

United States District Court,
District of Columbia.

ABBOTT GMBH & CO. KG,
Plaintiff.

v.
YEDA RESEARCH AND DEVELOPMENT CO., LTD,
Defendant.

Civil Action No. 00-1720 (RMU)

June 28, 2007.

Background: Owner of patent describing protein brought action against competitor to set aside decisions of Board of Patent Appeals and Interferences in interference proceedings holding that claims of patent were unpatentable.

Holding: The District Court, Ricardo M. Urbina, J., held that patent covered only one protein described in the patent application and not any man-made or naturally occurring muteins.

Claim construed.

5,344,915. Construed.

James R. Ferguson, Mayer Brown LLP, Chicago, IL, George Aloysius Hovanec, Jr., Buchanan Ingersoll, PC, R. Danny Huntington, Burns, Doane, Swecker & Mathis, LLP, Alexandria, VA, for Plaintiff.

Roger Lowen Browdy, Ronni S. Jillions, Browdy & Neimark, P.L.L.C., Washington, DC, Alexander E. Gasser, Oblon, Spivak, McClelland, Maier & Newstadt, PC., Alexandria, VA, Kevin M. Flowers, Matthew C. Nielsen, Michael F. Borun, Nabeela McMillian, Marshall, Gerstein & Borun LLP, Chicago, IL, for Defendant.

MEMORANDUM OPINION

RICARDO M. URBINA, District Judge.

I. INTRODUCTION

The plaintiff, Abbott GmbH & Co. KG, is the owner of U.S. Patent No. 5,344,915, also known as the LeMaire patent. Pursuant to 35 U.S.C. s. 146, the plaintiff seeks to set aside decisions made by the Board of

Patent Appeals and Interferences of the United States Trademark Office (the "Board") holding that the claims of the LeMaire patent are unpatentable and that therefore any interference claims are void. This matter is before the court on the issue of claim construction. The primary issue of this claim construction is whether the LeMaire patent covers a single protein, TBP-II, or if the LeMaire patent covers the TBP-II protein and all of its naturally occurring muteins. Based on the intrinsic record, the court concludes that the LeMaire patent covers only one protein, TBP-II, described in the plaintiff's patent application. That is, the patent includes neither man-made nor naturally occurring muteins. For this reason, the court adopts the plaintiff's claim interpretation.

II. BACKGROUND

A. Proteins

[1] Generally speaking, proteins are long chains of amino acids like beads on a string. *See In re O'Farrell*, 853 F.2d 894, 895-99 (Fed.Cir.1988). "Any sequence of amino acids of a significant length within a given protein will be unique to that protein." Pl.'s Claim Construction Br. ("Pl.'s Br." at 4). The chain begins at the N-terminus, the location of an amino group to which all other amino acids are sequentially attached. *Id.* The long chains of amino acids fold on themselves to form an often complex shape determined by the interplay of the amino acids in the chain. Both the sequence of amino acids and the folded structure are unique to each protein. Because a protein can be made up of a very long sequence of amino acids, scientists identify each protein by listing the sequence of amino acids beginning at the N-terminus. *Id.* The number of amino acids necessary to uniquely identify a protein varies. *Id.* (stating that amino acid sequences of varying lengths can be characteristic of a single protein). For example, the TBP-II protein is described in the patent by listing 22 of the amino acids located at the N-terminus. FN1 *Id.* at 7. The sole requirement in identifying a protein by a sequence of amino acids in a patent is that "one skilled in the art" be able to recreate the protein without experimentation. *In re Fisher*, 57 C.C.P.A. 1099, 427 F.2d 833, 836 (C.C.P.A.1970); *see generally In re O'Farrell*, 853 F.2d at 895-99.

FN1. The TBP-II protein is also described in the patent by listing seven, additional truncated forms. That is, the plaintiff described the TBP-II protein by listing the amino acids in the first 22 positions of the chain, as well as by listing the amino acids in positions 2-22, 3-22, 4-22, 5-22, 6-22, 7-22, and 8-22. Pl.'s Claim Construction Br. ("Pl.'s Br.") at 7.

B. The LeMarie Patent

On May 4, 1990, Hans-Georg LeMaire, Heinz Hillen, Achim Moeller, Lothar Daum, Thomas Doerper, and Thomas Subkowski filed an international patent application, PCT/EP90/00719, for a protein, called the TBP-II protein, that is isolated from the urine of individuals with a fever and from the ascites fluid of individuals with ovarian carcinomas. Mem. Op. (June 13, 2005) ("Mem.Op.") at 1. After the patent application entered the United States, on September 6, 1994, the Patent and Trademark Office ("the PTO") issued the LeMaire patent to BASF, a previous owner of the patent. *Id.* at 2. The plaintiff is now the owner of this patent.

Seeking to patent the same protein, the defendant, Yeda Research and Development, challenged the plaintiff's patent in an interference proceeding before the Board. *Id.* During the interference proceeding, the defendant argued that the LeMaire patent was invalid because it was described in an article, FN2 in violation of 35 U.S.C. s. 102(b). FN3 *Id.* In response, the plaintiff argued that it had patented the protein in

Germany before the article was published and was therefore entitled to the benefit of the earlier filing dates under 35 U.S.C. s. 119. FN4 *Id.* The Board held that the LeMaire claims were unpatentable because "the party LeMaire [did] not sustain[] its burden of establishing, by a preponderance of the evidence, that their earlier filed German applications satisf[ied] the first paragraph description requirement of 35 U.S.C. s. 112." Def.'s Claim Construction Br. ("Def.'s Br.") Ex. C at 8. In other words, the Board ruled that the German patent did not sufficiently describe the invention in the LeMaire patent and that the plaintiff's patent was invalid because it was described in the Engelmann article. The plaintiff now appeals the Board's decision to this court under 35 U.S.C. s. 146. FN5

FN2. The article, written by Helmut Engelmann, is titled *Two Tumor Necrosis Factor-Binding Proteins Purified from Human Urine*. Mem. Op. (June 13, 2005) at 2.

FN3. 35 U.S.C. s. 102(b) states that "[a] person shall be entitled to a patent unless the invention was ... described in a printed publication in this or a foreign country ... more than one year prior to the date of the application for patent in the United States."

FN4. 35 U.S.C. s. 119 states that "[a]n application for patent for an invention filed in this country by any person who has ... previously regularly filed an application for a patent for the same invention in a foreign country ... shall have the same effect as the same application would have if filed in this country on the date on which the application for patent for the same invention was first filed in such foreign country."

FN5. 35 U.S.C. s. 146 states that "[a]ny party to an interference dissatisfied with the decision of the Board of Patent Appeals and Interferences on the interference, may have remedy by civil action."

C. Procedural Background

[2] Both parties filed claim construction briefs to propose how the court should interpret the claims of the LeMaire Patent. Because the parties represented to the court that it could construe the claims without expert testimony, the court vacated the scheduled Markman hearing in favor of deciding on the paper record. FN6 The court now turns to the parties' claim construction briefs.

FN6. "Nothing ... mandates the use of a Markman hearing in every patent case. Courts retain the discretion to construe the claims on the basis of a paper record alone." *Aspex Eyewear, Inc. v. E'Lite Optik, Inc.*, 2002 WL 1751381 at * 11 n. 6 (N.D.Tex. Apr.4, 2002); *see also* *Interactive Gift Express v. Compuserve, Inc.*, 1998 WL 247485 at n. 3 (S.D.N.Y.1998) (stating that no Markman hearing was required because no expert or other testimony was required for claim construction) *vacated on other grounds*, 256 F.3d 1323 (Fed.Cir.2001); *LRC Elecs., Inc. v. John Mezzalingua Assocs., Inc.*, 974 F.Supp. 171, 181 (N.D.N.Y.1997).

III. ANALYSIS

A. Legal Standard for Claim Construction

In claim construction cases, the court must construe the often laconic statements of a patent claim.

Specifically, the court's task is to "understand and explain, but not to change, the scope of the claims." *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 1580 (Fed.Cir.1991). Claim construction is typically the first step in patent infringement litigation. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 385, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996).

Claim interpretation is a question of law. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed.Cir.1995) (en banc), *aff'd*, 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). When construing claims, "the analytical focus must begin and remain centered on the language of the claims themselves, 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, 1336 (Fed.Cir.2001) (internal quotations omitted) (citing 35 U.S.C. s. 112, para. 2). Because the patent must be defined precisely to give adequate notice to the public of the invention, "it is unjust to the public, as well as an evasion of the law, to construe it in a manner different from the plain import of its terms." *Id.* (quoting *White v. Dunbar*, 119 U.S. 47, 52, 7 S.Ct. 72, 30 L.Ed. 303 (1886)).

The court may consider both intrinsic and extrinsic evidence in construing the meaning of a patent's claims. *Zodiac Pool Care, Inc. v. Hoffinger Indus., Inc.*, 206 F.3d 1408, 1414 (Fed.Cir.2000). "Intrinsic evidence consists of the claim itself, the specification, and any prosecution history." *Id.* In contrast, the "extrinsic evidence includes expert testimony, investor testimony, dictionaries, treatises, and prior art cited in the prosecution history." *Id.* "The court turns to the extrinsic evidence only when the intrinsic evidence is insufficient to establish the clear meaning of the asserted claim." *Id.* (citing *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582-84 (Fed.Cir.1996)).

1. Intrinsic Evidence

[3] In analyzing intrinsic evidence, courts generally give the words of a patent claim their "ordinary and customary meaning" as would be understood by a person of ordinary skill in the art in question at the time of the invention. FN7 *Vitronics*, 90 F.3d at 1582; *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed.Cir.2005); *see also Ferguson Beauregard/Logic Controls v. Mega Sys., LLC*, 350 F.3d 1327, 1338 (Fed.Cir.2003). Although the court gives words their ordinary meaning by default, "a patentee may choose to be his own lexicographer and use terms in a manner other than their ordinary meaning, as long as the special definition of the term is clearly stated in the patent specification or file history." *Vitronics*, 90 F.3d at 1582.

FN7. A patent claim follows the description of the invention in the specification and "particularly point[s] out and distinctly claim[s] the subject matter which the applicant regards as his invention." 35 U.S.C. s. 112.

"The claims, of course, do not stand alone. Rather, they are part of a fully integrated instrument, consisting principally of a specification FN8 that concludes with the claims." *Phillips*, 415 F.3d at 1315 (quoting *Markman*, 52 F.3d at 978) (internal quotations omitted). The specification is the "single best guide to the meaning of a disputed term." *Vitronics*, 90 F.3d at 1582. Thus, it is "always highly relevant to the claim construction analysis" and usually dispositive. *Id.*

FN8. In a patent application, the specification of a patent is "a written description of the invention or discovery and of the manner and process of making and using the same." 37 C.F.R. s. 1.71(a); *see also* 35 U.S.C. s. 112.

[4] [5] [6] If in evidence, the prosecution history is the final piece of intrinsic evidence which the court may consider. The prosecution history includes the complete record of the proceedings before the Patent and Trademark Office, 35 U.S.C. s. 146, and details "whether the applicant clearly and unambiguously disclaimed or disavowed any interpretation during prosecution in order to obtain a claim allowance." *Middleton, Inc. v. Minn. Mining & Mfg. Co.*, 311 F.3d 1384, 1388 (Fed.Cir.2002) (quoting *Standard Oil Co. v. Am. Cyanamid Co.*, 774 F.2d 448, 452 (Fed.Cir.1985)). This history may reveal instances where "the patentee distinguished [a] term from prior art on the basis of a particular embodiment, expressly disclaimed subject matter, or described a particular embodiment as important to the invention." *CCS Fitness Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366-67 (Fed.Cir.2002) (citations omitted). Accordingly, once a patentee disclaims an interpretation during patent prosecution, she cannot reclaim it during claim interpretation. *Teleflex, Inc. v. Ficosa North Am. Corp.*, 299 F.3d 1313, 1326. Likewise, once a patent applicant disclaims an interpretation during patent prosecution, prosecution history estoppel attaches and that interpretation cannot be reintroduced by another party. *See generally Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 30-31, 117 S.Ct. 1040, 137 L.Ed.2d 146.

2. Extrinsic Evidence

[7] In circumstances in which the intrinsic evidence is not sufficiently clear, the court may avail itself of extrinsic evidence, particularly to help the court understand the underlying technology. *Interactive Gift Express*, 256 F.3d at 1332; *see Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1309 (Fed.Cir.1999) (stating that "consultation of extrinsic evidence is particularly appropriate to ensure that [a judge's] understanding of the technical aspects of the patent is not entirely at variance with the understanding of one skilled in the art"). Dictionaries, treatises, and expert testimony are the most common forms of extrinsic evidence, and may help a court understand the underlying technology or a particular meaning of a term in the pertinent field. *Phillips*, 415 F.3d at 1318. Despite this utility, extrinsic evidence may "never be used for the purpose of varying or contradicting the terms in the claims." *Markman*, 52 F.3d at 981.

B. The Court Adopts the Plaintiff's Construction of Claim 1

[8] Claim 1 of the LeMaire patent states that the subject of the patent is:

[a] purified and isolated TNF(alpha)-binding protein which has a molecular weight of about 42,000 daltons and has at the N terminus the amino acid sequence

Xaa Thr Pro Tyr Ala Pro Glu Pro Gly Ser Thr Cys Arg Leu Arg Glu

where Xaa is hydrogen, a phenylalanine residue (Phe) or the amino acid sequences Ala Phe, Val Ala Phe, Gln Val Ala Phe, Ala Gln Val Ala Phe, Pro Ala Gln Val Ala Phe, or Leu Pro Ala Gln Val Ala Phe.

Def.'s Br. Ex. A ("LeMaire Patent") at Col. 6, lines 38-46. The parties agree that the construction of claim 1 turns on whether the LeMaire patent covers only the TBP-II protein (as the plaintiff maintains), Pl.'s Br. at 3; Pl.'s Resp. to Def.'s Br. ("Pl.'s Resp.") at 1, or if the patent covers the TBP-II protein, as well as the naturally occurring muteins of the TBP-II protein (as the defendant argues), Def.'s Br. at 31, 32; Def.'s Resp. To Pl.'s Br. ("Def.'s Resp") at 4.FN9 Based on the intrinsic evidence (the plain language of the claim, the patent specification, and the prosecution history) the court concludes that the LeMarie patent covers only

the TBP-II protein.

FN9. According to the plaintiff, the "normal" form of the TBP-II protein is the form that is most prevalent in the population. Pl.'s Br. at 4.

1. The Language of Claim 1

The defendant argues that the court should construe claim 1 to cover: "a purified and isolated TNF(alpha)-binding protein [and its naturally-occurring mutations]." Def.'s Resp. at 9. Although the defendant argues that claim 1 encompasses muteins, the language of claim 1 does not include any reference to the term mutein. Because neither side claims that the term protein automatically includes the term mutein, it is unreasonable to alter the scope of the plain meaning of the term chosen by the plaintiff and include muteins in the definition of a protein. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed.Cir.2005) (quoting *McCarty v. Lehigh Valley R.R. Co.*, 160 U.S. 110, 116, 16 S.Ct. 240, 40 L.Ed. 358 (1895), for the proposition that "if we once begin to include elements not mentioned in the claim, in order to limit such claim ... we should never know where to stop").

Assuming *arguendo* that a person skilled in the art would use the term protein to refer not only to a protein but also to a mutated form of a protein, the court's conclusion would not change because claim 1 refers to proteins in the singular, not the plural. In short, it is unnatural to read the phrase "a purified and isolated TNF(alpha)-binding protein" in claim 1 to mean "a TNF(alpha)-binding protein and its naturally-occurring muteins," or "TNF(alpha)-binding proteins." FN10

FN10. The defendant also argues that the LeMaire patent should be construed to cover many proteins instead of just one because the indefinite article "a" in claim 1 should be construed to mean "one or more." Def.'s Claim Construction Br. at 24-25. Despite the defendant's arguments regarding the interpretation of the indefinite article, the plain and ordinary meaning of "a purified and isolated TNF(alpha)-binding protein" is a singular protein which is characterized by the binding properties, weight, and amino acid sequence described in the claim. While the court could read the indefinite article "a" as "one or many," "there is no indication in the patent specification that the inventors here intended it to have other than its normal singular meaning." *North Am. Vaccine v. Am. Cyanamid*, 7 F.3d 1571, 1576 (Fed.Cir.1993).

2. The Patent Specification

The patent specification also undermines the defendant's argument that claim 1 encompasses "a TNF(alpha)-binding protein and its naturally-occurring muteins." The LeMarie patent specification distinguishes muteins from the TBP-II protein by stating that muteins "are produced by the suitable exchange, deletion, or addition of amino acids of peptides in the protein chain without this leading to a large reduction in the action of the novel protein." LeMarie Patent, Col. 1, lines 31-35. According to the defendant, the definition of muteins in the specification refers only to man-made mutations of a protein. Def.'s Resp. at 10. Thus, under the defendant's theory of the case, it is of no moment that the claim language does not include the word mutein. In other words, the defendant bases its argument that claim 1 includes the TBP-II protein as well as its naturally occurring mutations on the assumption that the plaintiff restricted the meaning of the term mutein, as used in the specification, to man-made mutations. Def.'s Resp. at 11-12.

The term mutein, as used in the specification, however, is not limited to man-made mutations. For example,

the specification describes how TBP-II and its muteins are "isolated" from a naturally occurring substance and not "created" from the substance, indicating that at least some muteins must have natural origins. LeMarie Patent, Col. 1, lines 41-46. Also, the specification states that the "proteins [and muteins] described herein are present in urine and ascites fluid," further indicating that muteins can be naturally occurring products. *Id.*, Col. 1 lines 61-62.

The defendant also argues that because the specification states that "muteins ... are preferably prepared by genetic engineering methods," LeMarie Patent, Col. 2, lines 27-30, the word muteins only includes man-made mutations, Def.'s Resp. at 11-12. "In the course of construing the disputed claim terms, a court should not ordinarily rely on the preferred embodiments alone as representing the entire scope of the claimed invention." *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1370 (Fed.Cir.2002). Accordingly, the plaintiff's statement that muteins are preferably prepared by genetic engineering methods does not automatically serve to limit the meaning of the word to man-made mutations. The court therefore concludes that the specification does not limit the definition of the term mutein to man-made mutations.

3. The Prosecution History

The prosecution history provides the strongest support for the court's conclusion that the LeMarie patent does not encompass the naturally-occurring mutations of the TBP-II protein. The LeMaire patent originally included the phrase "and the muteins thereof" at the end of claim 1. After the patent examiner objected to this term because it potentially included an unlimited number of mutated proteins, Def.'s Br. Ex. F at 2, the plaintiff narrowed the scope of the claim by removing the objectionable phrase. Pl.'s Resp. at 5. Because the plaintiff removed the term mutein from the claim, the court cannot replace it to expand or reduce the claim's scope. *United States v. Teletronics, Inc.*, 857 F.2d 778, 783 (Fed.Cir.1988). That is, because the plaintiff expressly disavowed that its patent covered the muteins during prosecution stage, the court cannot reintroduce the term into the patent by construing claim 1 to include muteins. *Id.* (citing *Kistler Instrumente AG. v. United States*, 224 Ct.Cl. 370, 628 F.2d 1303, 1308 (1980) for the proposition that "courts are not permitted to read 'back into the claims limitations which were originally there and were removed during prosecution of the application through the Patent Office' "). Accordingly, the court rules that in conjunction with the language of the claim and the specification, the prosecution history shows that claim 1 encompasses the TBP-II protein but not its naturally-occurring muteins.

IV. CONCLUSION

For the foregoing reasons, the court adopts the plaintiff's claim interpretation. An order consistent with this Memorandum Opinion is separately and contemporaneously issued this 28th day of June, 2007.

D.D.C., 2007.

Abbott GmbH & Co. KG v. Yeda Research and Development Co., Ltd.

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