

NOT FOR PUBLICATION

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

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KING PHARMACEUTICALS, INC.;)	
KING PHARMACEUTICALS RESEARCH)	
AND DEVELOPMENT, INC.;)	
and)	
PHARMACEUTICAL IP HOLDING, INC.,)	
)	
	Plaintiffs,)	
)	
v.)	Civil Action No. 08-5974 (GEB-DEA)
)	
SANDOZ, INC,)	MARKMAN OPINION
)	
)	
	Defendant.)	
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BROWN, Chief Judge

This is a patent infringement case concerning a drug product known as metaxalone, which is used for treating musculoskeletal conditions. The patent is owned by Pharmaceutical IP and is exclusively licensed to King Pharmaceuticals, Inc (collectively “Plaintiffs”). King Pharmaceuticals sells the muscle relaxant Skelaxin which contains metaxalone as its active ingredient. This Hatch-Waxman litigation arises from Sandoz, Inc. (“Defendant”) filing an Abbreviated New Drug Application (“ANDA”) with the FDA pursuant to § 505(j) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, sale, and importation of a generic metaxalone. On November 5, 2008, Sandoz filed a paragraph IV certification, asserting that the claims of U.S. Patent No. 7,122,566 (the ’566 patent) are invalid, unenforceable, and/or will not be infringed by the proposed activities

described in Sandoz's ANDA.

A single patent is at issue, U.S. Patent No. 7,122,566. On July 27, 2009, the parties filed a Joint Claim Construction chart and Pre-Hearing Statement (Doc. No. 34) setting forth eleven disputed claim terms and the parties' proposed constructions thereof. The parties filed their opening claim construction briefs on October 13, 2009 (Doc. Nos. 40, 42) and their reply briefs on December 14, 2009 (Doc. Nos. 41, 43). A *Markman* hearing was held on March 15, 2010.

I. BACKGROUND

The '566 patent contains the following claim 1, which contains both of the terms that are disputed for the purposes of this Opinion:

1. A method of using metaxalone for treating a patient's condition, comprising providing a patient with metaxalone; and

informing the patient or a medical care worker that metaxalone affects activity of a cytochrome p450 isozyme, and that administration of metaxalone with a substance that affects activity of a cytochrome p450 isozyme can affect plasma concentration, safety, efficacy or any combination thereof of metaxalone, the substance, or both.

'566 Patent, 64:47-56¹.

At the *Markman* hearing, the Court ruled from the bench or declined to rule on all disputed terms except for two: (1) activity of cytochrome p450 isozyme and (2) substance. All necessary definitions are set forth in the order accompanying this Opinion. The two remaining disputed claim terms will be construed in this Opinion.

¹ "Substance" also appears in claims 2, 3, 5, 6, 8, and 9 of the '566 patent. The same construction will apply to all appearances of the term.

II. ANALYSIS

A. Standard of Review

The first step in a patent infringement analysis is to define the meaning and scope of the claims of the patent. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (*en banc*), *aff'd*, 517 U.S. 370 (1996). Claim construction, which serves this purpose, is a matter of law exclusively for the court. *Id.* at 979. When construing claims, the court must first consider the intrinsic evidence. Specifically, the focus of the court's analysis must begin and remain on the language of the claims, "for it is that language that the patentee chose to use to 'particularly point[] out and distinctly claim[] the subject matter which the patentee regards as his invention.'" *Interactive Gift Express, Inc. v. Compuserve, Inc.*, 256 F.3d 1323, 1331 (Fed. Cir. 2001) (quoting 35 U.S.C. § 112, ¶ 2).

Generally, there is a presumption that the words of a claim will receive the full breadth of their ordinary meaning. *NTP, Inc. v. Research In Motion, Ltd.*, 392 F.3d 1336, 1346 (Fed. Cir. 2004). The ordinary meaning may be derived from a variety of sources including the claim language, the written description, drawings, the prosecution history, and dictionaries or treatises. *Id.* The presumption may be rebutted if the patentee acted as his or her own lexicographer by clearly setting forth a definition of the claim term unlike its ordinary and customary meaning. *Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc.*, 334 F.3d 1294, 1298-99 (Fed. Cir. 2003). Any intent by the patentee to redefine a term must be expressed in the written description, and must be sufficiently clear. *Merck & Co, Inc. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1370 (Fed. Cir. 2005). When a patent applicant specifically defines a claim term in its description of its invention, that definition controls. *Philips v. AWH Corp.*, 415 F.3d 1303, 1316 (Fed. Cir. 2005)

(*en banc*) (“In such cases, the inventor’s lexicography governs.”) The Federal Circuit has “repeatedly encouraged claim drafters who choose to act as their own lexicographers to clearly define terms used in the claims in the specification.” *Sinorgchem Co. v. ITC*, 511 F.3d 1132, 1136 (Fed. Cir. 2007).

When the patentee has not provided an explicit definition of a claim term, the words of a claim are given their plain and ordinary meaning to a person of ordinary skill in the art. *Vitronics Corp. v. Conceptronc, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). The person of ordinary skill in the art is deemed to read the claim terms in the context of the entire patent, including the specification. *Phillips*, 415 F.3d at 1313.

A court may also consider extrinsic evidence when an analysis of the intrinsic evidence alone does not resolve the ambiguities of a disputed claim term. *Vitronics*, 90 F.3d at 1582-83. While a court may rely on extrinsic evidence to construe a claim, “what matters is for the court to attach the appropriate weight to be assigned to those sources.” *Phillips*, 415 F.3d at 1324.

B. Application

The Court ruled on most of the disputed claim terms during the March 15 *Markman* hearing, reserving the construction of only two for this Opinion. These terms are as follows: (1) activity of cytochrome p450 isozyme and (2) substance.

1. Activity of Cytochrome p450 Isozyme

The parties dispute the meaning of “activity of cytochrome p450 isozyme” found in claim 1 of the ’566 patent. Plaintiffs argue the term should be construed to mean “*the process or function performed by the enzyme as well as the effect of any such process or function.*” Plaintiffs contend that this definition is the ordinary meaning in light of language found in the

specification which explains what information a patient would be provided concerning the effects and activity of cytochrome p450 isozyme.² ('566 Patent, 14:34-66; 24:15-18; Doc. No. 1).

Defendants contend that the term “*refers broadly to the specific activity of the enzyme (i.e., the rate at which the enzyme transforms a substrate per mg or mole of enzyme) as well as the metabolic effect of such transformations.*” Defendants argue that cytochrome p450 isozyme is an enzyme, and therefore its activity should be defined consistent with the specification’s language concerning “enzyme activity.” ('566 Patent, 10: 47-50; Doc. No. 1.)

Defendants are correct to recognize that cytochrome p450 isozyme is an enzyme. But, as all enzymes are not isozymes, the term must be construed to recognize the scope of the particular activity. Therefore, as Plaintiff points out, to adopt the specification’s reference to “enzyme activity” would not be precise to the term as it is used in the claim and therefore not begin and remain on the language of the claim.

Accordingly, the Court will construe “activity of cytochrome p450 isozyme” in claim 1 of the '566 patent as follows: “the specific activity of the isozyme as well as the metabolic effect of that activity.” This construction adopts the '566 patent’s definition of “enzyme activity,” but modifies it to refer to the specific isozyme at issue. The explanatory parenthetical proposed by defendants is confusing and not necessary, and has been omitted.

2. Substance

The parties next dispute the meaning of “substance” found in claims 1–3, 6, 6, 8, and 9.

² During the *Markman* hearing, Plaintiffs argued a construction of the term “activity of cytochrome p450,” rather than the term “activity of cytochrome p450 isozyme.” As the word “isozyme” is critical to the definition of the activity of cytochrome p450, it would be improper to omit it. Further, all briefing by the parties as well as the joint claim construction chart include “isozyme” in the disputed term.

Plaintiff contends that the term means “*physical material from which something is made or which has discrete existence.*” This definition, states Plaintiff, is the plain and ordinary meaning of the term and is quoted directly from the 11th edition of Merriam-Webster’s Collegiate Dictionary. Defendants propose that “*a ‘substance’ taken or administered with metaxalone means a substance that affects the safety, bioavailability, plasma concentration, efficacy, or a combination comprising at least one of the foregoing of metaxalone or the substance. A ‘substance’ can be an active agent, an herbal supplement, a nutritional supplement, a vitamin, a xenobiotic, or an environmental contaminant.*” Defendants derive this proposed definition from language in the specification concerning “*a ‘substance’ taken or administered with metaxalone.*” (Ex. A at 10:38-44; Doc. No. 1.)

As the term “substance” does not have any particular meaning in this field, Defendants’ construction is limiting. While Defendants’ definition does derive from language found in the specification, this language defines the term *substance taken or administered with metaxalone* rather than disputed term *substance*. As the intrinsic evidence available does not provide a definition of “substance,” resort to an extrinsic source—here, a dictionary—is appropriate. *See Phillips*, 415 F.3d 1303, 1322–33 (Fed. Cir. 2005) (“Dictionaries or comparable sources are often useful to assist in understanding the commonly understood meaning of words.”). Furthermore, adopting the lay understanding found in a dictionary does not conflict with what intrinsic evidence is available. Thus, Defendant’s construction does not give the word the full breadth of its ordinary meaning as it is found in the claim.

Accordingly this Court will adopt Plaintiffs’ proposed definition and will construe the term “substance” to mean the following: “physical material from which something is made or

which has discrete existence.”

III. CONCLUSION

For the reasons set forth above, the disputed term “activity of cytochrome p450 isozyme” means “the specific activity of the isozyme as well as the metabolic effect of that activity,” and the disputed term “substance” means “physical material from which something is made or which has discrete existence.”

The Court ruled on the remaining seven disputed terms from the bench. Those terms are defined in the order accompanying this opinion. To the extent that the remaining term definitions differ slightly from the definitions given during the March 15 *Markman* hearing, the order will control.

Dated: March 22nd, 2010

s/ Garrett E. Brown, Jr.
GARRETT E. BROWN, JR., U.S.D.J.