

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

H. LUNDBECK A/S, et al.,	:	
	:	
Plaintiffs,	:	
v.	:	C.A. No. 18-88-LPS
	:	
APOTEX INC., et al.,	:	
	:	
Defendants.	:	

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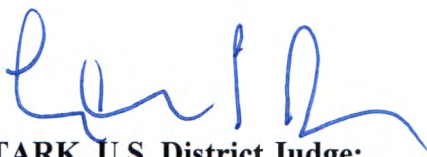
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MEMORANDUM OPINION

February 18, 2020
Wilmington, Delaware



STARK, U.S. District Judge:

Pending before the Court is the parties' second set of claim construction disputes related to terms in U.S. Patent Nos. 9,125,908 ("908 patent"), 9,125,909 ("909 patent"), 9,125,910 ("910 patent"), and 9,278,096 ("096 patent").¹ The parties submitted claim construction briefs (D.I. 411, 412, 442, 447) and exhibits (D.I. 411-1, 413-1, 413-2, 443-1). The Court held a claim construction hearing on December 18, 2019, at which both sides presented oral argument. (D.I. 642) ("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

¹ After the parties submitted their opening claim construction briefs, Defendant Cipla informed Plaintiffs that the '348 patent terms "1-[2- (2,4-dimethylphenyl-sulfanyl)phenyl]piperazine-HBr solvate" and "1-[2-(2,4-dimethylphenylsulfanyl)phenyl]piperazine-HBr isopropanol solvate" do not require construction. (See D.I. 447 at 1 n.1) Thus, the Court will not construe these terms.

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

A. “has to be ceased or reduced due to sexually related adverse events”²

<p>Plaintiffs No construction necessary</p> <p>Alternatively, “has to be ceased or reduced due to an adverse event involving dysfunction in one or more areas of sexual functioning, including, desire, arousal, physical response, orgasm, or satisfaction”</p>
<p>Defendants This term is indefinite</p>
<p>Court “has to be ceased or reduced due to an adverse event involving dysfunction in one or more areas of sexual functioning, including, desire, arousal, physical response, orgasm, or satisfaction”</p>

² This term appears in claim 1 of the ’096 patent.

A claim term is indefinite if it fails to “inform those skilled in the art about the scope of the invention with reasonable certainty.” *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2129 (2014). Defendants have not met their burden to prove indefiniteness “by clear and convincing evidence.” *See Sonix Tech. Co., Ltd., v. Publ’ns Int’l, Ltd.*, 844 F.3d 1370, 1377 (Fed. Cir. 2017). While Defendants argue that the patent provides no guidance for when treatment “has to be ceased or reduced,” they themselves provide no concrete evidence – such as expert testimony – showing that a person of ordinary skill in the art (“POSA”) reading the patent claim in context could not determine, with reasonable certainty, when treatment should be ceased or reduced. *See generally Koito Mfg. Co., Ltd. v. Turn-Key-Tech, LLC*, 381 F.3d 1142, 1156 (Fed. Cir. 2004) (“[A] patent applicant does not need to include in the specification that which is already known to and available to one of ordinary skill in the art.”).

Defendants argued at the hearing that this term is indefinite because it requires physicians to make decisions based on the “subjective determination of a patient.” (D.I. 642 at 15, 20) Defendants have not cited cases supporting this conclusion. The Court is not aware of cases invalidating method of treatment patent claims as indefinite based on the possibility that different physicians would treat different patients (or even the same patient) differently. By contrast, Plaintiffs identify cases that have found claim terms requiring physicians to make patient-specific judgments to be not indefinite. *See Abbott Labs. v. Lupin Ltd.*, 753 F. Supp. 2d 382, 410 (D. Del. 2010) (finding “no persuasive reason to infer that a person having ordinary skill in the art would not be able to understand and follow [the terms ‘treatment-limiting’ and ‘require treatment to be discontinued’]” and that “reliance on the informed medical judgment of a trained physician in the relevant art is notice enough”); *Talecris Biotherapeutics, Inc. v. Baxter Int’l, Inc.*, 510 F. Supp. 2d 356, 361 (D. Del. 2006) (concluding that “acceptable level suitable for

intravenous administration” was not “purely subjective” or indefinite even though “the determination of [its] meaning may depend on a number of variables”).

B. “cognitive impairment”³

Plaintiffs “a decline or deficit in one or more cognitive functions or cognitive domains”
Defendants “a CNS disorder including a decline in cognitive functions or cognitive domains, which is independent from depression or major depressive disorder.”
Court “a decline or deficit in one or more cognitive functions or cognitive domains”

Defendants ask the Court read into the disputed term a limitation that the pertinent cognitive impairments be restricted to a CNS disorder “which is independent from depression or major depressive disorder.” The claim language “cognitive impairment *in a patient diagnosed with depression*” suggests that these conditions are linked, not independent of one another. *See, e.g.*, ’910 patent at 30:30-34 (emphasis added). While Defendants argue that the claims consider depression and cognitive impairment to be “separate disorders” (D.I. 641 at 40), Defendants have not cited persuasive intrinsic evidence that no connection exists between these conditions; rather, as Defendants later acknowledged, these conditions “exist as two separate things, *sometimes together*.” (D.I. 642 at 41) (emphasis added).

The specification observes that “[t]here is also clear evidence that cognitive disorders are, indeed, independent from depression.” *See, e.g.*, ’910 patent at 7:42-56. But the specification also states that cognitive impairment and depression may be linked. *See, e.g.*, ’910 patent at 7:39-42 (stating that cognitive impairment “is among the classic features of depression” and “[c]ognitive disorders may to some extent be secondary to depression in the sense that an

³ This term appears in claim 1 of the ’910 patent, claim 1 of the ’908 patent, and claim 1 of the ’909 patent.

improvement in the depressive state will also lead to an improvement of the cognitive impairment”)

The prosecution history does not alter these conclusions. Rather, it shows only that the applicant and examiner believed that the invention treated the *symptoms* of cognitive impairment separately from those of depression – not that the condition of cognitive impairment was itself “independent from depression.” (D.I. 412 at 8-9; *see also* D.I. 397 Ex. T at TRINTELLIX_T_02353224-26)

III. CONCLUSION

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

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	:	
Plaintiffs,	:	
v.	:	C.A. No. 18-88-LPS
	:	
APOTEX INC., et al.,	:	
	:	
Defendants.	:	

ORDER

At Wilmington this **18th** day of **February, 2020**:

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

IT IS HEREBY ORDERED that the following claim terms are construed as follows:

Claim Term	Court's Construction
has to be ceased or reduced due to sexually related adverse events	has to be ceased or reduced due to an adverse event involving dysfunction in one or more areas of sexual functioning, including, desire, arousal, physical response, orgasm, or satisfaction
cognitive impairment	a decline or deficit in one or more cognitive functions or cognitive domains


UNITED STATES DISTRICT JUDGE