

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

SHIRE DEVELOPMENT, LLC, SHIRE
PHARMACEUTICAL DEVELOPMENT,
INC., COSMO TECHNOLOGIES
LIMITED and NOGRA PHARMA
LIMITED,

Plaintiffs,

v.

Case No: 8:12-cv-1190-T-36AEP

MYLAN PHARMACEUTICALS, INC. and
MYLAN, INC.,

Defendants.

ORDER

This cause comes before the Court upon the claim construction briefs submitted by Plaintiffs Shire Development, LLC, Shire Pharmaceutical Development, Inc., Cosmo Technologies Limited, and Nogra Pharma Limited (collectively, “Shire”), and Defendants Mylan Pharmaceuticals, Inc. and Mylan, Inc. (collectively, “Mylan”) (Docs. 175, 178). Each party responded in opposition to the other’s opening brief (Docs. 194, 192). Following a telephonic status conference with the Court, Doc. 195, Shire submitted a supplement limiting the terms it requests the Court to construe (Doc. 199). On December 22, 2014, the Court held a claim construction hearing (the “Hearing”). *See* Doc. 208; *see also* Transcript of Claim Construction Hearing held Dec. 22, 2014 (Doc. 215) (“Tr.”). After reviewing the parties’ submissions and hearing arguments of counsel, and being fully advised in the premises, the Court now construes the disputed claim terms as set forth herein.

I. BACKGROUND

This patent infringement case concerns United States Patent No. 6,773,720 (the “’720 patent”), which is entitled “Mesalazine Controlled Release Oral Pharmaceutical Compositions” and relates to controlled-release oral pharmaceutical compositions for the treatment of inflammatory bowel diseases, such as Crohn’s disease and ulcerative colitis. *See* ‘720 patent at 1:4-13. As alleged in the Complaint: Plaintiff Shire is the owner of New Drug Application (“NDA”) No. 22-000, approved by the U.S. Food and Drug Administration (“FDA”) for the manufacture and sale of mesalamine delayed release tablets, which are commercialized under the name “Lialda.” Doc. 1 (“Compl.”) ¶ 15. The ‘720 patent is listed by the FDA as covering Lialda. *Id.* ¶ 16. Defendant Mylan has filed an Abbreviated New Drug Application (“ANDA”) seeking FDA approval to manufacture and sell a generic version of Lialda. *Id.* ¶ 17.

Shire alleges that the product that is the subject of Mylan’s ANDA infringes claims 1 and 3 of the ‘720 patent, which recite as follows:

1. Controlled-release oral pharmaceutical compositions containing as an active ingredient 5-amino-salicylic acid, comprising:
 - a) an inner lipophilic matrix consisting of substances selected from the group consisting of unsaturated and/or hydrogenated fatty acid, salts, esters or amides thereof, fatty acid mono-, di- or triglycerid[e]s, waxes, ceramides, and cholesterol derivatives with melting points below 90° C., and wherein the active ingredient is dispersed both in said the lipophilic matrix and in the hydrophilic matrix;
 - b) an outer hydrophilic matrix wherein the lipophilic matrix is dispersed, and said outer hydrophilic matrix consists of compounds selected from the group consisting of polymers or copolymers of acrylic or methacrylic acid, alkylvinyl polymers, hydroxyalkyl celluloses, carboxyalkyl celluloses, polysaccharides, dextrans, pectins, starches and derivatives, alginic acid, and natural or synthetic gums;
 - c) optionally other excipients;

wherein the active ingredient is present in an amount of 80 to 95% by weight of the total composition, and wherein the active ingredient is dispersed both in the lipophilic matrix and in the hydrophilic matrix.

[. . .]

3. Compositions as claimed in claim 1, in the form of tablets, capsules, min[i]tablets.

The parties dispute the scope and meaning of a number of claim terms.

II. LEGAL STANDARD

Claim construction is an issue of law reserved for the district court. *See Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 970-71 (Fed. Cir. 1995) (*en banc*), *affirmed*, 517 U.S. 370 (1996). To ascertain the meaning of claims, the district court uses three primary sources constituting the intrinsic record: (1) the claims, (2) the specification, and (3) the prosecution history. *Id.* at 979.

Claim construction begins with the language of the claims. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005); *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996) (“[w]e look to the words of the claims themselves . . . to define the scope of the patented invention.”). “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*, 415 F.3d at 1312 (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004)); *see also Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257 (Fed. Cir. 1989) (“A claim in a patent provides the metes and bounds of the right which the patent confers on the patentee to exclude others from making, using, or selling the protected invention.”). The words of a claim generally are given the ordinary and customary meaning they have to persons of ordinary skill in the art in question at the time of the invention. *Phillips*, 415 F.3d at 1312-13; *Vitronics*, 90 F.3d at 1582. Moreover, claim terms are presumed to be used consistently throughout

the patent, such that the usage of a term in one claim can often illuminate the meaning of the same term in other claims. *Phillips*, 415 F.3d at 1314-15; *Vitronics*, 90 F.3d at 1582.

While the language of the claims is the first source for interpretation, “[t]he claims, of course, do not stand alone.” *Phillips*, 415 F.3d at 1315. Rather, they are part of a fully integrated written instrument consisting of a specification, of which they are a part. *Id.* (citing *Markman*, 52 F.3d at 978). Accordingly, “claims ‘must be read in view of the specification, of which they are a part.’” *Id.* (quoting *Markman*, 52 F.3d at 979).

The prosecution history is another component of the intrinsic evidence used to supply the proper context for claim construction. *Home Diagnostics, Inc. v. LifeScan, Inc.*, 381 F.3d 1352, 1356 (Fed. Cir. 2004). The prosecution history is comprised of the complete record of the proceedings before the United States Patent and Trademark Office (“PTO”), including prior art cited during examination. *Phillips*, 415 F.3d at 1317; *Vitronics*, 90 F.3d at 1582-83; *Markman*, 52 F.3d at 980. It also includes communications between the examiner and the applicant that may reveal if the applicant limited the invention in the course of prosecution, with the effect of making the claim scope narrower than it would otherwise be. *Phillips*, 415 F.3d at 1317. The history can indicate the inventor’s understanding of the invention, and “whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be.” *Id.*

In addition to intrinsic evidence, courts may also rely on extrinsic evidence, which “consists of all evidence external to the patent and prosecution history.” *Markman*, 52 F.3d at 980. Such evidence typically includes dictionaries, treatises, and testimony of the inventor or experts. *Id.* at 980. Extrinsic evidence, however, is “less significant than the intrinsic record in determining

the legally operative meaning of claim language,” and is appropriate only when the available intrinsic evidence is not dispositive. *Phillips*, 415 F.3d at 1317, 1319.

III. DISCUSSION

The ‘720 patent is currently being litigated in several other courts around the country. *See Shire Development LLC v. Watson Pharmaceuticals, Inc.*, Case No. 12-cv-60862 (S.D. Fla.) (“*Watson*”); *Shire Development LLC v. Osmotica Pharmaceutical Corp.*, Case No. 12-cv-904 (N.D. Ga.) (“*Osmotica*”); *Shire Development LLC v. Cadila Healthcare Ltd.*, Case No. 10-cv-581 (D. Del.). Of these litigations, *Watson* is the most procedurally advanced. In January 2013, the district court in *Watson* issued a claim construction order. *See Shire Development LLC v. Watson Pharmaceuticals*, Case No. 12-cv-60862, 2013 WL 174843 (S.D. Fla. Jan. 17, 2013) (“*Watson I*”). Upon appeal, in an order dated March 2014, the Federal Circuit reversed and remanded the district court’s construction of the terms “inner lipophilic matrix” and “outer hydrophilic matrix.” *See Shire Development, LLC v. Watson Pharmaceuticals, Inc.*, 746 F.3d 1326, 1334 (Fed. Cir. 2014) (“*Watson II*”). The district court in *Osmotica* subsequently issued a claim construction order, relying in part on the discussion in *Watson II*. *See Osmotica*, Doc. 173 (N.D. Ga. Sept. 25, 2014) (Doc. 175-6).

In January 2015, the Supreme Court issue its opinion in *Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831 (2015), holding that a district court’s factual findings incident to claim construction must be reviewed for clear error, and not *de novo*. Consequently, the Supreme Court vacated *Watson II* and remanded the case to the Federal Circuit for further consideration in light of *Teva*. *See Shire Development, LLC v. Watson Pharmaceuticals, Inc.*, Case No. 14-206, 2015 WL 303221 (Jan. 26, 2015).

Because *Watson II* has been vacated, there is no longer any precedent regarding the proper construction of the claim terms of the ‘720 patent that is binding upon this Court. Nevertheless, given

“the importance of uniformity in the treatment of a given patent,” *Markman*, 517 U.S. at 390, the Court will afford due consideration to the reasoning and conclusions of the other courts that have previously opined as to the meaning and scope of the ‘720 patent claim terms.

A. “lipophilic” / “hydrophilic”

Citing the ‘720 patent’s specification, Shire argues that “lipophilic” means “poor affinity towards aqueous fluids.” *See* ‘720 patent at 1:17-20 (“poor affinity towards aqueous fluids; such property being known as lipophilia”). Shire also argues that “hydrophilic” means “having an affinity for water,” as evidenced by the specification’s description of “the presence of strongly hydrophilic groups . . . increas[ing] viscosity inside the hydrated layer,” ‘720 patent at 1:21-26.

Mylan argues that these terms should have the additional limitation that they have “no properties” of the opposite type—i.e., “lipophilic” means “poor affinity towards aqueous fluids *and no hydrophilic properties*,” and “hydrophilic” means “having an affinity for water *and no lipophilic properties*.” In support of its position, Mylan relies on the statement in the now-vacated *Watson II* decision that the lipophilic matrix “cannot have hydrophilic properties,” *Watson II*, 746 F.3d at 1333.

The Court agrees with Shire’s position. The patent’s specification clearly and unambiguously defines “lipophilic” in the manner proposed by Shire. That is therefore the definition that must govern. *See Phillips*, 415 F.3d at 1316 (“the inventor’s lexicography governs”). On the other hand, Mylan’s proposed negative limitations appear nowhere in the intrinsic evidence. Accordingly, it would be improper for the Court to import them. *See Seachange Int’l, Inc. v. C-COR, Inc.*, 413 F.3d 1361, 1376 (Fed. Cir. 2005) (“it is improper to import a limitation into a claim where the limitation has no basis in the intrinsic record”).

Moreover, the reasoning of *Watson II* does not mandate the proposed negative limitations. In *Watson II*, the Federal Circuit stated only that, as a whole, a “*lipophilic matrix* cannot have

hydrophilic properties”—and not, as Mylan is suggesting, that the specific term “lipophilic” necessarily includes having no hydrophilic properties. *See Watson II*, 746 F.3d at 1333 (emphasis added). Indeed, the parties in *Watson* stipulated to construe “lipophilic” according to the construction now proposed by Shire. *See id.* at 1331. And the parties in *Osmotica* likewise agreed to construe “lipophilic” and “hydrophilic” according to the constructions now proposed by Shire. *See Osmotica*, Doc. 173 at 15 n. 14. Having found no reason to depart from those constructions, the Court will, therefore, give these terms the same constructions.

B. “inner lipophilic matrix” / “outer hydrophilic matrix”

The parties have two unrelated disputes concerning the construction of “inner lipophilic matrix” and “outer hydrophilic matrix.” *First*, Mylan argues that the Court should construe the matrices as “compositionally and spatially separate,” whereas Shire argues that the matrices need only be construed as “separate.” *Second*, the parties dispute how the matrices’ lipophilic and hydrophilic properties should be characterized. Specifically, with regard to the “inner lipophilic matrix,” Mylan argues that the matrix must “ha[ve] poor affinity towards aqueous fluids and ha[ve] no hydrophilic properties,” while Shire argues that the matrix need only “itself exhibit[] lipophilic characteristics.” Conversely, with regard to the “outer hydrophilic matrix,” Mylan argues that it must “ha[ve] an affinity for water and no lipophilic properties,” whereas Shire argues that it need only “itself exhibit[] hydrophilic characteristics.”¹

With regard to the first dispute, the Court disagrees with Mylan that the matrices should be given the construction of “compositionally and spatially separate.” Nothing in the intrinsic

¹ It appears that Shire is attempting to combine aspects of its proposed constructions for these terms with its proposed constructions for the “consisting of [substances / compounds]” terms. *See Doc. 175* at 7, 12 (proposing that each of the matrices “consists of *at least one* [lipophilic / hydrophilic] excipient”) (emphasis added). The Court declines to address that proposed limitation in this section, and instead discusses the issue of plurality in Section III.G, *infra*.

evidence supports Mylan's proposed language. Further, even if the now-vacated *Watson II* were binding on the Court, nothing in that opinion mandates such a construction. In *Watson II*, the Federal Circuit simply noted that the matrices are “*defined* by mutually exclusive spatial and compositional characteristics”—not that they are compositionally and spatially “*separate*.” See *Watson II* at 1332. Notably, the language of *Watson II* does not appear anywhere in the '720 patent. Rather, it is clear the Federal Circuit used that language simply as descriptors of other claim limitations.

To the extent that Mylan is attempting to use its construction to reinforce the idea that the matrices have mutually exclusive spatial and compositional characteristics, that is redundant. The plain language of the claims already unambiguously recites mutually exclusive spatial and compositional characteristics—teaching that one matrix is “inner” and “lipophilic,” while the other is “outer” and “hydrophilic.” Mylan's proposed language is therefore superfluous, and would introduce ambiguity into otherwise clear language.

The Court, however, agrees with Shire that the matrices must be construed as “separate.” As the Federal Circuit in *Watson II* made clear, “the logical reading of the claim requires separation between the matrices” as a consequence of the matrices' mutually exclusive spatial and compositional characteristics. See *Watson II* at 1332.

With regard to the second dispute, the Court cannot agree entirely with either parties' proposed construction. Shire's proposed language—that “the matrix itself exhibits [lipophilic / hydrophilic] characteristics”—fails to adequately limit the terms. Not only is it unclear what constitutes a “lipophilic characteristic” or a “hydrophilic characteristic,” a single mixed matrix consisting of both hydrophilic and lipophilic elements would theoretically exhibit both “lipophilic characteristics” as well as “hydrophilic characteristics.” Shire's proposed constructions would

blur the compositional distinctiveness of the matrices, and therefore would not be true to the claim language or align with the patent’s description of the invention. *See Watson II* at 1333.

On the other hand, appending Mylan’s proposed clauses—“and no [hydrophilic / lipophilic] properties”—onto the construction of these terms would only muddle their meanings. As is clear from the construction of the terms “lipophilic” and “hydrophilic,” a matrix that is lipophilic, for example, is necessarily one that is not hydrophilic. Therefore, defining a lipophilic matrix as one that is additionally not hydrophilic is circular and, rather than adding precision, adds only confusion.

Moreover, nothing requires that these terms be given the proposed negative limitations. Mylan appears to have derived the proposed negative limitations from *Watson II*, specifically from the statement that “the matrix that is deemed the ‘lipophilic’ matrix cannot have hydrophilic properties.” *Watson II* at 1333. However, although this language ostensibly supports Mylan’s proposed construction, the Court does not read it so literally. Rather, the Court interprets the Federal Circuit’s language as simply restating the fact that a matrix that has significant amounts of hydrophilic elements mixed with lipophilic elements—and that consequently does not have an *overall* poor affinity towards aqueous fluids—cannot be deemed the “lipophilic” matrix. *See id.* (holding that the district court’s construction was incorrect because “a matrix comprised of only one lipophilic substance and several hydrophilic substances . . . would meet the district court’s construction of ‘lipophilic matrix.’”); *see also id.* at 1331 (“[A] lipophilic matrix’ . . . itself must exhibit lipophilic characteristics. . . . [T]his occurs when ‘the *main component* of the matrix structure’ is lipophilic.”) (quoting ‘720 patent at 1:17-18) (emphasis added). The Court’s interpretation of this language is further supported by the Federal Circuit’s holding, later in the opinion, that a fact finder must resolve whether a composition with “a trace of hydrophilic

molecules in the inner volume” infringes, *id.* at 1333. If a lipophilic matrix literally cannot have *any* hydrophilic properties, then an inner composition with trace amounts of hydrophilic molecules would not infringe as a matter of law.

The Court recognizes that, by declining to impose the proposed negative limitations, it is departing from the constructions given to these terms by the district court in *Osmotica*, Doc. 173 at 15-16. While *Osmotica* is persuasive, the Court, as discussed above, respectfully disagrees that *Watson II*, even if not vacated, would mandate such limitations. Further, after carefully reviewing the *Osmotica* opinion, the Court remains unclear as to what these negative limitations help clarify.

Although the Court cannot agree with either of the parties’ proposed construction in regard to the lipophilic or hydrophilic characteristics of the matrices, the Court nevertheless agrees that the matrices must be given limitations that accurately reflect their lipophilic or hydrophilic characteristics. Fortunately, the Court need not look far, as there are already appropriate and adequately limiting constructions—namely, the constructions given to the terms “lipophilic” and “hydrophilic” in Section III.A, *supra*. The Court, therefore, will construe the matrices’ characteristics in the same manner, which “stays true to the claim language and most naturally aligns with the patent’s description of the invention,” *Phillips*, 415 F.3d at 1316.

Accordingly, the Court independently construes the terms as follows: (1) “inner lipophilic matrix” means “a macroscopically homogeneous structure in all its volume that is separate from the outer hydrophilic matrix and that has poor affinity towards aqueous fluids”; and (2) “outer hydrophilic matrix” means “a macroscopically homogenous structure in all its volume that is separate from the inner lipophilic matrix and that has an affinity for water.”

C. “dispersed”

Shire argues that “dispersed” means “sufficiently mixed to incorporate one substance with another,” while Mylan argues that it need not be construed, or, in the alternative, simply means “incorporated.”

The Court agrees with Mylan that this term requires no construction. *First*, there is no evidence that this word, as used in the ‘720 patent, means anything different from its plain and ordinary meaning. *Second*, nothing in the specification mandates Shire’s proposed construction. Shire notes that the specification states that “[t]he inert lipophilic matrix is reduced into granules by . . . any other known processes which retain the homogeneous *dispersion* . . . of the starting *mixture*,” ‘720 patent at 3:14-17 (emphases added). Nothing in that statement, however, necessarily correlates the act of “dispersion” with the act of “mixing.” *Finally*, even assuming that Shire’s proposed construction is consistent with common usage as reflected in general purpose dictionaries, standing alone, that fails to support that this term need be construed. *See Odorstar Tech., LLC v. SMM Distributors, LLC*, Case No. 13-cv-60136, 2014 WL 641474, at *4 (S.D. Fla. Jan. 28, 2014) (declining to construe a term because “Plaintiff has not made an adequate showing that imposing a dictionary definition would be helpful or necessary to understand the term”).

The Court recognizes that the district courts in *Watson* and *Osmotica* construed this term according to Shire’s proposed construction. *See Watson I* at *6; *Osmotica*, Doc. 119 at 33-35 (*adopted in relevant part by* Doc. 173). The courts in those cases, however, gave such constructions to distinguish the general concept of “dispersion” from the more specific concept of homogeneous distribution. While the Court agrees that “dispersion” does not necessarily mean that the resulting mixture is homogenous, neither of Mylan’s proposed constructions would erroneously redefine “dispersion” as only homogeneous distribution. Indeed, as Shire conceded

at oral argument, there is no appreciable difference between Mylan’s alternative proposed construction (“incorporated”) and Shire’s proposed construction (“sufficiently mixed to incorporate”). *See* Tr. at 118 (Shire’s counsel agreeing that “either one of them is probably acceptable”). And, as Mylan notes, there is no appreciable difference between the usage of “dispersed” and “incorporated” in the ‘720 patent. *See, e.g.*, ‘720 patent at 2:50-53.

At bottom, there simply does not appear to be a bona fide dispute over the scope and meaning of the term “dispersed.” The Court, therefore, declines to apply a construction beyond the plain and ordinary meaning. *See U.S. Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554, 1568 (Fed. Cir. 1997) (“[Claim construction] is not an obligatory exercise in redundancy.”).

D. “other excipients”

Shire argues that “other excipients” means “excipients, not including coatings, other than those substances forming the inner lipophilic matrix and those compounds forming the outer hydrophilic matrix.” Mylan argues that no construction of the term is necessary, but, to the extent clarification is warranted, “other excipients” should mean simply “excipients, other than those substances forming the inner lipophilic matrix and those compounds forming the outer hydrophilic matrix”—thus including any coatings that may be applied.

The Court agrees with Shire’s proposed construction. *First*, the structure of the claims makes clear that the “other excipients” are a part of the “oral pharmaceutical compositions.” ‘720 patent at claim 1. *Second*, the patent makes clear that any coatings are not part of the compositions. Claim 3 recites “[c]ompositions as claimed in claim 1, in the form of tablets, capsules, or min[i]tablets.” *Id.* at claim 3. The specification teaches that “the tablets, capsules, and/or minitables . . . can *optionally* be subjected to known coating processes.” *Id.* at 3:46-51 (emphasis added). These disclosures can therefore be read together as teaching that the compositions

according to the invention are the tablets, capsules, and/or minitablets prior to the application of any coating. Moreover, the examples in the specification are consistent in treating the coating as separate from the compositions. *See, e.g., id.* at 4:34-52 (“[t]he resulting tablets are *then* film coated”) (emphasis added). Therefore, because “other excipients” form a part of the compositions, but coatings do not, coatings are not included in “other excipients.”

Mylan’s arguments to the contrary are unpersuasive. *First*, its argument that the use of the term “comprising” in claim 1 would include *any* excipient (other than those substances and/or compounds constituting the inner lipophilic matrix or outer hydrophilic matrix) is undermined by the patent’s specification, which distinguishes coatings from any other purported excipient. *Second*, the fact that the patent describes the use of a coating material to achieve the controlled release of drugs is not inconsistent with the specification’s teaching that the pharmaceutical composition recited in claim 1 does not include coatings. Indeed, nothing in the ‘720 patent specification or claims defines “other excipient” to include *any* substance that affects the controlled release of the active ingredient. *Finally*, there is no support for Mylan’s assertion that the ‘720 patent includes coating weight in the total composition weight. To the contrary, as discussed in more detail in Section III.E, *infra*, the Court finds that the ‘720 patent actually supports that the weight of any coatings is not included in total composition weight.

E. “% by weight of the total composition”

Shire argues that “% by weight of the total composition” means “% by weight of the inner lipophilic matrix, the outer hydrophilic matrix, optionally other excipients, and the active ingredient.” Mylan argues that no construction is needed, but takes no issue with Shire’s proposed construction except to the extent that it would exclude coatings, if present, from the “total composition.”

The Court agrees with Shire’s position. As discussed in Section III.D, *supra*, the specification makes clear that coatings are not part of the claimed controlled-release oral pharmaceutical compositions. Moreover, the examples in the specification reinforce that the patentee intended to exclude coatings from the weight of the total composition—each example teaches that the final unitary weight is to be calculated *before* any coating is applied. *See, e.g.*, ‘720 patent at 4:9-31 (“After mixing, the final mixture is tabletted to unitary weight The resulting tablets are film-coated”). The reference to “total composition” in Claim 1 therefore excludes the weight of any coatings.

Mylan’s sole assertion—that there is no support in the intrinsic record that the ‘720 patent’s inventors intended to exclude coatings from the weight of the “total composition”—is incorrect. In its response brief, Mylan notes that each of the examples “concludes with film coating.” Doc. 194 at 12. As discussed above, however, that actually supports Shire’s position, as the film coating is applied only *after* each “final mixture” is “tabletted to a unitary weight.” *See, e.g.*, ‘720 patent at 4:9-31. In other words, if the coating is applied only after the composition is tabletted to a unitary weight, the unitary weight of the composition obviously does not include the weight of the coating.

F. “selected from the group consisting of”

Shire argues that the term “selected from the group consisting of” is an “exclusionary term specifying that the element contains only what is expressly set forth in a recited list, but does not exclude substances unrelated to, or outside of the context of said element,” while Mylan argues

that the term needs no construction, or that, to the extent clarification is warranted, means that the selection must be limited “exclusively” to the elements specified in the recited list.²

In principle, the Court agrees with Shire. As both parties acknowledge, although the use of a Markush group “signif[ies] restriction and exclusion,” *Vehicular Techs. Corp. v. Titan Wheel Int’l, Inc.*, 212 F.3d 1377, 1382 (Fed. Cir. 2000), “the restriction is not absolute,” *Conoco, Inc. v. Energy & Env’t Int’l, L.C.*, 460 F.3d 1349, 1360 (Fed. Cir. 2006). Specifically, Markush language “does not limit aspects unrelated to the invention.” *Norian Corp. v. Stryker Corp.*, 363 F.3d 1321, 1331 (Fed. Cir. 2004).

At the claim construction hearing, Mylan generally conceded this aspect of Shire’s proposed construction. *See* Tr. at 106. However, Mylan maintained its objection to Shire’s choice of wording—specifically, the clause “outside of the context of.” *See id.* Having carefully reviewed the parties’ arguments, the Court agrees with Mylan that the inclusion of this clause is inappropriate. To begin with, “outside of the context of” appears nowhere in the Federal Circuit’s language. But more importantly, the Court finds that introducing “outside of the context of” into the construction of the Markush language would create unwarranted ambiguity. Indeed, it is entirely unclear what “the context” of a lipophilic or hydrophilic matrix would be, much less what would be “outside” of that context.

Because the parties dispute the precise scope of the Markush language, the Court must construe it, even though such language is commonly used. *See O2 Micro Int’l Ltd. v. Beyond Innovation Tech. Co., Ltd.*, 521 F.3d 1351, 1362 (Fed. Cir. 2008) (“When the parties present a

² It appears that Mylan has attempted to combine aspects of its proposed construction for this term with aspects of its proposed constructions for the “consisting of substances” / “consisting of compounds” terms. *See* Doc. 178 at 14 (proposing that this term be limited to “two or more of the alternatives”) (emphasis added). The Court declines to rule on that proposed limitation in this section, and instead addresses this aspect in Section III.G, *infra*.

fundamental dispute regarding the scope of a claim term, it is the court’s duty to resolve it.”). Accordingly, the Court will construe the phrase “selected from the group consisting of” as follows: “an exclusionary term specifying that the element contains only what is expressly set forth in a recited list, but does not exclude substances or compounds³ unrelated to said element.”⁴

G. “consisting of substances selected from the group consisting of unsaturated and/or hydrogenated fatty acid, salts, esters or amides thereof, fatty acid mono-, di- or triglycerid[e]s, waxes, ceramides, and cholesterol derivatives with melting points below 90° C.” / “consists of compounds selected from the group consisting of polymers or copolymers of acrylic or methacrylic acid, alkylvinyl polymers, hydroxyalkyl celluloses, carboxyalkyl celluloses, polysaccharides, dextrans, pectins, starches and derivatives, alginic acid, and nature or synthetic gums”

The dispute over these two lengthy terms is simply whether “consisting of substances” and “consisting of compounds” means “one or more” of the substances or compounds, as proposed by Shire, or whether it means “two or more” substances or compounds, as proposed by Mylan.⁵

³ The Court adds “or compounds” to maintain the consistency of the construction as to the “inner lipophilic matrix,” which consists of “substances,” and the “outer hydrophilic matrix,” which consists of “compounds,” *see* ‘720 patent at claim 1.

⁴ The Court recognizes that its construction differs slightly from the construction of the same language given by the district court in *Watson*. However, the Court here is resolving a slightly different dispute—the dispute in *Watson* centered on the exclusionary scope of the phrase, not the appropriateness of the specific language used to describe the scope of the exclusion. *See Watson I* at *8.

⁵ Mylan again appears to be combining aspects of its proposed constructions for these terms with aspects of its proposed construction for the “selected from the group consisting of” term. *See* Doc. 178 at 16 (proposing that these terms be limited to “consisting *exclusively* of two or more [substances or compounds]”) (emphasis added). The Court declines to rule on that proposed limitation in this section, and instead addresses the exclusionary limitation in Section III.F, *supra*.

After careful consideration, the Court agrees with Mylan that these phrases require “two or more” substances or compounds.⁶ Critically, the claim language is written in plural form. The plain and ordinary meanings of the terms thus indicate that “two or more” of the substances or compounds are required. *Accord Leggett & Platt, Inc. v. Hickory Springs Mfg. Co.*, 285 F.3d 1353, 1357 (Fed. Cir. 2002) (recitation of the phrase “support wires” requires more than one support wire).

Further, there is no convincing reason to depart from the terms’ plain and ordinary meanings. Although a patentee’s use of a plural term does not necessarily require an interpretation of “two or more” if such usage serves merely to achieve grammatical consistency, *see In re Omeprazole Patent Litig.*, 84 Fed. App’x 76, 80 (Fed. Cir. 2003), such concerns do not arise here. Shire notes that the specific substances and compounds listed in the Markush groups are recited in plural form. The claim language, however, makes clear that the Markush groups’ use of the plural form does not correspond grammatically to the preceding clause reciting the selection of “*substances*” or “*compounds*” from those particular groups.

Further, nothing in the intrinsic evidence can be interpreted as a clear expression of the patentees’ intention to redefine the plural version of these terms to mean “one or more.” Shire notes that the specification describes, in one passage, forming the matrices from “one or more” substances or compounds. *See* ‘720 patent at 2:50-59 (“the active ingredient is first inglobated in a low melting excipient or mixture of excipients”). This single reference to the singular form, however, fails to plainly convey an intent to redefine the claim terms. *See Merck & Co., Inc. v. Teva Pharmaceuticals USA, Inc.*, 395 F.3d 1364, 1370 (Fed. Cir. 2005) (“The patentee’s

⁶ The Court notes that this construction is the same as that of the district court’s construction in *Osmotica*, *see Osmotica*, Doc. 173 at 5-8, but is different from that of the district court’s construction in *Watson*, *see Watson I* at *7.

lexicography must . . . appear with reasonable clarity, deliberateness and precision before it can affect the claim.”) (quotation marks and citations omitted). Indeed, as noted by Mylan, each of the subsequent examples describes using *two* lipophilic excipients and *two* hydrophilic excipients. *See, e.g.*, ‘720 patent at 4:32-52.

Even if, as Shire argues, nothing in the specification attaches significance to using two or more substances or compounds (as opposed to using only one substance or compound), the specification is, at most, ambiguous with regard to whether the claim terms are used in a manner inconsistent with their ordinary and customary meanings. This arguable ambiguity is insufficient to overcome the heavy presumption in favor of the plain and ordinary meaning. *See W.E. Hall Co., Inc. v. Atlanta Corrugating, LLC*, 370 F.3d 1343, 1353 (Fed. Cir. 2004).⁷ Accordingly, the Court must afford these terms their plain and ordinary plural meanings.

IV. CONCLUSION

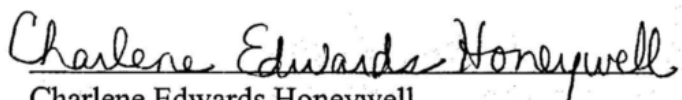
The disputed claim terms are hereby **CONSTRUED** as follows:

1. **“lipophilic”** means “poor affinity towards aqueous fluids”;
2. **“hydrophilic”** means “having affinity for water”;
3. **“inner lipophilic matrix”** means “a macroscopically homogeneous structure in all its volume that is separate from the outer hydrophilic matrix and that has poor affinity towards aqueous fluids”;

⁷ The Court also rejects Shire’s attempt to rely on the allegedly inconsistent position taken by Mylan in certain pre-litigation documents, *see* Doc. 175 at 20. Mylan’s prior informal interpretation of claim language has no legal force and is not evidence, either intrinsic or extrinsic.

4. **“outer hydrophilic matrix”** means “a macroscopically homogenous structure in all its volume that is separate from the inner lipophilic matrix and that has an affinity for water”;
5. **“dispersed”** shall be given its plain and ordinary meaning;
6. **“other excipients”** means “excipients, not including coatings, other than those substances forming the inner lipophilic matrix and those compounds forming the outer hydrophilic matrix”;
7. **“% by weight of the total composition”** means “% by weight of the inner lipophilic matrix, the outer hydrophilic matrix, optionally other excipients, and the active ingredient”;
8. **“selected from the group consisting of”** means “an exclusionary term specifying that the element contains only what is expressly set forth in a recited list, but does not exclude substances or compounds unrelated to said element”;
9. **“consisting of substances . . .”** means “consisting of two or more substances . . .”;
10. **“consisting of compounds . . .”** means “consisting of two or more compounds . . .”.

DONE AND ORDERED in Tampa, Florida on March 23, 2015.


Charlene Edwards Honeywell
United States District Judge

Copies to:
Counsel of Record and Unrepresented Parties, if any