United States District Court,
D. New Jersey.

**NEW ENGLAND MEDICAL CENTER HOSPITALS, INC., et al,**
Plaintiff.
v.
**PEPROTECH, INC,**
Defendant.

Civ. No. 91-5584(GEB)

**Aug. 30, 1993.**

Robert E. Hillman, Paul Louis Myers, and Dorothy P. Whelan of Fish & Richardson, Boston, MA, Hayden Smith, Jr. of McCarter & English, Newark, NJ, for plaintiff.

Jane Massey Licata and Gary Levin of Woodcock Washburn Kurtz Mackiewicz & Norris, Philadelphia, PA, Martin Jennings, Jr. of Martinez & Jennings, West Trenton, NJ, for defendant.

**MEMORANDUM AND ORDER**

GARRETT**,** E. BROWN, Jr.**, District Judge.**

This matter comes before the Court on cross-motions for summary judgment pursuant to Fed.R.Civ.P. 56 on the specific issue of whether the scope of Claim 12 of U.S. Patent No. 4,766,069 (Aug. 23, 1988) FN1 encompasses not only the full-length precursor of the IL-1B protein, but the protein's fragments as well.FN2 For the reasons set forth in this Memorandum and Order, the Court will deny defendant's motion and grant plaintiffs' motion with respect to this issue.

**I.BACKGROUND**

On August 23, 1988, the United States Patent and Trademark Office (the "PTO") issued U.S. Patent No. 4,766,069-entitled "Recombinant DNA which Codes for Interleukin-1B" (the "Auron Patent")-to Philip E. Auron, Charles A. Dinarello, Andrew C. Webb, Alexander Rich, and Sheldon M. Wolff. Compl. at para. 8. The Auron Patent was granted for an invention that made possible the commercial and artificial production of a class of proteins referred to as Interleukin-1B ("IL-1B"). *See* U.S. Patent No. 4,766,069 (Aug. 23, 1988). Plaintiffs-New England Medical Center Hospitals, Inc., Trustees of Tufts College, Massachusetts Institute of Technology, and Wellesley College-became the owners of the Auron Patent by assignment. Compl. at para. 8. Plaintiff Cistron Biotechnology, Inc. is the exclusive licensee of the Auron Patent. Id. at para. 9.

On December 19, 1991, plaintiffs commenced this action against defendant PeproTech, Inc. ("PeproTech"), alleging that defendant's method of manufacturing a certain protein known as "mature IL-1B" infringes

upon the Auron Patent. Id. at para. 10. Thereafter, on March 5, 1993, defendant moved before this Court for summary judgment on two separate grounds. The first claim involved an allegation of inequitable conduct in the prosecution of the Auron Patent. Specifically, defendant claimed that the individuals who prosecuted the Auron Patent intentionally withheld from the patent examiner a published article that was material to whether the Auron Patent should have been issued. Based upon this premise, defendant averred that the inventors engaged in "inequitable conduct" in procuring the patent, thereby rendering the patent unenforceable. During oral argument, this Court denied defendant's motion with respect to this issue, concluding that genuine issues of material fact existed. *See* Order dated March 1, 1993; J.P. Stevens & Co. v. Lex Tex Ltd., 747 F.2d 1553, 1559 (Fed.Cir.1984), *cert. denied,* 474 U.S. 822 (1985).

The second ground upon which summary judgment was sought by defendant was based on an assertion that plaintiffs have failed to establish an infringement of the Auron Patent as a matter of law since the terms contained in the specification are not broad enough to encompass defendant's protein manufacturing process. At the conclusion of oral argument, the Court took the matter under advisement. Thus, the sole issue addressed in this Memorandum and Order is whether the scope of Claim 12 of the Auron Patent encompasses not only the full-length precursor of the IL-1B protein, but the protein's fragments as well. This Court concludes that it does.

## II. DISCUSSION

### A. Standards for Summary Judgment

Summary judgment may be granted only if there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law. Fed.R.Civ.P. 56; Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986). In a summary judgment motion, the non-moving party receives the benefit of all reasonable doubts and any inferences drawn from the underlying facts. Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986). If the non-moving party bears the burden of proof at trial as to a dispositive issue, Rule 56(e) requires him to go beyond the pleadings and designate specific facts showing that there is a genuine issue for trial. Celotex, 477 U.S. at 324; Schoch v. First Fidelity Bancorporation, 912 F.2d 654, 657 (3d Cir.1990). Issues of material fact are genuine only "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986).

### B. Interpretation of Claim 12 FN3

"Claim interpretation is a question of law for the court." *Read,* 970 F.2d at 822 (citations omitted). To properly ascertain the scope of a patent claim, the court must examine the language employed in the asserted claim, the patent's specification, and the patent's prosecution history. *Id.* at 823 (citation omitted); Becton Dickinson & Co. v. C.R. Bard, Inc., 922 F.2d 792, 796 (Fed.Cir.1990) (citations omitted). "Also relevant are the other claims and expert testimony." Smithkline Diagnostics, Inc. v. Helena Lab. Corp., 859 F.2d 878, 882 (Fed.Cir.1988) (citation omitted). Although claim interpretation may require the resolution of certain factual issues-i.e., what occurred during the prosecution of the patent,

a mere dispute over the meaning of a term does not itself create an issue of fact. This is true even where the meaning cannot be determined without resort to the specification, the prosecution history or other extrinsic evidence, provided upon consideration of the entirety of such evidence the court concludes that there is no genuine underlying issue of material fact.

Johnston v. IVAC Corp., 885 F.2d 1574, 1579 (Fed.Cir.1989) (citations omitted). In other words, "[e]xcept

where evidence pertinent to a claim's interpretation creates a factual dispute, 'claim interpretation may be resolved as an issue of law by the court on summary judgment....' " Becton Dickinson, 922 F.2d at 796 (quoting Johnston, 885 F.2d at 1580). Furthermore, the mere fact that the parties' experts proffer differing views as to the actual meaning of the language in a claim does not create a genuine issue of material fact. *Id*. at 797 (citing Johnston, 885 F.2d at 1579).

**1. Claim Language**

"The first requirement in claim interpretation is to examine the claim language." Smithkline Diagnostics, 859 F.2d at 882 (citations omitted). Claim 12 of the Auron Patent provides:

12. A process for preparing human IL-1B which comprises culturing a microbe hosting a cloning vehicle comprising DNA encoding human IL-1B and recovering human IL-1B.

U.S. Patent No. 4,766,069 (Aug. 23, 1988), at col. 20, Claim 12. It is defendant's position that the DNA sequence referred to in Claim 12 is limited to the full-length IL-1B precursor protein and, as such, does not encompass DNA sequences that directly encode lower weight fragments of the precursor such as defendant's mature IL-1B. Adopting a broader interpretation, plaintiffs maintain that the common usage of the term "human IL-1B" refers generically to both the full-length precursor and its fragments.

It is well established that patent claims should be construed as one skilled in the art would construe them and interpreted consistently with their common usage. *See* Smithkline, 859 F.2d at 882 (citing Specialty Composites v. Cabot Corp., 845 F.2d 981, 986 (Fed.Cir.1988)); Fromson v. Advance Offset Plate, Inc., 720 F.2d 1565, 1571 (Fed.Cir.1983). In this regard, plaintiffs point out that in advertising its product, defendant refers to its artificially manufactured protein as "human IL-1B"-the same terminology employed in Claim 12 of the Auron Patent. *See* Pls.' Ex. 4 (attached to Opp.Br.). Although this fact is somewhat persuasive, it is worth noting that neither party was able to articulate the currently accepted scope of this term either in their briefs or during oral argument when the question was posed.

Moreover, although the plain language of Claim 12 of the Auron Patent proscribes the unauthorized use of a method of using a certain DNA-containing cloning vehicle to produce certain proteins, the specific language employed within Claim 12 gives this Court little assistance in defining the scope of "human IL-1B." Accordingly, the Court must look toward the patent specification, prosecution history, and other extrinsic evidence to determine its scope.

**2. Patent Specification**

With respect to the patent specification of the Auron Patent, defendant maintains that the language employed in the specification demonstrates that the term "IL-1B" in Claim 12 means the IL-1B precursor peptide. In support of its position, defendant quotes a line from the patent specification which states: "[H]uman IL-1[B] is initially synthesized as a precursor peptide with a molecular weight of 30,747." Def.'s Br. at 17 (quoting U.S. Patent No. 4,766,069 (Aug. 23, 1988), at col. 1, lines 66-68). The protein manufactured by defendant has a molecular weight of 17,500. Although the Auron Patent does not use the term "mature IL-1B" nor specifies a peptide with a molecular weight of 17,500, it is worth noting that the language quoted by defendant in support of its position explicitly states that "human IL-1[B] is *initially* synthesized as a precursor peptide," thereby suggesting the use of the protein's fragments. *See* U.S. Patent No. 4,766,069 (Aug. 23, 1988), at col. 1, lines 66-68.

Moreover, an examination of the language employed in the Auron Patent specification suggests that the term "human IL-1B" refers generically to both the full-length precursor and its fragments. *See, e.g.*, id. at Abstract, ("The subject invention concerns a nucleic acid comprising a nucleotide sequence encoding human [IL-1B], *and* fragments thereof, *and* the polypeptides and peptides obtained." (emphasis added)); id. at col. 1, lines 55-58 ("The subject invention concerns a nucleic acid comprising a nucleotide sequence coding for human [IL-1B], *and* fragments thereof, *and* the polypeptides and peptides obtained." (emphasis added)); id. at col. 4, lines 55-58 (describing the precursor and its fragments as involving a "proteolytic 'cascade' "); id. at col. 4, lines 61-64 ("Data derived from in vitro pulse-chase experiments support a precursor-product relationship between a large protein (approximately 31,000 molecular weight) and a series of smaller species...."); id. at col. 9, lines 64-68 ("Functionally equivalent nucleotide sequences encoding the novel amino acid sequence of human [IL-1B], *or* fragments thereof having IL-1[B] activity, can be prepared by known synthetic procedures."); id. at col. 10, lines 26-31 ("[T]he scope of the subject invention includes *not only* the specific nucleotide sequence depicted herein, *but also* all equivalent nucleotide sequences coding for molecules with substantially the same human IL-1[B] biological activity.... Within th[e] definition [of equivalent] are subfragments which have human IL-1[B] biological activity." (emphasis added)).

Therefore, this Court finds that the Auron Patent specification supports plaintiff's contention that the term "human IL-1B" encompasses not only the full-length precursor of the IL-1B protein, but the protein's fragments as well.

**3. Prosecution History**

Turning to the prosecution history of the Auron Patent, defendant claims that its prosecution history demonstrates "that the term 'IL-1B' as used in claim 12 can only mean the IL-1B precursor," stating:

During the prosecution of the patent, the inventors consistently referred to their invention as the "precursor" and consistently based their arguments for patentability, at least in part, on the fact that none of the cited prior art disclosed their 32,000 weight precursor. To the extent the specification does characterize the invention as concerning "fragments" of a "nucleotide sequence coding for human IL-1[B]" ... those fragments are *specifically* set forth and covered in claims 14-22, which have been structured as a separate set of claims.

Def.'s Br. at 17, 19 (emphasis in original). With respect to this issue, defendant points out and plaintiffs concede that although little was known about IL-1 when the Auron Patent application was filed, much more became known about it while the patent was being prosecuted. Based upon this premise, defendant alleges that these advancements prompted the inventors to: (1) add a definition of IL-1B to the Auron Patent; (2) distinguish between the molecular weights and amino acid compositions of IL-1B precursor, IL-1 alpha, and mature IL-1B; and, most significantly, (3) attempt to change the title of the invention to "Recombinant DNA which Codes for Interleukin-1 *Precursor*." *See* U.S. Patent No. 4,766,069 (Aug. 23, 1988), at col. 1, lines 66-68; Def.'s Ex. 10 at 7 (proposed amendments to the Auron Patent submitted to the PTO on October 22, 1986) (attached to Def.'s Br.); Def.'s Ex. 16 at 1-2 (Declaration of Dr. Philip E. Auron to the PTO dated June 29, 1987) (attached to Def.'s Br.).

Defendant further points out that while prosecuting the patent, the inventors made a conscious effort to distinguish their invention as the "32,000 molecular weight IL-1B precursor" as opposed to proteins with lower molecular weights. Id. Specifically, defendant claims:

Auron et al. aggressively argued to the Examiner that their IL-1[B] was different from Mizel et al.'s IL-1 and ultimately convinced the Examiner that there was a difference based on molecular weight and sequence. For Auron et al. to now suggest that "IL-1B" as used in claim 12 means mature IL-1B, which is likewise a low molecular weight species with a different sequence than the full-length precursor sequence, flies in the face of their position before the Patent Office during the prosecution of the Auron Patent.

Def.'s Br. at 21. On this basis, defendant insists that Claim 12 is therefore limited to DNA encoding the full-length precursor peptide of IL-1B.

With respect to the issues raised by defendant, plaintiffs maintain that "[i]t is clear throughout the specification that IL-1 and IL-1B were intended to cover both the precursor and its fragments." Opp. Br. at 8. In support of their position, plaintiffs note the existence of a "precursor-fragment relationship" in the Auron Patent, citing the various lines of the patent's specification referenced above that allude to such a relationship. Id. at 8-9 (citing U.S. Patent No. 4,766,069 (Aug. 23, 1988), at col. 4, lines 58, 62-64 & col. 10, lines 26, 36-38). Plaintiffs further aver that although PeproTech does not manufacture a protein specifically identified by the Auron Patent, "when inventors make a generic invention, they need not describe every specific example in the patent.... By giving the public the full DNA sequence for the precursor, the inventors gave the information needed to generate any and all fragments." Id. at 9-10 (citing United States v. Telectronics, Inc., 857 F.2d 778, 786 (Fed.Cir.1988) (citations omitted), *cert. denied,* 490 U.S. 1046 (1989)). With respect to defendant's assertions regarding plaintiffs' attempt to change the title of the invention to add the word "Precursor," plaintiffs note that what is significant is that the title was not so amended. *See* U.S. Patent No. 4,766,069 (Aug. 23, 1988).

Based upon the foregoing and the record presented to this Court, this Court finds that the prosecution history of the Auron Patent supports the broader definition advanced by plaintiffs regarding the scope of "human IL-1B" as employed in Claim 12. The Court will now focus on the overall claim structure of the Auron Patent.

**4. Claim Structure**

Defendant asserts that the claim structure in the Auron Patent demonstrates that the references to "IL-1B" in Claim 12 mean the full-length IL-1B precursor peptide. Specifically, defendant avers that the 24 claims of the Auron Patent are directed at two different proteins, neither of which is produced by defendant: (1) the full-length IL-1B precursor (Claims 1-13), and (2) a putative peptide with a molecular weight of 23,000-denoted as "human IL-1B peptide" (Claims 14-22).FN4 Based upon this premise, defendant claims that plaintiffs are now endeavoring to expand the meaning of Claim 12 beyond what was intended when the Auron Patent application was filed and beyond what was argued to the patent examiner during the Auron Patent's prosecution.

In Refrac International, Ltd. v. IBM, 689 F.Supp. 422 (D.N.J.1988), *aff'd.,* 891 F.2d 299 (Fed.Cir.1989), this Court declared: "a patent stands or falls on what is said, not what the holder of the patent hoped he had said nor what an expert speculates in hindsight about what the patent holder might have meant.... Claims may not be broadened by the specification, nor by hindsight." Id. at 430. As concluded in *supra* part II(B)(2) of this Memorandum and Order, however, the references to the IL-1B protein in Claim 12 of the Auron Patent specification are generic in nature and refer to both the full-length IL-1B precursor and the protein's fragments. Furthermore, " 'where some claims are broad and others narrow, the narrow claim limitations cannot be read into the broad whether to avoid invalidity or to escape infringement.' " Fromson v. Advance

Offset Plate, Inc., 720 F.2d 1565, 1570 (Fed.Cir.1983) (quoting Kalman v. Kimberly-Clark Corp., 713 F.2d 760, 770 (Fed.Cir.1983), *cert. denied,* 465 U.S. 1026 (1984)).

In light of the foregoing, this Court finds that a plain interpretation of Claim 12 of the Auron Patent encompasses not only the full-length precursor of the IL-1B protein, but the protein's fragments as well. Accordingly, the Court will deny defendant's motion for summary judgment pursuant to Fed.R.Civ.P. 56, and grant plaintiffs' cross-motion for the same on this specific issue.

**III. CONCLUSION**

For the foregoing reasons,

It is this 30th day of August 1993,

ORDERED that defendant's motion for summary judgment pursuant to Fed.R.Civ.P. 56 on the specific issue of whether the scope of Claim 12 of U.S. Patent No. 4,766,069 (Aug. 23, 1988) encompasses not only the full-length precursor of the IL-1B protein, but the protein's fragments as well be and is hereby DENIED; and it is

FURTHER ORDERED that plaintiffs' cross-motion for summary judgment pursuant to Fed.R.Civ.P. 56 on the specific issue of whether the scope of Claim 12 of U.S. Patent No. 4,766,069 (Aug. 23, 1988) encompasses not only the full-length precursor of the IL-1B protein, but the protein's fragments as well be and is hereby GRANTED.

FN1. Originally, plaintiffs asserted two claims of infringement involving: (1) the unauthorized use of a DNA-containing cloning vehicle (Claim 1), and (2) the unauthorized use of a method of using the DNA-containing cloning vehicle to produce certain proteins (Claim 12). *See* Def.'s Br. at 1; Opp.Br. at 1. In their opposition brief and at oral argument, however, plaintiffs declared that they were relying solely on Claim 12 to establish an infringement. *See* Opp.Br. at 4 ("At trial plaintiffs will rely solely on [C]laim 12 [to establish an infringement.]").

FN2. Although the plaintiffs failed to file a formal cross-motion for summary judgment, in their brief in opposition to defendant's motion plaintiffs suggested to the Court that they are entitled to summary judgment on the infringement issue, stating: "[G]iven [the] admissions [made] by PeproTech in its brief, summary judgment on the infringement issue could properly be granted in plaintiff's favor.... In light of PeproTech's admission that there is no dispute regarding the specifics of Peprotech's process, summary judgment should be granted in plaintiffs' favor." Opp.Br. at 1, 13 (emphasis omitted). *But see* id. at 13 ("[F]actual issues exist which preclude summary judgment."). Thereafter, on March 5, 1993, during oral argument, both sides conceded that the specific issue of whether the plain interpretation of Claim 12 of U.S. Patent No. 4,766,069 (Aug. 23, 1988) covered defendant's product was in fact dispositive on cross-motions for summary judgment.

FN3. Because defendant conceded both in its brief and at oral argument that if the Court adopts plaintiffs' interpretation of the scope of Claim 12 of the Auron Patent, its manufacturing process infringes upon Claim 12, *see* Def.'s Br. at 2-3; Opp.Br. at 5-6, the sole issue before the Court involves claim interpretation. *See*

Read Corp. v. Portec Inc., 970 F.2d 816, 821 (Fed.Cir.1992) (The determination as to whether a patent claim has been infringed is a two-step process: (1) interpreting the scope of the language of the patent claim, and (2) comparing the accused device to the asserted claim. (citations omitted)).

FN4. With respect to defendant's assertion, it is worth noting that Claims 23 and 24 are explicitly directed at Recombinant Plasmid pcD-1218 and Recombinant Plasmid pA-26 respectively. *See* U.S. Patent No. 4,766,069 (Aug. 23, 1988), at col. 24, claims 23-24.

D.N.J.,1993.
New England Medical Center Hospitals, Inc. v. Peprotech, Inc.