from the plain meaning of a claim term, "there must be a clear and unmistakable disclaimer." *Thorner v. Sony Computer Entm't Am. LLC*, 669 F.3d 1362, 1366-67 (Fed. Cir. 2012). *See also Epistar Corp. v. Int'l Trade Comm'n*, 566 F.3d 1321, 1334 (Fed. Cir. 2009) (requiring "expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope" to limit claims based on language in the specification) (citation omitted).

Furthermore, each asserted claim already requires "a cast ***film***" and a "flowable . . . matrix ***capable of being dried***," making it all the more improper and unnecessarily duplicative to read the same attributes into the term "flowable" itself. For reasons that are unclear to Plaintiffs, Defendants are seeking to freight this readily understood term with a meaning and significance that clearly was not intended. The term should simply be given its plain and ordinary meaning.\

2. Defendants' Answering Position

Plaintiffs ask this Court to construe at least four separate limitations of the '514 patent to constitute a single requirement. The plain language of the claims requires that: (1) the viscosity

must aid in ***maintaining*** the non-self-aggregating uniformity of the flowable matrix; (2) the particulate active must be ***substantially uniformly stationed*** in the flowable matrix; (3) the flowable matrix must be capable of being dried without ***loss*** of substantial uniformity; and (4) subsequent to casting and drying, the individual unit doses do not vary by more than 10% of the desired amount of active. Plaintiffs' proposal collapses these limitations into one, rendering much of the claim language superfluous and disregarding the plain language of the claim.

First, Plaintiffs contend that "[t]he simple term 'flowable' is readily understood and should be given its plain and ordinary meaning," yet notably absent from Plaintiffs' brief is any indication as to what the "plain and ordinary meaning" of that term is. Where "the meaning of a claim term as understood by a person of skill in the art is . . . not immediately apparent," the Court must look to "the words of the claims themselves, the remainder of the specification, [and] the prosecution history." *Phillips*, 415 F.3d at 1314 (quotations and citations omitted).

Contrary to Plaintiffs' assertion, ample evidence exists throughout the specification for Defendants' proposed construction. The specification expressly refers to a "flowable water-soluble film forming matrix." (Ex. D, at 5:45 (emphasis added).) It goes on to state that "[t]he flowable water-soluble film forming matrix is formable into a dry film," (*id.* at 5:66-67 (emphasis added)) and "the flowable water-soluble film forming matrix is capable of being dried." (*Id.* at 5:47-58.) Thus, Defendants' proposed construction is well-supported by the intrinsic evidence. *See O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1362 (Fed. Cir. 2008) ("A determination that a claim term 'needs no construction' or has the 'plain and ordinary meaning' may be inadequate when a term has more than one 'ordinary' meaning or when reliance on a term's 'ordinary' meaning does not resolve the parties' dispute.").

3. Plaintiffs' Reply Position

See Plaintiffs' Opening Position. Defendants' contention mixes up "flowable" with the "matrix." The matrix is formed into a film and dried. "Flowable" simply is an adjective describing the matrix and has its plain and ordinary meaning.

4. Defendants' Sur-Reply Position

Defendants agree with Plaintiffs that "flowable is simply an adjective describing the matrix." (*Supra*.) But as Plaintiffs have repeatedly argued (*infa* at 61, 63-64), the '514 patent claims a finished film product. Simply put: a finished film product cannot be "flowable." (*See* Ex. D at 67:34-36.) Defendants' construction—which resolves this unmistakable ambiguity and has not been substantively challenged by Plaintiffs—should, therefore, be adopted.

G. '514 Patent—Term 2

Term	Plaintiffs' Proposed Construction	Defendants' Proposed Construction
"viscosity sufficient to aid in substantially maintaining non-self aggregating uniformity of the active in the matrix" (claims 1, 28, 62)	A viscosity sufficient to provide little to no aggregation of the active within the film such that individual dosage units do not vary by more than 10% from the intended amount of active for that dosage unit.	viscosity sufficient to provide little to no aggregation of the active within the film

1. Plaintiffs' Opening Position

Three disputed claim terms (terms 2, 3 and 5) recite "substantial uniformity" of the active or a close variation of that phrase. Plaintiffs' position is that all three terms should be consistently construed, as the last clause of the claims requires, to mean that the resulting film product dosage units do not vary by more than 10% from the desired amount of active ingredient. That is, the resulting uniformity of the active in the dried film is a proxy for or measure of the uniformity in the matrix throughout the film-making process. This follows from

the claims themselves and from the whole thrust of the specification, and this precise understanding was expressly stated by the applicants during prosecution.

a. Substantial Uniformity Of Active Means The Amount Of Active In The Film Does Not Vary By More Than 10% From The Intended Amount

Each of the three asserted independent claims (claims 1, 28, and 62) ends with the following clause, which the parties have agreed has its plain and ordinary meaning and does not need further construction:

> 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.

The "Background of the Related Technology" section identifies the origin of this claim limitation, explaining that the prior art failed to provide methods for making pharmaceutical films in which the active was sufficiently uniformly distributed to result in film dosage units that would meet the "stringent standards of government or regulatory agencies, such as the U.S. Federal [sic; Food and] Drug Administration ('FDA'), relating to the variation of active in dosage forms." JCCS Ex. D, 2:40-42. The specification specifically points out what that uniformity standard is – the uniformity standard at which the entire patent is aimed:

> Currently, as required by various world regulatory authorities, dosage forms may not vary more than 10% in the amount of active present. When applied to dosage units based on films, this virtually mandates that uniformity in the film be present.

Id. at 2:42-46. The patentee acted as its own lexicographer and clearly set forth a definition of "uniformity" in the patent specification.*See Edwards Lifesciences LLC v. Cook, Inc.*, 582 F.3d 1322, 1329 (Fed. Cir. 2009).

This desired level of uniformity of distribution of active is also referred to as "a substantially non-self aggregating uniform heterogeneity throughout the area of the films." S*ee, e.g.*, Ex. D, 4:9-11, 8:56-64. The specification describes controlled drying of the film "in order

to maintain a non-self-aggregating uniform heterogeneity." *Id*. at 4:48-51. During such controlled drying, "the visco-elastic properties of the film are such that the film components are 'locked' in place and cannot move to cause non-uniformity." *Id*. at 4:51-56. And the polymer used in the matrix "may be selected in order to provide a viscosity that maintains the non-self-aggregating uniform heterogeneity." *Id*. at 4:61-64.

Throughout the specification, these references to the uniformity of distribution of active provided by the invention of the '514 patent refer to sufficient uniformity to meet the rigorous FDA standard for uniformity among dosages, namely a variation of 10% or less from the intended amount of active per dosage unit. It is precisely this uniformity, needed to obtain FDA approval and to sell such an active-containing film commercially, that the entire patent is aimed at achieving and is what is meant when the specification discloses that: "The present invention yields exceptionally uniform film products . . . ." *Id*. at 23:14-15.Thus, the invention of the '514 patent provides for the "manufacture of a pharmaceutical film suitable for commercialization and regulatory approval." *Id*. at 3:59-60.

b. Substantial Uniformity Of Active In The Finished Film Is The Measure Of Substantial Uniformity Prior To Drying The Film

The objective of the specification is thus a film product that does not vary more than 10% from the desired amount of active to meet requirements for regulatory approval. *Id*. at 2:38-46. It is clear from the claim language itself that this uniformity exists prior to finishing the film by drying and is "maintain[ed]" and not "los[t]" during processing leading to the finished film. As was reinforced during prosecution, the resulting uniformity of the film is therefore a measure or reflective of, and results from, the uniformity in the matrix, which is maintained. Responding to an objection from the Examiner that the application allegedly did not particularly point out how the viscosity was measured, the applicants responded:

> Claim 1 . . . has been amended to recite an [sic] explicit parameters for the ***measure of uniformity*** [i.e., ***the 10% limitation***]. By extension, the parameters provide a ***measure for the viscosity*** of the matrix, which is ***sufficient to maintain this uniformity*** of the active.

JCCS Ex. V, Amendment/Response filed December 19, 2012, at 10 (MSL_0002558) (emphasis added).

The three disputed uniformity terms read (with some context added for terms 3 and 5):

- Term 2 – "***viscosity sufficient to aid in substantially maintaining non-self-aggregating uniformity of the active in the matrix***"
- Term 3 – "***substantially uniformly stationed*** in the matrix"
- Term 5 – "matrix is ***capable of being dried without loss of substantial uniformity***"

The claimed matrix viscosity, uniform stationing, and drying capability are those that result in films with only the claimed variation in active content (no more than 10% from the intended amount). Thus, as dictated by the intrinsic evidence, Plaintiffs' position is that all three terms should be read to be measured by the recited uniformity limitation that applies to the claimed film: "such that individual dosage units do not vary by more than 10% from the intended amount of active for that dosage unit."

2. Defendants' Answering Position

At the outset, the parties agree that this term requires "a viscosity sufficient to provide little to no aggregation of the active within the film." But the parties' proposed constructions differ where Plaintiffs attempt to conflate this term with the ***separate*** requirement that the "individual unit doses . . . do not vary by more than 10% of said desired amount of said at least one active." As described further below with respect to Term 5, the claims contemplate that this limitation is a distinct requirement, and there is no basis for reading it into this term as well.

3. Plaintiffs' Reply Position

Contrary to Defendants' unfounded assertion that the '514 patent "contemplates separate uniformity requirements, it is clear that the disputed "uniformity limitations" of the '514 patent are all measured by the claimed uniformity in the finished film. This is reflected in and required by the last clause of the independent claims in question, a claim term which the parties agree requires no construction.

Although Defendants agree that Terms 3 and 5 should be construed to include the "do not vary by more than 10% from desired amount" limitation,[22] they argue that construing Term 2 to include that requirement would "conflate" the claim terms because the "do not vary by more than 10% from desired amount" limitation is somehow a "distinct requirement" that cannot be applied to Term 2. Defendants' inclusion of this limitation in Terms 3 and 5 but not in Term 2 makes no sense: either the limitation is distinct for each recitation of uniformity or it is not. The reality is that it is not. The entire objective of the '514 patent is to produce a film product whose uniformity of active ingredient content is (as the specification and claims repeatedly state) "***maintained***" throughout the casting and drying manufacturing process and results in a film that can satisfy FDA regulatory requirements as to active uniformity (i.e., such that individual dosages do not vary by more than 10%).[23] The process of forming the inventive film compositions *begins* with blending of ingredients to form a "uniform matrix." JA Ex. D, 26:9-12. According to the patent, that uniformity is "maintained" throughout the manufacturing process: "Uniformity must be maintained as flowable mass was formed into a film and dried."

[22] Defendants' proposed constructions of Terms 3, 5 are flawed for other reasons addressed below.

[23] *See e.g.*, 3:59-60; 4:62-64; 11:17-22; 4:48-51: " maintain a non-self-aggregating uniform heterogeneity ... the film components are 'locked' in place and cannot move to cause non-uniformity."

Id. at 30:34-37. The patent teaches the skilled person to avoid complications that disrupt uniformity, such as aggregation, agglomeration, rippling, and the like. *E.g.*, *id*. at 22:41-50.

Term 2, the term as to which Defendants refuse to apply the "do not vary by more than 10% from desired amount" limitation, relates to viscosity: "viscosity sufficient to aid in substantially maintaining non-self aggregating uniformity of the active in the matrix." The specification confirms that the whole point of selecting an appropriate viscosity is to maintain uniformity of the final film product. *See, e.g*., 11:34-37, 23:7-11, 23:21-28 and 4:62-64. Accordingly, the only reasonable way to read Term 2 is that the referenced uniformity is consistent with and measured by the final "do not vary by more than 10% from desired amount" of active uniformity limitation. Plainly, the point of requiring a "viscosity.... maintaining non-self aggregating uniformity" is to ensure the maintenance of uniformity of active within the required parameters.

For these reasons, it is clear that there are no "separate" uniformity requirements in the claims of the '514 patent. All references to uniformity in the claims are directed to and measured by the last clause of the independent claims in question, i.e., by the "do not vary by more than 10% from desired amount" limitation. Defendants' proposed construction of Term 2 which eschews this measure of uniformity should be rejected, as should their construction of Term 5 that tries to read a separate uniformity limitation into that Term.

4. Defendants' Sur-Reply Position

The disputed term appears in an element directed to viscosity ***before*** the matrix is cast and dried. Plaintiffs seek to import into this term a limitation from claim 1(iii), which is expressly directed to the uniformity of the matrix "***subsequent*** to casting and drying" (emphasis added). (*Supra*.) But Plaintiffs do not cite any basis for such an importation. Accordingly, Defendants' construction should be adopted.

H. ’514 Patent—Term 3

Term	Plaintiffs’ Proposed Construction	Defendants’ Proposed Construction
“substantially uniformly stationed” (claims 1, 28, 62)	Stationed in the matrix such that individual dosage units do not vary by more than 10% from the intended amount of active for that dosage unit.	10% or less variation of the particulate active and taste masking agent between measured samples, measured by visual, weight, or chemical analyses

1. Plaintiffs’ Opening Position

As discussed above with regard to term 2, the intrinsic evidence shows that this “substantial uniformity” term is measured by the variation in the amount of active in the film dosage units. Defendants’ inclusion of a 10% limitation confirms that they agree that the uniformity subsequent to casting and drying informs one’s understanding of the present “substantially uniformly stationed” term. However, Defendants make three improper additions to the claim. First, it is unclear what “measured samples” are being referred to. Second, Defendants improperly add a requirement that uniformity apply to a taste masking agent when the claims only recite uniformity of an active: “a particulate active substantially uniformly stationed in the matrix.” Third, the language specifying that measurements be “by visual, weight, or chemical analyses” makes no sense when Defendants agree that what is being measured is a 10% or less variation from the desired content of an active—i.e., a chemical compound. Such a measurement requires chemical analysis. Visual inspection of a sample or weighing the sample cannot necessarily ascertain whether a 10%-variation-in-active-content limitation is satisfied. Defendants’ improperly added limitations should be rejected.

2. Defendants’ Answering Position

Plaintiffs assert that Defendants’ proposed construction would “make three improper additions to the claims.” Plaintiffs are incorrect. First, the patent specifically contemplates

determining uniformity by sampling one part of the final film product, measuring distribution of the active agent within that sample, and comparing that measurement with another part of the film product. (Ex. D, at 17:61-18:1.) Thus, the specification makes clear that in order to be "uniformly stationed," the amount of particulate must not vary when one sample is compared to another—not merely when measured against the intended dosage. [24]

Second, Plaintiffs' characterization of what must be "substantially uniformly stationed" in the matrix ignores the claim language, which requires the taste-masked particulate—not just the active—to be substantially uniformly stationed in the matrix. Indeed, the claims expressly require that (1) the particulate active be "coated or intimately associated with" the taste-masking agent and (2) the "combined particulate and taste-masking agent" has a specific size. (*See, e.g.*, *id.* claims 1, 28 and 62, elements (ii) and (iii).) The plain language of the claims dictates that *both* the particulate active and the taste-masking agent together as one "combined particle" be "substantially uniformly stationed" in the matrix. Plaintiffs' proposed construction must be rejected to the extent it contradicts the plain language of the claims. *Phillips*, 415 F.3d at 1312.

Third, Plaintiffs contend that measuring the variation of the "desired content of an active…requires chemical analysis." (*Supra* at 65.) Plaintiffs further aver that "[v]isual inspection of a sample or weighing the sample simply cannot necessarily ascertain whether a 10%-variation in active content is satisfied." (*Id.*) Plaintiffs' attempts to limit the way uniformity is measured must be rejected because it squarely contradicts the specification, which explains how "any conventional means for examining and testing the film pieces may be

[24] Plaintiffs' argument that the term "measured samples" somehow renders Defendants' proposed construction unclear lacks merit, as the specification makes clear that uniformity can be assessed by comparing active samples. Nonetheless, Defendants would also not oppose the alternative construction "10% or less variation of the particulate active and taste masking agent between individual dosage units, measured by visual, weight, or chemical analyses."

employed, such as, for example, visual inspection, use of analytical equipment, and any other suitable means known to those skilled in the art." (Ex. D, at 36:57-62.) Additionally, the specification explains how "uniformity is determined by the presence of no more than a 10% *by weight of drug variance* throughout the matrix." (*id.* at 18:4-5 (emphasis added).) Further, the specification describes how "[t]he uniform distribution of the components within the film was apparent by examination by either the naked eye or under slight magnification. By viewing the films it was apparent that they were substantially free of aggregation…." (*Id*. at 41:37-40; *see also, id.,* at 52:60-62.) Thus, Plaintiffs' contention that the measurement of uniform stationing can only be conducted by chemical analysis is wrong and not supported by the specification. In sum, Defendants' construction reflects the plain meaning of the term, and is supported by the claim itself, and the specification which provides that the active agents in the claimed film composition are in a "taste-masked…form." (*Id.* at 14:4-6). One of ordinary skill in the art would understand that "substantially uniformly stationed" taste-masked particulate actives must be capable of being evaluated by visual, weight, or chemical analyses.

By contrast, Plaintiffs' proposed construction is improperly narrow and excludes the requirement that the particulate active is visible within the film itself. Moreover, Plaintiffs' proposed construction contradicts the plain claim language. Finally, Plaintiffs fail to explain the meaning of the phrase "desired content of an active" or how that phrase represents the plain and ordinary meaning of the disputed term. Thus, Defendants' construction should be adopted.

3. Plaintiffs' Reply Position

Defendants' suggestion that Plaintiffs' proposed construction "limit[s] the way uniformity is measured" is disingenuous given that the claims require that the content of the active not vary by more than 10% between individual dosages. Clearly, to assess that uniformity requires a chemical analysis; visual inspection alone is not enough and a weight analysis could

be misleading. The section on "Testing Films for Uniformity" in the patent notes that it may be desirable to test "chemical and physical uniformity," such as "[f]ilm thickness, color, ***assay of active ingredients***, and overall appearance…." *Id*. at 36:20-26 (emphasis added). The specification explains that "[a]ny conventional means for examining and testing the film pieces may be employed, such as, ***for example***, visual inspection, use of analytical equipment, and any other suitable means known to those skilled in the art." *Id.* at 36:57-61 (emphasis added).

One of ordinary skill in the art would understand that various types of tests may be suitable for testing different physical and chemical uniformities. For example, obviously, a visual inspection cannot be used to make "an assay of active ingredients"—which relates to chemical uniformity, but it can be used to evaluate physical uniformity relating to physical characteristics of the film such as color, thickness, and overall appearance. *Id*. at 36:20-26; 37:9-13. Weight analysis alone would also not be suitable to accurately measure less than 10% variation of the active, because the active is stationed in a matrix including several other components, and cannot be segregated from those other components, without chemical treatment or analysis. Defendants do not contend that the FDA would accept visual or weight analysis alone as proof that the regulatory content-of-active uniformity (10% variation) requirement is satisfied.[25]

In addition, Defendants' proposed construction also requires 10% content uniformity for both the active ***and*** taste masking agent, rather than for the active alone, also improperly narrows the scope of the claims. There is no "clear and unmistakable" support for Defendants' suggestion that "active" refers to the combination of the particulate active and the taste-masking

[25] The specification makes clear that the 10% content uniformity in the amount of active relates to the FDA requirement that "dosage forms may not vary more than 10% in the amount of active present." '514 at 2:42-45.

agent. The claims explicitly recite that the content uniformity relates to the active alone and nowhere indicate that the 10% content uniformity must apply to the taste masking agent as well.[26] Finally, the clear language of the claims as a whole requires the 10% variation to be measured in relation with the "***desired amount***," *i.e.*, the intended amount, as proposed by Plaintiffs.

4. Defendants' Sur-Reply Position

Defendants' construction stays true to the plain and ordinary meaning of the term and the specification, which describes and exemplifies three analytical methods used to measure substantial uniformity: visual, weight, and chemical. Further, the plain language of the claims encompasses all three methods. Inexplicably, Plaintiffs contend, without any support, that this term should be limited to just one of these methods: chemical analysis. (*Supra* at 68.) Further, Plaintiffs ignore that claim 1(iii) requires a particulate, taste-masked active having a particular size: 200 microns or less. Plaintiffs do not explain how one of ordinary skill in the art would use "chemical" analysis to determine whether the particulate, taste-masked active meets this ***size*** limitation. Accordingly, because Plaintiffs' construction ignores the claim language and improperly excludes embodiments described in the specification, it should be rejected.

I. '514 Patent—Term 4

Term	Plaintiffs' Proposed Construction	Defendants' Proposed Construction
"taste-masking of the active" (claims 1, 28, 62)	The term should be given its plain and ordinary meaning. If the Court determines to further construe the term, the plain and ordinary meaning is providing a	Coating or intimately associating the active with a taste-masking agent to achieve a uniform distribution of the taste-masked active throughout the film

[26] Defendants also propose a construction that requires the measured variation to be "between measured samples," but the plain language of the claim measures the 10% variation against "the desired amount" and the specification portion they cite (17:61-18:1) does not require that limitation.

Term	Plaintiffs' Proposed Construction	Defendants' Proposed Construction
	taste-masking effect with respect to the active.	

1. Plaintiffs' Opening Position

The plain and ordinary meaning of "taste-masking of the active" is self-evident: it means providing a taste-masking effect with respect to the active, i.e., masking to some extent the taste of the active. While some preferred embodiments in the specification accomplish this by coating or intimately associating the active with a taste-masking agent, that is not a proper reason to read such a limitation into the absolutely clear language of the claims. There was no "clear and unmistakable disclaimer" to support narrowing the claim scope. *See Thorner v. Sony Computer Entm't Am. LLC*, 669 F.3d 1362, 1366-67 (Fed. Cir. 2012); *Epistar Corp. v. Int'l Trade Comm'n*, 566 F.3d 1321, 1334 (Fed. Cir. 2009); *SuperGuide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004); *Kara Tech. Inc. v. Stamps.com Inc*., 582 F.3d 1341, 1348 (Fed. Cir. 2009) ("The claims, not specification embodiments, define the scope of patent protection. The patentee is entitled to the full scope of his claims, and we will not limit him to his preferred embodiment or import a limitation from the specification into the claims.") (citing *Phillips*, 415 F.3d at 1323).

Furthermore, "coating or intimately associating" the active with a taste-masking agent is already expressly required in claims 1 and 28: "(iii) a taste-masking agent coated or intimately associated with said particulate to provide taste-masking of the active." It makes no sense to repeat this limitation in the construction of "taste-masking of the active" in those claims. And in claim 62 Defendants are obviously importing a limitation which is conspicuously absent from the claim.

Defendants also want to specify that taste-masking is supposedly done to "achieve a uniform distribution of the taste-masked active throughout the film." But there is no support for

construing the purpose of taste masking to be achieving uniformity—the purpose of taste-masking is obviously to provide a taste-masking effect.

2. Defendants' Answering Position

Plaintiffs' construction misstates the plain and ordinary meaning of the term "taste-masking of the active" and ignores critical admissions made during prosecution. Plaintiffs narrowed the scope of the claims to overcome prior art that disclosed simply mixing taste-masking agents with actives prior to casting. Specifically, Applicants distinguished Chen, as "merely mix[ing] taste modifying agents into the film-forming mix without recognizing the problem of separation or aggregation of the taste-modifying agents from the unpleasant tasting pharmaceutical agents." (Ex. S, at 15.) Applicants stressed the importance of the alleged invention as ensuring "high-taste-masked pharmaceutical active content films which have enhanced…***uniformity***." (*Id*. (emphasis in original).) Accordingly, Applicants cannot now adopt an interpretation of "taste-masking of the active" that would cover merely mixing taste-masking agents with actives. Plaintiffs do not and cannot make any argument to the contrary.

Additionally, Plaintiffs fail to explain how a skilled artisan could accomplish the claimed uniformity required by the claims without "coating or intimately associating" the active with a taste-masking agent. In response to the Examiner's argument that mixing the taste-masking agent with the active had been known for years, Applicants stated that the prior art was not their invention: "[t]he claimed invention is directed to solving the problems associated with achieving a taste-masked drug which is uniformly distributed throughout a film." (Ex. T, at 17.) Applicants reiterated that Chen unlike the alleged invention, "merely mixes" a taste-masking agent with an active in the film-forming composition. (*Id*.) Plaintiffs are now bound by the those arguments. *Norian Corp. v. Stryker Corp*., 432 F.3d 1356, 1363 (Fed. Cir. 2005) (narrowing claims by amendment results in presumptive surrender of all scope between the

broader and narrower claims); *Spectrum Int'l, Inc. v. Sterilite Corp.*, 164 F.3d 1372, 1378-79 (Fed. Cir. 1998). Plaintiffs' proposed construction now tries to recapture "merely mixing" as long as a "taste-masking effect [is provided] with respect to the active." (*Supra* at 70.) Plaintiffs' broad construction, however, improperly covers Chen's disclosure and is inappropriate in view of Applicants' "clear and unmistakable disclaimer" during prosecution. *See Spectrum*, 164 F.3d at 1379.

Plaintiffs' arguments that Defendants' proposed constructions (1) attempt to read in limitations from the specification and (2) include inappropriate requirements are wrong in view of the Applicants' own description of the invention— "achieving a taste-masked drug which is uniformly distributed." (Ex. T, at 17.) Defendants' proposed construction is consistent with the intrinsic record and the plain and ordinary meaning of this term—it should be adopted.

3. Plaintiffs' Reply Position

Plaintiffs' proposed construction for the term "taste-masking of the active" in claims 1, 28, and 62 of the '514 patent, follows the plain and ordinary meaning, *i.e.*, "providing a taste-masking effect with respect to the active." Defendants contend, that Plaintiffs' construction (1) "misstates the plain and ordinary meaning of [Term 4]" and (2) "ignores critical admissions made during prosecution."

Defendants' first argument is without merit as it does nothing more than offer the conclusion that "Plaintiffs' construction misstates the plain and ordinary meaning of [Term 4]." Defendants fail to provide any reason **why** the plain and ordinary meaning of "taste-masking of the active" can be anything other than "providing a taste-masking effect with respect to the active" (the plain meaning of the term) as proposed by Plaintiffs. Accordingly, Defendants' argument on this point should be rejected.

Defendants' second argument regarding an alleged prosecution disclaimer is equally without merit. There is a "heavy presumption that a claim term carries its ordinary and customary meaning." *CCS Fitness,* Inc. *v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002) (citations omitted). In order to prevail on their argument that a limitation (namely, that simply mixing an active and a taste-masking agent is somehow precluded) should be imported into the claim, Defendants' must show that the alleged "critical admissions" during prosecution rose to the level of a "clear and unmistakable" disavowal of claim scope. *Thorner v. Sony Computer Entm't Am. LLC*, 669 F.3d 1362, 1366-67 (Fed. Cir. 2012).

Defendants cannot remotely approach carrying this burden. The alleged "admission" was nothing of the kind, let alone an unmistakable disavowal of claim scope. The patentee nowhere stated that its invention was limited to coating or intimately associating the active with a taste-masking agent, or that its invention excluded mixing the taste-masking agent with the active. To the contrary, the patentee disclosed embodiments in which the taste-masking agent and the active were combined by mixing, while ensuring that film active uniformity was achieved.

During prosecution, the Examiner initially rejected proposed claim 1 as obvious over the Chen reference. In response, the patentee spent several pages (JCCS Ex. S, e.g., 13-16) emphasizing that the thrust of the patent is to produce a pharmaceutical film having sufficient active content uniformity to meet "the stringent governmental or agency standards relating to variation of active dosage forms (*id.* at 14), while providing sufficient taste-masking to the drug particles without interfering with uniformity, such as by self-aggregation or conglomeration of particles (*id.* at 13-15). The patentee repeatedly pointed out that "Chen completely fails to appreciate uniformity," *id.* at 16[27], but Defendants selectively rely on the following statement by

[27] "Chen does not recognize the problem to be solved by the claimed invention, i.e. attaining low

the patentee: "Chen merely mixes taste modifying agents into the film-forming mix ***without recognizing the problem of separation or aggregation*** of the taste-modifying agents from the unpleasant tasting pharmaceutical agents." *Id*. (emphasis added). Plainly, the patentee is simply arguing here that Chen's step of "merely mixing" alone ***without "recognizing the problem of separation or aggregation," and thus without ensuring the claimed uniformity requirements were also met,*** was insufficient to render proposed claim 1 obvious. Obtaining content uniformity in order to satisfy FDA requirements is the central objective of the '514 patent. This passage in the file history was clearly not meant to preclude the claims from encompassing the "mere mixing" of one or more actives with a taste-masking agent. The patentee did not disclaim "mixing" *per se*, as Defendants contend, but instead distinguished processes that do not recognize or achieve film uniformity. There was no disclaimer.

Furthermore, unlike other independent claims of the patent, claim 62 does not recite that the "taste-masking agent [is] coated or intimately associated with said particulate [agent]."[28] Insofar as Defendants' prosecution disclaimer argument is tied to that claim term, that argument cannot apply to claim 62 because it does not recite that term. Claim 62 was not even part of the application when the patentee made the statements during prosecution now relied on by Defendants. It was added in May 2013–almost two and a half years later. JCCS Ex. X, 5/10/13 Response at 16-17. Therefore, this limitation and any statements made in reference to claim 1 earlier in the prosecution history cannot be used to limit claim. *Omega Eng'g, Inc., v. Raytek*

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adjuvant content, high-taste-masked pharmaceutical active content films which have enhanced flexibility, structural integrity and **uniformity**." (emphasis in original). *Id*.

[28] Claim 62 recites in relevant part: "a taste-masking agent selected from the group consisting of flavors, sweeteners, flavor enhancers, and combinations thereof to provide ***taste-masking of the active***" (emphasis added).

Corp., 334 F.3d 1314, 1331 (Fed. Cir. 2003) (no disclaimer where claims did not contain term to which any alleged disavowal was made).

Finally, there is no support for limiting claim scope to require coating of the active when the claim language is of broader scope. The specification discloses embodiments in which the taste-masking agent and the active are combined by mixing. *See*, *e.g.*, 67:19-25 ("***mixing until a uniform mixture was achieved***") (emphasis added); *see also* 54:1-10; 62:1-6. Thus, "mixing" was clearly contemplated by the patentee and is not outside the scope of the claims.

4. Defendants' Sur-Reply Position

To obtain the '514 patent, the applicants distinguished ***two*** prior art references by emphasizing intimate association versus the "mixing" of components. They cannot escape the import of these arguments now. *Gemalto S.A. v. HTC Corp.*, 754 F.3d 1364, 1369 (Fed. Cir. 2014) (noting that proposed claim interpretation "conflicts with the prosecution history" where the applicants "repeatedly distinguished invalidating prior art" in a way that conflicted with the proposed interpretation). During prosecution, the applicants argued that the prior art methods did not effectively mask the taste of the active ingredients because of insufficient aggregation of the active with the taste-masking agent. For instance, the applicants argued that "Chen ***merely mixes*** taste modifying agents into the film-forming mix without recognizing the problem of separation or aggregation ***of the taste-modifying agents from the unpleasant tasting pharmaceutical agents***." (Ex. S, at 15) (emphasis added). Accordingly, Chen did "not recognize the problem to be solved by the claimed invention, i.e., attaining…high-taste-masked pharmaceutical active content films which have enhanced…uniformity." (*Id*.) Similarly, the applicants distinguished the Schiraldi reference by arguing that it only disclosed that "the components are ***merely mixed*** together." Plaintiffs now aver that these arguments cannot apply to claim 62, because that claim uses the term "taste-masking agent" slightly differently. (*Supra*

at 74.) It is axiomatic that "the same terms appearing in different portions of the claims" are presumed to have the same meaning absent intrinsic evidence to the contrary. *PODS, Inc. v. Porta Stor, Inc.*, 484 F.3d 1359, 1366 (Fed. Cir. 2007). Here, there is no such evidence. The meaning of "taste-masking agent," as determined by the intrinsic record and Plaintiffs' arguments during prosecution, applies to all claims that use this term, including claim 62.

In sum, the intrinsic record and the prosecution history make clear that a "taste-masking agent" must be intimately associated with the active, and may not be merely mixed. This construction applies to each and every claim in which the term "taste-masking agent" appears.

J. '514 Patent—Term 5

Term	Plaintiffs' Proposed Construction	Defendants' Proposed Construction
"capable of being dried without loss of substantial uniformity" (claims 1, 28, 62)	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.	Wherein, after drying, 10% or less variation of the particulate active and taste masking agent is observed when compared to the sample before drying, measured by visual, weight, or chemical analyses

1. Plaintiffs' Opening Position

The third and final disputed "substantial uniformity" term is straightforward: the claimed characteristic of the matrix is that it be capable of being dried such that individual dosage units do not vary by more than 10% from the intended amount of active, i.e., capable of being substantially uniform after drying.

To the extent Defendants' proposed construction can be understood, it appears to completely disregard the intended result, as conveyed by the clear claim language, and actually allows loss of substantial uniformity during drying. For instance, if the active content before drying is 95% of the intended amount, everyone agrees there is substantial uniformity of active

content (within 10% of the intended amount). If the same sample has 10% less active after drying compared to before drying, and therefore meets Defendants' construction of this term, it will have 85.5% (95 - (0.10 x 95)) of the intended amount of active. This is not "substantially uniform" because it varies by more than 10% from the intended amount. That is, substantial uniformity was lost during drying, even though Defendants' construction of term 5 was satisfied because "after drying, 10% or less variation of the particulate active and taste masking agent is observed when compared to the sample before drying." A construction that allows loss of substantial uniformity during drying cannot be the correct construction of the term "capable of being dried without loss of substantial uniformity."

As with term 3, Defendants also improperly add a requirement that uniformity apply to a taste masking agent when the claims only recite uniformity of an active: "capable of being dried without loss of substantial uniformity in the stationing of said particulate active." And Defendants again add language specifying that measurements be "by visual, weight, or chemical analyses," which makes no sense when Defendants agree that what is being measured is a 10% or less variation in the content of an active, which requires chemical analysis. Plaintiffs' straightforward construction should be adopted.

2. Defendants' Answering Position

Plaintiffs' proposed construction takes this claim term out of context and ignores the remainder of the claim language. When viewed in the context of the entire claim and the specification, a person of ordinary skill would recognize that the '514 patent contemplates separate uniformity requirements. First, the plain language of the claim makes clear that the flowable film must be capable of being dried without ***loss*** of substantial uniformity. ***Separately***, the resulting film must vary by no more than 10% of the desired amount of active. The plain meaning of the language "***loss*** in substantial uniformity" requires not just a particular measure of

uniformity of the final film; it also requires that the uniformity not be substantially reduced when compared to the sample before drying. Contrary to Plaintiffs' assertion, the patentee did not act as his own lexicographer and revise the meaning of ***loss*** in uniformity—he simply recited a separate and distinct uniformity requirement, which is reflected ***elsewhere*** in the claims.

It is well established that "[c]laims must be interpreted with an eye toward giving effect to all terms in the claim." *Becton, Dickinson & Co. v. Tyco Healthcare Grp., LP*, 616 F.3d 1249, 1257 (Fed. Cir. 2010); *see also Merck & Co. v. Teva Pharm. USA, Inc.*, 395 F.3d 1364, 1372 (Fed. Cir. 2005). Yet, Plaintiffs' proposal would render the requirement that the matrix be "capable of being dried without loss in substantial uniformity" entirely superfluous, because the claim term would be coextensive with the requirement that the final film be uniform. This interpretation improperly ignores multiple, separate limitations and collapses them all into a single requirement, with no evidence that this was the patentee's intent.

Plaintiffs assert that under Defendants' proposed construction, a film would fall within the scope of the claimed invention if the final dose varies by more than 10% of the active. That is plainly not the case. Such a film would still not fall within the scope of the claimed invention, because it would not satisfy the ***separate*** claim limitation (which the parties have agreed does not require construction) that the individual doses after casting and drying do not vary by more than 10% of the desired amount of active. Accordingly, Defendants respectfully submit that "capable of being dried without loss of substantial uniformity" should be construed to require 10% or less variation in uniformity when compared to the flowable matrix before drying.

3. Plaintiffs' Reply Position

Plaintiffs' Reply Position is presented under Term 4 above.

4. Defendants' Sur-Reply Position

Defendants incorporate here their answering brief on Term 5.

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Respectfully submitted,

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