IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CYDEX PHARMACEUTICALS, INC.	:	
	:	
Plaintiff,	:	
	:	
v.	:	C.A. No. 19-956-LPS
	:	
ALEMBIC GLOBAL HOLDING SA, ALEMBIC PHARMACEUTICALS, LTD., and ALEMBIC PHARMACEUTICALS, INC.	:	
	:	
Defendants.	:	

Jack B. Blumenfeld, Jeremy A. Tigan, MORRIS, NICHOLS, ARSHT & TUNNELL LLP, Wilmington, DE

Joseph M. Reisman, Ashley Morales, KNOBBE, MARTENS, OLSON & BEAR, LLP, San Diego, CA

Benjamin A. Katzenellenbogen, Ali S. Razai, Karen M. Cassidy, KNOBBE, MARTENS, OLSON & BEAR, LLP, Irvine, CA

Attorneys for Plaintiff

Kevin M. Capuzzi, Kate Harmon, Noelle B. Torrice, BENESCH, FRIEDLANDER, COPLAN & ARONOFF LLP, Wilmington, DE

Michael S. Weinstein, BENESCH, FRIEDLANDER, COPLAN & ARONOFF LLP, Cleveland, OH

Manish K. Mehta, Zaiba Baig, Samuel J. Ruggio, Theresa L. Starck, BENESCH, FRIENDLANDER, COPLAN & ARONOFF LLP, Chicago, IL

Charanjit Brahma, BENESCH, FRIEDLANDER, COPLAN & ARONOFF LLP, San Francisco, CA

Attorneys for Defendant

MEMORANDUM OPINION

November 2, 2020
Wilmington, Delaware

STARK, U.S. District Judge:

Plaintiff CyDex Pharmaceuticals, Inc. ("Plaintiff" or "CyDex") filed suit against Defendants Alembic Global Holding SA, Alembic Pharmaceuticals, Ltd., and Alembic Pharmaceuticals, Inc. (collectively, "Defendants" or "Alembic") on May 23, 2019, alleging infringement of U.S. Patent Nos. 9,200,088 (the "'088 patent") (D.I. 1 Ex. A); and 9,493,582 (the "'582 patent") (D.I. 1 Ex. B). (*See generally* D.I. 1) By amendment on February 7, 2020, CyDex alleged infringement of an additional patent, U.S. Patent No. 8,410,077 (the "'077 patent") (D.I. 41 Ex. C). (*See generally* D.I. 41) The patents-in-suit generally relate to compositions of cyclodextrins purified using activated carbon to enhance active agent stability.

The parties submitted their joint claim construction brief on August 10, 2020. (D.I. 69) The parties' submissions also include expert declarations. (D.I. 70 Exs. 74, 93) The Court held a claim construction hearing on September 1, 2020. (*See* D.I. 77) ("Tr.")

I. LEGAL STANDARDS

A. Claim Construction

The ultimate question of the proper construction of a patent is a question of law. *See Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 321 (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 citation and 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) (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*, 574 U.S. at 331. "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)).

B. Indefiniteness

A patent claim is 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." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 910 (2014). A claim may be indefinite if the patent does not convey with reasonable certainty how to measure a claimed feature. *See Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1341 (Fed. Cir. 2015). But "[i]f such an understanding of how to measure the claimed [feature] was within the scope of knowledge possessed by one of ordinary skill in the art, there is no requirement for the

specification to identify a particular measurement technique." *Ethicon Endo-Surgery, Inc. v. Covidien, Inc.*, 796 F.3d 1312, 1319 (Fed. Cir. 2015). A party seeking to prove indefiniteness must do so by clear and convincing evidence. *See BASF Corp. v. Johnson Matthey Inc.*, 875 F.3d 1360, 1365 (Fed. Cir. 2017).

II. CONSTRUCTION OF DISPUTED TERMS

A. "A sulfoalkyl ether cyclodextrin (SAE-CD) composition" [1] / "An alkylated cyclodextrin composition"[2]

Plaintiff "A sulfoalkyl ether cyclodextrin (SAE-CD) composition" / "An alkylated cyclodextrin composition"
Defendant "A sulfoalkyl ether cyclodextrin (SAE-CD) composition prior to mixing with active agents and/or excipients"/"An alkylated cyclodextrin composition prior to mixing with active agents and/or excipients"
Court "A sulfoalkyl ether cyclodextrin (SAE-CD) composition"/ "An alkylated cyclodextrin composition"

These terms appear in preambles, which the parties agree are limiting. (D.I. 69 at 10 n.7) There is also no dispute that the properties of the cyclodextrin called out in the claims are properties attributable to the cyclodextrin independent of the active agents and excipients. (*See id.* at 12, 14) The Court agrees with CyDex that the terms require no additional construction.

"[A]n alkylated cyclodextrin composition" is defined in the '582 patent as "a composition comprising alkylated cyclodextrins having a degree of substitution or an average degree of substitution (ADS) for a specific substituent." ('582 patent at 6:19-34) The Court's construction

[1] This term appears in the '088 patent at claims 1 and 15-16 and the '077 patent at claims 20, 21, 57, 62, 64, and 75.

[2] This term appears in the '582 patent at claims 1 and 20-21.

must be consistent with this express definition. *See Phillips*, 415 F.3d at 1316. In the context here, remaining true to the patentee's definition does not require any further construction, just rejection of Defendant's suggestion that the claimed composition may fall outside of the claims as soon as it is mixed with an active ingredient or other excipient (i.e., the claims only cover what exists "prior to mixing").

In the disputed claims, excipients and active agents are not a part of an "SAE-CD composition." ('077 patent at 2:35-38, 44-48) In determining the properties of any formulation, it is the inactive SAE-CD composition that is relevant, as evidenced by the patent itself. (*See, e.g.*, Tr. at 7) Contrary to Defendant's contention, however, this does not mean that an SAE-CD composition must only exist "prior to mixing" with any active agents or excipients.[3] The structure of the claims indicates that formulations may contain both SAE-CD compositions and active agents, which would require mixing. (*See, e.g.*, '088 patent claims 1, 14)

B. "Phosphate-Free Activated Carbon"[4]

Plaintiff "a carbon that was not activated using, or otherwise exposed to phosphoric acid"
Defendant "an activated carbon that does not contain phosphate"
Court "a carbon that was not activated using, or otherwise exposed to phosphoric acid"

[3] Although Alembic insists it is not trying to impose a temporal limitation (*see, e.g.*, D.I. 69 at 14), the purported "structural limitation" it would impose on the claims would have the consequence of limiting the claims to the time before mixing in an active ingredient or excipient. In effect, then, it is a temporal limitation. Regardless of how it is characterized, Alembic has not persuaded the Court its limitation should be part of the proper construction.

[4] This term appears in the '077 patent at claims 21, 62, 64, and 75 and the '582 patent at claims 1 and 20-21.

The parties' dispute is whether "phosphate-free" modifies the term "activated" (and therefore relates to a process) or whether instead it modifies "activated carbon" (in which case it relates to the result of a process). CyDex proposes that it modifies only "activated," so the term refers to any carbon that has been activated without phosphate, regardless of whether the resulting carbon has phosphate. (D.I. 69 at 14-16) In support, CyDex points to the specifications' statement that "[g]enerally, phosphate-free activated carbon is a carbon that was not activated using, or otherwise exposed to, phosphoric acid." ('077 patent at 20:40-42; *see also* '582 patent at 25:60-62) Alembic counters that "phosphate-free" modifies "activated carbon," so the term requires that the activated carbon itself must be free of phosphate. ('077 patent at 20:37-39; D.I. 70 Ex. 10 ¶ 12)

In the Court's view, a person of ordinary skill in the art ("POSA") would understand the claim as referring to the method by which the carbon is activated (i.e., without phosphate), and not as referring to something else (such as the phosphate content of the carbon or the phosphate content of the final composition).

In addition to the specification support already noted, the Court's conclusion is supported by the prosecution history, which includes a declaration from inventor Dr. Antle. (*See* D.I. 70 Ex. 10 ¶ 12)

C. "ppm of a phosphate"[5]

Plaintiff "parts per million of a phosphate (PO4)"
Defendant Indefinite
Court "parts per million of a phosphate (PO4)"

Alembic does not dispute that a POSA would understand "ppm of a phosphate" means "parts per million of a phosphate (PO_4)." (D.I. 69 at 11, 21-22) Rather, Alembic argues that the multiplicity of methods available to measure parts per million renders the patent indefinite. (*Id.* at 22) Alembic has not shown indefiniteness by clear and convincing evidence.

When there are multiple methods for measurement, a party asserting indefiniteness must show that those methods result in different outcomes; that is, that measurement under one method could yield infringement while another measurement would not. *See W.L. Gore & Assocs., Inc. v. C.R. Bard, Inc.*, 2015 WL 12831300, at *3 (D. Del. Sept. 28, 2015); *see also Butamax Advanced Biofuels LLC v. Gevo, Inc.*, 117 F. Supp. 3d 632, 639-42 (D. Del. 2015). While Alembic argues that this is the situation here, citing its expert's declaration (*see, e.g.*, D.I. 70 Ex. 54 ¶ 49), CyDex disagrees, citing its expert (*id.* Ex. 93 ¶ 33 ("A POSA would understand that the method chosen for measuring the levels of phosphate recited in the claims would have to be validated in order to demonstrate that the measurements that result from using the method are trustworthy."); *id.* ¶ 32 ("Two different validated methods should not result in different results that are statistically significant if each method has been properly validated.")). The Court agrees with CyDex that, at this stage, Defendants have not offered clear and convincing evidence that

[5] This term appears in the '088 patent at claims 1 and 15-16 and the '077 patent at claims 20 and 57.

"choosing between various accepted methods for measuring phosphate content would be outcome determinative as to infringement." (D.I. 69 at 25)[6]

D. "drug degrading agent"[7] / "drug degrading impurities"[8]

Plaintiff "agent capable of degrading an active agent"/ "impurities capable of degrading an active agent"
Defendant Indefinite/Indefinite
Court "agent capable of degrading an active agent, as demonstrated by UV fluorescence of the overall composition at 245-270 nm and by actual degradation of any of budesonide, triazole, or aripiprazole"/ "impurities capable of degrading an active agent, as demonstrated by UV fluorescence of the overall composition at 245-270 nm and by actual degradation of any of budesonide, triazole, or aripiprazole"

The parties each point to language that a "drug-degrading agent" "refers to a species, moiety, and the like, that degrades an active component in an aqueous solution." ('077 patent at 21:57-59; D.I. 69 at 33, 36, 39) CyDex argues that "a drug degrading agent may not degrade all drugs" ('582 patent at 27:28-32) and, to satisfy the claim, it need only be capable of degrading an active ingredient. Alembic takes the view that the claims require actual degradation of all "active agents." (D.I. 69 at 35; D.I. 70 Ex. 54 ¶ 52) The intrinsic evidence supports CyDex. (*See, e.g.*, '582 patent at 27:28-32) ("It will be understood that a drug degrading agent may not degrade all drugs with which an alkylated cyclodextrin composition may be combined,

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[6] Alembic may renew its indefiniteness challenges at trial, should it believe in good faith it can prove them by clear and convincing evidence.

[7] This term appears in the '077 patent at claims 20-21, 57, 62, 64, and 75 and the '582 patent at claims 1 and 20-21.

[8] This term appears in the '077 patent at claims 21, 62, 64, and 75 and the '582 patent at claims 1 and 20-21.

depending on the chemical structure of the drug and its degradation pathways.") Hence, the Court sides with CyDex on this dispute.

Alembic contends that a POSA would not know how to determine, for any given active agent, whether a cyclodextrin composition would be capable of degrading that active ingredient. (D.I. 69 at 35-37) CyDex responds that a POSA could reasonably make that determination if the prospective "drug-degrading agent" is both (1) present, as determined by UV spectroscopy, and (2) actually degrades any of budesonide, triazole, or aripiprazole. (D.I. 69 at 30; '077 patent at Examples 31, 32, 34) At the hearing, CyDex agreed, therefore, that the "drug-degrading agent" must actually degrade at least one of budesonide, triazole, or aripiprazole. (Tr. at 61) The specification teaches that a POSA can determine that something is a drug-degrading agent if it has both UV fluorescence and actually degrades budesonide, triazole, or aripiprazole. ('077 patent at 21:58-61, 48:14-52:27) This is reflected in the Court's construction.[9]

Alembic also argues that these claim terms are indefinite because, under CyDex's proposed constructions, they mean essentially the same thing. (*See* D.I. 69 at 34-35) The Court disagrees. *See Edwards Lifesciences LLC v. Cook Inc.*, 582 F.3d 1322, 1329 (Fed. Cir. 2009) ("The interchangeable use of the two terms is akin to a definition equating the two."). Alembic has not demonstrated by clear and convincing evidence that these claim terms are indefinite.

[9] As CyDex points out (and Alembic does not appear to disagree), the term "drug-degrading impurity" is interchangeable with "drug-degrading agent," so no different disputes need to be discussed in connection with the latter term.

E. "an absorption of less than 0.5 A.U. due to a U.V-active impurity"[10] / "an absorption of less than [0.2 / 0.5] A.U. due to a drug-degrading agent"[11]

Plaintiff "an absorption of less than 0.5 absorbance units due to a UV-active impurity"/ "an absorption of less than [0.2 / 0.5] absorbance units due to a drug-degrading agent"
Defendant Indefinite/Indefinite
Court "an absorption of less than 0.5 absorbance units due to a UV-active impurity" / "an absorption of less than [0.2 / 0.5] absorbance units due to a drug-degrading agent"

To a great extent, the parties' disputes with respect to these terms are the same as the disputes already resolved in CyDex's favor in connection with the preceding terms. (*See supra* Part D.) The Court's conclusions are the same here.

The parties agree that a "UV-active impurity" is "an impurity that absorbs light in the ultraviolet region of the electromagnetic spectrum." (*See* D.I. 69 at 32; D.I. 73) Alembic argues that a POSA would not be able to determine whether a compound that exhibits absorbance does so "due to" that impurity or, instead, due to something else present in the composition. Alembic has not demonstrated that the term is indefinite.

CyDex points to extrinsic evidence that cyclodextrins and known impurities are not active at the pertinent wavelengths. (D.I. 70 Ex. 10 ¶¶ 25-26) The inventors of the patents-in-suit determined that if a compound is active at UV wavelengths, then its activity must be due to the presence of UV active impurities. (*Id.* ¶¶ 15-26) There is nothing in the record to support Alembic's suggestion that a POSA might suspect that "other non-impurity components" might cause a POSA to lack reasonable certainty as to claim scope. (D.I. 69 at 29)

[10] This term appears in the '088 patent at claims 1 and 15-16.

[11] This term appears in the '077 patent at claims 20-21, 57, 62, 64, and 75.

F. "an active agent assay"[12]

Plaintiff "an empirically determined amount of active agent"
Defendant Indefinite
Court "an empirically determined amount of active agent"

Alembic's indefiniteness challenge rests on its contention that the applicable test parameters are not adequately disclosed. However, as CyDex points out, the specification teaches that the goal of an "active agent assay" is to perform a "stability challenge" by subjecting a composition to a 120-minute test at 80 degrees Celsius. ('088 patent at 25:50-65) The specification also discloses an HPLC test performed as described in Example 31 ('088 patent at 47:25-34), and mentions that an HPLC was used in Examples 32 and 34 (*id.* at 48:25-27, 51:15-17). Neither the intrinsic evidence nor the extrinsic evidence[13] constitutes clear and convincing evidence that any lack of clarity as to test parameters would leave a POSA with a lack of reasonable certainty as to whether a particular embodiment infringes or does not infringe.

[12] This term appears in the '088 patent at claims 15-16.

[13] Alembic argues that parameters inherent to the type of test – such as flow rate, column temperature, injection volume, solvent, or mobile phase – would vary for each active agent and can impact results. (D.I. 70 Ex. 54 ¶ 30) CyDex has presented expert evidence that a POSA "would be able to design and develop assays to determine the amount of active agent in a given formulation." (D.I. 70 Ex. 54 ¶ 44)

G. "unwanted components"[14]/ "to remove one or more unwanted components"[15]

Plaintiff "components that are not wanted"/ "to reduce the amount of one or more components that are not wanted"
Defendant Indefinite/Indefinite
Court "components that are not wanted"/ "to reduce the amount of one or more components that are not wanted"

Alembic has not shown by clear and convincing evidence that a POSA could not determine, with reasonable certainty, whether a component is "wanted" or "unwanted." The intrinsic evidence provides examples of "unwanted components," including unreacted starting material, salts, degraded cyclodextrin, unreacted sulfoalkylating agents, and other process impurities. ('077 patent at 21:42-52) The claims also provide that an "unwanted component" is separate from a "sulfoalkyl ether cyclodextrin" and a "drug-degrading impurit[y]." (*Id.* at claim 21(a)) Further, as CyDex has explained, the claimed invention is a process yielding known impurities and undesired components. (Tr. at 56-57) The expert declarations support a conclusion that, for any given process, a POSA would know what to expect as far as impurities – and, therefore, would know which components are "unwanted." (*Id.* at 55-57; *see also* D.I. 70 Ex. 93 ¶¶ 64-66; *id.* Ex. 54 ¶ 63)

[14] This term appears in the '077 patent at claims 21, 62, 64, and 75 and the '582 patent at claims 1 and 20-21.

[15] This term appears in the '077 patent at claims 21, 62, 64, and 75 and the '582 patent at claims 1 and 20-21.

H. "activated carbon having a residual conductivity of 10 μS or less"[16]

Plaintiff "activated carbon having a wash eluent with a conductivity of 10 microSiemens per centimeter or less"
Defendant Indefinite
Court "activated carbon having a wash eluent with a conductivity of 10 microSiemens per centimeter or less"

The parties agree that "residual conductivity" is related to the wash eluent of activated carbon and that μS means "microSiemens per centimeter." (*See* D.I. 69 at 57) Alembic contends, nonetheless, that the scope of the disputed term is indefinite for failing to sufficiently define (1) "residual conductivity" and (2) the temperature conditions needed to measure "residual conductivity." (*Id.*) Alembic has not shown indefiniteness by clear and convincing evidence.

Instead, the specification provides a POSA some certainty, at least suggesting that conductivity at the end of the water wash is the same as "residual conductivity." (*See* '582 patent at 32:34-36 (correlating chloride content and "conductivity level at the end of the water wash"); *id.* at 5:44-51 (describing Figure 9 as relating residual chloride and residual conductivity)) The prosecution history further shows the inventor referred to repeated washing as determinative of "residual conductivity." (*E.g.*, *id.* Ex. 6 at 20 ("activated carbon generally needs washing with several thousand liters before an acceptable residual conductivity is reached"); *id.* at 21 (similar)) The Examiner appears to have shared this understanding. (*Id.* Ex.

[16] This term appears in the '582 patent at claims 1 and 20-21.

9 at 2 (distinguishing prior art as not teaching "a process of washing a column with water until the residual conductivity of the flow-through reaches the lowest possible level"))

Alembic points to the use of other terms relating to "conductivity" to argue that "residual conductivity" is not clear. (D.I. 69 at 58-61) These arguments do not satisfy Alembic's burden. At most, Defendants may have shown that the patent uses "determined conductivity" interchangeably with "residual conductivity" ('582 patent at 34:31-33; *see also* D.I. 69 at 55), but this does not render the claim term indefinite. Nor do Alembic's arguments about "absolute conductivity," "relative conductivity," and "minimum conductivity" (D.I. 70 Ex. 9 at 2; Ex. 6 at 20), which were the subject of prosecution history (D.I. 70 Ex. 6 at 20; *id.* Ex. 8 ¶ 5; *see also* Tr. at 67).

Alembic also argues that the claim term is indefinite because there are multiple outcome-determinative ways to measure conductivity at various temperatures. (D.I. 70 Ex. 74 at ¶ 41) ("Thus, a POSA could take two samples of the same activated carbon, run conductivity tests using wash solutions at different temperatures, and obtain conductivity results that are both inside and outside of the claim scope.")) CyDex, relying on its expert, counters that a POSA would understand with reasonable certainty that correct temperature measurements are taken at 25 degrees Celsius (unless otherwise specified). (D.I. 90 Ex. 93 ¶¶ 81-82) Again, Alembic has not met its burden.

I. "washed with [solvent / water] until the eluted [solvent / water] has reached the residual conductivity in (c)"[17]

Plaintiff "subjected to a washing process that consistently produces [solvent / water] eluent conductivity at or below a target level of no more than 10 microSiemens per centimeter"
Defendant Indefinite
Court "subjected to a washing process that consistently produces [solvent / water] eluent conductivity at or below a target level of no more than 10 microSiemens per centimeter"

For the same reasons just given with respect to the "residual conductivity" term, this disputed term has also not been proven indefinite.

CyDex's proposed construction is further challenged by Alembic as (i) improperly requiring "consistent" achievement of a target level and (ii) being indefinite for failure to disclose the temperature of washing.

The Court is persuaded that the term should require "consistent" production of residual conductivity. The intrinsic evidence supports this conclusion. (*See* D.I. 70 Ex. 7 at 14 ("[T]he process of claim 1 is consistently applied . . . ."); '582 patent at 32:7-22 (noting that inconsistent processes are not claimed)) During prosecution, the distinction between consistent and inconsistent processes was emphasized to overcome an anticipation rejection. (D.I. 70 Ex. 7 at 16 ("Because the presently claimed method consistently produces a SAE-CD composition having a lower chloride content . . . the argument that the claims 'contain limitations inherently present in the prior art' is in error."); *see also* '582 patent at 32:34-36 ("[T]here is a direct correlation between the level of chloride . . . and the conductivity level at the end of the water

[17] This term appears in the '582 patent at claims 20-21.

wash.")) This distinction merits weight in the Court's analysis. *See Spectrum Int'l, Inc. v. Sterilite Corp*, 164 F.3d 1372, 1378-79 (Fed. Cir. 1998).

Alembic's temperature-based challenge to this term fails for the same reasons as already given above in connection with the preceding term.

J. Sequence of Steps[18]

Plaintiff Defendants have not proposed a construction, but rather presented an argument regarding how the claim language should be applied. CyDex disagrees with Defendants' argument. The claim language should be interpreted as written, and does not require the recited limitations be performed in any specific order.
Defendant "Claims 21 and 64 [of the '077 patent] are each product by process claims in which claimed steps (a), (b) and (c) must be performed in order"/ "Claims 1, 20, and 21 [of the '582 patent] require that process steps (a), (b), and (c) must be performed in order"
Court Claims 21 and 64 of the '077 patent require that process step (a) occur before process step (b) which occurs before process step (c). Claims 1, 20, and 21 of the '582 patent require that process step (a) occur before process step (b) which occurs before process step (c).

The parties disagree whether the division of claims 21 and 64 of the '077 patent and claims 1, 20, and 21 of the '582 patent into subparts (a), (b), and (c) require that those steps be performed in order. Alembic argues that both the structure of the claims and the process being claimed require a sequential order, while CyDex appears to dispute that any order is required. (D.I. 69 at 72-74)

"A claim requires an ordering of steps when the claim language, as a matter of logic or grammar, requires that the steps be performed in the order written, or the specification directly or implicitly requires an order of steps." *Mformation Techs., Inc. v. Research in Motion Ltd.*, 764

[18] This issue arises in the '077 patent at claims 21, 62, 64, and 75 and in the '582 patent at claims 1 and 20-21.

F.3d 1392, 1398 (Fed. Cir. 2014) (internal quotation marks omitted). The Court is persuaded that the steps of each claim must be performed in order, but without limitation on intervening steps.

Claim 21 of the '077 patent, for example, indicates that part (a) requires formation of an "aqueous milieu"; part (b) requires "the aqueous milieu" form a "partially purified solution"; and in part (c) the "partially purified solution" is treated. The specification discloses that same order of steps. ('077 patent at 5:6-31, 35-60, 5:65-6:24, 6:25-42, 7:7-18, 8:26-42, 43:52-44:49) Logic requires that these steps be undertaken in this order.

CyDex correctly points to the fact that the preamble includes "comprising." From this the Court concludes that the claims are not limited to the disclosed steps (i.e., steps (a), (b), and (c)). Intervening steps may occur between steps (a) and (b), or between steps (b) and (c).

III. 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

CYDEX PHARMACEUTICALS, INC.	:	
	:	
Plaintiff,	:	
	:	
v.	:	C.A. No. 19-956-LPS
	:	
ALEMBIC GLOBAL HOLDING SA, ALEMBIC PHARMACEUTICALS, LTD., and ALEMBIC PHARMACEUTICALS, INC.	:	
	:	
Defendants.	:	

ORDER

At Wilmington this **2nd** day of **November, 2020**:*

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

IT IS HEREBY ORDERED that the following claim terms of U.S. Patent Nos. 8,410,077 (the "'077 patent"); 9,200,088 (the "'088 patent"); and 9,493,582 (the "'582 patent") are construed as follows:

Claim Term	Patent Number	Court's Construction
"agent"	'077 '582	The parties agree to construe the term as "substance."
"aqueous"	'077	The parties agree to construe the term as "water based."
"can be readily mixed"	'088	The parties agree to construe the term according to its plain and ordinary meaning.
"less than 200"	'088	The parties agree to construe the term as "less than 200."
"less than 100"	'077	The parties agree to construe the term as "less than 100."

"partially purified aqueous solution"	'077	The parties agree to construe the term according to its plain and ordinary meaning.
"partially purified solution"	'582	The parties agree to construe the term according to its plain and ordinary meaning.
"producing the alkylated cyclodextrin"	'582	The parties agree to construe the term as "producing the alkylated cyclodextrin composition."
"impurity"/"impurities"	'077, '088, '582	The parties agree to construe the term as "something other than the claimed SAE-CD."
"wherein the one or more separations include a process selected from the group consisting of: ultrafiltration, diafiltration, centrifugation, extraction, solvent precipitation, and dialysis"	'077, '582	The parties agree to construe the term as "one or more separations are performed, and one or more of the separations includes a process selected from the claimed list."
"UV-active impurity"	'088	The parties agree to construe the term as "an impurity that absorbs light in the ultraviolet region of the electromagnetic spectrum."
A sulfoalkyl ether cyclodextrin (SAE-CD) composition" [Claims 1, 15-16 of the '088 patent; claims 20-21, 57, 62, 64, and 75 of the '077 patent]	'088, '077	"A sulfoalkyl ether cyclodextrin (SAE-CD) composition"
"An alkylated cyclodextrin composition" [Claims 1, 20-21 of the '582 patent]	'582	"An alkylated cyclodextrin composition"
"Phosphate-Free Activated Carbon"	'077, '582	"a carbon that was not activated using, or otherwise exposed to phosphoric acid"

[Claims 21, 62, 64, and 75 of the '077 patent; claims 1, 20-21 of the '582 patent]		
"ppm of a phosphate" [Claims 1, 15-16 of the '088 patent; claims 20 and 57 of the '077 patent]	'088, '077	"parts per million of a phosphate (PO4)"
"an absorption of less than 0.5 A.U. due to a U.V-active impurity" [Claims 1, 15-16 of the '088 patent]	'088	"an absorption of less than 0.5 absorbance units due to a UV-active impurity"
"an absorption of less than [0.2 / 0.5] A.U. due to a drug-degrading agent" [Claims 20-21, 57, 62, 64, and 75 of the '077 patent]	'077	"an absorption of less than [0.2 / 0.5] absorbance units due to a drug-degrading agent"
"drug degrading agent" [Claims 20-21, 57, 62, 64, and 75 of the '077 patent; claims 1, 20-21 of the '582 patent]	'077, '582	"agent capable of degrading an active agent"
"drug degrading impurities" [Claims 21, 62, 64, and 75 of the '077 patent; claims 1, 20-21 of the '582 patent]	'077, '582	"impurities capable of degrading an active agent"
"an active agent assay" [Claims 15-16 of the '088 patent]	'088	"an empirically determined amount of active agent"
"unwanted components" [Claims 21, 62, 64, and 75 of the '077 patent;	'077, '582	"components that are not wanted"

claims 1, 20-21 of the '582 patent]		
"to remove the one or more unwanted components" [Claims 21, 62, 64, and 64 of the '077 patent; claims 1, 20-21 of the '582 patent]	'077, '582	"to reduce the amount of one or more components that are not wanted"
"activated carbon having a residual conductivity of 10 µS or less" [Claims 1, 20-21 of the '582 patent]	'582	"activated carbon having a wash eluent with a conductivity of 10 microSiemens per centimeter or less"
"washed with [solvent / water] until the eluted [solvent / water] has reached the residual conductivity in (c)" [Claims 20-21 of the '582 patent]	'582	"subjected to a washing process that consistently produces [solvent / water] eluent conductivity at or below a target level of no more than 10 microSiemens per centimeter"
Sequence of Steps [Claims 21, 62, 64, and 75 of the '077 patent; claims 1, 20-21 of the '582 patent]	'077, '582	Claims 21 and 64 of the '077 patent require that process step (a) occur before process step (b) which occurs before process step (c). Claims 1, 20, and 21 of the '582 patent require that process step (a) occur before process step (b) which occurs before process step (c).

UNITED STATES DISTRICT JUDGE