IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

VALEANT PHARMACEUTICALS INTERNATIONAL, SALIX PHARMACEUTICALS LTD. and COSMO TECHNOLOGIES LIMITED,	:	
Plaintiff,	:	
v.	:	C.A. No. 18-1288-LPS
ACTAVIS LABORATORIES FL., INC., ACTAVIS PHARMA, INC., TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES LTD.,	:	
Defendants.	:	

Jack B. Blumenfeld and Michael Flynn, MORRIS, NICHOLS, ARSHT & TUNNELL LLP, Wilmington, DE
Thomas P. Steindler, William Rose, and Christopher M. Bruno, McDERMOTT WILL & EMERY, LLP, Washington, D.C.
Counsel for Plaintiffs Valeant Pharmaceuticals International and Salix Pharmaceuticals
Gray Frischling and Yite John Liu, IRELL & MANELLA, LLP, Los Angeles, CA
Counsel for Plaintiff Cosmo Technologies

John C. Phillips, Jr. and David A. Bilson, PHILLIPS, GOLDMAN, MCLAUGHLIN & HALL, P.A., Wilmington, DE
Elizabeth J. Holland, GOODWIN PROCTER, LLP, New York, NY
Samuel Sherry, John T. Bennett, and Christie Larochelle, GOODWIN PROCTER, LLP, Boston, MA
Counsel for Defendants Actavis Laboratories FL, Inc., Actavis Pharma, Inc., Teva Pharmaceuticals USA, Inc., and Teva Pharmaceuticals Industries Limited

MEMORANDUM OPINION

August 2, 2019
Wilmington, Delaware

STARK, U.S. District Judge:

Plaintiffs Valeant Pharmaceuticals International, Salix Pharmaceuticals Ltd., and Cosmo Technology Ltd. ("Plaintiffs") filed suit against Actavis Laboratories Fl., Inc., Actavis Pharma Inc., Teva Pharmaceuticals USA Inc., and Teva Pharmaceutical Industries, Ltd. ("Defendants") on August 22, 2018, alleging infringement of U.S. Patent Nos. 10,052,286 (the "'286 patent"), 10,064,878 (the "'878 patent"), 10,105,374 (the "'374 Patent"), 10,143,698 (the "'698 Patent"), 10,154,964 (the "'964 Patent"), and 10,172,799 (the "'799 Patent") (collectively "the patents-in-suit"). (D.I. 1) These patents may be grouped into the "Villa I patents" (the '374, '878, and '698 patents) claiming priority to a 1999 application,[1] and the "Villa II patents" (the '286, '964, and '799 patents) claiming priority to a 2011 application. (D.I. 143 at 1 n.1) The Villa I and Villa II patents claim "controlled release budesonide formulations with a tablet core inside a gastro-resistant coating." (*Id.* at 6) Closely-related patents were the subject of litigation in *Cosmo Technologies Limited et al v. Alvogen Pine Brook LLC*, C.A. Nos. 16-164-LPS, 15-193-LPS (D. Del. 2017) ("*Uceris I*"). (*Id.* at 2) "All six patents [currently in-suit] share the same set of inventors and the same assignee, and their specifications contain identical disclosures of Cosmo's multi-matrix budesonide formulation" as the patents-in-suit in *Uceris I.* (*Id.* at 8)

The parties dispute whether the terms "matrix," "mixture," and "compressed blend" require a homogenous system, and whether the term "controls the release kinetics" excludes contribution from "physically discrete elements." Significantly, the parties contest the persuasiveness of the Court's *Uceris I* decision (construing similar terms) and certain post-allowance prosecution statements made by applicants following the Court's decision in *Uceris I*, finding non-infringement.

[1] Defendants state that the Villa I patents' priority date is June 9, 2000 (D.I. 143 at 8), but the difference of one year does not appear to affect claim construction.

Consolidated claim construction briefing was submitted on June 17, 2019, an amended version was filed on June 27, 2019 (D.I. 143) ("CC"), and the Court held a claim construction hearing on July 2, 2019 (D.I. 147) ("Tr.").

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) (citation and 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 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)) (alteration in original) (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 [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)).

CONSTRUCTION OF DISPUTED TERMS

1. "Matrix"[2]

Plaintiffs "a structure for controlling the release of an active ingredient that does not have layers"
Defendants "a homogeneous structure in all its volume"
Court "a homogeneous structure in all its volume"

Plaintiffs argue that "[a] person of ordinary skill in the art would understand that a 'matrix' as used in these claims is a structure for controlling the release of an active ingredient ***that does not have layers***." (CC at 12) (citing D.I. 133, Appel Decl., ¶¶ 49, 55-56, 61-62, 67) (emphasis added) Plaintiffs emphasize the lack of layers as the reason why the patents were distinguished over prior art; the point of distinction was not, they insist, homogeneity. Plaintiffs argue against a homogenous limitation, despite its inclusion in similar *Uceris I* claim constructions, because (1) the word homogenous does not appear in the asserted claims, as it did in some of the claims addressed in *Uceris I*; and (2) "the references in the specifications to a 'homogenous' composition pertain to . . . particular embodiments, not to all embodiments of the claimed inventions." (*See id.* at 13) ("The compression of the mixture . . . ***yields a***

[2] '374 patent (claims 1-2, 7-8, 10-11, 16-17, and 19-20); '286 patent (claims 1-4, 7-14, 17-22); '964 patents (claims 29-30).

macroscopically homogeneous structure in all its volume, namely a matrix containing a dispersion of the lipophilic granules in a hydrophilic matrix.") (quoting '374 patent at 5:17-22) (emphasis added) For intrinsic support, Plaintiffs point to instances in the specification in which matrices are described without the express requirement of homogeneity. (*Id.* at 14 (citing '374 patent at 1:29-40; 2:64-3:12; 3:16-27; 3:56-4:14; 7:16-49; 7:65-8:11; 8:41-58; 8:31-10:19); *see also id.* at 20-21 (citing '374 patent, at 5:17-21) (characterizing specification's use of homogenous as single embodiment, not all embodiments); Tr. at 9 ("But what is now really important is that the critical teaching for a person of ordinary skill in the art in this patent [is] in the examples, something I think that was largely overlooked in *Uceris I.*")) Additionally, Plaintiffs argue that "homogenous dispersion" and "matrix structure" are used "disjunctively" in the specification, supporting a conclusion they carry different meanings.[3]

Plaintiffs then argue at length that "[t]he prosecution history makes clear that an unrecited 'homogeneity' limitation is not a requirement for the 'matrix' claims." (CC at 14) Plaintiffs point to statements by the applicant in the prosecution of both the Villa I and Villa II patents that "the 'matrix' requires, and only requires, the absence of layers." (*Id.* at 15-16) (quoting D.I. 97-1, Ex. M, '964 patent file history, Rule 312 Amendment and Comments on Statement of Reasons for Allowance dated Oct. 18 2018) Plaintiffs equate these statements to the applicant acting as its own lexicographer. (*See id.* at 16 (citing *Microsoft Corp. v. Multi-Tech Sys.*, 357 F.3d 1340, 1350-51 (Fed. Cir. 2004); *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1343 n.5 (Fed. Cir. 2015)); *see also* Tr. at 6-7) At oral argument Plaintiffs emphasized that these statements serve a public notice function, and suggested that broadening the claims

[3] The Court agrees with Defendants that the usage is not actually disjunctive, because "'[a]nd' is not a disjunctive term and the passage uses the terms 'homogenous dispersion', 'matrix structure' and 'mixture' interchangeably." (CC at 29 n.10)

with post-allowance statements is permissible if supported by the specification.[4] (Tr. at 15-17) Finally, Plaintiffs argue that the dictionary definitions of "matrix" do not require homogeneity.

Defendants contend that the Court should adopt the same construction it did in *Uceris I*, where it "construed the claim term 'matrix' to mean 'a homogeneous structure in all its volume'" based on identical disclosures in the specification.[5] (CC at 17; *see also* Tr. at 29-30) In *Uceris I*, Plaintiffs advocated for the construction the Court adopted there.[6] Defendants argue that the Court got it right in *Uceris I*, as the intrinsic evidence supports a requirement of homogeneity. (*See* CC at 18) ("The compression of the mixture . . . yields a macroscopically homogeneous structure in all its volume, namely a matrix . . .") (quoting '286 patent at 5:15-19; '374 patent at 5:17-21; '964 patent at 5:15-19; D.I. 134, Mullen Decl., at ¶¶ 35-36) Further, Defendants note that "the Federal Circuit previously construed 'matrix' to mean 'a macroscopically homogeneous

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[4] Defendants respond, persuasively, that the public was also entitled to rely on Plaintiffs' position in *Uceris I*. (*See* Tr. at 54; *see also id.* at 43 ("I would also listen to what plaintiff said in *Uceris I*, which is that their invention here, in other words, their invention disclosed in this specification, same specification, is a uniform distribution throughout the core."); Tr. at 37 ("[P]laintiffs in this case have offered expert evidence on claim construction that is the exact opposite of the expert evidence that they offered in *Uceris I*."))

[5] In *Uceris I*, although Plaintiffs only went to trial on claims expressly limited to "macroscopically homogenous" structures, during the claim construction stage the Court construed matrix to require homogeneity also for claims without an express homogeneity limitation. (Tr. at 54-55)

[6] Defendants also contend that "Plaintiffs should be collaterally and/or judicially estopped from advocating for a different construction given that the claim language and relevant intrinsic evidence at issue here are identical to that in *Uceris I* and Plaintiffs' position is inconsistent with its earlier arguments." (CC at 18 n.6) The Court agrees with Plaintiffs, however, that the additional prosecution history and new claims distinguish the case from *Uceris I* for purposes of estoppel. (*See, e.g.*, D.I. 76) (denying Defendants' motion to dismiss because "nothing about this Court's decision in [*Uceris I*], nor the Federal Circuit's affirmance of it, necessarily renders Plaintiffs' proposed complaint futile") Plaintiffs are, therefore, free to argue for a different construction. Nevertheless, the Court is free to (as it has) again find persuasive the arguments (made by Plaintiffs) it found persuasive in *Uceris I*. In any event, the Court today also reaches the same conclusion de novo.

structure in all its volume' in a different patent from the same inventor featuring the same language in the specification in a litigation to which Plaintiff Cosmo was a party."[7] (*See id.*) (quoting *Shire Dev., LLC v. Watson Pharms., Inc.*, 787 F.3d 1359, 1365 (Fed. Cir. 2015)) Defendants also point to statements demonstrating the '286 patent examiner's understanding that the "the tableted core [i]s a homogeneous matrix." (CC at 18 (quoting D.I. 97, Ex. II (July 12, 2018 Notice of Allowance) at 6); *see also* Tr. at 30)

The Court agrees with Defendants that the intrinsic evidence supports a homogeneity limitation, just as it did in *Uceris I*. The only new intrinsic evidence Plaintiffs point to is post-allowance statements made by the applicant. (*See, e.g.* CC at 22-23) While these statements are relevant to claim construction (*see id.* at 23-24) (citing *Microsoft Corp. v. Multi-Tech Sys.*, 357 F.3d 1340, 1350 (Fed. Cir. 2004)), their timing – post-allowance and after Plaintiffs' loss in *Uceris I* – significantly reduce their weight. As Defendants note, this "post-allowance commentary" contradicts Plaintiffs' position in *Uceris I* and broadens the scope of the allowed claims in a way that benefits Plaintiffs' position in this litigation (i.e., they were not analogous to statements against interest). (*Id.* at 26)[8] Although the parties agree that a patent examiner may

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[7] Plaintiffs are correct that *Shire* "involved different claims from a different patent in a different patent family covering a different drug with a different specification and different prosecution history," limiting its probative value. (CC at 21) However, the general technological parallels cannot be ignored: "[t]he '720 patent [at issue in *Shire*] . . . concerns controlled-release oral pharmaceutical compositions for treating inflammatory bowel diseases." *Shire*, 787 F.3d at 1361. That the Federal Circuit found it correct to include a homogeneity requirement based on the teachings of the specification is instructive, even though not directly applicable. (*See* Tr. at 40)

[8] In full, Defendants contend:

> All of the patents with "matrix" claims were applied for on a "fast track" before the PTO after this Court's ruling from the bench in *Uceris I* finding that Actavis's ANDA product did not infringe the related '888 patent because of a lack of homogeneity. In view of

"pull the patent" post-allowance based, for example, on the patentee's post-allowance commentary, an examiner is not obligated to do so, and the Court sees little significance in the absence here of that (likely highly unusual) occurrence. (*See* Tr. at 17 (citing 37 C.F.R. § 1.313)[9]; *id.* at 32 ("There's nothing that requires the examiner to do that. In fact, the examiner understands the post allowance statements by the applicant don't really have any legal weight, so why would it be something to withdraw from allowance?")) The Court perceives no statements

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> that ruling, Plaintiffs attempted to create prosecution history they could cite in this case to support a broader claim construction that could ensnare Actavis's non-homogeneous product. This came in the form of gratuitous, self-serving comments submitted to the PTO after allowance disagreeing with the Examiner's finding that the claimed "matrix" was homogenous and thus patentable over non-homogeneous prior art.

(CC at 26)

Plaintiffs never directly contest this characterization of their intent in making these statements, emphasizing that the Court must rely on applicant statements in the prosecution history regardless of context or intent.

The Court agrees it must consider the post-allowance statements as intrinsic evidence but also concludes that their context should be considered as well. The Court has, therefore, considered these statements and finds that given their lack of affirmation by the examiner, their inconsistency with Plaintiffs' prior litigation position, and their obviously self-serving purpose, they do not, in context, support a conclusion different from the one reached in *Uceris I*, a conclusion which remains strongly supported by the specification and prior prosecution history. *C.f. Joao Bock Transaction Systems, LLC v. Jack Henry Associates, Inc.*, 2014 WL 2960363, at *2 (D. Del. June 30, 2014) ("Particularly when a special definition of a term is added through amendment, such a definition must be consistent with the use of that term in the application as filed.").

[9] This provision was first mentioned at oral argument. *See* 37 C.F.R. § 1.313(b) ("Once the issue fee has been paid, the Office will not withdraw the application from issue at its own initiative for any reason except: (1) A mistake on the part of the Office; (2) A violation of § 1.56 or illegality in the application; (3) Unpatentability of one or more claims; or (4) For an interference or derivation proceeding."). Plaintiffs have not convinced the Court that the examiner accepted or ratified the patentee's post-allowance statements based on the patent office's ability to withdraw the allowance of the patent and its failure to do so.

in the patent or prosecution history that constitute pertinent lexicography. *See Lear Siegler, Inc. v. Aeroquip Corp.*, 733 F.2d 881, 889 (Fed. Cir. 1984).

Plaintiffs' strongest "evidence" is the specification's silence as to homogeneity in certain examples (*see* Tr. at 9-14 (citing 17 of the 18 examples in the '374 patent); *id.* at 50-52), but in the overall context of these patents,[10] this silence does not persuade the Court that Plaintiffs' new construction is correct.[11]

2. "Mixture"[12] and "Compressed Blend"[13]

Plaintiffs "a composition of two or more substances that have been mixed" *and* "a composition of two or more substances that have been mixed and compressed"
Defendants "a homogeneous composition of two or more substances" *and* "a compressed matrix (or homogeneous structure in all its volume)"
Court "a homogeneous composition of two or more substances" *and* "a compressed matrix (or homogeneous structure in all its volume)"

[10] Notably, in *Uceris I* Plaintiffs did not merely advocate for the construction of matrix Defendants now propose (and Plaintiffs now abandon). In *Uceris I*, Plaintiffs represented to the Court that a POSA "reading the specification would also understand that the tablet core is designed to be a macroscopically homogenous composition of the recited recipients in which the budesonide is dispersed," repeating representations they had made to the PTO during prosecution. (*See, e.g.*, Plaintiffs' *Uceris I Markman* slide 26 (7-11-16 Hrg.) (displayed as Defs.' slide 18 at 7-2-19 Hrg. in instant action); *see also* Tr. at 35-36 (discussing other examples of Plaintiffs' arguments in *Uceris I*)) That is, Plaintiffs already undertook the analysis in *Uceris I* of how a POSA would interpret the intrinsic record – and, in the Court's continuing view, Plaintiffs got it right in *Uceris I.*

[11] While Plaintiffs insist the specification does not expressly define matrix to require homogeneity, they also fail to point to anything in the specification indicating that homogeneity is not important or not required. (*See* Tr. at 51-52)

[12] '698 patent (claims 1-3, 5, 7-9, 11, 13-14, 16, 20-21, 23-24, and 27-29); '878 patent (claims 1-5, 7-9, and 14-15).

[13] '799 (claims 22-23).

The question here is again whether a "homogenous" limitation should be included. Plaintiffs argue that the Court should draw its definition of mixture from a Wikipedia page in the patent file history. (*See* CC at 30 (quoting D.I. 97-1, Ex. N, '698 patent file history, Amendment dated May 29, 2018, at 11) ("In chemistry, a mixture is a material made up of two or more different substances which are mixed."); Tr. at 22-23) This Wikipedia definition, Plaintiffs say, is consistent with the specifications' ordinary usage of the term: "two or more substances that have been mixed." (CC at 30) Plaintiffs continue that the "specifications unambiguously show that homogeneity is not a requirement" because "numerous examples describe a mixture or mixing without any requirement of homogeneity" and because "there are example processes where some intermediate mixing steps require sufficient mixing to achieve homogeneity but other mixing steps, such as the final mixture before compression, do not." (*Id.* at 31-32) Lastly, Plaintiffs point to the same prosecution history statements by the applicant that they relied on for "matrix," to argue that the patent was distinguished over the prior art ***only*** due to its lack of layers, not its homogeneity. (*Id.* at 32-33; Tr. at 25-28) Plaintiffs offer similar arguments for "compressed blends." (CC at 33-34; *see also* Tr. at 22 ("[T]he specification uses blend and mixture interchangeably."))

Defendants respond that these two terms require homogeneity because "[t]he core itself is homogeneous. That's clear from the specification. It doesn't matter if you call it a mixture or a compressed blend or a matrix. It still has to be homogeneous." (Tr. at 34) They assert that contrary to Plaintiffs' recent self-serving prosecution statements, from the start "Plaintiffs made clear that the claimed invention was different from the prior art because it was a homogeneous system." (CC at 34-35) (citing D.I. 97, Ex. N, May 29, 2018 Reply to December 29, 2017 Office Action at 11; D.I. 97, Ex. P, March 19, 2018 Response to December 22, 2017 Final Office

Action at 7-8) Defendants add that the applicants distinguished the claimed invention by "attribut[ing] its delayed release functionality to 'a mixture of budesonide and other recited components in the form of a macroscopically homogeneous structure.'" (*Id.* at 35) (quoting D.I. 97, Ex. LL, March 19, 2018 Amendment at 8)

Regarding "compressed blend" specifically, Defendants point to "the only possible support for it in the specification," which "provides that '[t]he compression of the mixture . . . yields a macroscopically homogeneous structure in all its volume, namely a matrix.'" (*Id.* at 36) (quoting '799 patent at 5:14-18) Defendants also point out that in the '799 application, the applicant filed a preliminary amendment which "replaced the term 'matrix' with the term 'compressed blend.'" (*Id.* at 37) (citing D.I. 97, Ex. R, October 15, 2018 Preliminary Amendment at 2) Lastly, Defendants note that because the USPTO issued a certificate of correction changing "matrix" to "ingredient" in claim 22, the Patent Office saw this change as not affecting claim scope, which makes more likely that compressed blend is equivalent to matrix in claim 23. (*Id.* at 37-38) In response to Plaintiffs' arguments, Defendants reiterate that "self-serving" post-allowance prosecution history statements are unpersuasive. (*See id.* at 45; Tr. at 31 ("There is a difference between putting a disclaimer in the record that narrows your invention between what plaintiffs did here which is essentially just by self-help broaden their invention using [these] post-allowance statements."))

The Court agrees with Defendants. The specifications use the terms mixture and compressed blend in substantially the same way as they use the term matrix – and, importantly, all three terms refer to a homogenous structure. This is confirmed by both the prosecution history (*see, e.g.*, D.I. 9, Ex. HH at 2, 7 (Examiner Reasons for Allowance, '698 patent: "[T]he Amendment requires that any components in the core are in a homogenous mixture."); Tr. at 52

(Plaintiffs' counsel acknowledging Examiner did not agree with position Plaintiffs are now advocating)), and the ordinary usage of the terms. The Court reaches this finding despite Plaintiffs' identification of patent prosecution statements by the applicant, because, again, such statements are self-serving, made post-allowance, and are contradicted by more persuasive segments of the prosecution history and the specification.

If the Court were to look to extrinsic evidence, dictionary definitions further support a construction requiring homogeneity, in the context of the current invention. (*See* CC at 48 (citing McGraw-Hill Concise Encyclopedia of Science and Technology (6th ed. 2003) at 253); *see also* Tr. at 47-48)

3. "Pharmacokinetic terms"[14]

The Court will adopt the parties' stipulated constructions for the "pharmacokinetic terms." (*See* D.I. 142)

4. "Controls the release kinetics"[15]

Plaintiffs Plain and ordinary meaning, i.e. "controls the release kinetics"
Defendants "controls the release kinetics without effects from physically discrete elements"
Court Plain and ordinary meaning, i.e. "controls the release kinetics"

Plaintiffs argue that "[a] POSA would readily understand the claim language 'controls the release kinetics' to mean what it says," while Defendants propose to include the additional limitation of "without effects from physically discrete elements." (CC at 50; Tr. at 55-56) Plaintiffs contend that (1) this term is part of an open "comprising claim" (Tr. at 56) and (2) that

[14] '286 patent (claims 1-22); '964 patent (claims 29-30); '799 patent (claims 22-23).

[15] '878 patent (claims 1-5, 7-9, and 14-15).

the gastro-resistant coating of claim 1 of the '878 patent is a physically-discrete element that controls the release kinetics of budesonide (CC at 50). They point to the portion of the specification that describes how the gastro-resistant coating is used "for controlling the dissolution rate of the active ingredient." ('878 patent at 2:60-61) Defendants respond that the prosecution history contains evidence that applicants "distinguish[ed] the claimed invention from prior art containing physically discrete elements that contributed to the control of the release of the active ingredient." (CC at 51) They also point out instances where the specification and the claim state that the matrix structure "controls the release kinetics in the gastrointestinal tract." ('878 patent at 1:27-36, claim 2)

The Court agrees with Plaintiffs: "there is nothing in specification to support Defendants' proposed construction that a homogenous matrix structure be ***the only*** component that controls release" (CC at 53) (emphasis added), and in fact the patent teaches that the gastro-resistant coating also plays a role in controlling the release kinetics of budesonide.[16] The patent specification expressly describes how "a plurality of systems [can] control . . . the dissolution of the active ingredient." ('878 patent at 1:27-36) Similarly, the prosecution history statements on

[16] In their answering brief and during oral argument, Defendants argued that "[t]he coating ***prevents*** release while the macroscopically homogenous structure ***controls*** release," thus conceding that the gastro-resistant coating is a discrete element, but still contending its function is not to control release kinetics. (*See* CC at 55 (emphasis added); Tr. at 59 ("The way the specification and the claims use control, controlling release kinetics, it refers to the rate at which the budesonide is released, the duration of the budesonide release. . . . [The gastro-resistant coating] simply delays the start of the kinetics.")) While the coating and macroscopically homogenous structure may control the release kinetics in different ways, the intrinsic evidence does not support Defendants' distinction between prevention and control. (*See* Tr. at 66) Effectively, Defendants argue that delaying the release of an active ingredient is not a form of controlling the release kinetics of that active ingredient. The Court finds no intrinsic or extrinsic support for this understanding of "control" or "release kinetics," nor have Defendants pointed to such support.

which Defendants rely do not preclude "any other structure, such as a gastro-resistant coating surrounding the core, from affecting release." (CC at 54)

CONCLUSION

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

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

VALEANT PHARMACEUTICALS INTERNATIONAL, SALIX PHARMACEUTICALS LTD. and COSMO TECHNOLOGIES LIMITED,	:	
Plaintiff,	:	
v.	:	C.A. No. 18-1288-LPS
ACTAVIS LABORATORIES FL., INC., ACTAVIS PHARMA, INC., TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES LTD.,	:	
Defendants.	:	

ORDER

At Wilmington this **2nd** day of **August, 2019**:

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

IT IS HEREBY ORDERED that the following terms in U.S. Patent Nos. 10,052,286, 10,064,878, 10,105,374, 10,143,698, 10,154,964, and 10,172,799 are construed as follows:

Claim Term	Court's Construction
"Matrix"	"a homogeneous structure in all its volume"
"Mixture" *and* "Compressed Blend"	"a homogeneous composition of two or more substances" *and* "a compressed matrix (or homogeneous structure in all its volume)"
"an $AUC_{0\text{-infinity}}$ of said budesonide in said human of about 16431.2±10519.8(pg)x(h)/mL" *and* "an AUC of said budesonide in said human of about 16.43 ±10.52 (ng)x (h)/mL"	"an $AUC_{0\text{-}\textit{infinity}}$ of said budesonide in said human of approximately 16431.2±10519.8 (pg)x(h)/mL, i.e. approximately between 5,911.4 (pg)x(h)/mL and approximately 26,951 (pg)x(h)/mL" *and* "an AUC of said budesonide in said human of approximately 16.43±10.52 (ng)x(h)/mL, i.e. between approximately 5.91 (ng)x(h)/mL and approximately 26.95 (ng)x(h)/mL"
"a C_{max} of said budesonide in said human of about 1348.8±958.8 pg/mL" *and* "a C_{max} of said budesonide in said human of about 1.35±0.96 ng/mL"	"a C_{max} of said budesonide in said human of approximately 1348.8±958.8 pg/mL, i.e. between approximately 390 pg/mL and approximately 2307.6 pg/mL" *and* "a C_{max} of said budesonide in said human of approximately 1.35±0.96 ng/mL, i.e. between approximately 0.39 ng/mL and approximately 2.31 ng/mL"
"a T_{max} of said budesonide in said human of about 13.3±5.9 hour[s]"	"a T_{max} of said budesonide in said human of approximately 13.3±5.9 hours, i.e. between approximately 7.4 hours and approximately 19.2 hours"
"oral administration of the oral dosage form to a human" *and* "oral administration of the tablet to a human"	No constructions necessary
"said human"	No construction necessary
"Controls the release kinetics"	Plain and ordinary meaning, i.e. "controls the release kinetics"

UNITED STATES DISTRICT JUDGE