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., Defendants.	Civil Action 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.	Civil Action No. 14-422-RGA

MEMORANDUM OPINION

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December 12, 2014

[redacted]

ANDREWS, U.S. DISTRICT JUDGE:

Before this Court is the issue of claim construction of disputed terms found in three U.S. Patents, 8,017,150 ("the '150 patent"), 8,475,832 ("the '832 patent"), and 8,603,514 ("the '514 patent").

I. BACKGROUND

Plaintiffs assert that Defendants' ANDAs infringe the '150 patent, the '832 patent, and the '514 patent. (D.I. 106). The Court has considered the parties' claim construction briefing (D.I. 106, 107, 108) and held a *Markman* hearing on December 3, 2014.

II. LEGAL STANDARD

"It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (internal quotation marks omitted). "'[T]here is no magic formula or catechism for conducting claim construction.' Instead, the court is free to attach the appropriate weight to appropriate sources 'in light of the statutes and policies that inform patent law.'" *SoftView LLC v. Apple Inc.*, 2013 WL 4758195, at *1 (D. Del. Sept. 4, 2013) (quoting *Phillips*, 415 F.3d at 1324). When construing patent claims, a matter of law, a court considers the literal language of the claim, the patent specification, and the prosecution history. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 977–80 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). Of these sources, "the specification is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Phillips*, 415 F.3d at 1315 (internal quotations and citations omitted).

Furthermore, "the words of a claim are generally given their ordinary and customary meaning . . . [which is] the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Phillips*, 415 F.3d at 1312–13 (internal citations and quotation marks omitted). "[T]he ordinary meaning of a claim term is its meaning to [an] ordinary artisan after reading the entire patent." *Id.* at 1321 (internal quotation marks omitted). "In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words." *Id.* at 1314 (internal citations omitted).

A court may consider extrinsic evidence, which "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises," in order to assist the court in understanding the underlying technology, the meaning of terms to one skilled in the art and how the invention works. *Id.* at 1317–19 (internal quotation marks and citations omitted). However, extrinsic evidence is less reliable and less useful in claim construction than the patent and its prosecution history. *Id.*

Moreover, "[a] claim construction is persuasive, not because it follows a certain rule, but because it defines terms in the context of the whole patent." *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998). It follows that "a claim interpretation that would exclude the inventor's device is rarely the correct interpretation." *Osram GmbH v. Int'l Trade Comm'n*, 505 F.3d 1351, 1358 (Fed. Cir. 2007) (internal quotation marks and citation omitted).

III. CONSTRUCTION OF DISPUTED TERMS

A. The '150 Patent

Claim 1 of the '150 patent is representative:

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

('150 patent, claim 1).

1. "the polyethylene oxide comprises one or more low molecular weight polyethylene oxides and one or more higher molecular weight polyethylene oxides, the molecular weight of the low molecular weight polyethylene oxide being in the range 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)

a. *Plaintiffs' proposed construction*: The plain and ordinary meaning is a polyethylene oxide component comprising polyethylene oxide within the molecular weight range

of 600,000 to 900,000 Daltons and at least about 60% polyethylene oxide within the molecular weight range of 100,000 to 300,000 Daltons.

b. *Defendants' proposed construction*: The polyethylene oxide comprises (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.

c. *Court's construction*: The polyethylene oxide comprises (i) one or more polyethylene oxides having a lower average molecular weight in the range of 100,000 to 300,000; and (ii) one or more polyethylene oxides having a higher average molecular weight 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 in the polymer component.

Plaintiffs argue that "molecular weight" in this term should be actual molecular weight or "the sum of the atomic weights of all the atoms in a molecule." (D.I. 106 at p.8). Defendants argue that molecular weight must be an average, but that a person of ordinary skill in the art "would also understand that there are multiple methods of calculating the 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." (*Id.* at p.29) (emphasis in original). According to Defendants, therefore, because the patent does not provide guidance for calculating molecular weight of the PEOs, the term molecular weight should be indefinite. (*Id.*).

The Court finds that "molecular weight" means "average molecular weight," not actual molecular weight. When the patent describes examples of films that include the blend of different weight polymers in Table 22 of the patent, it lists percentages of PEOs of different weights such as 100,000, 200,000, 300,000, and 900,000. ('150 patent, 50:7-34). When explaining properties of these different resulting films, the patent refers to the particular weights listed in Table 22 as "higher molecular weight PEOs" and "lower molecular weight PEOs." (*See, e.g.*, '150 patent, 51:29-38). Defendants' expert points to the examiner in the '150 prosecution history citing a brochure from Union Carbide that describes the average molecular weight of certain polymer samples using viscosity average. (D.I. 107-5 at 15-16). At the hearing, Defendants noted that common commercial polymers have single molecular weights, which a person of ordinary skill in the art would understand to be an average weight. (D.I. 147 at 39). Defendants, at the hearing, explained that a person skilled in the art would look at Table 22 of the patent and understand those molecular weight PEOs as the type made by commercial companies, described with average weights. (D.I. 147 at 48). The Court agrees. Molecular weight in the patent, therefore, must mean average molecular weight.

Both sides cite to *Teva Pharmaceuticals USA, Inc.* v. *Sandoz Inc.*, 723 F.3d 1363 (Fed. Cir. 2013) to support their position, but *Teva* cuts against Plaintiffs' position. Plaintiffs argue that the current claim is nearly identical to the "Group II" claims in *Teva*, where the court found that molecular weight referred to precise points on a distribution curve, or what the Plaintiffs call actual molecular weight. (D.I. 106 at p.9). A representative claim from Group II in *Teva* reads: "Co-polymer-1 having over 75% of its mole fraction within the molecular weight range from about 2 kDa to about 20 kDa..." *Teva*, 723 F.3d at 1367. Plaintiffs force a comparison to the Group II claims, arguing that claim 1 of the '150 patent recites 60% of the lower molecular

weight PEOs falling within the molecular weight boundary of 100,000 to 300,000. (D.I. 106 at p.11). Claim 1, however, describes lower molecular weight PEOs within a certain weight range and higher molecular weight PEOs within a certain range; the lower molecular weight PEOs then make up at least 60% of the polymer component, which also includes hydrophilic cellulosic polymer. Claim 1 does not say that 60% of the low molecular weight PEOs fall within a 100,000 to 300,000 boundary. Instead, the 60% refers to the composition of the lower weight PEOs in the final polymer component, which in addition to the two PEOs, also includes hydrophilic cellulosic polymer. In short, *Teva* does not support Plaintiffs' position on using actual molecular weight.

Even though *Teva* found that another set of claims with "molecular weight" construed as "average molecular weight" were indefinite because there are several different approaches to calculating average molecular weight, I believe that any indefiniteness arguments about "average molecular weight" are for another day. Defendants argue that a person skilled in the art would not know which measure of average weight to use because there is no guidance from the patent or prosecution history, and therefore "molecular weight" is indefinite. (D.I. 106 at p.34). Defendants' expert, however, points to prosecution history of the patent referring to using viscosity average, for example. (D.I. 107-5 at 15-16).[1] At a later date, experts may provide further guidance on the indefiniteness question.

Defendants argue that the polymer component, comprised of low average molecular weight PEOs and high average weight PEOs, must come from two different sources. (D.I. 106 at

[1] I also note that commercial polyethylene oxide products appear to use average molecular weight to describe themselves. I would expect persons of ordinary skill in the art to understand which method was in use in the commercial products, which might inform any understanding of the patent.

pp.3-6). Plaintiffs respond that only the presences of the required PEOs is relevant; "how they got there (from one bottle or two) is completely irrelevant." (D.I. 106 at p.16). The Court agrees that the source of the PEOs, whether from one or two bottles, to adopt Plaintiffs' characterization, is not relevant to the construction. Nonetheless, it is clear from the patent that discrete sets of the low average molecular weight PEOs and the high average weight PEOs must be present in the product. For example, the description of the invention in the patent describes "combining" "small amounts" of the high molecular weight PEOs with "larger amounts" of the low molecular weight PEOs. ('150 patent, 18:6-28). Therefore, at a minimum, there must be some amount of each PEO. Defendants have voiced concern that Plaintiffs were trying to read the claims such that essentially only lower average molecular weight PEOs would be present in the component, with stray molecules being counted as higher average weight PEOs.[2] Whether or not Plaintiffs were trying to read the claims this way, the Court agrees with Defendants that the product cannot be comprised of only low average molecular weight PEOs, or only low average molecular weight PEOs with stray higher average molecular weight PEOs.

Defendants propose that the construction include an upper limit for the lower average molecular weight polyethylene oxides that is "less than 100%" of the weight of the polymer component. (D.I. 106 at pp.6-7). Defendants are concerned that Plaintiffs proposed construction would allow a product comprised of 100% of the low molecular weight PEO but 0% of the high molecular weight PEO. (*Id.* at p.7). While the Court will not adopt the Defendant's upper limit requirement in its construction of the terms (as the construction already requires the presence of

[2] In the briefing, Defendants argue that "[b]ecause 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." (D.I. 106 at p.5)(citations omitted).

some higher average molecular weight PEOs), it seems clear that the product cannot contain only the low molecular weight PEOs. Indeed, Plaintiffs agreed to this point in the *Markman* hearing. (D.I. 147 at 31-32).

2. "molecular weight" (claims 1, 10)

a. *Plaintiffs' proposed construction*: The plain and ordinary meaning is the sum of the atomic weights of all the atoms in a molecule.

b. *Defendants' proposed construction*: Average molecular weight calculated from the molecular weights of all the chains in the sample. Alternatively, the term "molecular weight" is indefinite.

c. *Court's construction*: Average molecular weight

The court has provided its reasoning for construing "molecular weight" as "average molecular weight" above.

B. The '832 Patent

Claim 1 of the '832 patent is representative:

> A film dosage composition comprising:
>
> a. A polymeric carrier matrix;
>
> b. A therapeutically effective amount of buprenorphine or a pharmaceutically acceptable salt thereof;
>
> c. A therapeutically effective amount of naloxone or a pharmaceutically acceptable salt thereof; and
>
> d. A buffer in an amount to provide a local pH for said composition of a value sufficient to optimize absorption of said buprenorphine, wherein said local pH is from about 3 to about 3.5 in the presence of saliva.

('832 patent, claim 1).

1. "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)

a. *Plaintiffs' proposed construction*: 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.

b. *Defendants' proposed construction*: 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.

c. *Court's construction*: provide a local pH for the composition sufficient to optimize absorption of said buprenorphine wherein said local pH is about 3 to about 3.5 in the presence of saliva in the mouth, 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.

Both parties at the *Markman* hearing agreed to construing the term to read "in the presence of saliva in the mouth." (D.I. 147 at 69-70).[3] Two disputes remain: 1) the construction of "provide a local pH" and 2) the relevance of "...sufficient to optimize absorption of said buprenorphine wherein said local pH is..."

The Court agrees with Plaintiffs that the construction of "provide a local pH" is "provide a local pH," not Defendants' proposal of "control the pH of the region..." Defendants argue that a buffer must provide a local pH "sufficient to optimize absorption of said buprenorphine," which cannot be done only in a "fleeting moment," something that the language "provide," rather than "control," allows. (D.I. 106 at p.45). The Court disagrees. There is no compelling reason to change "provide" to "control," when "provide" is the language used by the claim. The interchangeable use of "provide" and "control" in the specification does not mean "provide" means "control" any more than it means that "control" means "provide."

The Court further agrees with Plaintiffs that the "sufficient to optimize" phrase must be included in the construction of the term. Defendants argue that the phrase is unnecessary because it describes a result, not a limitation, of the claim. (D.I. 106 at p.46). Plaintiffs argue that it is a requirement of the claim. (D.I. 106 at p.44). The Court agrees. If the provided local pH is not sufficient to optimize absorption of said buprenorphine, the claim is not met.

2. "provide a local pH" (claims 1, 9)

[3] The dispute about "saliva" and "in the mouth" was not really a claim construction dispute. Rather, the parties were just jockeying for position in regard to possible evidentiary arguments at trial.

a. *Plaintiffs' proposed construction*: Plaintiffs propose to construe as part of the longer phrase (see claim term 1 above).

b. *Defendants' proposed construction*: 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.

c. *Court's construction*: provide a local pH

The Court has provided its reasoning for construing "provide a local pH" as "provide a local pH" above.

3. "bioequivalent absorption of buprenorphine to that of a tablet having an equivalent amount of buprenorphine" (claims 2, 10)

a. *Plaintiffs' proposed construction*: 80% to 125% of the Cmax and AUC values for buprenorphine in a tablet having an equivalent amount of buprenorphine.

b. *Defendants' proposed construction*: 80% to 125% of the Cmax and AUC values for buprenorphine in a Suboxone® tablet having the same amount of buprenorphine.

c. *Court's construction*: 80% to 125% of the Cmax and AUC values for buprenorphine in a Suboxone® tablet having an equivalent amount of buprenorphine

At the *Markman* hearing, Plaintiffs agreed that the "tablet" in the term is a Suboxone® tablet. (D.I. 147 at 71-72). Therefore, the two proposed constructions differ materially only in that Defendants propose "same amount," rather than "equivalent amount," of buprenorphine. The Court agrees with Plaintiffs that "equivalent amount" should be used because that is what the claims say.

C. The '514 Patent

Claim 1 of the '514 patent is representative:

> A drug delivery composition comprising:
>
> > (i) a cast film comprising a flowable water-soluble or water swellable film-forming matrix comprising one or more substantially water soluble or water swellable polymers; and a desired amount of at least one active;
> >
> > wherein said matrix has a viscosity sufficient to aid in substantially maintaining non-self-aggregating uniformity of the active in the matrix;
> >
> > (ii) a particulate active substantially uniformly stationed in the matrix; and
> >
> > (iii) a taste-masking agent coated or intimately associated with said particulate to provide taste-masking of the active;
> >
> > wherein the combined particulate and taste-masking agent have a particle size of 200 microns or less and said flowable water-soluble or water swellable film-forming matrix is capable of being dried without loss of substantial uniformity in the stationing of said particulate active therein; and
> >
> > wherein the uniformity subsequent to casting and drying of the matrix is measured by substantially equally sized individual unit doses which do not vary by more than 10% of said desired amount of said at least one active.

('514 patent, claim 1).

1. "flowable" (claims 1, 28, 62)

a. *Plaintiffs' proposed construction*: The term should be given its plain and ordinary meaning.

b. *Defendants' proposed construction*: Capable of being formed into a film and dried.

c. *Court's construction*: The term should be given its plain and ordinary meaning.

At the *Markman* hearing, the Defendants' withdrew their proposal, accepting the plain and ordinary meaning of the term. (D.I. 147 at 106-8). Defendants reserve the right to argue the

term is indefinite, something they may do at a later date.[4]

2. "viscosity sufficient to aid in substantially maintaining non-self aggregating uniformity of the active in the matrix" (claims 1, 28, 62)

a. *Plaintiffs' proposed construction*: 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.

b. *Defendants' proposed construction*: viscosity sufficient to provide little to no aggregation of the active within the film

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

The Court agrees with Defendants that Plaintiffs' proposed construction would import a limitation of substantial uniformity, which does not apply to this particular term. ('514 patent, 67:53-56; *see* D.I 106 at p. 64). This uniformity is subsequent to casting and drying, not applied to each step along the way.

3. "substantially uniformly stationed" (claims 1, 28, 62)

a. *Plaintiffs' proposed construction*: 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.

b. *Defendants' proposed construction*: 10% or less variation of the particulate active and taste masking agent between measured samples, measured by visual, weight, or

[4] I take the plain and ordinary meaning of "flowable" to be "able to flow."

chemical analyses

c. *Court's construction*: 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.

The parties' proposed constructions differ materially in two ways: 1) Defendants include "taste masking agent" in their construction, and 2) Defendants include that measurements be conducted by "visual, weight or chemical analyses." The "substantially uniformly stationed" phrase only applies to the particulate active, not to the taste masking agent as Defendants assert: "(ii) a particulate active substantially uniformly stationed in the matrix." ('514 patent, 67:42-43). Furthermore, the claims make no mention of the particular type of measurement techniques that could be conducted to determine appropriate uniformity. The appropriate measurement techniques are best left to another day, as they do not involve claim construction. Therefore, the Court adopts the Plaintiffs' construction.

4. "taste-masking of the active" (claims 1, 28, 62)

a. *Plaintiffs' proposed construction*: 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 taste-masking effect with respect to the active.

b. *Defendants' proposed construction*: Coating or intimately associating the active with a taste-masking agent to achieve a uniform distribution of the taste-masked active throughout the film

c. *Court's construction*: The term should be given its plain and ordinary meaning.

The construction of this term applies to claims 1, 28 and 62. Claims 1 and 28 recite a "taste-masking agent coated or intimately associated with said particulate to provide taste-

masking of the active." Claim 62, however, provides "a taste-masking agent selected from the group consisting of flavors, sweeteners, flavor enhancers, and combinations thereof to provide taste-masking of the active." It cannot be the case that Defendants' proposal of "[c]oating or intimately associating the active" applies to all three references of "taste-masking of the active," when two of the claims explicitly spell it out and the third does not.

The Court also does not believe that the taste-masking agent is "to achieve a uniform distribution of the taste-masked active throughout the film." The uniformity required by the patent is to be "subsequent to casting and drying" in each of the three claims.

Defendants make much of the prosecution history's discussion of the Chen reference, arguing the inventors distinguished their invention from Chen as possessing taste-making uniformity, ruling out merely mixing taste-masking agents with actives. (D.I. 106 at p.71). Plaintiffs argue that Defendants selectively rely on quotations from the Chen reference. (*Id.* at pp.73-74). The Court agrees with Plaintiffs. It is not self-evident that the inventors sought to disavow Chen for lacking taste-masking uniformity. (D.I. 108-19 at 18). Instead, the inventors appeared to be concerned with uniformity of the film product, after it is dried, not at the taste-masking agent step. (*Id.* at 18-19).

5. "capable of being dried without loss of substantial uniformity" (claims 1, 28, 62)

a. *Plaintiffs' proposed construction*: 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.

b. *Defendants' proposed construction*: 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

c. *Court's construction*: 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.

The Court's analysis is similar to term 3 of this patent provided above. The Court agrees with Plaintiffs that the proper comparison is between the intended amount and the film matrix after drying. It is not proper to compare the sample before and after drying. Furthermore, the claims make no mention of the particular type of measurement techniques to determine appropriate uniformity. The appropriate measurement techniques are not a matter for resolution by claim construction.

IV. CONCLUSION

Within five days the parties shall submit a proposed order consistent with this Memorandum Opinion suitable for submission to the jury.