IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ACORDA THERAPEUTICS, et al.,	:	
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Plaintiffs,	:	
	:	
v.	:	C.A. No. 14-882-LPS
	:	
ALKEM LABORATORIES LTD., et. al.,	:	
	:	
	:	
Defendants.	:	
	:	

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MEMORANDUM OPINION

March 16, 2016
Wilmington, Delaware

STARK, U.S. District Judge:

This is a patent infringement action brought by Acorda Therapeutics, Inc. and Alkermes Pharma Ireland Limited ("Plaintiffs") under the Hatch-Waxman Act. Plaintiffs filed suit against Defendants Aurobindo Pharma Ltd., Aurobindo Pharma USA, Inc., Alkem Laboratories Limited, Accord Healthcare, Inc., Mylan Pharmaceuticals, Inc., Teva Pharmaceuticals USA, Inc., Roxane Laboratories, Inc., Apotex Corp., and Apotex, Inc ("Defendants"). Each defendant submitted an Abbreviated New Drug Application ("ANDA") to market a generic version of Amypra, a drug containing the active pharmaceutical ingredient 4-aminopyridine ("4-AP"). Plaintiffs assert five Orange Book-listed patents: U.S. Patent Nos. 5,540,938 (the "'938 patent"), 8,007,826 (the "'826 patent"), 8,354,437 (the "'437 patent"), 8,440,703 (the "'703 patent"), and 8,663, 685 (the "'685 patent"). The asserted patents relate generally to the use of a sustained release formulation of 4-AP.

The parties submitted claim construction briefs (D.I. 125, 127, 172, and 173) and the Court held a claim construction hearing on March 7, 2016 ("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." *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 TERMS[1]

A. "therapeutically effective concentration"[2]

Plaintiffs Plain and ordinary meaning. Alternatively: "blood plasma level of drug that ameliorates a symptom"
Defendants "an amount sufficient to decrease or prevent the symptoms associated with a medical condition or infirmity or to normalize body functions in disease or disorders that result in impairment of specific bodily functions"
Court "blood plasma level of drug that ameliorates a symptom"

The parties agree that the term "concentration" refers to "blood plasma levels." They also agree that the preambles of the asserted claims, each of which describes maintaining a "therapeutically effective concentration" of 4-AP in order to "improve walking in a human with multiple sclerosis," are limiting. (Tr. at 25, 31) They disagree, however, about which of two descriptions of "therapeutically effective amount" found in the '826 patent the Court should adopt as the construction of this term.

The specification contains a list of defined terms, including that "therapeutically effective amount" means "an amount sufficient to decrease or prevent the symptoms associated with a medical condition or infirmity or to normalize body functions in disease or disorders that result in impairment of specific body functions." '826 patent col. 5:51-61. In the next column of the specification, the patent states that a "therapeutically effective amount" of drug provided by the

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[1]The parties have stipulated to the construction of certain terms discussed in their briefing. (*See* D.I. 187, 193) Accordingly, the Court will not construe them, nor include their construction in its written order.

[2]This term appears in claims 1, 2, 5-7, 10, 11, 14-16, 18-22, and 24-29 of the '826 patent.

sustained-release pharmaceutical compositions is "an amount . . . that when administered to a patient or subject ameliorates a symptom of a neurological disease." *Id.* at 6:5-19. Given that, as the parties agree, the claims at issue are limited by preambles that refer to improving a particular category of symptoms (those related to walking) of a particular neurological disease (multiple sclerosis), the Court finds that the latter construction is more pertinent in the context of the asserted claims. Therefore, the Court adopts Plaintiffs' proposed construction.[3]

B. "therapeutically effective blood levels"[4]

Plaintiffs Plain and ordinary meaning. Alternatively: "blood levels sufficient to produce the desired effect"
Defendants "an amount present in the patient's blood sufficient to decrease or prevent the symptoms associated with a medical condition or infirmity"
Court "blood levels sufficient to produce a therapeutic effect"

The parties' dispute again centers on the meaning of "therapeutically effective," this time in the context of the '938 patent. Defendants contend that a drug is present in the body in a "therapeutically effective" amount if the amount is sufficient to "decrease or prevent symptoms" of the medical condition it is meant to treat. Plaintiffs argue that this construction would inappropriately limit the claims, because a drug can have therapeutic effects without actually

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[3]Plaintiffs would most prefer that the Court not construe the term at all and instead give it its "plain and ordinary meaning." However, the Court finds that the parties have presented an actual dispute regarding the scope of the claim term. It is the Court's duty to resolve this dispute by providing a construction. *See O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co., Ltd.*, 521 F.3d 1351, 1361-62 (Fed. Cir. 2008).

[4]This term appears in claims 3 and 8 of the '938 patent.

decreasing or preventing symptoms of a disease. (D.I. 125 at 11)[5]

The Court agrees with Plaintiffs that it would be improper to equate therapeutic effectiveness with "decreas[ing] or prevent[ing] symptoms." The '826, '437, '703, and '685 patents, which are part of the same family as the '938 patent, demonstrate that a drug may have desirable effects besides decreasing or preventing symptoms. For example, the '703 patent describes a drug as therapeutically effective if it "decrease[s] or prevent[s] the symptoms associated with a medical condition or infirmity, . . . normalize[s] body functions in disease or disorders that result in impairment of specific bodily functions, or . . . provide[s] improvement in one or more of the clinically measured parameters of the disease." '703 patent col. 6:33-38. The intrinsic record of the '938 patent does not suggest that the claims are limited to just one of these therapeutic effects. Instead, the prosecution history of the '938 patent indicates that a drug is therapeutically effective if it "ameliorate[s]" a neurological disease – with no requirement that the drug benefit the afflicted patient in a particular way. (D.I. 138-1 at 3) Though Defendants' expert declares that a person of ordinary skill in the art would understand both "therapeutically effective" and "ameliorate" to require improvement in the ***symptoms*** of a disease, his statements are conclusory and unsupported by the intrinsic record. (D.I. 130-32) Thus, the disputed term will be given its plain and ordinary meaning of "blood levels sufficient to produce a therapeutic effect."[6]

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[5]Plaintiffs would again prefer that the Court not construe the term at all, and instead give it its "plain and ordinary meaning." However, the Court finds that the parties have presented an actual dispute regarding the scope of the claim term, and the Court has resolved that dispute by providing a construction.

[6]Plaintiffs agreed at the claim construction hearing that this construction was an acceptable variation of their proposed construction. (Tr. at 47)

C. "a sustained release composition"[7]

Plaintiffs Plain and ordinary meaning. Alternatively: "Composition that provides slower release of the active agent over an extended period of time compared to an immediate release formulation."
Defendants "a formulation designed to release a therapeutically effective amount of drug or other active agent such as polypeptide or synthetic compound over an extended period of time, with a result being a reduction in the number of treatments necessary to achieve desired therapeutic effect"
Court "a formulation designed to release a therapeutically effective amount of drug or other active agent such as polypeptide or synthetic compound over an extended period of time"

The parties agreed at the claim construction hearing that a sustained release composition is a composition that is designed to release an active agent over an extended period of time, but disagree about whether the Court's construction should compare such compositions to immediate release compositions. (Tr. 54 and 59) Because the parties agree that a person of ordinary skill in the art at the time of the invention would have understood that the words "extended period of time" distinguish sustained release compositions from immediate release compositions (*Id.* at 55 and 61), the Court sees no need to include words requiring such a comparison in its construction. The Court thus adopts the definition of the term "sustained release formulation" set forth in the patent specifications: "a formulation designed to release a therapeutically effective amount of drug or other active ingredient such as a polypeptide or a synthetic compound over an extended period of time"[8] '826 patent col. 5:33-38; '685 patent col. 5:37-42.

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[7]This term appears in the asserted claims of the '826, '703, and '685 patents.

[8]Defendants' proposed construction includes an additional clause from the specification. Both Plaintiff and Defendant agreed at the claim construction hearing that it is not inappropriate to strike this clause from the Court's construction. (Tr. 54-55, 63) Because the Court finds that

D. "a sustained release tablet"[9]

Plaintiffs Plain and ordinary meaning. Alternatively: "tablet that provides slower release of the active ingredient over an extended period of time compared to an immediate release formulation"
Defendants "a tablet designed to release a therapeutically effective amount of drug or other active agent such as a polypeptide or synthetic compound over an extended period of time, with the result being a reduction in the number of treatments necessary to achieve therapeutic effect"
Court "a tablet designed to release a therapeutically effective amount of drug or other active agent such as a polypeptide or synthetic compound over an extended period of time"

The parties agree that the term "sustained release" has an identical meaning in this term as in the term "sustained release composition" in the '826 patent. The parties also agree that disputed term "sustained release tablet" simply requires that the sustained release composition be formulated as a tablet. The Court thus adopts the same construction of "sustained release" as for the '826 patent claims, but specifies that in this context that the composition is a tablet.

III. CONCLUSION

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

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the clause confuses rather than clarifies the construction, the Court has excluded the clause from its construction.

[9]This term appears in claims 32, 33, 36, and 37 of the '437 patent.