

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

CADENCE PHARMACEUTICALS,	:	
INC., SCR PHARMATOP, and	:	
MALLINCKRODT IP,	:	
	:	
Plaintiffs,	:	C.A. No. 14-1225-LPS
	:	
v.	:	
	:	
INNOPHARMA LICENSING LLC and	:	
INNOPHARMA, INC.,	:	
	:	
Defendants.	:	

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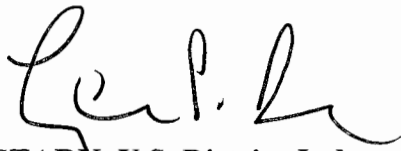
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MEMORANDUM OPINION

July 8, 2016
Wilmington, Delaware



STARK, U.S. District Judge:

On September 24, 2014, Plaintiffs Cadence Pharmaceuticals, SCR Pharmatop, and Mallinckrodt IP (“Plaintiffs”) filed suit against Defendants InnoPharma Licensing, LLC, and InnoPharma, Inc., (“Defendants”) alleging infringement of U.S. Patent Nos. 6,028,222 (the “222 patent”) and 6,992,218 (the “218 patent”). The patents claim aqueous acetaminophen formulations and methods for making them.

The parties submitted technology tutorials (D.I. 59 and 60) and claim construction briefs (D.I. 62, 65, 85 and 90). The Court held a claim construction hearing on May 9, 2016.

I. LEGAL STANDARDS

The ultimate question of the proper construction of a patent is a question of law. *See Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 837 (2015) (citing *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 388-91 (1996)). “It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (internal quotation marks omitted). “[T]here is no magic formula or catechism for conducting claim construction.” *Id.* at 1324. Instead, the court is free to attach the appropriate weight to appropriate sources “in light of the 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. Conceptoronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996).

While “the claims themselves provide substantial guidance as to the meaning of particular claim terms,” the context of the surrounding words of the claim also must be considered.

Phillips, 415 F.3d at 1314. Furthermore, “[o]ther claims of the patent in question, both asserted and unasserted, can also be valuable sources of enlightenment . . . [b]ecause claim terms are normally used consistently throughout the patent” *Id.* (internal citation omitted).

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

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

F.3d 898, 906 (Fed. Cir. 2004)) (internal quotation marks omitted).

In addition to the specification, a court “should also consider the patent’s prosecution history, if it is in evidence.” *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995), *aff’d*, 517 U.S. 370 (1996). The prosecution history, which is “intrinsic evidence,” “consists of the complete record of the proceedings before the PTO [Patent and Trademark Office] and includes the prior art cited during the examination of the patent.” *Phillips*, 415 F.3d at 1317. “[T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be.” *Id.*

In some cases, “the district court will need to look beyond the patent’s intrinsic evidence and to consult extrinsic evidence in order to understand, for example, the background science or the meaning of a term in the relevant art during the relevant time period.” *Teva*, 135 S. Ct. at 841. Extrinsic evidence “consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises.” *Markman*, 52 F.3d at 980. For instance, technical dictionaries can assist the court in determining the meaning of a term to those of skill in the relevant art because such dictionaries “endeavor to collect the accepted meanings of terms used in various fields of science and technology.” *Phillips*, 415 F.3d at 1318. In addition, expert testimony can be useful “to ensure that the court’s understanding of the technical aspects of the patent is consistent with that of a person of skill in the art, or to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field.” *Id.* Nonetheless, courts must not lose sight of the fact that “expert reports and

testimony [are] generated at the time of and for the purpose of litigation and thus can suffer from bias that is not present in intrinsic evidence.” *Id.* Overall, while extrinsic evidence “may be useful” to the court, it is “less reliable” than intrinsic evidence, and its consideration “is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence.” *Id.* at 1318-19. Where the intrinsic record unambiguously describes the scope of the patented invention, reliance on any extrinsic evidence is improper. *See Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1308 (Fed. Cir. 1999) (citing *Vitronics*, 90 F.3d at 1583).

Finally, “[t]he construction that stays true to the claim language and most naturally aligns with the patent’s description of the invention will be, in the end, the correct construction.” *Renishaw PLC v. Marposs Societa’ per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998). It follows that “a claim interpretation that would exclude the inventor’s device is rarely the correct interpretation.” *Osram GmbH v. Int’l Trade Comm’n*, 505 F.3d 1351, 1358 (Fed. Cir. 2007) (quoting *Modine Mfg. Co. v. U.S. Int’l Trade Comm’n*, 75 F.3d 1545, 1550 (Fed. Cir. 1996)).

II. CONSTRUCTION OF DISPUTED TERMS

A. “free radical scavenger and free radical antagonist”¹

Plaintiffs substance that functions in the formulation as an antioxidant
Defendants substance that prevents oxidation by reacting with a free radical
Court substance that prevents oxidation by reacting with a free radical

The parties agree that free radical scavengers are one of several types of antioxidants.

(*See, e.g.*, D.I. 85 at 10; D.I. 90 at 12-13) They disagree about whether the term includes within its scope all antioxidants or, instead, only antioxidants that function by scavenging free radicals.²

The Court construed this claim term in a prior litigation. *See Cadence Pharm., Inc. v. Exela Pharma Scis.*, 2013 WL 11083852 (D. Del. Nov. 14, 2013), *aff'd*, 780 F.3d 1364 (Fed. Cir. 2015). Plaintiffs urge the Court to adopt the same construction it did in that earlier case.

Defendants contend that the Court should reevaluate its prior construction, arguing that the Plaintiffs limited the claims through statements made during a reexamination that post-dated the

¹This term appears in claims 1, 37, and 44 of the '222 patent.

²Plaintiffs argue that the Court should not even construe the term because Defendants did not raise a dispute regarding its construction until more than a week after filing the parties' joint claim construction statement, yet Defendants' arguments are primarily based on intrinsic evidence developed during the earlier reexamination, which concluded more than two years ago. (D.I. 65 at 13) Plaintiffs have not moved to strike Defendants' new construction, nor demonstrated that Defendants' timing was unfairly prejudicial. Moreover, claim construction often involves a fluid process. Under the totality of circumstances, the Court believes the proper exercise of its discretion here is to resolve the parties' genuine, material claim construction dispute.

Court's earlier construction.³

“Under the doctrine of prosecution disclaimer, a patentee may limit the meaning of a claim term by making a clear and unmistakable disavowal of scope during prosecution.” *Purdue Pharma L.P. v. Endo Pharm. Inc.*, 438 F.3d 1123, 1136 (Fed. Cir. 2006). In keeping with this doctrine, “[a] patentee’s statements during reexamination can be considered during claim construction.” *Krippelz v. Ford Motor Co.*, 667 F.3d 1261, 1266 (Fed. Cir. 2012). For example, when a patentee overcomes a prior art rejection by characterizing a claim term in a particular way, the patentee’s statements may limit the scope of the claims. See *In re Katz Interactive Call Processing Patent Litig.*, 639 F.3d 1303, 1325 (Fed. Cir. 2011). Similarly, if a patentee relies on a particular construction of the claims to overcome an obviousness rejection, the patentee should be held to that construction in future proceedings. See *N. Am. Container, Inc. v. Plastipak Packaging, Inc.*, 415 F.3d 1335, 1345 (Fed. Cir. 2005).

³Amended claim 1, which is exemplary, now reads:

A stable, liquid formulation **for intravenous administration** consisting essentially of acetaminophen dispersed in an aqueous medium containing a buffering agent and at least one member of the group consisting of a free radical scavenger and a **free** radical antagonist,

wherein the at least one member is selected from the group consisting of ascorbic acid, ascorbic acid derivatives, thioglycolic acid, thiolactic acid, dithiothreitol, reduced glutathione, thiourea, α-thioglycerol, cysteine, acetyl-cysteine, mercaptoethane sulfonic acid, mannitol, sorbitol, inositol, glucose, levulose, glycerol, and propylene glycol; and

wherein the formulation has an acetaminophen concentration of 5 mg/mL to 20 mg/mL

³222 pat. ex parte reexamination certificate col. 1:27-40 (emphasis added to highlight additions)

During the reexamination of the '222 patent, the Patent Examiner found that the broadest reasonable interpretation of the terms “free radical scavenger” and “free radical antagonist” is “a compound that prevents oxidation by reacting with a free radical.” (D.I. 61-4 at 7, 9) Plaintiffs did not object to this construction. To the contrary, they relied on it to overcome prior art and obviousness rejections.

Specifically, the patentee relied on the Examiner’s construction to overcome two, separate prior art rejections. With respect to each, the patentee distinguished the claimed antioxidants from the prior art antioxidants by arguing that, in contrast to the claimed antioxidants, the prior art antioxidants were not free radical scavengers/antagonists. (See D.I. 61-4 at 72, 96-97 (“Thus, from the teachings of the prior art, one of ordinary skill would not anticipate that anti-oxidants – and in particular, the subset of anti-oxidants called free radical scavengers/antagonists – could improve the stability of acetaminophen formulations”), 112; *see also id.* at 120-21 (distinguishing claimed antioxidants from prior art antioxidant EDTA by noting that EDTA did not act as free radical scavenger/antagonist))

Also, the patentee overcame an obviousness rejection by limiting its claims to a list of particular free radical scavenger/antagonists. The patentee submitted an inventor declaration explaining that each substance was a free radical scavenger or antagonist because each prevented or limited oxidation through “anti-radical effects.”⁴ (D.I. 61-2 at 2-3, 11-17) The PTO accepted this explanation and allowed the claims.

The patentee’s statements clearly and unmistakably rely on the Patent Examiner’s

⁴Although the patentee acknowledged that the claimed compounds might also prevent oxidation in other ways, the patentee overcame the obvious rejection by pointing to the unexpected results associated with free radical scavenging. (D.I. 61-2 at 2-3, 11-17)

construction in order to overcome prior art. When a patentee makes such “definitive statements” about claim scope during prosecution (including reexamination), the public is entitled to rely on those statements to ascertain the scope of the patentee’s property right. *See Saffran v. Johnson & Johnson*, 712 F.3d 549, 559 (Fed. Cir. 2013).

Although the Court previously construed “free radical scavenger and free radical antagonist” as a “substance that functions as an antioxidant,” *see Cadence Pharm., Inc. v. Paddock Labs. Inc.*, 886 F. Supp. 2d 445 (D. Del. 2012), *aff’d sub nom. Cadence Pharm. Inc. v. Exela PharmSci Inc.*, 780 F.3d 1364 (Fed. Cir. 2015) (“*Cadence I*”), the patentee’s disclaimer during the subsequent reexamination requires that the Court modify what was previously a correct construction. Additionally, in other litigation subsequent to *Cadence I*, Plaintiffs argued during claim construction that “free radical scavenger/antagonist” should be construed as a “substance that functions in the formulation as an antioxidant by scavenging free radicals,” and did so in order to “clarif[y] that the substance function[s] as as an antioxidant ‘by scavenging free radicals.’” (D.I. 63-4 at 26-7) The Court’s construction today is entirely consistent with Plaintiffs’ position in that other litigation.

B. “ascorbic acid derivatives”⁵

Plaintiffs chemical substances related structurally to ascorbic acid and at least theoretically derivable from ascorbic acid
Defendants a compound derivable from ascorbic acid having an ascorbate functional group
Court chemical substances related structurally to ascorbic acid and at least theoretically derivable from ascorbic acid

The parties agree that an ascorbic acid derivative is a compound derivable from ascorbic acid. They disagree about whether the term is limited to compounds having an “ascorbate functional group.” Defendants argue that the claims’ use of the term “ascorbic acid derivatives” as a category of free radical scavenger/antagonist indicates that the compounds’ free radical scavenging activity should result from a structural feature common to all ascorbic acid derivatives. (D.I. 62 at 18) While Defendants acknowledge it is “theoretically” possible that one could derive from ascorbic acid a compound with an alternative mechanism for scavenging free radicals, they argue that the patent makes clear that the term “ascorbic acid derivatives” refers to compounds that use an ascorbate functional group. (D.I. 62 at 21) As support for their position, Defendants provide reports from an expert who opines that a person of ordinary skill in the art would understand that a portion of the structure identified by the expert is both “responsible for ascorbic acid’s free radical scavenging ability” and provides the minimum “meaningful structural similarity” to make a compound identifiable as a derivative of ascorbic acid. (D.I. 64 at 18-20)

Plaintiffs contend that Defendants’ position cannot be correct, because the term

⁵This term appears in claims 1, 37, and 44 of the ’222 patent.

“ascorbate functional group” would not have been known to or understood by a person of ordinary skill in the art at the relevant time. (D.I. 90 at 22-25) Further, they point to a number of differences among the structures highlighted in Defendants’ expert report, arguing that these differences undermine Defendants’ position that the concept of an “ascorbate functional group” clarifies the claims.

Having reviewed Defendants’ expert reports, the Court is not persuaded that a person of ordinary skill in the art would have understood the term “ascorbic acid derivative” to require the presence of an ascorbate functional group. The specification does not define “ascorbic acid derivative” as having a particular functional group. Nor does it indicate that all of the claimed derivatives contain specific functional groups. Defendants have not been able to identify with clarity a particular “root structure” that makes a compound identifiable as an “ascorbic acid derivative.” In short, Defendants’ construction would add a limitation not supported by the record.

While Defendants raise concerns with the breadth of Plaintiffs’ proposed construction, that construction is not unbounded. The claimed ascorbic acid derivatives must function as free radical scavengers or antagonists. Further, the claimed derivatives are limited to those a person of ordinary skill in the art at the time of the invention would perceive to be (at least) theoretically derivable from ascorbic acid. (Tr. at 36) Finally, Plaintiffs concede that the “ascorbic acid derivatives” of the claims must be structurally similar to ascorbic acid. (*Id.*) Given these meaningful limitations, the Court is confident that Plaintiffs’ proposed construction is not unduly broad, and will adopt it.

C. “preserving for a prolonged period”⁶

Plaintiffs the aqueous solution does not decompose substantially such that the formulation has a prolonged pharmaceutically acceptable shelf life
Defendants indefinite
Court The Court has not construed this term at this time.

The Court understands that the parties do not wish for the Court to construe this term at this time and have only identified it to preserve their rights to argue about its potential indefiniteness at a later point in this case. For this reason, the Court has not construed this term.

III. CONCLUSION

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

⁶This term appears in claim 1 of the '218 patent.