IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

COSMO TECHNOLOGIES LIMITED, VALEANT PHARMACEUTICALS INTERNATIONAL, and VALEANT PHARMACEUTICALS LUXEMBOURG S.A.R.L.,	:	
Plaintiffs,	:	C.A. No. 15-164-LPS
v.	:	
ACTAVIS LABORATORIES FL, INC.,	:	
Defendant.	:	
COSMO TECHNOLOGIES LIMITED, VALEANT PHARMACEUTICALS INTERNATIONAL, and VALEANT PHARMACEUTICALS LUXEMBOURG S.A.R.L.,	:	
Plaintiffs,	:	C.A. No. 15-193-LPS
v.	:	
ALVOGEN PINE BROOK, LLC.,	:	
Defendant.	:	

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MEMORANDUM OPINION

September 7, 2016
Wilmington, Delaware

STARK, U.S. District Judge:

Plaintiffs Cosmo Technologies Limited, Valeant Pharmaceuticals International, and Valeant Pharmaceuticals Luxembourg S.A.R.L. ("Plaintiffs") filed suit against Defendants Actavis Laboratories FL, Inc. and Alvogen Pine Brook, LLC, ("Defendants") alleging infringement of U.S. Patent Nos. 7,410,651 (the "'651 patent"), RE 43,799 (the "'799 patent"), 8,784,888 (the "'888 patent"), 8,293,273 (the "'273 patent"), and 9,320,716 (the "'716 patent").[1] The patents are directed to formulations containing budesonide, which are used to treat ulcerative colitis. Presently before the Court is the construction of disputed terms of the patents' claims.

The parties submitted technology tutorials (D.I. 65 and 69) and claim construction briefs (D.I. 66, 70, 75, 80, 138, 139, 145, and 147). The Court held a claim construction hearing on July 11, 2016. (*See* D.I. 163 ("Tr."))

I. LEGAL STANDARDS

The ultimate question of the proper construction of a patent is a question of law. *See Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 837 (2015) (citing *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 388-91 (1996)). "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) (internal quotation marks omitted). "[T]here is no magic formula or catechism for conducting claim construction." *Id.* at 1324. Instead, the court is free to attach the appropriate weight to appropriate sources "in light of the

[1]Plaintiffs also first sued Par Pharmaceutical, Inc. *See Cosmo Techs. Ltd. v. Par Pharm., Inc.*, C.A. No. 1:15-cv-00116-LPS. That case has since settled. (*See* D.I. 160) However, all of the docket entries cited in this Memorandum Opinion were filed in the *Par* case, so each D.I. reference herein is to C.A. No. 15-116, unless otherwise noted.

statutes and policies that inform patent law." *Id.*

"[T]he words of a claim are generally given their ordinary and customary meaning . . . [which is] the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Id.* at 1312-13 (internal citations and quotation marks omitted). "[T]he ordinary meaning of a claim term is its meaning to the ordinary artisan after reading the entire patent." *Id.* at 1321 (internal quotation marks omitted). The patent 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 Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996).

While "the claims themselves provide substantial guidance as to the meaning of particular claim terms," the context of the surrounding words of the claim also must be considered. *Phillips*, 415 F.3d at 1314. Furthermore, "[o]ther claims of the patent in question, both asserted and unasserted, can also be valuable sources of enlightenment . . . [b]ecause claim terms are normally used consistently throughout the patent . . . ." *Id.* (internal citation omitted).

It is likewise true that "[d]ifferences among claims can also be a useful guide . . . . For example, the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." *Id.* at 1314-15 (internal citation omitted). This "presumption is especially strong when the limitation in dispute is the only meaningful difference between an independent and dependent claim, and one party is urging that the limitation in the dependent claim should be read into the independent claim." *SunRace Roots Enter. Co., Ltd. v. SRAM Corp.*, 336 F.3d 1298, 1303 (Fed. Cir. 2003).

It is also possible that "the specification may reveal a special definition given to a claim

term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor's lexicography governs." *Phillips*, 415 F.3d at 1316. It bears emphasis that "[e]ven when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction." *Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1372 (Fed. Cir. 2014) (quoting *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004)) (internal quotation marks omitted).

In addition to the specification, a court "should also consider the patent's prosecution history, if it is in evidence." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370 (1996). The prosecution history, which is "intrinsic evidence," "consists of the complete record of the proceedings before the PTO [Patent and Trademark Office] and includes the prior art cited during the examination of the patent." *Phillips*, 415 F.3d at 1317. "[T]he 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." *Id.*

In some cases, "the district court will need to look beyond the patent's intrinsic evidence and to consult extrinsic evidence in order to understand, for example, the background science or the meaning of a term in the relevant art during the relevant time period." *Teva*, 135 S. Ct. at 841. 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. For instance, technical dictionaries can assist the court in determining the meaning of a

term to those of skill in the relevant art because such dictionaries "endeavor to collect the accepted meanings of terms used in various fields of science and technology." *Phillips*, 415 F.3d at 1318. In addition, expert testimony can be useful "to ensure that the court's understanding of the technical aspects of the patent is consistent with that of a person of skill in the art, or to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field." *Id.* Nonetheless, courts must not lose sight of the fact that "expert reports and testimony [are] generated at the time of and for the purpose of litigation and thus can suffer from bias that is not present in intrinsic evidence." *Id.* Overall, while extrinsic evidence "may be useful" to the court, it is "less reliable" than intrinsic evidence, and its consideration "is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." *Id.* at 1318-19. Where the intrinsic record unambiguously describes the scope of the patented invention, reliance on any extrinsic evidence is improper. *See Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1308 (Fed. Cir. 1999) (citing *Vitronics*, 90 F.3d at 1583).

Finally, "[t]he construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." *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) (quoting *Modine Mfg. Co. v. U.S. Int'l Trade Comm'n*, 75 F.3d 1545, 1550 (Fed. Cir. 1996)).

II. CONSTRUCTION OF DISPUTED TERMS[2]

A. "matrix"[3]

Plaintiffs a macroscopically homogeneous structure in all its volume
Defendants a homogeneous structure in all its volume in which an ingredient or ingredients are dispersed
Court a homogeneous structure in all its volume

The parties agree that a matrix is a "homogeneous structure in all its volume." They disagree about whether the matrices of the patents-in-suit must have an ingredient or ingredients dispersed within them. Plaintiffs argue that the concept of a matrix generally does not include such a requirement and that they do not believe one should be included here. (*See* Tr. at 39) Defendants contend that in the context of the disputed claim term the Court should construe "matrix" as a structure in which an ingredient is or ingredients are dispersed because the asserted claims impose such a requirement.

Defendants may be correct as to the overall scope of the claims, but this does not mean that a dispersion requirement must be included in the "matrix" term. "Extracting a single word from a claim divorced from the surrounding limitations can lead construction astray." *IGT v. Bally Gaming Int'l, Inc.*, 659 F.3d 1109, 1117 (Fed. Cir. 2011). To the extent the claims are

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[2]Plaintiffs and Defendant Alvogen previously disputed the meaning of "hydrophilic first matrix," which appears in claims 1-13 of the '943 patent. The parties subsequently stipulated that the term would have the same construction as the "hydrophilic matrix" portion of the term "outer hydrophilic matrix," discussed below. (*See* C.A. No. 15-193-LPS D.I. 153; *see also* Tr. 35-38) Hence, the Court will not address "hydrophilic first matrix" separately.

[3]This term appears in claims 1-4 and 6-9 of the '651 patent and claims 1-7 of the '799 patent.

concerned principally (or even exclusively) with structures in which ingredients are dispersed, it is not the word "matrix" that imposes this limitation. Rather, other claim language establishes whether and what (if any) ingredients are dispersed in the matrix. *See, e.g.* '651 pat. col. 8:1-14 (claiming composition consisting essentially of "a lipophilic matrix . . . in which ***the active ingredient is at least partially inglobulated***; . . . an amphiphilic matrix; . . . and an outer hydrophilic matrix consisting of hydrogel forming-compounds in which the lipophilic matrix and the amphiphilic matrix are dispersed . . .") (emphasis added). For this reason, the Court will not construe "matrix" as inherently including an ingredient or ingredients dispersed within its structure – although separate limitations in some of the claims may impose such a requirement.

The parties also disagree about whether the claimed matrices must be ***macroscopically*** homogeneous. The specifications of the patents in which this term appears describe compression of a lipophilic and amphiphilic matrix to yield "a macroscopically homogeneous structure in all its volume, namely a matrix containing a dispersion of lipophilic granules in a hydrophilic matrix." *See, e.g.* '651 pat. col. 4:45-51. Although this statement indicates that a matrix ***may*** be macroscopically homogeneous, it does not specify that the claimed matrices ***must*** be macrosopically homogeneous, or that macroscopic homogeneity is an inherent property of matrices in general. Absent implicit or explicit lexicography or disavowal, the Court may not read limitations from the specification into the claims. *See Thorner v. Sony Computer Entm't Am. LLC*, 669 F.3d 1362, 1366-68 (Fed. Cir. 2012). Thus, the Court will not limit the claims to "macroscopically" homogeneous structures.

Defendants' extrinsic evidence – including an expert declaration and dictionary definitions – does not alter the outcome.

B. "macroscopically homogeneous composition"[4] and "macroscopically homogeneous structure"[5]

Plaintiffs a composition of uniform structure throughout, as observed by the naked eye
Defendants a matrix containing a dispersion of lipophilic granules containing active ingredient, in a hydrophilic matrix
Court a composition of uniform structure throughout, as observed by the naked eye

The parties disagree about whether these terms are limited to one particular type of composition or structure that is described in the specification. As already noted, the Court may not read limitations from the specification into the claims absent express or implicit lexicography or disavowal. A patentee need not use "explicit[ly] definitional" language to express its intent to limit claim scope. *SciMed Life Sys. Inc. v. Advanced Cardiovascular Sys. Inc.*, 242 F.3d 1337, 1344 (Fed. Cir. 2001). However, any implicit definition or disclaimer must be "so clear that it equates to an explicit one." *Thorner*, 669 F.3d at 1638.

Defendants contend that the patent defines "macroscopically homogeneous structure" as "a matrix containing a dispersion of lipophilic granules in a hydrophilic matrix." In support of their position, Defendants point to language in the specification that describes a process of "compression of [a] mixture of lipophilic and/or amphiphilic matrix, hydrogel-forming compound and, optionally, active ingredient not inglobulated in the lipophilic matrix, yield[ing] a macroscopically homogeneous structure in all its volume, ***namely***, a matrix containing a

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[4]This term appears in claim 1 the '888 patent.

[5]This term appears in claims 1, 12, 22, and 24-26 of the '716 patent.

dispersion of lipophilic granules in a hydrophilic matrix." '888 pat. col. 5:5-10; '716 pat. col. 5:5-10 (emphasis added).

It is apparent that the words "matrix containing a dispersion of lipophilic granules in a hydrophilic matrix" describe a particular macroscopically homogeneous structure that results from compressing a particular mixture as described in the patent specification. But the specification nowhere suggests that these words define the term "macroscopically homogeneous structure" itself. As such, the term "macroscopically homogeneous structure" will be given its plain and ordinary meaning, which is set forth in Plaintiffs' proposed construction.[6]

C. "outer hydrophilic matrix"[7]

Plaintiffs a matrix with an affinity for water within which other matrices are incorporated
Defendants a matrix with the overall property of having an affinity for water that is located outside separate, inner matrices
Court a matrix with an affinity for water within which other matrices are incorporated

The parties agree that the claimed matrix is hydrophilic, meaning that it has an affinity for water. (D.I. 66 at 15; D.I. 70 at 17) Defendants ask the Court to specify that the matrix has an

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[6]With respect to the '716 patent, Defendants argue that during prosecution the patentee disavowed structures other than those described in the specification. However, the patentee distinguished the claimed invention from a prior art patent on the ground that the prior art included no description of structure, whereas the invention of the '716 patent includes a "controlled release mechanism in the form of a macroscopically homogeneous structure." (D.I. 139 Exh. 4 at 4) Because Defendants have not shown that controlled release requires "a matrix containing a dispersion of lipophilic granules containing active ingredient, in a hydrophilic matrix," the Court is not persuaded that the patentee's statements about controlled release limit the claims to the embodiment set forth in Defendants' construction.

[7]This term appears in claim 1 of the '651 patent and claim 1 of the '799 patent.

affinity for water "overall." The Court agrees with Defendants that the term "hydrophilic" modifies "matrix" (i.e., that the matrix itself must have the property of hydrophilicity). (*See* D.I. 70 at 17; Tr. at 62-63) But adding the term "overall" is not necessary to make this clear, so the Court will not do so.

The parties also disagree about the meaning of the modifier "outer." Plaintiffs argue that "outer" merely conveys that the hydrophilic matrix is the "dominant presence" in the claimed formulations, and that the claims do not require the inner and outer matrices to have a particular defined, spatial relationship. (Tr. 52, 71-73, 80-84) Defendants argue that the inner and outer matrices are each a single, distinct geometry, with the outer matrix subsuming the inner matrix. (Tr. at 63-66)

In support of their position that the inner and outer matrices have defined, separate geometries, Defendants cite the Federal Circuit's decision in *Shire Dev. LLC v. Watson Pharm., Inc.*, 787 F.3d 1359 (Fed. Cir. 2015). (*See* Tr. at 63-66) There, the Federal Circuit construed terms of a patent (not one of the patents-in-suit here) claiming pharmaceutical compositions having "inner" and "outer" matrices. *Id* at 1367-68. The Federal Circuit found that the patent involved in *Shire* used these terms to specify that the relationship between the inner and outer matrices was that of an "inner volume . . . separate from the outer volume." *Id*. at 1367.

The patents-in-suit here, by contrast, do not require the claimed outer matrices to embody a single volume that is distinct from, or has a defined spatial relationship with, the other matrices. The patents' claims describe the outer hydrophilic matrix as "consisting of hydrogel forming compounds in which the lipophilic matrix and amphiphilic matrix are dispersed." *See*, '651 pat. col. 8:10-14; '799 pat. col. 12:7-9. The specification refers to embodiments prepared by mixing

"matrix granules" of the lipophilic and amphiphilic matrices with "hydrophilic excipients" until the matrices are "homogeneously dispersed" within the hydrophilitic substance. *See* '799 pat. col. 7:33-55; *see also* 1:19-24. The specification describes how such a mixture may form a "macroscopically homogeneous structure in all its volume, namely . . . a dispersion of lipophilic granules in a hydrophilic matrix." '799 pat. col. 4:50-56. These examples do not refer to "two matrices with a defined spatial relationship," wherein the outer matrix is located outside separate, inner matrices, each having a single, defined geometry. *See Shire*, 787 F.3d. at 1368. Therefore, the Court will adopt Plaintiffs' proposed construction, which more broadly describes a dominant matrix in which other matrices are incorporated.

D. "lipophilic matrix"[8]

Plaintiffs a matrix with a poor affinity towards aqueous fluids
Defendants a matrix with the overall property of having an affinity for lipids
Court a matrix having an affinity for lipids and a poor affinity towards aqueous fluids

At the claim construction hearing, the parties agreed it is appropriate to construe "lipophilic matrix" as "a matrix having an affinity for lipids with a poor affinity towards aqueous fluids." (Tr. at 58-59) Their only remaining dispute with respect to this term pertains to whether "lipophilic matrix" should be described as having the "overall property" of being lipophilic. Defendants argue that the words "overall property" clarify that the matrix ***itself***, and not just some substances within the matrix, must have the property of being lipophilic. (*See* Tr. at 62-63

[8]This term appears in claims 1, 3, 4 and 6 of the '651 patent and claims 1, 3, 4, and 6 of the '799 patent.

(discussing Defendants' view of meaning of "overall property" using the term "hydrophilic" as an example)) As noted above, the Court agrees with Defendants that "hydrophilic" modifies "matrix" – so, here, the matrix itself must have the quality of being lipophilic – but, as also already noted, the Court does not believe the words "overall property" are required in order to convey this meaning.

E. "amphiphilic matrix"[9]

Plaintiffs a matrix with substance(s) that have both an affinity for lipids and an affinity for water
Defendants a matrix with the overall properties of having an affinity for lipids and having an affinity for water
Court a matrix containing amphiphilic substances, and as a result having both an affinity for lipids and an affinity for water

At the claim construction hearing, the parties agreed that the amphiphilic matrices of the claims contain amphiphilic substances. (Tr. at 87-88, 90-91) They further agreed that the term "amphiphilic" modifies "matrix" as a whole, meaning that the matrix itself has both an affinity for lipids and an affinity for water. (*Id.*) Finally, there is no dispute that the matrix has amphiphilic properties ***because*** it contains amphiphilic substances (as opposed to, for example, having such properties because it contains both hydrophilic and lipophilic substances in equal amounts).[10] (Tr. at 90-92) The Court has construed the claim term accordingly.

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[9]This term appears in claims 1, 2, and 5 of the '651 patent and claims 1, 2, and 5 of the '799 patent.

[10]Plaintiff argues that the Court must construe "amphiphilic matrix" in a way that specifies that the matrix has amphiphilic properties ***due to its*** amphiphilic ingredients, in order to clarify that the matrix is not comprised of just lipophilic and hydrophilic substances (and not

F. "melting point"[11]

Plaintiffs the temperature at which a solid begins to change from a solid to a liquid
Defendants the temperature at which solid and liquid phases of a compound are at equilibrium
Court the temperature at which solid and liquid phases of a compound are at equilibrium

The parties agree that the patents-in-suit do not define "melting point." Each contends that its proposed construction is the plain and ordinary meaning of the term to a person having ordinary skill in the art. Each also submitted expert reports and dictionary definitions in support of its construction.

The intrinsic record does not define "melt" and does not favor one party's proposed construction over the other's. Plaintiffs highlight the fact that the specification lists as examples of lipophilic compounds – the compounds whose melting point is specified in the claims – only mixtures that melt over a range of temperatures. (Tr. at 91-96) Plaintiffs' expert opines that, because the claims refer to the "melting point" of substances that in fact melt over a range of temperatures, a person of ordinary skill would understand that the patents' "focus with respect to the claimed melting point(s) is when the melting transition begins." (*Id.* at ¶¶ 22, 23) Plaintiffs' expert further finds the specifications' references to "melting or softening" to provide additional

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amphiphilic substances) that together cause the matrix to exhibit amphiphilic properties overall. The Court is persuaded that this specificity helps to clarify this term and includes it in its construction. The absence of such specificity in the Court's construction of the lipophilic and hydrophilic matrix terms should not be understood as a determination that the claims do not require lipophilic and hydrophilic matrices to have lipophilic and hydrophilic properties resulting from their lipophilic or hydrophilic ingredients. That issue has not been put before the Court.

[11]This term appears in claim 1 of the '651 patent and claim 1 of the '799 patent.

support for Plaintiffs' construction, because a person of ordinary skill in the art would know that "[i]mpure compounds and mixtures generally melt over a range of temperatures, and may first soften." (D.I. 68 ¶ 21) As further support, Plaintiffs cite a number of general scientific dictionaries that describe "melting point" as the beginning of the transition from solid to liquid phase. (*Id.* at ¶ 24) Plaintiffs argue that these dictionaries are more relevant than those Defendants cite because Defendants' dictionaries refer to melting points of pure substances, each of which melt at a single temperature. (Tr. at 96-97)

Defendants' expert contends that the specialized dictionaries on which Defendants rely provide the definition of melting point a person of ordinary skill in the art of chemistry and pharmaceutical science would understand to be used in the patents-in-suit: the temperature at which a compound that is melting would reach an equilibrium between its solid and liquid phases. (D.I. 71 at ¶ 35) While Defendants' expert agrees that the claimed compounds may change phase over a range of temperatures, he contends that a person of ordinary skill in the art would be able to determine the equilibrium point of the solid and liquid phases for the claimed compounds – so there would still be a single "melting point." (*Id.* ¶ 35) He further contends that a person of ordinary skill in the art would not view the term "melting point" differently just because it is mentioned alongside "softening." Rather, the expert explains, a person of ordinary skill in the art would understand that "softening" is a separate term and refers to a different way in which materials change from solid to liquid phase, and that "melting" and "softening" occur in different types of substances. (D.I. 81 at ¶ 5) Thus, the patents' references to "melting or softening" should be read as "melting or softening – whichever would occur in this material." (*See id.* at ¶ 6)

Based on the extrinsic evidence – which the Court reads in light of the intrinsic evidence (and only after finding the intrinsic evidence lacks sufficient clarity to point to the proper construction) – the Court finds that "melting point" is a term of art in chemistry and to pharmaceutical scientists. The Court is persuaded that the specialized dictionaries cited by the Defendants reflect the plain and ordinary meaning of "melting point" to a person of ordinary skill in the art at the time of the invention.[12]

Defendants' "equilibrium" definition is consistent with the intrinsic record. The parties agree that a compound may "melt" over a range of temperatures, and it is undisputed that a person of ordinary skill in the art could determine the melting point of the claims' "lipophilic compounds." Further, the patents' use of the terms "soften" and "melt" in the alternative (e.g., "soften or melt" or "soften and/or melt") suggests that the patentee understood melting and softening to be separate processes. *See, e.g.*, '651 pat. col. 3:30-35, 4:4-14; '799 pat. col. 3:39-45, 4:11-21.

Thus, the Court credits Defendants' expert's position that, while a layperson may understand "softening" as the first step in the process of "melting," a person of ordinary skill in the art would understand that softening and melting are two distinct forms of phase change. The Court adopts Defendants' proposed construction.

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[12]The parties generally agree that a person of ordinary skill in the art is an individual with a formal education in pharmaceutical science or a related field, along with either an advanced degree or work experience. (*See* D.I. 68 ¶ 18 and D.I 71 ¶ 22)

G. "lipophilic/amphiphilic matrix"[13]

Plaintiffs lipophilic or amphiphilic
Defendants The term is indefinite
Court lipophilic and amphiphilic matrices

Defendants contend that this term is indefinite, arguing that a person of ordinary skill in the art reading the specification and claims would not know whether "lipophilic/amphiphilic" refers to "lipophilic ***and*** amphiphilic," "lipophilic ***or*** amphiphilic," or "***both*** lipophilic ***and*** amphiphilic."

"[I]n assessing definiteness, claims are to be read in light of the patent's specification and prosecution history." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2128 (2014). A patent claim is only indefinite if, "viewed in light of the specification and prosecution history, [it fails to] inform those skilled in the art about the scope of the invention with reasonable certainty." *Id.* at 2129.

Here, a person of ordinary skill in the art reading the term "lipophilic/amphiphilic" in its full context would know that the term means "lipophilic ***and*** amphiphilic." The intrinsic evidence provides such a person with at least reasonable certainty.

Claim 1 recites a lipophilic matrix, an amphiphilic matrix, and an outer hydrophilic matrix in which the lipophilic and amphiphilic matrices are dispersed. The claim then describes the active ingredient as dispersed in both the hydrophilic matrix and the lipophilic/amphiphilic

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[13]This term appears in claim 1 of the '799 patent.

matrix. This context suggests that "lipophilic/amphiphilic matrix" refers collectively to the two inner matrices that are dispersed within the outer hydrophilic matrix. The specification, which repeatedly refers to lipophilic and amphiphilic inner matrices as both being dispersed within the outer hydrophilic matrix, provides further support for this construction. *See, e.g.*, '799 pat. col. 3:4-12. The parties have not cited any special knowledge or technical understanding that would lead a person of ordinary skill in the art to interpret this term any differently. Thus, the Court construes the term as "lipophilic and amphiphilic matrices."

III. CONCLUSION

The Court will construe the disputed claim terms as described above. An appropriate Order follows.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

COSMO TECHNOLOGIES LIMITED, VALEANT PHARMACEUTICALS INTERNATIONAL, and VALEANT PHARMACEUTICALS LUXEMBOURG S.A.R.L.,	:	
Plaintiffs,	:	
v.	:	C.A. No. 15-164-LPS
ACTAVIS LABORATORIES FL, INC.,	:	
Defendant.	:	
COSMO TECHNOLOGIES LIMITED, VALEANT PHARMACEUTICALS INTERNATIONAL, and VALEANT PHARMACEUTICALS LUXEMBOURG S.A.R.L.,	:	
Plaintiffs,	:	
v.	:	C.A. No. 15-193-LPS
ALVOGEN PINE BROOK, LLC.,	:	
Defendant.	:	

ORDER

At Wilmington, this **7th** day of **September, 2016**:

For the reasons set forth in the Memorandum Opinion issued this date,

IT IS HEREBY ORDERED that the disputed claim terms in U.S. Patent Nos. 7,410,651 ("'651 patent"), RE 43,799 ("'799 patent"), 8,784,888 ("'888 patent"), 8,293,273 ("'273 patent"), and 9,320, 716 ("'716 patent") are construed as follows:

Claim Term	Court's Construction
matrix ['651 patent, claims 1-4 and 6-9; '799 patent, claims 1-7]	a homogeneous structure in all its volume
macroscopically homogeneous composition / macroscopically homogeneous structure ['888 patent, claim 1; '716 patent, claims 1, 12, 22, 24-26]	a composition of uniform structure throughout, as observed by the naked eye
outer hydrophilic matrix ['651 patent, claim 1; '799 patent, claim 1]	a matrix with an affinity for water within which other matrices are incorporated
lipophilic matrix ['651 patent, claims 1, 3, 4, 6; '799 patent, claims 1, 3, 4, 6]	a matrix having an affinity for lipids and a poor affinity towards aqueous fluids
amphiphilic matrix ['651 patent, claims 1, 2, 5; '799 patent, claims 1, 2, 5]	a matrix containing amphiphilic substances, and as a result having an affinity for lipids and an affinity for water
melting point ['651 patent, claim 1; '799 patent, claim 1]	the temperature at which solid and liquid phases of a compound are at equilibrium
lipophilic/amphiphilic matrix ['799 patent, claim 1]	lipophilic and amphiphilic matrices

HON. LEONARD P. STARK
UNITED STATES DISTRICT JUDGE