IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CADENCE PHARMACEUTICALS, INC., SCR PHARMATOP, and MALLINCKRODT IP,	:	
Plaintiffs,	:	C.A. No. 14-1499-LPS
v.	:	
AGILA SPECIALTIES INC. and MYLAN LABORATORIES LIMITED,	:	
Defendants.	:	

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MEMORANDUM OPINION

August 29, 2016
Wilmington, Delaware

STARK, U.S. District Judge:

On December 19, 2014, Plaintiffs Cadence Pharmaceuticals, Inc., SCR Pharmatop, and Mallinckrodt IP ("Plaintiffs") filed suit against Defendants Agila Specialties Limited and Mylan Laboratories Limited ("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 of manufacturing them.

The parties submitted technology tutorials (D.I. 65 and 66) and claim construction briefs (D.I. 68, 69, 74 and 76). The Court held a claim construction hearing on June 27, 2016. (*See* D.I. 130 ("Tr.")) The parties submitted additional, unsolicited letters after the hearing, which the Court has considered. (D.I. 131 and 134)

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. 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)) (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 TERM[1]

A. "liquid formulation for intravenous administration consisting essentially of acetaminophen dispersed in an aqueous medium"[2]

Plaintiffs a solution of acetaminophen dissolved in a medium containing water or aqueous mixtures of water and a polyhydric compound and/or a water soluble alcohol for intravenous administration
Defendants a solution of acetaminophen dissolved in a medium containing water or aqueous mixtures of water and a polyhydric compound and/or water soluble alcohol for intravenous solution, that is not reconstituted
Court a solution of acetaminophen dissolved in a medium containing water or aqueous mixtures of water and a polyhydric compound and/or a water soluble alcohol for intravenous administration

This claim term includes amendments made during a recent *ex parte* reexamination of the '222 patent. (D.I. 67-1 at 17) Prior to reexamination, claim 1 was directed to a "liquid formulation consisting essentially of acetaminophen dispersed in an aqueous medium." The Court previously construed that version of the claim term as "a solution of acetaminophen dispersed in a medium containing water or aqueous mixtures of water and a polyhydric compound and/or a water soluble alcohol." *Cadence Pharm., Inc. v. Paddock Labs. Inc.*, 886 F. Supp. 2d 445, 455 (D. Del. 2012), *aff'd sub nom. Cadence Pharm. Inc. v. Exela PharmSci Inc.*, 780 F.3d 1364 (Fed. Cir. 2015).

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[1]The parties previously disputed, and submitted claim construction briefs regarding, the term "[a]n injectable aqueous solution containing, as an active ingredient, a principle of phenolic nature susceptible to oxidation, preserved by the method of claim 1," which appears in claim 19 of the '218 patent. The Court understands that the parties have now stipulated that no construction of this term is necessary. (*See* Tr. at 4-5)

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

During the reexamination, the patentee added language specifying that the claims are directed to a liquid formulation "***for intravenous administration***." Defendants argue that the patentee added this term to the claims "in order to exclude reconstituted products from their claims." (D.I. 68 at 6) Plaintiffs disagree.

The portions of the prosecution history bearing directly upon the reasons for the "intravenous administration" amendment show that it was for purposes other than excluding reconstituted products from the scope of the claims. After receiving an initial rejection in view of prior art references directed to "injectable" formulations of acetaminophen, the patentee added "intravenous administration" in order to distinguish its invention from "injectable" (i.e., into muscle) formulations. (D.I. 62-1 at 105) The patentee explained that its amendment differed from the prior art because the prior art references were directed to formulations for administration into muscle or fatty tissue. (D.I. 62-1 at 148-149) In contrast, the claimed formulations were designed for administration into veins. (*Id.*) Hence, the amendment had nothing to do with the issue Defendants now press: whether the claim excludes reconstituted products.

Defendants nevertheless argue that the patentee's description of its products during prosecution shows that the patentee's amendment also ruled out the possibility of a reconstituted product. As evidence of such a disclaimer, they point to portions of the prosecution history in which the patentee notes that the claimed formulations are distinct from prior art formulations that needed to be reconstituted immediately prior to use. (D.I. 68 at 9-12)

Careful examination of the prosecution history shows, however, that the patentee distinguished the patented formulations based on their stability, not based on whether they were

"reconstituted." During reexamination, the examiner found that the patent owner had "established that there was a persistent need for a stable, aqueous" form of acetaminophen. (D.I. 67 Ex. K at 59) The examiner noted that, at the time of the patentees' invention, the most similar commercial product was unstable as a liquid. (*Id.*) As a result, it could not be mixed at the manufacturing site and shipped as a liquid, but instead needed to be "sold as a powder that had to be reconstituted" at the treatment site shortly before use. (*Id.*) This was inconvenient because the need to reconstitute the formulation precluded healthcare providers from using the drug in "time sensitive, emergency situations." (*Id.*; *see also* D.I. 62-2 ¶¶ 40, 50 (explaining that need to take time to reconstitute prior art intravenous products "immediately before" administration was problematic because acetaminophen is often needed urgently))

This discussion indicates that the patentee's invention differed from the prior art because of its stability in liquid form. It also establishes that this stability could be beneficial because, unlike unstable prior art products, stable products do not ***require*** reconstitution ***immediately prior to use***. But it does not suggest that the claims ***do not cover*** solutions made by reconstituting a solid. Rather, the claims potentially include within their scope any products that are stable – be they reconstituted or not. Indeed, Defendants conceded at the claim construction hearing that the claims do cover preferred embodiments that consist of solutions prepared by dissolving solid excipients.[3] (*See* Tr. 27-31; *see also id.* at 8-9)

The patentee's emphasis on stability, as opposed to a lack of reconstitution, is evident in other portions of the prosecution history. For example, the file history includes a rejection based

[3]Defendants did not explain how a solution whose excipients were at some point solids could be characterized as "not reconstituted." (Tr. at 29-30)

on the examiner's finding that the claims were not commensurate in scope with the long-felt need for a shelf-stable liquid formulation of acetaminophen. The examiner explained that these claims were too broad because they covered formulations that were not shelf-stable. (D.I. 67 Ex. K at 59) In response, the patentee amended the claims to add a claim limitation on the concentration of acetaminophen. (D.I. 62-1 at 12) The patentee explained that this limitation would address the stability requirement, ensuring that any formulation covered by the claims could if needed be made "ready for direct patient administration without mixing, reconstitution, or further processing." (D.I. 62-1 at 120, 146-47)[4]

Thus, having found that the patentee did not disavow reconstituted solutions, the Court adopts Plaintiffs' proposed construction.

B. "while preserving for a prolonged period"[5]

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

[4]At most, this history suggests that, in determining whether a formulation meets the claims' stability requirement, one might consider how far in advance the formulation could be reconstituted. If a formulation were stable for only minutes at a time, such that healthcare providers could not avoid the difficulties associated with reconstituting the product at inopportune moments, then one might be able to argue that the formulation would fail to meet the long-felt need for a "stable" formulation. That dispute is not before the Court today.

[5]This term appears in claim 1 of the '218 patent.

The Court understands that the parties do not want the Court to construe this term at this time, and have only identified the term as disputed in order to preserve their rights to raise a dispute about its construction in the future. For this reason, the Court has not construed this term.

III. CONCLUSION

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

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CADENCE PHARMACEUTICALS, INC., SCR PHARMATOP, and MALLINCKRODT IP,	:	
Plaintiffs,	:	C.A. No. 14-11499-LPS
v.	:	
AGILA SPECIALTIES INC. and MYLAN LABORATORIES LIMITED,	:	
Defendants.	:	

ORDER

At Wilmington, this **29th** day of **August, 2016**:

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

IT IS HEREBY ORDERED that the disputed claim term of U.S. Patent Nos. 6,028,222 (the "'222 patent") is construed as follows:

Claim Term	Court's Construction
"liquid formulation for intravenous administration consisting essentially of acetaminophen dispersed in an aqueous medium" ['222 patent, claims 1, 37, 44]	"a solution of acetaminophen dissolved in a medium containing water or aqueous mixtures of water and a polyhydric compound and/or a water soluble alcohol for intravenous administration"

UNITED STATES DISTRICT COURT