United States District Court,
N.D. Ohio, Eastern Division.

BEN VENUE LABORATORIES, INC. d/b/a Bedford Laboratories,
Plaintiff.
v.
HOSPIRA, INC,
Defendant.

Nov. 16, 2006.

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MEMORANDUM OPINION AND ORDER

DONALD C. NUGENT**, District Judge.**

This patent action is before the Court subsequent to a Markman hearing. The parties have filed opening Markman briefs on claim construction, response briefs, as well as supplemental briefs.

I. BACKGROUND FN1

FN1. The background set forth in this Memorandum Opinion and Order is taken from the record before the Court for purposes of providing context to this decision. As such, it should not be construed as findings of this Court.

Prior to undertaking claim construction in this case, the Court first examines a brief history of the relevant technology. AstraZeneca was the first company to develop emulsion compositions of propofol, an injectable anesthetic, which it sold under the name Diprivan(R). Because AstraZeneca's original formulation was discovered to support microbial growth leading to post-operative fevers and infections, AstraZeneca reformulated its product to include an antimicrobial agent to prevent contamination of the product. U.S. Patent No. 5,714,520 ("the '520 patent") constitutes that reformulation. In the '520 patent, the inventors determined that ethylene diamine tetraacetic acid ("EDTA") was a suitable antimicrobial agent, and that it prevented the post-operative fevers and infections.

U.S. Patent No. 6,140,373 ("the '373 patent"), entitled "Propofol Composition," like the '520 patent,

describes emulsion formulations of propofol. It likewise contains antimicrobial agents to prevent microbial growth, or to combat contamination, in the composition. It is the '373 patent that is at issue in this case.

II. STANDARD OF REVIEW

An infringement analysis entails two steps. The first step is determining the meaning and scope of the patent claims asserted to be infringed. The second step is comparing the properly construed claims to the product accused of infringing. *See* Markman v. Westview Instruments, Inc., 52 F.3d 967, 976 (Fed.Cir.1995) (*en banc*), aff'd, 517 U.S. 370 (1996). It is the first step, commonly known as claim construction or interpretation, that is at issue at this juncture. Construction of patent claims is a question of law for the court. *See* id. at 970-71.

In construing claims, the court should consider first intrinsic evidence of the record: the patent itself, including the claims, the specification, and, if in evidence, the prosecution history. *See* Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed.Cir .1996). This is the most significant source of the legally operative meaning of disputed claim language. *See id*. When analysis of the intrinsic evidence permits unambiguous definition of the meaning and scope of the claims, as it will in most cases, reference to extrinsic evidence is improper. *See id*. at 1583. The Federal Circuit has recently reaffirmed this principle in Phillips v. AWH Corp., 415 F.3d 1303, 1314 (Fed.Cir.2005). Although courts can put general or specialized dictionaries and comparable extrinsic sources to appropriate use in helping to ascertain the commonly understood meaning of words, they must give this evidence only the relatively limited weight it is due and not divorce claim terms from the context of the intrinsic evidence. *See* id. at 1318-19, 1322-24.

A court's examination of the intrinsic evidence in a claim construction analysis begins with the words of the disputed claim itself. *See* Vitronics Corp., 90 F.3d at 1582. The claims define the scope of the right to exclude. *See* Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1324 (Fed.Cir.2002) (*quoting* Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1248 (Fed.Cir.1998)). In the absence of a patentee's "express intent to impart a novel meaning to the claim terms," the words of the claims take on the " 'ordinary and customary meanings attributed to them by those of ordinary skill in the art.' " Mars, Inc. v. H.J. Heinz Co., 377 F.3d 1369, 1373 (Fed.Cir.2004) (*quoting* Int'l Rectifier Corp. v. IXYS Corp., 361 F.3d 1363, 1369 (Fed.Cir.2004); BrookhillWilk 1, LLC v. Intuitive Surgical, Inc., 334 F.3d 1294, 1298 (Fed.Cir.2003)).

In assessing the meaning of the claim terms, a court must always review the specification. *See* Vitronics Corp., 90 F.3d at 1582. The specification is the part of the patent that "teaches" the invention so that one skilled in the art can make and use it. Amgen, Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1334 (Fed.Cir.2003). The specification is highly relevant to claim construction because it may contain special or novel definitions of claim terms when the patentee has chosen to be his own lexicographer, *see* Vitronics, 90 F.3d at 1582, or it may help to resolve ambiguity when the ordinary and customary meaning of a term is not sufficiently clear, *see* Teleflex, 299 F.3d at 1325. In sum, the specification is the " 'single best guide to the meaning of a disputed term,' " Phillips, 415 F.3d at 1315 (*quoting* Vitronics Corp., 90 F.3d at 1582), and is usually "dispositive," *Vitronics Corp.,* 90 F.3d 1582.

The final source of intrinsic evidence plays a role similar to the specification in the claim construction analysis. The prosecution history of the patent-the complete record of the proceedings before the Patent and Trademark Office-"provides evidence of how the PTO and the inventor understood the patent" and should be considered by the court. Phillips, 415 F.3d at 1317. "The patent applicant's consistent usage of a term in

prosecuting the patent may enlighten the meaning of that term." Metabolite Lab., Inc. v. Laboratory Corp. of Am. Holdings, 370 F.3d 1354, 1360 (Fed.Cir.2004). The prosecution history may contain "express representations made by the applicant regarding the scope of the claims." Vitronics Corp., 90 F.3d at 1582. But any limitation found in the history must be "clear and unmistakable." Anchor Wall Sys., Inc. v. Rockwood Retaining Walls, Inc., 340 F.3d 1298, 1307 (Fed.Cir.2003).

If a claim is amenable to more than one construction, the claim should, when possible, be construed to preserve its validity. *See* Karsten Mfg. Corp. v. Cleveland Golf Co., 242 F.3d 1376, 1384 (Fed .Cir.2001); ACS Hosp. Sys., Inc. v. Montefiore Hosp., 732 F.2d 1572, 1577 (Fed.Cir.1984). However, the court is not permitted to redraft claims. Quantum Corp. v. Rodime, PLC, 65 F.3d 1577, 1584 (Fed.Cir.1995).

III. DISCUSSION

Before this Court is relatively narrow issue of claim construction. The parties have submitted a Joint Claim Construction Chart, indicating that they disagree as to the meaning of only one claim term in the '373 patent, namely the term "oil-in-water emulsion." (ECF # 24.) Defendant requests that the Court adopt the following definition of oil-in-water emulsion:

a mixture of two or more immiscible liquids held in suspension by one or more emulsifiers, which consists of two phases, an oil phase (disperse phase) and a water phase (continuous phase) such that the two phases are in equilibrium, and the system is kinetically stable and thermodynamically unstable.

(ECF # 32 at 2.) Plaintiff requests that the Court adopt the following construction for the same term:

A mixture of two or more immiscible liquids stabilized by one or more emulsifiers.

(ECF # 33 at 2.) Both parties argue that the intrinsic evidence supports their definition of the disputed claim term.

After a thorough review of the '373 patent, the argument presented at the Markman hearing, as well as the extensive briefs filed by the parties in this case, the Court hereby adopts Defendant's definition of oil-in-water emulsion. The Court makes this finding based upon a review of the record before it, including but not limited to the incorporation of the '520 patent, FN2 which sets forth the following definition for oil-in-water emulsion:

FN2. The '373 patent provides that, "The compositions of the present invention may be prepared by conventional processes as for example that disclosed in [the '520 patent.]" (U.S. Patent No. 6,140,373, col. 2, lines 29-31.) In addition, the specification expressly incorporates the '520 patent, stating, "Specific reference is made to U.S. Pat. No. 5,714,520 which is hereby incorporated by reference." (Id. at col. 3, lines 1-2.)

By an oil-in-water emulsion we mean a distinct two-phase system that is in equilibrium and in effect, as a whole, is kinetically stable and thermodynamically unstable.
(U.S. Patent No. 5,714,520, col. 4, lines 46-48.) The Court finds it consistent with logic that the '373 patent, which is a generic version of Diprivan(R), incorporates the definition of oil-in-water emulsion set forth in the '520 patent. FN3
FN3. This Court has carefully reviewed Schwarz Pharma, Inc. v. Warner-Lambert Co., 95 Fed. Appx. 994

(Fed.Cir.2004), the unpublished decision relied upon by Plaintiff in support of its position, and finds it to be distinguishable from the instant case. Unlike in that case, Plaintiff has failed to establish that its suggested definition of the term oil-in-water emulsion is the ordinary, art-recognized meaning. Moreover, the language incorporating the '520 patent in the '373 patent is not so limited as the incorporating language in *Schwarz Pharma*. Hence, the Court finds Plaintiff's argument concerning the relevance of the '520 patent to be without merit.

Based upon the foregoing, oil-in-water emulsion shall mean a mixture of two or more immiscible liquids held in suspension by one or more emulsifiers, which consists of two phases, an oil phase (disperse phase) and a water phase (continuous phase) such that the two phases are in equilibrium, and the system is kinetically stable and thermodynamically unstable.

IV. CONCLUSION

For the reasons set forth above, the disputed claim term is construed in the manner set forth by Defendant.

IT IS SO ORDERED.

N.D.Ohio,2006.
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