IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SUNOVION PHARMACEUTICALS, INC.,	:	
Plaintiff,	:	
v.	:	C.A. No. 12-993-LPS
ACTAVIS, INC. (F/K/A WATSON PHARMACEUTICALS, INC.)	:	
Defendants.	:	

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MEMORANDUM OPINION

March 21, 2014
Wilmington, Delaware

STARK, U.S. District Judge:

Presently before the Court is the issue of claim construction of two disputed terms of U.S. Pat. No. 7,256,310 B2 (filed Dec. 8, 2003) ("the '310 patent").

I. BACKGROUND

Plaintiff Sunovion Pharmaceuticals, Inc. (hereinafter "Sunovion" or "Plaintiff") filed this patent infringement action against Defendant Actavis Pharmaceuticals, Inc. (formerly known as Watson Pharmaceuticals, Inc., hereinafter "Actavis" or "Defendant") on July 27, 2012. This case arises from Defendant's filing of an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to market a generic version of the Plaintiff's Xopenex HFA® Inhalation Aerosol drug product. (D.I. 1)

II. LEGAL STANDARDS

"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). Construing the claims of a patent presents a question of law. *See Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 977-78 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370, 388-90 (1996). "[T]here is no magic formula or catechism for conducting claim construction." *Phillips*, 415 F.3d 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." *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004) (internal quotation marks omitted), *aff'd*, 481 F.3d 1371 (Fed. Cir. 2007).

In addition to the specification, a court "should also consider the patent's prosecution history, if it is in evidence." *Markman*, 52 F.3d at 980. 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.*

A court also may rely on "extrinsic evidence," which "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 ordinary 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.

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. ITC*, 505 F.3d 1351, 1358 (Fed. Cir. 2007).

III. CONSTRUCTION OF DISPUTED TERMS

A. "levalbuterol" [all claims]

Plaintiff's Proposed Construction	"substantially optically pure levalbuterol"
Defendant's Proposed Construction	The claim term 'levalbuterol' refers to the R-enantiomer of albuterol. Claim 1, which recites 'levalbuterol L-tartrate,' reads on levalbuterol tartrate in any form, including crystalline form, alone (pure) or in combination with any amount of any other substance or substances.
Court's Construction	"substantially optically pure levalbuterol"

Plaintiff proposes to construe the term "levalbuterol" as "substantially optically pure levalbuterol." Defendant proposes that "levalbuterol" in the context of Plaintiff's patent claims refers to levalbuterol in combination with any amount of any other substance or substances, including, most importantly in this case, in combination with any amount of the corresponding enantiomer S-albuterol. (D.I. 152 at 4) That is, Defendant's construction would include racemic albuterol. (*See* D.I. 175 ("Tr.") at 13) However, as the patent makes clear, racemic albuterol was known in the prior art. (*See* D.I. 151 Ex. A at col.3, l.43-47) In addition to the general

unlikelihood that the patentee would attempt to patent a claim that was plainly anticipated, the fact that the examiner never suggested an anticipation rejection weighs heavily against Defendant's proposal.[1]

The Court finds that a person of ordinary skill in the art ("POSA"), having read the entire '310 patent, would understand the meaning of "levalbuterol" to be optically active, substantially pure R-albuterol. The patent cites a process for obtaining optically pure (R)-benzylalbuterol, a precursor compound for the production of levalbuterol, as disclosed in U.S. Patent No. 5,545,745 (the "'745 patent") entitled "Enantioselective Preparation of Optically Pure Albuterol." (*See* D.I. 151 Ex. A at col.1, l.19-21) Moreover, the patent specification identifies and distinguishes racemic albuterol sulfate in the drug product Proventil HFA™. (*Id.* at col.3 l.43-47)

Defendant argues that the prosecution history of the '310 patent supports a claim scope for levalbuterol L-tartrate broadly encompassing (S)-albuterol. (D.I. 152 at 4-5) Defendant focuses on language in the patent applicant's response to an office action: "The claim reads on levalbuterol L-tartrate in any form, including any crystalline form, alone (pure) or in combination with any amount of any other substance or substances." (D.I.151 Ex.D, at SUN 123) In context, however, it is clear the applicant intended to claim substantially optically pure levalbuterol even when it was mixed with other compounds. *See id.* ("In real life, it is

[1] During prosecution, the examiner rejected the claims based on 35 U.S.C. § 103, stating that enantiomers were *prima facie* obvious absent unexpected results. (D.I.151 Ex. D at SUN 111) Plaintiff emphasizes, and the Court agrees, that had the examiner believed the applicant was claiming the racemate, the rejection would instead have been made for anticipation. (*See* D.I. 151 at 7) These facts parallel the facts of *In re May*, where claims to enantiomers were rejected for obviousness rather than anticipation. *See* 574 F.2d 1082, 1089, 1095 (CCPA 1978) (holding that claims to enantiomers, rejected by the PTO as *prima facie* obvious, were ultimately nonobvious based on unexpected results).

impossible to obtain a chemical substance in a form totally free of other substances . . . . Any real product containing levalbuterol L-tartrate will in fact contain levalbuterol L-tartrate in a form that is a combination of levalbuterol L-tartrate and some other substance or substances."). The patentee was not stating that the claims encompassed a racemic mixture of levalbuterol and the corresponding enantiomer S-albuterol. As Defendant conceded during the hearing, the '310 patent does not expressly claim, nor does its prosecution history indicate a desire to claim, racemic albuterol. (Tr. at 20, 22)

Defendant cites several cases for the general proposition that reciting a compound encompasses that compound in any surrounding. *See, e.g.*, *In re Williams,* 171 F.2d 319, 320 (CCPA 1948) ("The existence of a compound as an ingredient of another substance does not negative novelty in a claim to the pure compound."); *Smithkline Beecham Corp. v. Apotex Corp.*, 403 F. 3d 1331, 1346 (Fed. Cir. 2005) (holding that presence of claimed compound as minor contaminant in prior art drug was sufficient to invalidate claim by inherent disclosure); *Schering Corp. v. Geneva Pharmaceuticals*, 339 F. 3d 1373, 1381 (Fed. Cir. 2003) (holding that "compound claims are inherently anticipated by a prior art disclosure of a drug that metabolizes into the claimed compound"). However, it is well understood that "there is no indication that . . . a plain-English purity limitation is the only way to distinguish the prior art." *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 348 F. Supp. 2d 713, 725 (N.D.W. Va. 2004). There is substantial intrinsic evidence manifesting the clear intent of the applicant to claim substantially optically pure levalbuterol, not levalbuterol in racemic albuterol. Thus, the Court finds the cases cited by Defendant distinguishable and unpersuasive.

B. "a solution of levalbuterol" [all claims]

Plaintiff's Proposed Construction	"a solution containing substantially optically pure levalbuterol"
Defendants' Proposed Construction	The phrase 'a solution of levalbuterol' in Claim 18 reads on levalbuterol dissolved in one or more solvents, alone (pure) or in combination with any amount of any other substance or substances.
Court's Construction	"a solution containing substantially optically pure levalbuterol"

For the same reasons already discussed, the Court will construe the term "a solution of levalbuterol" as "a solution containing substantially optically pure levalbuterol."

IV. CONCLUSION

For the foregoing reasons, the Court will construe the disputed claim terms of the '310 patent consistent with this Memorandum Opinion. An appropriate Order follows.