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

TAP PHARMACEUTICAL PRODUCTS, INC., Takeda Chemical Industries, Ltd. and Wako Pure Chemical Industries, Ltd,
Plaintiffs.
v.
ATRIX LABORATORIES, INC. and Sanofi-Synthelabo, Inc,
Defendants.

July 27, 2005.

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MEMORANDUM OPINION AND ORDER

JAMES B. ZAGEL**, District Judge.**

I. Background

On November 3, 2003, Plaintiffs TAP Pharmaceutical Products Inc. ("TAP"), Takeda Chemical Industries, Ltd. ("Takeda"), and Wako Pure Chemical Industries, Ltd. ("Wako") (collectively "TAP") filed suit against Defendants Atrix Laboratories, Inc. ("Atrix") and SanofiSynthelabo, Inc. ("Sanofi") alleging infringement of United States Patent No. 4,728,721 ("721 patent"). FN1 The subject of the ' 721 patent is a polymer that allows for the sustained release of a drug used in the treatment of prostate cancer. TAP, the holder of the ' 721 patent, claims that the polymer system used in Atrix's Eligard products, the Atrigel formulation, infringes on the polymer system used in its Lupron Depot products. Prior to filing this suit, TAP successfully pursued a similar claim against Oakwood Laboratories, L.L.C. ("Oakwood") in the United

States District Court for the Northern District of Ohio, Eastern Division, before Judge Solomon Oliver.

FN1. Takeda and Wako are joint owners of the '721 patent and TAP is their exclusive licencee.

II. The Black Letter Rules of Claim Construction

On July 8, 2005, a *Markman* hearing was held during which the parties elaborated on their earlier filed claim construction briefs. Claim construction is a matter of law for the court to decide. Markman v. Westview Instruments, Inc., 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). In order "[t]o ascertain the meaning of claims, [the court] consider[s] three sources: The claims, the specification, and the prosecution history." Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed.Cir.1995). These three sources are considered to be intrinsic evidence, as they are public records available for all to consult when determining the meaning and scope of a patent claim. Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed.Cir.1996). When the intrinsic evidence unambiguously describes the scope of a patented invention, reliance on extrinsic evidence, such as expert testimony and treatises, is inappropriate. Id. at 1583.

Claim interpretation begins with the actual words of the claims. Bell Communications Research v. Vitalink Communications Corp., 55 F.3d 615, 619-20 (Fed.Cir.1995). Generally, the words, phrases, and terms in patent claims should receive their ordinary and accustomed meaning. Johnson Worldwide Assocs., Inc. v. Zebco Corp., 175 F.3d 985, 989 (Fed.Cir.1999); Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1249 (Fed.Cir.1998). The strong presumption in favor of the ordinary meaning may only be overcome when the patentee clearly sets forth a definition for a claim term in the patent specification. Anchor Wall Sys. v. Rockwood Retaining Walls, Inc., 340 F.3d 1298, 1306 (Fed.Cir.2003) (*citing* Johnson Worldwide, 175 F.3d at 989-90). "[A] technical term used in a patent claim is interpreted as having the meaning a person of ordinary skill in the field of the invention would understand it to mean." Dow Chem. Co. v. Sumitomo Chem. Co. ., 257 F.3d 1364, 1372 (Fed.Cir.2001). "Because dictionaries, and especially technical dictionaries, endeavor to collect the accepted meanings of terms used in various fields of science and technology, those resources have been properly recognized as among the many tools that can assist the court in determining the meaning of particular terminology to those of skill in the art of the invention. *Phillips v. AWH Corp.,* 2005 U.S.App. LEXIS 13954, 38-39 (Fed.Cir., 2005) (citations omitted).

The patent specification is the first resource, beyond the actual words of the claims themselves, used to aid in claim construction. Fromson v. Anitec Printing Plates, 132 F.3d 1437, 1442 (Fed.Cir.1997). In general, technical terms are deemed to have the same meaning in the claims as in the body of the specifications. *Id.* Additionally, I may review the specifications as an aid in determining the meaning of a claim term in the context of the entirety of the disclosed invention. Interactive Gift Express, Inc. v. Compuserve, Inc., 231 F.3d 859, 866 (Fed.Cir.2000). In looking to the specifications, however, the claims are not limited to the embodiment shown there. Anchor Wall Sys., 340 F.3d at 1307; Transmatic, Inc. v. Gulton Indus., 53 F.3d 1270, 1277 (Fed.Cir.1995). Limitations appearing only in the specifications cannot be read into a claim because "the claim, not the specification, measures the invention." Howes v. Zircon Corp., 992 F.Supp. 957, 961 (N.D.Ill.1998) (*citing* SRI Int'l v. Matsushita Elec. Corp., 775 F.2d 1107 (Fed.Cir.1985)).

Each patent has a corresponding publicly available record called the prosecution history that details the proceedings before the Patent and Trademark Office ("PTO"). The prosecution history may limit the interpretation of claim terms by excluding any interpretation that was disclaimed during prosecution to overcome or distinguish the prior art. Vitronics, 90 F.3d at 1583. However, "unless altering claim language

to escape an examiner rejection, a patent applicant only limits claims during prosecution by clearly disavowing claim coverage." Kopykake Enters. v. Lucks Co., 264 F.3d 1377, 1382 (Fed.Cir.2001) (quotation omitted). Any such disavowal "must be clear and unmistakable." Anchor Wall, 340 F.3d at 1307.

Finally, "extrinsic" evidence such as expert testimony and the like may be considered only where the language of the claims remains ambiguous after consideration of the claim language, specification, and file history. Key Pharm., Inc. v. Hercon Labs. Corp., 161 F.3d 709, 716 (Fed.Cir.1998). "[E]xtrinsic evidence in general, and expert testimony in particular, may be used only to help the court come to the proper understanding of the claims; it may not be used to vary or contradict the claim language." Vitronics, 90 F.3d at 1584.

A. Disputed Claim Language

The disputed language arises from Claims 1 & 2 of the '721 patent, which are as follows:

1. A biodegradable high molecular polymer useful as an excipient in producing a pharmaceutical preparation comprising a copolymer or homopolymer of about 50-100 mole percent of lactic acid and about 50-0 mole percent of glycolic acid having a weight average molecular weight of about 2,000-50,000 and wherein the contents of water-soluble low molecular weight compounds, as calculated on the assumption that each of said compounds is a monobasic acid, is less than 0.10 mole per 100 grams of said high molecular polymer.

2. The biodegradable high molecular polymer according to claim 1, wherein the molecular polymer has an inherent viscosity of about 0.05-.5 di/g as determined with a 0.5 weight percent chloroform solution thereof and a weight average molecular weight of about 5,000-35,000. ('721 patent Claims 1-2).

The most significant dispute arises over whether the claim language calling for "a copolymer or homopolymer ... of lactic acid and ... glycolic acid" includes polymers which were formed using monomers of lactide and/or glycolide. This issue was addressed by Oakwood litigation who found that the claim language was inclusive of polymers formed by lactide and/or glycolide. *See TAP Ph arm. Prod. Inc. v. OWL Pharm., LLC.,* No. 99 CV 2715 (N.D.Ohio Sept.4, 2002). After reviewing the relevant evidence, I find that Judge Oliver's interpretation is the correct one and base much of my reasoning on his careful and detailed analysis.

Like Judge Oliver, I look first to the claim language itself. As seen above, the claim language references only lactic acid and glycolic acid, not lactide or glycolide. Similarly, the patent specifications and examples refer only to lactic acid and glycolic acid. However, the specification states that "[t]he biodegradable high molecular polymer to serve as the starting material in performing the method of the invention ***may be produced by any method.***" (emphasis added). TAP argues that one of ordinary skill in the art would have known that lactide and glycolide could be used to make that biodegradable high molecular polymer.

According to TAP, copolymers of lactic acid and glycolic acid were known by those of ordinary skill in the art FN2 to be made by two different methods: direct polycondensation, using lactic acid and glycolic acid, and ring-opening polymerization, using lactide and glycolide. In the direct polycondensation polymerization process, lactic acid and glycolic acid are heated, while water, which is generated during the reaction by the release of one oxygen and two hydrogen atoms, is rapidly removed. In the ring-opening polymerization process, lactide and glycolide, which are cyclic dimers formed by a condensation reaction occurring between two lactic acid or two glycolic acid molecules,FN3 are opened, usually in the presence of a

catalyst, and become pairs of mers that react with each other to form a polymer.

FN2. One with ordinary skill in this art in 1985, the parties seem to agree, would have worked for at least two years as a researcher in the field of biodegradable polymers and drug delivery systems on a Ph.D. level in industry, a research institute, or in a university.

FN3. There was some discussion at the *Markman* hearing as to whether the dimerization necessary to form the lactide and glycolide should be considered as a step in the ring-opening polymerization process. Defendants argue that it should not be because they tend to purchase the already formed cyclic dimers of lactide and glycolide instead of performing the dimerization themselves. I find this line of thinking to be largely irrelevant. There is no dispute that lactide and glycolide are made from lactic acid and glycolic acid molecules respectively. Whether the dimerization was performed at a different time than the polymerization makes no difference in my construction of the claims.

TAP argues further that one skilled in the art would not differentiate between polymers formed through the ring-opening method and direct polycondensation method. These methods, TAP contends, could each be used to generate the copolymers of lactic acid and glycolic acid that are the subject of the '721 patent. As evidence of the interchangeability of the direct polycondensation and ring-opening methods, TAP points to prior art cited by the '721 patent, which references both methods and shows that each can be used to create copolymers of lactic acid and glycolic acid.FN4 (See U.S. patent 3,565,869, col. 1, ln. 49-54; U.S. patent 3,890,283, col. 1, ln. 33-36). FN5

FN4. *See* Kumar v. Ovonic Battery Co., 351 F.3d 1364, 1368 (Fed.Cir.2003) ("[o]ur cases establish that prior art cited in a patent or cited in the prosecution history of the patent constitutes intrinsic evidence").

FN5. In making their respective arguments, both parties have referenced published statements made by the other's experts and scientists over the course of the last decade. For the reasons I outlined at the *Markman* hearing, I give these statements very little, if any, weight in making my decision.

TAP also points to a number of treatises which recognize that copolymers of lactic acid and glycolic acid can be made by both direct polycondensation or ring-opening. It appears from these treatises and peer-reviewed articles, that scientists in the industry frequently use the term copolymer of lactic acid and glycolic acid when referring to a polymer that was synthesized using lactide and glycolide. *See Donald L. Wise et al.,* "Lactic/Glycolic Acid Polymers," in *Drug Carriers in Biology and Medicine* 237, 241-45 (Gregory Gregoriadis, ed., Academic Press 1979) ("lactic acids and glycolic acids may be polymerized directly from the linear monomer or oligomers ... For most applications it will be preferable to prepare the polymer or copolymer using the cyclic dimers as the starting material.); D.K. Gilding and A.M. Reed. "Biodegradable polymers for use in surgery: polyglycolic/poly(lactic acid) homo-and co-polymers," 20 Polymer 1459, 1459 (1979) (The preferred method for producing high MW polymers is the ring-opening polymerization of the cyclic diester, glycolide (lactide) using antimony, zinc, lead, or preferably tin catalysts."); Robert Langer and Nikolaos Peppas, "Chemical and Physical Structure of Polymers as Carriers for Controlled Release of Bioactive Agents," C23 *Journal of Macromolecular Science-Reviews of Macromolecular Chemistry and Physics* 61, 90 (1983) ("Polymers and copolymers of lactic acid and glycolic acid can be polymerized

directly by a polycondensation mechanism. This method is limited to lower molecular weights so the preferred method is catalytic ring-opening polymerizations of the corresponding cyclic dimers.); Cowsar, Tice and English, "Chapter 8: Poly(lactide- *co*-glycolide) Microcapsules for Controlled Release of Steroids," in *Drug and Enzyme Targeting Part A* 101-116 (Widder & Green, eds., 1985 at 102-03).

To rebut TAP's arguments, Defendants rely primarily on statements made by TAP during the prosecution of the European counterpart to the '721 patent. However, to the extent that I can consider the European patent prosecution, I, like Judge Oliver, find that it supports TAP's interpretation, not the Defendants. During its prosecution of the European counterpart to the '721 patent, TAP's attorneys argued that the European claims did not include polymers made from lactide and glycolide. This statement, however, was rejected as erroneous by the European patent examiner who found that "the Applicant does not appear to be correct in saying that the polymer of the present application is different from the polymerized glycolide and/or lactide." (TAP Ex. 14 '065 PH, office action of 2/8/1991). The Federal Circuit has consistently held that "incorrect statement[s] in the prosecution history do [ ] not govern the meaning of ... claims." Rambus Inc. v. Infineon Tech. AG, 318 F.3d 1081, 1090 (Fed.Cir.2003); *see also* Intervet America, Inc. v. Kee-Vet Labs., Inc., 887 F.2d 1050, 1054 (Fed.Cir.1989) ("When it comes to the question of which should control, an erroneous remark by an attorney in the course of prosecution of an application or the claims of the patent finally worded and issued by the Patent and Trademark Office as an official grant, we think the law allows for no choice. The claims themselves control ... [I]t is not for the courts to say that they contain limitations which are not in them.") Since the European examiner's interpretation is consistent with TAP's position that copolymers of lactic acid and glycolic acid include those made from lactide and glycolide, I find that whatever weight it carries favors TAP.

I also disagree with Defendants' argument that TAP expressly disavowed claim coverage of copolymers made from lactide and glycolide by making these statements to the European patent office. In Gillette Co. v. Energizer Holdings, Inc., 405 F.3d 1367, 1374 (Fed.Cir.2005), the primary case cited by Defendants, the Court relied on the patent holder's statements in a foreign prosecution to support a broader reading of the patent claim at issue. While the Court did consider statements made during the prosecution of a foreign counterpart to the patent in suit, it did not suggest that those statements would create the sort of prosecution history or file wrapper estoppel Defendants are seeking to apply here.FN6

FN6. I also find that the other cases cited by Defendants do not support their prosecution estoppel argument. In Tanabe Seiyaku Co. v. ITC, 109 F.3d 726 (Fed.Cir.1997), the Court relied on the statements made in a foreign prosecution in determining whether the doctrine of equivalents would apply, not during claim construction. Even in that context, the Court found that "representations to foreign patent offices should be considered ... when [they] comprise relevant evidence" but declined to recognize any "estoppel related to the prosecution of foreign counterparts." Id. at 733. (*citing* Caterpillar Tractor Co. v. Berco, S.P.A., 714 F.2d 1110, 1116 (Fed.Cir.1983)). Similarly, in *Caterpillar,* the Court found that while statements made in a foreign patent prosecution relevant to determining the application of the doctrine of equivalents, those statements could not "serve as a basis for reading a limitation" into the claim. Caterpillar, 714 F.2d at 1116.

The second dispute arises over whether and to what extent the copolymer of lactic acid and glycolic acid could contain additional monomers and other compounds or elements. In their reply brief, TAP agreed that the copolymer of lactic acid and glycolic acid could contain other monomers. TAP, however, does not agree that the copolymer of lactic acid and glycolic acid could include the open-ended array of compounds, elements, and macromolecules suggested by Defendants.FN7 TAP would limit the compounds and elements

to initiator compounds, including various alcohols, and catalysts generally associated with direct condensation and ring-opening polymerizations. I find that TAP's interpretation is the more reasonable of the two. Allowing the basically unlimited combination of macromolecules, compounds, and elements suggested by the Defendants, would effectively swallow the ' 721 patent. The additional compounds, elements, and macromolecules should be limited to those things that a person skilled in the art would expect to be present in a polymer of this sort.

FN7. Defendants spent much of their time at the *Markman* hearing and much of their Surreply brief suggesting that TAP has taken a position different from the one argued in the Oakwood case. As I stated at the *Markman* hearing, I find that it is perfectly acceptable for TAP to make new or slightly different arguments in this case so long as they are not fundamentally inconsistent with arguments relied upon by Judge Oliver. From what I have seen so far, I do not believe that any such inconsistencies have arisen.

The third dispute between the parties has arisen over whether the preamble, which describes the patented polymer as "a biodegradeable high molecular polymer useful as an excipient in producing a pharmaceutical preparation," should constitute a claim limitation. As a general rule, "a preamble is not limiting where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention." Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc., 289 F.3d 801, 808 (Fed.Cir.2002) (quotation omitted). However, "clear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art transforms the preamble into a claim limitation because such reliance indicates use of the preamble to define, in part, the claimed invention." *Id*.

TAP argues that the statement in dispute was added to the claim in an amendment dated May 11, 1987 in order to distinguish two pieces of prior art dealing with similar polymers used as sutures. Defendants disagree claiming that TAP distinguished the prior art on other grounds. After reading the relevant communication with the examiner, I find that TAP sought to distinguish its polymer on many grounds-including its use as a "biodegradable high molecular polymer useful as an excipient." First, the author of the letter states that, unlike the disclosed polymers, which are homopolymers of glycolic acid, the proposed polymer is a homopolymer of lactic acid or a copolymer of lactic acid and glycolic acid. Second, the author argues that the two prior art references do not suggest that treating the lactic acid and glycolic acid copolymers would increase their usefulness as sutures, i.e., improve their extrusion and strength properties or their strength retention. Essentially, the author is arguing that when removed of impurities, the polymers described by the prior art and the proposed polymer differ in their usefulness as sutures. Moreover, it was easy to see that this is a crowded field even in the early nineteen eighties, making it entirely reasonable for the patentee to differentiate its polymer by its use. I do note, however, that the preamble may well play little or no role in the ultimate resolution of this case, at least as it currently appears to me.

For the reasons stated above, I adopt the following claim construction: "a copolymer, useful as an excipient in producing pharmaceutical preparation, comprised of lactic acid and glycolic acid mers produced by any method, including the use of lactide and glycolide."

B. Indefiniteness

Defendants contend that the term "water-soluble low molecular compound" is indefinite. "[D]etermination of claim indefiniteness is a legal conclusion that is drawn from the court's performance of its duty as the construer of patent claims." Exxon Research & Eng'g Co. v. United States, 265 F.3d 1371, 1376

(Fed.Cir.2001). Patent claims should be found indefinite only if reasonable efforts at claim construction prove futile. *Id*. "If the meaning of the claim is discernible, even though the task may be formidable and the conclusion may be one over which reasonable persons will disagree, ... the claim [is] sufficiently clear to avoid invalidity on indefiniteness grounds." *Id*. at 1375.

As I stated during the *Markman* hearing, the term "water-soluble low molecular compound" is a relative term. Again, by way of example, we can think of the difference between salt and pasta. When salt is placed in a pot of boiling water it dissolves immediately. Pasta, on the other hand, softens over time and becomes tender. However, if left long enough, the pasta will break down completely and dissolve. Thus, we must think of water-solubility in terms of degrees. The Federal Circuit has found that "[w]hen a word of degree is used, the district court must determine whether the patent's specification provides some standard for measuring that degree." Id. at 1381 (quotation omitted). Here, the patent provides the amount of "water-soluble low molecular compounds" that should be present and describes methods by which the reader can measure those amounts. Accordingly, I find the term "water-soluble low molecular compound" is not indefinite.

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