IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

UCB, INC., UCB BIOPHARMA SPRL, RESEARCH CORPORATION TECHNOLOGIES, INC. and HARRIS FRC CORPORATION,	)	
Plaintiffs,	)	
v.	)	C.A. No. 13-1206-LPS
	)	**CONSOLIDATED**
ACCORD HEALTHCARE, INC., et al.,	)	
Defendants.	)	

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MEMORANDUM OPINION

May 14, 2015
Wilmington, DE

STARK, U.S. District Judge:

Plaintiffs Research Corporation Technologies, Inc., Harris FRC Corporation, and UCB BioPharma SPRL ("Plaintiffs") filed patent infringement actions against multiple defendants ("Defendants") for infringing U.S. Reissued Patent No. RE 38,551 ("the '551 Patent") after Defendants filed Abbreviated New Drug Applications with the U.S. Food and Drug Administration. (D.I. 1) The '551 Patent generally relates to an anticonvulsant drug, marketed under the name Vimpat, having lacosamide as its active ingredient. (*Id.*)

Pending before the Court is the issue of claim construction for one term in the patent-in-suit: "therapeutic composition," as used in claim 10. The parties completed briefing on claim construction on November 24, 2014. (D.I. 158, 160, 176, 178) In addition to briefing, the parties submitted multimedia technology tutorials. (D.I. 167, 168) The Court held a claim consturction hearing on December 15, 2014. (*See* Transcript ("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." *Phillips*, 415 F.3d 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." *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004) (internal quotation marks omitted), *aff'd*, 481 F.3d 1371 (Fed. Cir. 2007).

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 ordinary 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).

II. CONSTRUCTION OF THE DISPUTED TERM

A. "therapeutic composition"[1]

Plaintiffs' Proposal:	"A composition suitable for use as a treatment regimen over an extended period of time (chronic administration)"
Defendants' Proposal:	The preamble is not a claim limitation; needs no construction. Or alternatively: "pharmaceutical composition"
Court's Construction:	"A composition suitable for use as a treatment regimen over an extended period of time (chronic administration)"

The claims of the '551 Patent are directed to compounds, compositions, and methods of treating cental nervous system disorders. The term "therapeutic composition" appears in the preamble to claim 10 of the '551 Patent. The parties dispute whether the preamble is a claim limitation, and therefore whether "therapeutic composition" even needs to be construed; and, if so, whether limiting the term to long-term or chronic use is appropriate.

A preamble is limiting only under certain circumstances, such as when it recites an essential structure or steps, or is necessary to give life, meaning, and vitality to a claim. *See Poly-Am., L.P. v. GSE Lining Tech., Inc.*, 383 F.3d 1303, 1309 (Fed. Cir. 2004). "[W]hether to treat a preamble as a claim limitation is determined on the facts of each case in light of the claim as a whole and the invention described in the patent." *Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 952 (Fed. Cir. 2006). A court reviews the entirety of the patent to gain an understanding of what the inventors actually invented and intended to encompass by the claim to determine what effect the preamble language should be given. *See Corning Glass Works v. Sumitomo Elec.*

[1]While the parties have not agreed on the definition of a person having ordinary skill in the art, they agree that the Court's resolution of their claim construction dispute is not affected by this disagreement. (*See* Tr. at 9-10, 28)

U.S.A., Inc., 868 F.2d 1251, 1257 (Fed. Cir. 1989).

Defendants assert that the term "therapeutic composition" as it appears in claim 10 is a non-limiting preamble. Defendants further argue that the preamble here only states a "purpose or intended use for the invention" and, therefore, is not limiting. (D.I. 160 at 7) (citing *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.,* 289 F.3d 801, 808 (Fed. Cir. 2002))

Claim 10 recites, in its entirety:

> A therapeutic composition comprising an anticonvulsant effective amount of a compound according to any one of claims 1-9 and a pharmaceutical carrier therefor.

The specification, in describing the treatment of epileptic and other disorders prior to the invention of the patent-in-suit, states that "[t]oxicities may appear upon repeated dosing that are not apparent with acute administration. Because many drugs which require chronic administration ultimately place an extra burden on the liver . . . many anticonvulsants have associated therewith liver toxicity." ('551 Patent, col. 2 l. 67 - col. 3 l. 6) The specification goes on to identify four goals for an anticonvulsant drug, including for the treatment of chronic conditions like epilepsy:

> [T]he ideal anticonvulsant drug is one that satisfies the following four criteria: (1) has a high anticonvulsant activity . . .; (2) has minimal neurological toxicity . . . relative to its potency; (3) has a maximum protective index (sometimes known as selectivity or margin of safety), which measures the relationship between the doses of a drug required to produce undesired and desired effects . . .; and (4) is relatively safe as measured by the median lethal dose (LD_{50}) relative to its potency and is non-toxic to the animal that is being treated, e.g., it exhibits minimal adverse effects on the remainder of the treated animal, its organs, blood, its bodily functions, etc. even at high concentrations, ***especially during long term chronic administration of the drug.*** Thus, for example, it exhibits minimal, i.e., little or no liver toxicity.

(*Id.* at col. 3 ll. 13-32) (emphasis added) The patent specification then describes the compound of the invention as non-toxic to the liver. (*See, e.g., id.* at col. 37 ll. 26-40) "These compounds of the present invention exhibit advantages that have not heretofore been realized. They therefore can be used in a treatment regimen requiring administration thereof over extended periods of time (chronic administration)." (*Id.* at col. 37 ll. 47-50)

Relatedly, the patent states that it is directed to "epilepsy or related central nervous system disorders." (*Id.* at col. 1 ll. 28-29)[2] It is undisputed that epilepsy requires long-term, often lifelong, treatment. (*See* Tr. at 14, 31-32) The specification goes on to disclose that the compounds and compositions of the invention provide the desired "little, if any, liver toxicity" ('551 Patent, col. 24 ll. 50-51) and, hence, have advantageous characteristics making the invention useful for long-term treatment of conditions such as epilepsy.[3] (*See id.* at col. 24 ll. 31-

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[2]*See also* '551 Patent, col. 4 ll. 17-21 ("Moreover, the administration of an effective amount of the present compounds in their pharmaceutically acceptable forms provides an excellent regime for the treatment of epilepsy, nervous anxiety, psychosis, insomnia, and other related central nervous disorders."); *id.* at col. 21 ll. 12-15 ("The compounds of the present invention are useful for the treatment of central nervous disorders, such as epilepsy, nervous anxiety, psychosis, insomnia and the like in animals. . . .").

[3]*See also* '551 Patent, col. 3 ll. 56-60 ("However, the present inventor has found such a group of compounds that is generally potent, exhibit minimal neurological toxicity, has a high protective index and is relatively non-toxic to the body organs, including the liver upon multiple dosing."); *id.* at col. 4 ll. 23-25 ("These anti-convulsants [in the present invention] are utilized in a treatment regime requiring acute dosing, and especially chronic dosing thereof to the patient."); *id.* at col. 24 ll. 31-53 ("There is thus still another factor which must be taken into consideration relating to the toxicity of the drug when administered for extended periods to the animal. Obviously, even if the drug has excellent anti-convulsant activity and an excellent PI ratio, the drug will not be useful if the drug is toxic upon chronic dosing to the patient. . . . Based upon the above data, both the furyl derivative and the compounds of the present invention have an excellent drug profile; and both could be used in acute administration. However, . . . the furyl compound is more toxic to the animal . . . . On the other hand, the compounds of the present invention as shown hereinbelow are significantly less toxic than the furyl compound, and in fact exhibit little, if any, toxicity to the animal. Thus, the compounds of the present invention are

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In the Court's view, these repeated, extended discussions of use of the invented compounds for long-term (potentially lifelong) treatment of conditions including epilepsy mean that the "therapeutic composition" claimed in claim 10 must at least be capable of providing safe and effective chronic treatment. From this conclusion, it follows that the term "therapeutic composition" is a claim limitation, as it states a fundamental characteristic of the invention of claim 10. In this case, construing the term is necessary to give life, vitality, and meaning to claim 10.

Having determined that "therapeutic composition" requires construction, the Court further concludes that Plaintiffs' proposed construction of the term tracks the pertinent language recited in the specification. (*See id.* at col. 37 ll. 48-50) Accordingly, the Court adopts Plaintiffs' proposed construction.

In adopting Plaintiffs' construction, the Court is ***not*** holding that claim 10 is limited only to methods of treating epilepsy, a concern Defendants have raised. (*See, e.g.*, Tr. at 26-27) The Court is, instead, only holding that to fall within the scope of claim 10, a therapeutic composition must ***at least*** be safe and effective for the long-term treatment of epilepsy. Compositions within the scope of claim 10 may also be safe and effective for treatment of other conditions, including those called out in the specification (e.g., central nervous system disorders, insomnia, anxiety).

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useful for administration to the treated animal for an extended period."); *see generally id.* at col. 3 ll. 32-41) ("Although not as critical in short term or acute administration of an anticonvulsant, . . . the fourth criteria outlined above is extremely important for an anti-convulsant which is to be taken over a long period of time (chronic administration) or in high dosage. It may be the most important factor in determining which anti-convulsant to administer to a patient, especially if chronic dosing is required.")

None of Defendants' arguments persuade the Court to endorse Defendants' positions – either that the preamble is not limiting or that "therapeutic composition" should be construed as "pharmaceutical composition." For the reasons already explained in concluding that the preamble is a limitation requiring construction, the Court does not agree with Defendants that in adopting Plaintiffs' construction the Court is improperly limiting the claim to a preferred embodiment. Nor does the Court find in the patent what Defendants contend is a rigid and consistent distinction between "compounds" and "therapeutic compositions." Defendants premise much of their claim construction position on the view that it is only the "compounds" claimed by the patentee that have the advantageous characteristics described in the portions of the specification Plaintiffs cite (and on which the Court relies). Defendants suggest further that the disclosures in the specification have no impact on what the patentee meant when he claimed "therapeutic compositions" in claim 10. However, claim 10 explicitly references both "compounds" and "therapeutic composition," and expressly (and undisputedly) requires as a limitation that the therapeutic composition include one of the compounds of claims 1-9. Therefore, Defendants' rigid distinction between "compounds" and "therapeutic compositions" fails and, with it, much of the force of Defendants' claim construction argument. (*See also id.* at 62-63)

At the hearing, substantial attention was devoted to the issue of whether claim 10 covers a composition that is ***only*** suitable for short-term/acute administration. Plaintiffs admit that under their construction (which is now the Court's construction) a composition that is suitable only to short-term use (e.g., a hypothetical injection that may only be used once and never again) is not within the scope of the claim. (*See id.* at 62-63) Given all of the references to suitability for safe

and effective chronic (even lifelong) administration, and given the Court's conclusion that the preamble is a limitation requiring construction, the Court agrees with Plaintiffs that the patentee did not claim such a short-term embodiment (which anyway may not exist). The Court is not persuaded by Defendants' argument that this conclusion undermines support for Plaintiffs' construction, a conclusion based on Defendants' premise that the specification – particularly in discussing acute treatments, including injectable compounds (*see, e.g.*, *id.* at 33-34, 54-55) – discloses preferred embodiments that are only acceptable for short-term use. Contrary to Defendants' reading of the specification, the Court is unable to find from the evidence before it (intrinsic and extrinsic) that injectable compounds containing lacosamide that are suitable for acute treatment of epilepsy cannot also be used as part of a therapeutic composition that is safe and effective for the long-term treatment of chronic epilepsy. Among other things, as Plaintiffs explained at the hearing (and as appears to be undisputed), chronic treatment may ***begin*** with acute treatment. (*See id.* at 15) ("[A]cute use applies to the treatment for a particular seizure and long-term use starts with acute administration. . . . [I]n other words, if you are going to be treated for epilepsy with Vimpat, you will be treated acutely and then over a long period of time.")[4]

Additionally, the Court does not agree with Defendants that "therapeutic" and "pharmaceutical" are consistently used interchangeably in the patent. (*See, e.g.*, *id.* at 46) Claim 10 itself, short as it is, uses both "therapeutic" and "pharmaceutical," and there is no persuasive basis to overcome the presumption that the patentee's use of different adjectives in such

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[4]Thus, compounds that are suitable for acute treatment are within the scope of claim 10, as long as such compounds are ***also*** suitable for chronic treatment. "[The compounds] exhibit excellent anti-convulsant activity, and of course . . . can thus be administered for short term treatment. Moreover, the compounds of the present invention have the added advantage of being useful in drug regimes for long-term treatment." ('551 Patent, col. 21 ll. 17-21)

proximity to one another indicates that the patentee intended the different words to have different meaning. *See generally Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1119 (Fed. Cir. 2004).

Finally, the Court finds that Defendants have not presented clear and convincing evidence showing that claim 10 is indefinite. Defendants base this contention on their uncertainty as to "exactly how long" a period is required to constitute "chronic administration" and further suggest there is an absence of data to demonstrate that lifelong treatment with lacosamide actually is safe. (*See* Tr. at 34-35, 56-58) The record does not contain clear and convincing evidence that a person of ordinary skill in the art at the time of the invention would lack reasonable certainty as to what the patent means by "chronic administration." *See Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2124 (2014); *see also* Tr. at 60. Nor is the Court convinced that the novelty of the chronic administration of the patented therapeutic compositions containing lacosamide (which have received FDA approval) – and the unavoidable lack of incontrovertible evidence that lifetime treatment will prove to be safe and effective – somehow renders the patent's claim indefinite.

III. CONCLUSION

An appropriate Order follows.