IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

Biovail Laboratories International SRL,	:	
Plaintiff,	:	
v.	:	Civ. No. 09-605-LPS
Intelgenx Corp.,	:	
Defendant.	:	

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MEMORANDUM OPINION

December 27, 2010
Wilmington, Delaware

Stark, District Judge:

This action was filed by plaintiff, Biovail Laboratories International SRL ("Biovail"), against defendant, Cary Pharmaceuticals Inc. ("Cary"), on August 13, 2009, alleging infringement of U.S. Patent No. 6,096,341 ("the '341 patent" or the "patent-in-suit"). (D.I. 1)[1] The Court conducted a Markman hearing on the disputed claim terms on June 29, 2010. (*See* Transcript of June 29, 2010 Markman hearing (D.I. 61) (hereinafter "Tr .")) The Court now provides constructions of the two disputed terms from claim 30 of the '341 patent, which is the only claim asserted in this case.

BACKGROUND

The patent-in-suit held by Biovail describes a delayed release tablet formulation of bupropion hydrochloride. (D.I. 1 ¶¶ 1, 5, 6) Bupropion hydrochloride is the active ingredient in the anti-depressant drug sold by Biovail under the tradename Wellbutrin XL. (*Id.* ¶¶ 1, 5) The '341 patent was issued on August 1, 2000 and expires on October 30, 2018. (*Id.* ¶¶ 1, 6; D.I. 34 at 4)

Defendant Cary filed with the United States Food and Drug Administration ("FDA") New Drug Application ("NDA") No. 22-497, for a drug also containing the active ingredient bupropion hydrochloride. (D.I. 1 ¶ 1) Cary filed its NDA and a paragraph IV certification indicating its intent to market a 450mg extended-release bupropion hydrochloride tablet. (D.I. 7 ¶ 1) Biovail contends that Cary's product would infringe claim 30 of the '341 patent. (D.I. 1 ¶ 9)

The parties have placed two claim term disputes before the Court. Both disputed terms appear in claim 30 and are highlighted below:

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[1]On October 19, 2010, the Court granted Cary's Unopposed Motion to Substitute Intelgenx Corp. for Cary. (D.I. 63) Because all of the filings relating to claim construction refer to Defendant as "Cary," the Court will do as well.

> A bupropion hydrochloride delayed release tablet **free of stabilizer** and free of pore-forming agent, exhibiting a **dissolution profile** such that after 1 hour, from 0 up to 30% of the bupropion hydrochloride is released, after 4 hours, from 10 to 60% of the bupropion hydrochloride is released, after 6 hours, from 20 to 70% of the bupropion hydrochloride is released, after 8 hours, more than 40% of the bupropion hydrochloride is released.

(D.I. 35 Ex. 1) (emphasis added) In particular, the parties disagree as to the proper construction of the term "free of stabilizer"[2] and as to the test conditions under which the "dissolution profile" of the delayed release tablet must be measured.

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

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[2]As will be discussed further below, while Biovail proposed construction of the term "stabilizer," Cary requested construction of the larger phrase "free of stabilizer."

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., 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. Int'l Trade Comm'n*, 505 F.3d 1351, 1358 (Fed. Cir. 2007). If possible, claims should be construed to uphold validity. *See In re Yamamoto*, 740 F.2d 1569, 1571 (Fed. Cir. 1984).

CONSTRUCTION OF THE DISPUTED TERMS

I. "free of stabilizer"

The parties first dispute the meaning of "free of stabilizer." Actually, they dispute even whether the term to be construed is "stabilizer," as Biovail contends, or "free of stabilizer," as Cary insists. Biovail proposes that the truncated term "stabilizer" be construed to mean "any substance or agent that prevents significant change in the potency of a buproprion hydrochloride tablet as determined under storage test conditions in the United States Pharmacopeia 23." (D.I. 31, 42) Cary, by contrast, proposes that the fuller term "free of stabilizer" be construed to mean "the tablet is free of any substance or agent that tends to prevent changes to the chemical integrity of the tablet." (D.I. 53 at 1) The Court agrees with Cary that Biovail is collaterally estopped from seeking the construction Biovail proposes here. The Court will adopt Cary's proposed construction.

In three other patent infringement actions in which Biovail has asserted claim 30 of the '341 patent, courts have construed the term "free of stabilizer." In each case, the court adopted a

construction that is inconsistent with the construction of "stabilizer" proposed by Biovail here. *See Biovail Labs. Inc. v. Anchen Pharm. Inc.*, No. SACV 04-1468-JVS (RCx) (C.D. Cal. Feb. 8, 2006) (amending Jan. 12, 2006 Order) (D.I. 35 Exs. 3 & 4) (construing "free of stabilizer" in claim 30 of '341 patent to mean "the tablet is free of any substance or agent that tends to prevent changes to the chemical integrity of the tablet"); *Biovail Labs. Int'l SRL v. Impax Labs., Inc.*, 433 F. Supp. 2d 501, 519-20 (E.D. Pa. 2006) (D.I. 35 Ex. 5) (construing claim term "free of stabilizer" in claims 1 and 30 of '341 patent to mean "lacking any substance or agent that tends to prevent bupropion hydrochloride from changing its form or chemical nature," and noting rejection of Biovail's alternative proposed construction "[f]or the same reason as the *Anchen* court"); *Biovail Labs. Int'l SRL v. Abrika LLLP*, No. 04-61704-CIV, 2006 WL 6111777, at *13-15 (S.D. Fla. Aug. 24, 2006) (D.I. 35 Ex. 6) (adopting "highly persuasive analysis" of *Impax* decision and construing "free of stabilizer" in claims 1 and 30 of '341 patent to mean "lacking any substance or agent that inhibits the decomposition of bupropion hydrochloride").[3]

Subsequently, based on its construction of the term "free of stabilizer," the *Anchen* Court granted defendant Anchen summary judgment of non-infringement. (D.I. 35 Ex. 8 at 5, 20, 25-26) Biovail appealed that judgment, but later withdrew its appeal. (D.I. 35 Ex. 9) The *Impax* and *Abrika* cases were settled following entry of the courts' claim construction orders. (D.I. 35 Exs. 10, 12)

The Third Circuit has identified four requirements for the application of collateral estoppel: "(1) the identical issue was previously adjudicated; (2) the issue was actually litigated; (3) the previous determination was necessary to the decision; and (4) the party being precluded from

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[3]Cary would be content if the Court adopted any of the *Anchen*, *Impax*, or *Abrika* courts' constructions. (D.I. 53 at 1) Because the Court concludes that Biovail is collaterally estopped from relitigating the *Anchen* construction, the Court adopts the *Anchen* construction.

relitigating the issue was fully represented in the prior action." *Jean Alexander Cosmetics, Inc. v. L'Oreal USA, Inc.*, 458 F.3d 244, 249 (3d Cir. 2006) (internal quotation marks omitted). More specifically, the Federal Circuit has made clear that collateral estoppel applies to a claim construction ruling upon the entry of a final judgment in which the court construes the claim at issue, as long as the claim construction was "essential" to the final judgment. "[W]here a determination of the scope of patent claims was made in a prior case, and the determination was essential to the judgment there on the issue of infringement, there is collateral estoppel in a later case on the scope of such claims, i.e., the determined scope cannot be changed." *Molinaro v. Fannon/Courier Corp.*, 745 F.2d 651, 655 (Fed. Cir. 1984); *see also Pfaff v. Wells Electronics, Inc.*, 5 F.3d 514, 518 (Fed. Cir. 1993) ("The prior claim interpretation has issue preclusive effect in the present case insofar as it was necessary to the judgment of noninfringement in the previous case.").

Each of the requirements for application of collateral estoppel are present here with respect to the prior litigation in *Anchen*. In *Anchen*, the proper construction of the term "free of stabilizer' in claim 30 of the '341 patent was adjudicated; this very issue was actually litigated. Then a final judgment of non-infringement was entered, a judgment for which the *Anchen* claim construction was necessary. The necessity of the claim construction to the non-infringement conclusion is apparent from the two-step nature of an infringement analysis: first the claims are construed, then the properly construed claim is compared to the accused product. *See Markman*, 52 F.3d at 976. Moreover, in *Anchen*, in granting summary judgment of non-infringement to the defendant, the Court made plain that it was applying its construction of the term "free of stabilizer." (D.I. 35 Ex. 8 at 5, 20) Finally,

and obviously, Biovail was fully represented in the *Anchen* action, an action initiated by Biovail.[4]

Biovail's proposal that this Court construe not "free of stabilizer" but, instead, just "stabilizer," appears to be an attempt to evade application of the collateral estoppel effect of Anchen's construction of "free of stabilizer." Biovail's effort is unavailing. The *Anchen* Court explained that "Claim 30 requires that the 'tablet' be 'free of stabilizer'" and that "[t]he term 'free of' is a 'negative limitation,' which defines the claimed invention by what it is not." (D.I. 35 Ex. 3 at 6) That court continued: "[t]he summary of the invention states, '[t]he invention thus provides a new bupropion hydrochloride controlled release composition under the form of a tablet *free of stabilizer of any kind*.'" (*Id.* at 6-7) (emphasis added by *Anchen* opinion) To now construe "stabilizer" as Biovail proposes – as "any substance or agent that prevents *significant* change in the potency of a buproprion hydrochloride tablet as determined under storage test conditions in the United States Pharmocopeia 23" (emphasis added) – would be inconsistent both with the *Anchen* construction (which requires the tablet be "free of *any* substance or agent that tends to prevent changes to the chemical integrity of the table") (emphasis added) and the patent.

Accordingly, the Court construes the term "free of stabilizer," as used in claim 30 of the '341 patent, as "the tablet is free of any substance or agent that tends to prevent changes to the chemical integrity of the tablet."

II. "dissolution profile"

Biovail proposes that the Court construe "dissolution profile" to mean "[t]he percentage of

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[4]By determining that Biovail is precluded from proposing any construction of "free of stabilizer" other than that adopted by the *Anchen* court, the Court is not ruling on the question of whether Biovail is also collaterally estopped from contending that Cary infringes claim 30 of the '341 patent. That is an issue that may require resolution at a later point in this action.

bupropion hydrochloride released from the tablet over time as determined under conditions set forth for the characterization of 'delayed release' in the United States Pharmacopeia." (D.I. 38 at 12) Cary proposes, instead, "[t]he percentage of bupropion hydrochloride released over time as determined under 1000 ml 0.1 N HCl, 75 rpm, USP Apparatus I," which is the same construction adopted by the *Abrika* Court. (D.I. 34 at 2-4, 17-23) The Court will adopt Cary's proposed construction.

Claim 30 reads, in relevant part, "[a] bupropion hydrochloride delayed release tablet . . . exhibiting a dissolution profile" such that after fixed intervals of time, a varying percentage of the bupropion hydrochloride is released. ('341 patent, col. 12 lines 3-10) The claim, however, is silent regarding the test conditions to be used when assessing the claimed "dissolution profile." The specification contains 11 examples, and each example reports a corresponding dissolution profile. (*See, e.g.*, D.I. 34 at 18-19) The only test conditions disclosed in the specification appear in conjunction with the patent's Example 1. Example 1 discloses that the dissolution profile obtained for the formulation was generated by utilizing 1000 ml of 0.1N HCl at 75 rpm and using USP Apparatus I. ('341 patent, col. 5, lines 10-13)

This and other points are made in the *Abrika* Court's claim construction opinion, which this Court treats as persuasive authority. Based on the intrinsic evidence, *Abrika* held that the claim term "dissolution profile" means the results of dissolution testing conducted under the conditions set forth in the specification of the '341 patent. Thus, the term "dissolution profile," as used in claim 30 of '341 patent, meant "the percentage of bupropion hydrochloride released over time as determined under 1000 ml 0.1 N HCl, 75 rpm, USP Apparatus I," which are the specific testing conditions used in Example 1 of the specification of the '341 patent. (*See* D.I. 34 at 20-24)

Further, in *Abrika*, the defendant argued that when a claim term recites a characteristic or value substantially based on the methodology used to obtain it, and the methodology is not in the claim, then the claim term "is interpreted to incorporate the specific methodology under which it was obtained." *Abrika*, 2006 WL 6111777, at *6. Applying this rule to the claim term "dissolution profile," Abrika argued that "dissolution profile" is properly construed to require the test conditions disclosed in the specification, namely, the 0.1N HCl test conditions. *Id.* The *Abrika* Court agreed, noting that "there is nothing in the context of the specification to indicate that the patentee contemplated any alternative to the 0.1 N HCl test conditions." *Id.* at *9. The Court continued: "based on an exhaustive review of the intrinsic evidence, . . . Abrika provides a narrower construction of the claim limitation at issue which better reflects the disclosures in the specification and more closely conforms to the patentee's own expressed description of his invention." *Id.* at *13.

The *Abrika* Court also considered the prosecution history, concluding: "review of the patentee's correspondence with the PTO reveals that the patentee relied on the dissolution profile claim limitation – and particularly, the 0.1 N HCl test conditions – to differentiate the invention from prior art." *Id.* at *11. For example, during prosecution of 'the 341 patent application, the Examiner rejected Claims 1, 2, and 4 of the application under § 102(b) for being anticipated by U.S. Patent No. 4,769,027 ("*Baker*"). *Id.* at *11; *see also* D.I. 35 Ex. 11 at 4. The Examiner cited the *Baker* patent and stated that this patent disclosed a "controlled release delivery system" of similar composition to that described in the '341 patent, wherein "[t]he release rate of the delivery system is such that about 60% is released after 2 hours and about 80% is released after 4 hours." *Abrika*, 2006 WL 6111777, at *11; *see also* D.I. 35 Ex. 11 at 4. In response to the rejection, the patentee argued that *Baker* did not anticipate the claimed invention because "Baker is silent on the dissolution medium and conditions

that are used," while "*[t]he dissolution medium and conditions that are used in the invention ['341 patent] is, on the contrary, disclosed in example 1*, page 8." *Abrika*, 2006 WL 6111777, at *11 (emphasis added); *see also* D.I. 35 Ex. 11 at 6. As noted above, Example 1 of the patent specification – to which the patentee was referring – states that the dissolution test conditions are 1000 ml 0.1 N HCl, 75 rpm, USP Apparatus 1. The Court agrees with *Abrika*, which concluded: "Accordingly, based on the file history of the '341 patent, a reasonable competitor of Biovail would surmise that the patentee would measure satisfaction of the 'dissolution profile' claim limitation by testing the accused formulation in 0.1N HC1 test conditions." 2006 WL 611177, at *12.[5]

Thus, the Court construes "dissolution profile" as used in claim 30 of the '341 patent to mean "[t]he percentage of bupropion hydrochloride released over time as determined under 1000 ml 0.1 N HCl, 75 rpm, USP Apparatus I."

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[5]The *Abrika* Court further observed:

> Biovail contests the import of the patentee's response by attempting to cast it in a different light. According to Biovail, the patentee's response indicated solely that the Baker patent made no reference to any details of dissolution testing, and therefore, provided no context for one of ordinary skill in the art to develop a dissolution test. Biovail's argument on this point is entitled to little weight, however, as it entirely ignores the patentee's unequivocal statement that "[t]he dissolution medium and conditions that are used in the invention" are the 0.1N HC1 test conditions. In fact, Biovail's expert witness acknowledged that he did not reference this portion of the prosecution history when advancing his opinion on the meaning of the claim term. [See 3/29 Hr'g. Tr. 111:6-113:4 (Williams)]

2006 WL 6111777, at *12.

CONCLUSION

An Order, consistent with this Memorandum Opinion resolving the parties' claim construction disputes, will be entered.