UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

HORIZON PHARMA AG and JAGOTEC AG, Plaintiffs, v. WATSON LABORATORIES, INC. – FLORIDA, Defendant.	HONORABLE JOSEPH E. IRENAS CIVIL ACTION NO. 13-5124 (JEI/JS) **CLAIM CONSTRUCTION OPINION**

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IRENAS, Senior District Judge:

The parties in this pharmaceutical patent infringement case have asked this Court to construe two disputed claim terms. The Court held a claim construction hearing pursuant to *Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996) on October 16, 2014, and now adopts Plaintiffs' construction of both of these terms for the reasons set forth below.

I. Relevant Facts

Plaintiffs Horizon Pharma AG ("Horizon") and Jagotec AG ("Jagotec") have brought claims of patent infringement against Defendant Watson Laboratories, Inc. ("Watson") for filing an Abbreviated New Drug Application ("ANDA") to market a generic version of Horizon's pharmaceutical product RAYOS®, in alleged infringement of three patents held by Plaintiffs. The claim construction dispute before the Court today concerns only two of those patents: U.S. Patent No. 8,394,407 (the "'407 patent") and U.S. Patent No. 8,309,124 (the "'124 patent"). Inventors

Guy Vergnault of Kembs, France; Pascal Grenler of Kappelen, France; and Christophe Dragan of Geispitzen, France, filed the ’124 patent on March 19, 2012 (issued November 13, 2012) and the ’407 patent on March 23, 2012 (issued March 12, 2013). By recorded assignment, both patents now belong to Plaintiff Jagotec.

Both patents concern the “Delayed Release Tablet with Defined Core Geometry,” which is designed to release an active agent “rapidly after a lag time during which time no active agent is released.” (Abstract, ’124 Patent at 2 and Abstract, ’407 patent at 2) The patents suggest that the invention may prove particularly useful to patients suffering from rheumatoid arthritis, who require a dose of the drug prednisone in the middle of the night to maximize effectiveness of the treatment and prevent morning stiffness and pain. (’124 Patent at 5, col. 1, ll. 40-56 and ’407 patent at 6, col. 1, ll. 31-47) Rather than waking up in the middle of the night to take a pill, a patient can take the patents’ delayed-release tablet prior to bedtime and have the tablet release its active agent a few hours later, while the patient is sleeping. (Id.)

The prior art had delayed release by surrounding the active agent with a coating that is gelled or of a heavier weight in order to slow diffusion. (’124 Patent at 5, col. 2, ll. 16-36 and ’407 patent at 6, col. 2, ll. 6-26) However, diffusion

releases the drug too gradually and thicker pills are both more expensive to make and more difficult for patients to swallow, among other problems. (Id.)

The patentees address these problems by encasing the active agent core inside an oval-shaped coating that varies in thickness and material along its shorter (A-B) and longer (X-Y) axes. (*See* Fig. 1, ’124 Patent at 3 and ’407 patent at 4) While the coating around the A-B axis is relatively dense to prevent the release of the active agent in the core, the coating around the X-Y axis of the tablet is “relatively porous and permissive towards the ingress of aqueous media,” allowing such media to enter the tablet through the X-Y axis, cause the core to swell on contact, and thereby break open the tablet like “an opened clam shell.” (’124 Patent at 6, col. 4, ll. 4-23 and ’407 patent at 7, col. 3, l. 59-col. 4, l. 11). The timing of release is therefore managed not only through the thickness of the coating around the active agent core but also the density and porosity of its material. A key aspect of the patents is that the active agent is released through a rupturing of the tablet rather than diffusion through the coating.

The parties have identified two claim terms, both related to the substance of the tablet’s coating, that now require construction: (1) “insoluble or poorly water soluble hydrophobic material” and (2) “wherein the coating comprises calcium

phosphate salt, glyceryl behenate, and polyvinyl pyrollidone, or mixtures thereof." The Court addresses each of these terms in turn.

II. Legal Standard

Claim construction is a matter of law for the Court to decide. *Markman*, 517 U.S. at 391. The purpose of claim construction is to "determin[e] the meaning and scope of the patent claims asserted to be infringed," *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979–80 (Fed. Cir. 1995), *aff'd* 517 U.S. 370 (1996), and "[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, 1319 (Fed. Cir. 2005) (en banc) (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004)).

The Court begins a claim construction analysis by examining the intrinsic evidence, which includes the claims, the specification, and the prosecution history of each patent.[1] *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). "A claim construction analysis must begin and remain centered on the claim language itself," *Innova*, 381 F.3d

[1] The prosecution history "consists of the complete record of the proceedings before the [U.S. Patent and Trademark Office] and includes the prior art cited during the examination of the patent." *Phillips,* 415 F.3d at 1317.

at 1116, and every word should be assumed to have meaning and given effect, *Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 950 (Fed. Cir 2006).

The claims themselves and the context in which a term is used within the claims can "provide substantial guidance as to the meaning of particular claim terms," and other claims of the patent may be useful in construing a term, as "claim terms are normally used consistently throughout the patent." *Phillips,* 415 F.3d at 1314. Similarly, claims that differ from each other may provide insight into how a term should be read. *Laitram Corp. v. Rexnord, Inc.*, 939 F.2d 1533, 1538 (Fed. Cir. 1991).

There is a heavy presumption that a claim term conveys its 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." *Phillips*, 415 F.3d at 1312-13. But a patentee may overcome this presumption and choose "to be his or her own lexicographer by clearly setting forth an explicit definition for a claim term." *Johnson Worldwide Assocs., Inc. v. Zebco Corp.,* 175 F.3d 985, 990 (Fed. Cir. 1999); *see also Schering Corp. v. Amgen Inc.,* 222 F.3d 1347, 1353 (Fed. Cir. 2000); *Markman,* 52 F.3d at 979–80.

After examining the claims, "it is always necessary to review the specification to determine whether the inventor has used any terms in a manner inconsistent with their ordinary

meaning." *Vitronics*, 90 F.3d at 1582. "For claim construction purposes, the description [contained within a specification] may act as a sort of dictionary, which explains the invention and may define terms used in the claims." *Markman*, 52 F.3d at 979. For this reason, "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." *Vitronics*, 90 F.3d at 1582.

Finally, the Court should also examine the prosecution history, if it is in evidence: "The prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Phillips*, 415 F.3d at 1317.

"[I]deally there should be no 'ambiguity' in claim language to one of ordinary skill in the art that would require resort to evidence outside the specification and prosecution history." *Markman*, 52 F.3d at 986. But if the term remains unclear or ambiguous after examining the intrinsic evidence, the Court may turn to extrinsic evidence. *Pall Corp. v. Micron Separations, Inc.*, 66 F.3d 1211, 1216 (Fed. Cir. 1995). "Extrinsic evidence consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries,

and learned treatises." *Markman*, 52 F.3d at 980. Although extrinsic evidence is useful in determining how a person of ordinary skill in the art would understand the term, it is less reliable for the purposes of claim construction than the patent and its prosecution history. *Phillips*, 415 F.3d at 1318-19. Therefore, extrinsic evidence must be viewed within the context of intrinsic evidence. *Id.* at 1319.

III. Discussion

In the course of briefing, the parties identified two disputed claim terms in the '407 and '124 patents: (1) "insoluble or poorly water soluble hydrophobic material" explicitly appearing in claims 1 and 8 of the '124 patent and claims 1 and 3 of the '407 patent, and (2) "wherein the coating comprises calcium phosphate salt, glyceryl behenate, and polyvinyl pyrollidone, or mixtures thereof" appearing in claim 4 of the '407 patent. The Court now addresses each of these terms, and for the reasons below, adopts Plaintiffs' construction of both claims.

a. "[I]nsoluble or poorly water soluble hydrophobic material"

Plaintiffs define the term "insoluble or poorly water soluble hydrophobic material" as "an excipient that is hydrophobic and either insoluble or poorly soluble in water," a construction that largely tracks the term itself. (Pls.' Claim

Const. Br. 9) Defendant construes the phrase "insoluble or poorly water soluble hydrophobic material" to mean "material that is less water soluble than materials defined as 'very soluble' in the [United States Pharmacopeia ("USP")]," including those that are "freely soluble."[2]

In evaluating the intrinsic evidence, the Court finds that the claim language, the patent specifications, and the prosecution history support Plaintiffs' construction of the phrase without ambiguity.

Claim language

The Court looks first to the language of the claims themselves. In Patent '124, the term at issue appears in independent claims 1 and 8, and identical language in each states in relevant part:

> [T]he coating comprises at least one insoluble or poorly water soluble hydrophobic material such that the glucocorticosteroid active substance is released from the core as a result of the rupturing of the coating and not as a result of the glucocorticosteroid active substance diffusing through the coating[.]

'124 Patent at 13, col. 18, ll. 23-28 and ll. 62-67

In Patent '407, the term appears in independent claim 1 and dependent claim 3. Claim 1 states:

[2] The USP differentiates among seven levels of solubility based on the number of parts of solvent required to dissolve 1 part solute: "Practically insoluble, or Insoluble" (10,000 or more), "Very Slightly Soluble" (1000 to 10,000), "Slightly Soluble," (100 to 1000), "Sparingly Soluble" (30 to 100), "Soluble," (10 to 30 parts), "Freely Soluble" (1 to 10), and "Very Soluble" (less than 1). (Def.'s Claim Const. Br. 16, Table 1)

> . . . [The] coating is formed of an insoluble or poorly water soluble hydrophobic material and said coating is sufficiently porous about the (X-Y) plane of the tablet to permit the ingress of aqueous media to the core at a rate to ensure release of the active agent after a period of time between 2 to 6 hours wherein said period of time is followed by rupture of the coating along the X-Y axis, wherein the compression coating lacks ingredients that swell and gel to such an extent that the coating acts as a diffusion barrier to the release of the active agent.

’407 patent at 14, col. 18, ll. 12-22

Claim 3 states:

> The tablet of claim 1, wherein said water insoluble or poorly soluble hydrophobic material is selected from the group consisting of hydrophobic cellulosic derivatives and polymers including alklylcellulose, hydroxypropyl cellulose, hydroxypropylmethyl cellulose, carboxymethyl cellulose, and derivatives therof; polymethacrylic polymers, polyvinyl acetate and cellulose acetate polymers, fatty acids, fatty acid esters, fatty acid salts, long chain fatty alcohols, polyoxyethylene alkyl ethers, polyoxyethylene stearates, sugar esters, lauroyl macrogol-32 glyceryl, and stearoyl macrogol-32 glyceryl, and combinations thereof.

’407 patent at 14, col. 18, ll. 27-37.

Plaintiffs argue that “[a] person of ordinary skill in the art would understand from this language that a material that is ‘insoluble or poorly water soluble’ would be unable to dissolve in water to any appreciable degree” while “a material that is ‘hydrophobic’ would lack any significant affinity for water such that it possesses a decreased ability to dissolve in water.” (Pls.’ Claim Const. Br. 10)

This understanding of the term is consistent with the claim language’s emphasis of the tablet’s role as a barrier to

diffusion. "[C]laim 1 of the '407 patent expressly excludes materials that 'swell and gel' from the coating," which hydrophilic materials tend to do. (Pls.' Supp. Claim Const. Br. 8) Specifically, the tablet's "compression coating is formed of an insoluble or poorly water soluble hydrophobic material . . . wherein the compression coating lacks ingredients that swell and gel to such an extent that the coating acts as a diffusion barrier to the release of the active agent." ('407 patent at 14, col. 18, ll. 12-22) Similarly, claims 1 and 8 of Patent '124 specify that the tablet "coating comprises at least one insoluble or poorly water soluble hydrophobic material such that the glucocorticosteroid active substance is released from the core as a result of the rupturing of the coating and not as a result of the glucocorticosteroid active substance diffusing through the coating . . . ." ('124 Patent at 13, col. 18, ll. 23-28 and ll. 62-67) If Defendant's construction were adopted, the claim term would include materials that would be too soluble to act as a barrier to diffusion. Given the claim language's emphasis of this function, that construction cannot be correct.

Nonetheless, Defendant argues that the patents must have been using the phrase "insoluble or poorly water soluble" at least broadly enough to include all the examples of excipients that the '407 explicitly names. Some of these excipients would be excluded under Plaintiffs' construction of the terms

"hydrophobic" and "poorly water soluble," according to Defendant, because they are defined as soluble in the USP. (Def.'s Claim Const. Br. 16)

Plaintiffs point out that the majority of excipients listed are undisputedly hydrophobic, water insoluble or poorly water soluble materials. (Pls.' Claim Const. Br. 11) Plaintiffs acknowledge that some of the examples of excipients explicitly named in the '407 patent are soluble under certain circumstances,[3] (id. at 9), but they also have poorly soluble, hydrophobic derivatives that would fit under Plaintiffs' construction (id. at 11). A person of ordinary skill in the art would know not to use the hydrophilic varieties of any excipients, because "claim 3 expressly limits the selection of the material to those 'hydrophobic' materials" at the outset of the claim, and as discussed above, claim 1 "expressly excludes materials that 'swell and gel,'" (Pls.' Supp. Claim Const. Br. 8)

More importantly, given the presumption that a claim term conveys its ordinary and customary meaning, *Phillips*, 415 F.3d at 1312-13, the inclusion of example excipients that have derivatives with varying solubility is not sufficient reason to

[3] Defendant points specifically to three of the sixteen materials: hydroxypropyl cellulose, hydroxypropylmethyl cellulose, and polyoxyethylene alkyl ethers. (Def.'s Supp. Claim Const. Br. 7)

infer that a patentee is "be[ing] his or her own lexicographer by clearly setting forth an explicit definition for a claim term," *Johnson Worldwide Assocs., Inc.,* 175 F.3d at 990. In order to rewrite the plain meaning of "hydrophobic" and "poorly water soluble" to include material that is "freely soluble," the patentees would have had to be more explicit about their intentions than simply listing among examples of the term *some* excipients, only *some* varieties of which are more soluble than the term's plain meaning suggests.

The claim language supports Plaintiff's construction, is consistent with the term's plain meaning, and explicitly contradicts Defendant's suggested construction. The examples of more hydrophilic excipients that Defendant note are included in the patent, to the limited extent they oppose Plaintiffs' construction, are insufficient to rewrite the term's plain meaning as Defendant suggests.

Specifications

Plaintiffs' construction is further supported by the specifications of the patents. As the specifications explain, the innovation at issue primarily seeks to control the timing of the release of an active agent inside a tablet. That timing is controlled by placing the active agent core within the tablet and by varying the density and porosity of the coating around that core. The coating around the X-Y axis of the tablet is

"relatively porous and permissive towards the ingress of aqueous media," thereby allowing such media to enter the tablet, cause the core to swell on contact, and thereby break open the tablet like "an opened clam shell." ('124 patent at 6, col. 4, ll. 4-23 and '407 patent at 7, col. 3, l. 59-col. 4, l. 11).

Critical to the patents' significance is the coating around the shorter A-B axis, which is relatively dense compared to the coating around the X-Y axis, and prevents too much aqueous media from reaching the core too quickly. If the coating around the A-B axis were freely soluble, the aqueous media within the body would reach the active agent within the core prior to the desired lag time, thereby defeating the purpose of the "Delayed Release Tablet." As the specifications explicitly state, "the coating optimally acts merely as a barrier to the ingress of aqueous physiological media thereby providing a drug release lag time" and that it should be "recalcitrant to the ingress of moisture . . . so long lag times can be achieved with relatively thin coatings." ('124 Patent at 7, col. 5, ll. 20-22, 27-29; '407 patent at 8, col. 5, ll. 8-10, 15-17).

In addition to preventing the premature release of the drug by diffusion, once the "clam shell" does pop open, the hydrophobic and poorly water soluble coating enables the release of the active agent all at once. Slow diffusion through the coating is unhelpful "[i]n the case of drugs that have a narrow

absorption window" or cases where the drug must be released at a particular location in the body. ('124 Patent at 5, col. 2, ll. 16-23 and '407 patent at 6, col. 2, ll. 6-13) In those cases, "once the lag time has expired it is desirable to release the drug as rapidly as possible to ensure that all or substantially all of the drug [is] released at the desired site." Id. Releasing the drug suddenly from an open tablet rather that diffusing it slowly through a tablet's soluble coating is a key aspect of the patents at issue.

Given the emphasis on the tablet's release of the active agent by rupturing rather than diffusion, the specification supports Plaintiffs' construction of the term, which indicates the tablet coating's imperviousness to water. Defendant's construction of the term would rewrite the tablet to allow diffusion and fail to meet a central purpose of the invention. Such a construction cannot be correct.

Prosecution History

Plaintiffs point to the prosecution history of the '407 patent, in which the '407 patent is distinguished from the prior art of US 6,365,185 ("the '185 patent"), in support of its construction as well. (Pls.' Claim Const. Br. 14) In relevant part, the '185 patent describes a "non-porous membrane material having pores" in which the pores are "obtained by including a water soluble ingredient within the insoluble matrix." (Pls.

Claim Const. Br., Ex. 4, at 9) These pores in the ’185 patent tablet “are initially filled with a water soluble material and thus” only appear when “the system is immersed in aqueous media” wherein “the soluble ingredient dissolves.” (Id.) Consistent with their construction of the claim term at issue, Plaintiffs note that the “water soluble material” is described as a “soluble ingredient [that] dissolves,” to be contrasted from “the insoluble matrix,” within which the dissolving takes place. (Pls.’ Claim Const. Br. 14) This use of the words “soluble” and “insoluble” in the prosecution of the ’407 patent is consistent with the construction Plaintiffs suggest here.

Defendant contends that reference to this portion of the prosecution history is inapposite, because it does not “provide[] any express definition for ‘insoluble or poorly water soluble hydrophobic material.” (Def.’s Resp. Claim Const. Br. 17) However, such an express definition is exactly what must be provided in order to redefine the claim term as Defendant suggests Plaintiffs have done. Because no such explicit definition is provided, Defendant’s construction cannot be correct.

Finally, also within the prosecution history, Defendant points again to the inclusion of “soluble” or “freely soluble” materials among examples of “insoluble or poorly soluble hydrophobic material” in the applications that issued as the

’124 and ’407 patents. (Def.’s Claim Const. Br. 18-20) As explained with regard to the claim language, these examples are arguably limited to their less soluble derivatives, and more importantly, the inclusion of some materials that are not hydrophobic or poorly water soluble under all circumstances, especially among a majority of other materials that are hydrophobic, does not amount to the patentee being his or her own lexicographer and setting forth an explicit redefinition of a claim term sufficient to override the presumption that the term conveys its ordinary and customary meaning.

Plaintiffs’ construction of the term “insoluble or poorly water soluble hydrophobic material” comports with its plain meaning in the claim language, which is not explicitly redefined by the patentees; finds further support in the patents’ specifications, including the central purpose of the patents as stated therein; and is consistent with the prosecution history. As a result, the intrinsic evidence supports Plaintiffs’ construction without ambiguity.

Extrinsic Evidence

In an argument raised for the first time during the October 16, 2014, hearing, Defendant argues that the tablet described in both patents must be soluble to some degree in order to open, because the porosity of the tablet would not be sufficient for a hydrophobic tablet to split like “an opened clam shell” within

the time period the patents describe. (Claim Const. Hr'g Tr. 89-92) Recognizing this assertion to be a scientific assertion, the Court requested that the parties provide supplemental briefing on this point. (Id. at 100)

In its supplemental brief, Defendant draws no support for its argument from the intrinsic evidence. Instead, Defendant relies on testimony given by Plaintiffs' expert, Robert O. Williams III (Def.'s Supp. Claim Const. Br. 11-12), wherein Dr. Williams states:

> *[A]nd the patent doesn't say this, this is what I think*, having read the patent now several times, if you only use a hydrophobic material in the coating, basically, you render it hydrophobic and water won't ingress, or if it ingresses, it's going to be a very long time. And I think PVP is also playing a role to help water kind of set the – you know, help water ingress at a rate that's going to allow the lag time that's in the patent claims.

Def.'s Supp. Claim Const. Br., Ex. 2, at 5 (Williams Dep. 64:15-65:6) (emphasis added).

Though Defendant does not include the italicized portion in its selective reference, Plaintiffs' expert explicitly states that he is providing his own, extrinsic opinion, not rephrasing an intrinsic requirement of the patent. Such testimony cannot be considered authoritative in the face of contradictory intrinsic evidence and should not be considered where the intrinsic evidence is not ambiguous. As stated above, extrinsic evidence is less reliable for the purposes of claim construction

than the patent and its prosecution history and should only be viewed within the context of the intrinsic evidence. *Phillips*, 415 F.3d at 1318-19.

The intrinsic evidence supports Plaintiffs' construction. Plaintiffs argued in their briefs and during the October 16, 2014, hearing that in order to facilitate the ingress of water, the patented tablet relies only on a distinction in porosity and density between the two axes — not solubility. As Plaintiffs reassert in their supplemental briefs, "[t]he claims [of the '407 patent] do not require the presence of a hydrophilic material because none is needed for the claimed invention to function in the manner described by the inventors." (Pls.' Supp. Claim Const. Br. 6) While a hydrophilic material, polyvinyl pyrollidone ("PVP") is suggested "as a 'granulating agent' that functions as a binder, nowhere do the inventors indicate that the materials to be used as granulating or binding agents must be hydrophilic, rather than hydrophobic." (Id. at 7)

The parties have not disagreed that the tablet as a whole must have hydrophobic properties to function, even if some of its components do not. In other words, even if the presence of a hydrophilic binding agent may facilitate the ingress of water into otherwise hydrophobic material, Defendant does not dispute that 90 per cent of the tablet is explicitly hydrophobic. ('407

patent at 13, col. 15, Table 2) There is also no dispute that the more rapid disintegration along the A-B axis, where the tablet is designed to split open, is due to the tablet's greater porosity there, relative to the X-Y axis. Defendant has not indicated that the A-B axis is more hydrophilic than the X-Y axis, or that such solubility is responsible for the tablet opening along that axis before it opens anywhere else.

Given this consistency in the intrinsic evidence, there is no evidence at this time that the inventors intended the tablet to rely on its solubility, rather than its porosity, to allow the ingress of water. The parties appear to have a legitimate scientific disagreement regarding whether hydrophilic material must be included within a tablet in order for it to open as the patents describe, or if porosity is sufficient, but the resolution of that issue in either parties' favor would not alter the claim construction analysis here, and the Court does not seek to resolve it at this stage. For the purposes of claim construction, there is no need to rely on extrinsic evidence, including Plaintiffs' expert testimony, particularly given that Dr. Williams explicitly divorces his comments from the patent itself. The Court hereby rejects Defendant's construction of the term "insoluble or poorly water soluble hydrophobic material" and adopts Plaintiffs' construction as the one more faithful to the patents at issue.

b. “[W]herein the coating comprises calcium phosphate salt, glyceryl behenate, and polyvinyl pyrollidone, or mixtures thereof”

Plaintiffs construe the phrase “wherein the coating comprises calcium phosphate salt, glyceryl behenate, and polyvinyl pyrollidone, or mixtures thereof” to mean that the coating comprises all three named excipients or any two of them in combination, “i.e., the coating comprises calcium phosphate salt and glyceryl behenate; calcium phosphate salt and polyvinyl pyrollidone; glyceryl behenate and polyvinyl pyrollidone; or calcium phosphate salt, glyceryl behenate, and polyvinyl pyrollidone.” (Pls.’ Claim Const. Br. 14).

Defendant claims that the plain meaning of the phrase, as written, refers only to a combination of all three excipients, and “[t]he addition of the phrase ‘of mixtures thereof’ merely modifies and permits the differing grades and types of the three required elements . . . .” (Def.’s Claim Const. Br. 18). In other words, all three elements must be present in the coating, and the phrase “mixtures thereof” means that “different types and/or grades of” each element “may optionally be mixed together in lieu of using a single type of that excipient.” (Id. at 19)

The intrinsic evidence supports Plaintiffs’ construction of the term “wherein the coating comprises calcium phosphate salt, glyceryl behenate, and polyvinyl pyrollidone, or mixtures thereof,” and the Court adopts it.

Claim language

The claim language supports Plaintiffs' construction of this term, because Defendants' construction, rather than giving each word meaning and effect, *Bicon*, 441 F.3d at 950, would render part of the term redundant.

Claim 4 of the '407 patent states:

> The tablet of claim 1, wherein the coating comprises calcium phosphate salt, glyceryl behenate, and oyvinyl pyrollidone, or mixtures thereof.

'407 patent at 14, col. 18, ll. 38-40.

Defendant suggests that this claims requires all three elements to be present in the coating, and the phrase "mixtures thereof" means that any type or grades of an excipient may be used, rather than just one particular type or grade. (Def.'s Claim Const. Br. 18) However, the fact that multiple grades of an excipient exist is no reason to assume that the excipient when named would be limited to only one particular grade of the excipient, to the exclusion of others, such that the phrase "or mixtures thereof" would be necessary to specify the inclusion of all grades. As Plaintiffs point out, "mixtures of the chemical species," wherein "mixtures" refers to different types or grades of the species, "are inherently within the definition of" each of the species. (Pls.' Resp. Claim Const. Br. 18) Therefore, even without "or mixtures thereof," the phrase "wherein the coating comprises calcium phosphate salt, glyceryl behenate, and

oyvinyl pyrollidone" would necessarily already include all grades or types of each excipient. Defendants' construction would leave the phrase "or mixtures thereof" superfluous and cannot be correct. Instead, the phrase "or a mixture thereof" as used in the '407 patent specifications more plausibly refers to a combination of two of the three elements listed, consistent with Plaintiffs' construction.

Specifications

Defendant looks for support to the specifications of the '407 patent, which state that "Glyceryl behenate may be present in its mono-, di-, or tri-ester form, or a mixture thereof." ('407 patent at 8, col. 6, ll. 2-3) Because the three elements listed here happen to be grades of glyceryl behenate, the phrase incidentally also specifies a combination of grades; however, where the three elements being modified by "or [a] mixture[s] thereof" are each different excipients, as in the claim term at issue, the phrase indicates a combination of two of the three elements listed, consistent with Plaintiffs' construction, not the inclusion of each element's various grades or types.

Prosecution History

Neither party has indicated that anything in the prosecution history supports or contradicts the claim language or patent specifications with regard to this term.

Having ruled out any ambiguity through the available intrinsic evidence, the Court need not reach any extrinsic evidence, including experts' reports. The Court hereby adopts Plaintiffs' construction of this claim term.

IV. Conclusion

For the reasons stated, the Court adopts Plaintiffs' construction of both claim terms at issue. An appropriate Order accompanies this Opinion.

Date: November ___, 2014

s/ Joseph E. Irenas
JOSEPH E. IRENAS, S.U.S.D.J.