IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

UCB, INC., UCB PHARMA GMBH, and LTS LOHMANN THERAPIE-SYSTEME AG,	:	
Plaintiffs,	:	
v.	:	C.A. No. 19-474-LPS
ACTAVIS LABORATORIES UT, INC.,	:	
Defendant.	:	

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MEMORANDUM OPINION

February 7, 2020
Wilmington, Delaware

STARK, U.S. District Judge

Plaintiffs UCB, Inc., UCB Pharma GmbH, and LTS Lohmann Therapie-Systeme AG (collectively "Plaintiffs") filed suit against Defendant Actavis Laboratories UT, Inc. ("Defendant") on March 6, 2019, alleging infringement of U.S. Patent No. 10,130,589 (the "'589 Patent"). (D.I. 1) The patent-in-suit relates to the Neupro® patch, a rotigotine transdermal patch which treats the signs and symptoms of idiopathic Parkinson's disease and moderate-to-severe restless leg syndrome. (*Id.*)

Presently before the Court is the issue of claim construction. The parties completed briefing on November 15, 2019, and submitted supplemental letter briefing on January 24, 2020 and January 28, 2020. (D.I. 45, 46, 57, 58, 74, 77) The Court held a claim construction hearing on November 25, 2019. (D.I. 62) ("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) (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)).

II. CONSTRUCTION OF DISPUTED TERMS[1]

A. "A method for stabilizing rotigotine"[2]

Plaintiffs "A method for stabilizing rotigotine" is not a preamble, but is an express limitation of claim 1, and it carries its plain and ordinary meaning. To the extent a construction is necessary: A method for inhibiting rotigotine crystallization.
Defendant Non-limiting preamble – Only a statement of intent. To the extent the Court finds it is a limitation, Defendant agrees "a method for stabilizing rotigotine" means "a method for inhibiting rotigotine crystallization."

[1] The Court will also adopt the parties' agreed-upon constructions.

[2] This term appears in claim 1 of the '589 patent.

Court
The preamble is not limiting and need not be construed.

In general, a preamble is construed as a limitation "if it recites essential structure or steps, or if it is necessary to give life, meaning, and vitality to the claim." *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002) (internal quotation marks omitted). A preamble is not limiting, however, "where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention." *Id.* (internal quotation marks omitted). In *Catalina*, 289 F.3d at 801, 808-09, the Federal Circuit identified several "guideposts" useful for determining whether a preamble constitutes a claim limitation: (1) the claim is written as a *Jepson* claim; (2) the preamble is essential to understand limitations or terms in the claim body; (3) the preamble establishes antecedent basis for a term in the claim body; (4) the preamble recites structure or steps underscored as important by the specification; or (5) there was clear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art.

Plaintiffs argue that "a method for stabilizing rotigotine" is the express and fundamental utility of the invention described in the claim language and specification of the '589 patent, and, thus, should be limiting. *See, e.g.*, '589 patent at 3:12-36, 5:22-45. If the preamble were not limiting, Plaintiffs argue, the method, and therefore the claim, would lack utility.[3] Defendant argues that the preamble of claim 1 does not function as a limitation but merely states the purpose or intended use of the invention. (*See* D.I. 45 at 15-16) It further argues that the language of the claim body is complete without reference back to the language of the preamble.

[3] Plaintiffs also underscore that the parties agree that the other preamble terms contained in claim 7 ("pharmaceutical composition") and claim 10 ("a transdermal therapeutic system") of the '589 patent are limiting. (*See* D.I. 46 at 5)

Additionally, the preamble term was not relied on during patent prosecution as being patentably significant or to distinguish prior art. (*See* D.I. 45 at 16)

The Court finds that the preamble of claim 1, "a method for stabilizing rotigotine," is not limiting and, therefore, requires no construction. The Court agrees with Defendant that the claim body defines a structurally complete invention and the claim uses the preamble only to state the purpose or intended use of the invention. (*See* Tr. at 26) ("Deletion of the preamble phrase does not affect the structure or steps of the claimed invention.")[4]

The body of claim 1, without the preamble, describes the steps required to prepare a solid dispersion comprising rotigotine and polyvinylpyrrolidone ("PVP"). The claim body recites the manipulative steps of "providing" and "preparing" the claimed mixture, resulting in a stable dispersion, giving the claim utility. (*See* Tr. at 29-30) The claim here differs from that considered in *Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 320 F.3d 1339, 1345 (Fed. Cir. 2003), which recited a method "reduc[ing] to nothing more than a process for producing cytopathic effects in sheets of cultured MA–104 cells – a process whose absence of fathomable utility rather suggests the academic exercise." The *Boehringer* claim required the

[4] Plaintiffs recently proposed a construction for this term in a case involving the '589 patent brought against Mylan in Vermont. (*See* D.I. 74) Their proposed construction, "a method for inhibiting rotigotine crystallization, capable of maintaining the non-crystalline rotigotine in noncrystalline form for at least 2 years at room temperature or temperatures not exceeding 25° C," incorporates a description of "stabilization" from the patent specification. *See UCB, Inc. et al. v. Mylan Technologies, Inc. et al.*, 19-128-cr, D.I. 57 (D. Vt.). After Plaintiffs notified the Court of their Vermont proposal, Defendant responded that Plaintiffs' construction hinges on the method being "capable of" achieving a desired result, which depends on the inherent properties of components of the claimed solid dispersion, thereby improperly importing a limitation from the specification. (*See* D.I. 77) The Court agrees with Defendant that the preamble does nothing more than state an intended purpose. While Plaintiffs' Vermont construction incorporates an embodiment disclosed in the specification, "claims are not typically limited to the embodiments disclosed in the specification, even when just one such embodiment (or type of embodiment) is disclosed." *Ruckus Wireless, Inc. v. Innovative Wireless Sols., LLC*, 824 F.3d 999, 1009 (Fed. Cir. 2016).

preamble to be limiting in order to claim a structurally complete invention with utility, but claim 1 of the '589 patent does not. *See generally Intirtool, Ltd. v. Texar Corp.*, 369 F.3d 1289, 1296 (Fed. Cir. 2004) (holding that district court erred in construing preamble as limiting where claim body was detailed, defined complete structural invention, and did not rely on the preamble for any antecedent basis).[5]

Nor does the prosecution history demonstrate any clear reliance by the patentee on the preamble term. *See id.* ("[C]lear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art transforms the preamble into a claim limitation."). Instead, during prosecution, the patentee focused on the claim requirement of "a weight ratio of rotigotine free base to polyvinylpyrrolidone (PVP) in a range from 9:4 to about 9:6." (D.I. 40 Ex. B (Resp. to 17 May 2018 Office Action) at 6-7)

B. "A method for preparing a transdermal therapeutic system"[6]

Plaintiffs "A method for preparing a transdermal therapeutic system" is not a preamble, but is an express limitation of Claim 11, and it carries its plain and ordinary meaning. To the extent a construction is necessary: A method for preparing a system for the transdermal administration of a medicament.
Defendant Non-limiting preamble – only a statement of intent. To the extent the Court finds it is a limitation, Defendant agrees "a method for preparing a transdermal therapeutic system" means "a method for preparing a system suitable for the transdermal administration of a medicament."

[5] Plaintiffs' argument is also too broad, as, on their reasoning, claim 2, which is directed to the same solid dispersion as claim 1 but without the "stabilizing rotigotine" preamble, would lack utility because it references the same dispersion but does not mention stability.

[6] This term appears in claim 11 of the '589 patent.

Court
The preamble is not limiting and need not be construed.

In arguing that "therapeutic transdermal system" in claim 11 is limiting, because it is fundamental to the invention, Plaintiffs cite to examples in the specification describing a stabilized solid dispersion to prepare a transdermal therapeutic system. *See, e.g.*, '589 patent, 1:19-27, 2:54-58, 2:62-67, 3:21-24, 5:24-45, 10:33-36, 15:43-51. Defendant contends that claim 11 recites a complete invention, to which the preamble adds no needed structure or steps. (D.I. 45 at 16)

The Court agrees with Defendant that the preamble of claim 11, "a method for preparing a transdermal therapeutic system," only describes an intended purpose or use for the invention and is not limiting. The method step is "preparing a solid dispersion" and the remainder of the claim describes the structural features of the solid dispersion. The claim steps, without the preamble, capture the fundamental characteristic of the invention, as described in the patent specification, which is to prepare a solid dispersion that inhibits crystallization. *See, e.g.*, '589 patent at 3:28-36 ("It is now surprisingly found that when used in a specific weight ratio to rotigotine, PVP is unexpectedly able to stabilize the non-crystalline form of rotigotine and prevent rotigotine from re-crystallization in a solid dispersion, such as a self-adhesive matrix of a transdermal therapeutic system, thereby imparting sufficient long term storage stability properties to the transdermal therapeutic system, preferably at room temperature, and without negatively influencing other relevant parameters of the TTS."). The preamble generally describes the intended use of the invention, a transdermal therapeutic system, but does not recite steps that are "the essence of the invention without which performance of the recited steps is nothing but an academic exercise." *Boehringer*, 320 F.3d at 1345. Further, both parties agree

that patentee did not rely clearly on the preamble to distinguish the claimed invention from the prior art during prosecution.

C. "A dispersing agent"[7]

Plaintiffs Plain and ordinary meaning, which means "[t]he continuous or outer phase among the two phases of a solid dispersion."
Defendant Any solid or semi-solid permeable silicone-based polymer or copolymer or an acrylate" that "provides sufficient activity and stability for the solid dispersion as well as sufficient release of rotigotine."
Court Plain and ordinary meaning. No construction necessary.

As Defendant points out, the specification describes "a dispersing agent" as a solid or semi-solid silicone-based polymer or an acrylate that provides sufficient activity and stability for the solid dispersion, as well as sufficient release of rotigotine. (D.I. 45 at 13) (citing '589 patent at 6:8-17) However, as Plaintiffs emphasize, the specification explains that "the dispersing agent ***may*** be any solid or semi-solid semi-permeable silicone-based polymer or copolymer, ***or in another embodiment***, the dispersing agent is an acrylate." '589 patent at 6:12-15 (emphasis added). The Court agrees with Plaintiffs that the claims are not limited to the permissive embodiments to which Defendant seeks to limit them.

The specification of the '589 patent broadly describes dispersing agents, which can be a "mixture of adhesives." '589 patent at 4:6-10; *see also* '589 patent at 6:12-19 ("The dispersing agent of the solid dispersion may be any solid or semi-solid permeable silicone-based polymer or copolymer . . . Usually this polymer will be a pressure sensitive adhesive (PSA) or a mixture of such adhesives."). The specification describes how "different types of pressure sensitive

[7] This term appears in claims 2, 11, and 12 of the '589 patent.

adhesives may be used in the present invention" ('589 patent, 7:39-53) and that "usually, this polymer will be a pressure sensitive adhesive (PSA) or mixture of such adhesives" ('589 patent, 6:18-19).

The record does not contain a "clear and unambiguous disavowal of claim scope" by the inventor other than that the claims are limited to a silicone- or acrylate-based pressure sensitive adhesive. (*See* D.I. 40 Ex. C ("Wolff Declaration") at NEU-1770371-373) Instead, the patentee generally explained the unpredictability of developing a transdermal therapeutic system. Thus, this case is unlike *Trustees of Columbia Univ. in City of New York v. Symantec Corp.*, 811 F.3d 1359, 1364 (Fed. Cir. 2016), as here Defendant attempts to rely on what are "simply descriptions of the preferred embodiment and not definitional statements" to support its unpersuasive argument that a patentee's choice of preferred embodiments – here, the silicone and acrylate polymers described in the specification – give "special meaning" to the term "dispersing agent." (D.I. 45 at 13-15; D.I. 57 at 9; Tr. at 52-53)

A person of ordinary skill in the art, after reviewing the claims and specification of the '589 patent, would understand "a dispersing agent" to have its plain and ordinary meaning.

III. CONCLUSION

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