IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TALECRIS BIOTHERAPEUTICS, INC., Plaintiff v. BAXTER INTERNATIONAL INC., et al., Defendants	C.A. No. 05-349 GMS
BAXTER HEALTHCARE CORP., Counterclaimant v. TALECRIS BIOTHERAPEUTICS, INC. and BAYER HEALTHCARE LLC, Counterdefendants	

MEMORANDUM

I. INTRODUCTION

The plaintiff, Talecris Biotherapeutics, Inc., ("Talecris") filed the above-captioned action against Baxter International Inc. and Baxter Healthcare Corporation (collectively, "Baxter") on June 1, 2005. (D.I. 1.) In its complaint, Talecris alleges that Baxter is infringing U.S. Patent No. 6,686,191 (the "'191 patent"). On August 31, 2005, Baxter answered Talecris's complaint and counterclaimed for a declaratory judgment of noninfringement and invalidity. (D.I. 5.) In this

memorandum, the court will address Baxter's motion for summary judgment that the '191 patent is invalid for indefiniteness. For the reasons that follow, the court will deny Baxter's motion for summary judgment that the '191 patent is invalid for indefiniteness, and grant summary judgment in favor of Talecris that the patent is not indefinite.

II. BACKGROUND

The asserted claims of the '191 patent are directed to methods of treating a solution of antibodies to make an intravenously injectable immunoglobulin G solution ("IGIV"). The first step in the claimed treatment requires contacting the solution with a trialkylphosphate (a solvent) and a detergent "under conditions sufficient to substantially reduce any virus activity and resulting in an increased level of anticomplement activity." The second step in the claimed treatment requires incubating the solution "under conditions of controlled time, pH, temperature, and ionic strength, such that the increased anticomplement activity of the solution is reduced to an acceptable level suitable for intravenous administration." (D.I. 232, Ex. 1,'the 191 patent, cl. 1.)

III. LEGAL STANDARD

Summary judgment is appropriate "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c); *see also Boyle v. County of Allegheny Pa.*, 139 F.3d 386, 392 (3d Cir. 1998). Thus, summary judgment in favor of the movant is appropriate only if the moving party shows there are no genuine issues of material fact that would permit a reasonable jury to find for the non-moving party. *Boyle*, 139 F.3d at 392. A fact is material if it might affect the

outcome of the suit. *Id*. (*citing Anderson v. Liberty Lobby, Inc*., 477 U.S. 242, 247-248 (1986)). An issue is genuine if a reasonable jury could possibly find in favor of the non-moving party with regard to that issue. *Id*. In deciding the motion, the court must construe all facts and inferences in the light most favorable to the non-moving party. *Id*.; *see also Assaf v. Fields*, 178 F.3d 170, 173-74 (3d Cir. 1999). If the moving party has demonstrated an absence of material fact, the non-moving party then "must come forward with 'specific facts showing that there is a genuine issue for trial.'" *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986) (*quoting* Federal Rule of Civil Procedure 56(e)). The mere existence of some evidence in support of the non-moving party, however, will not be sufficient for denial of a motion for summary judgment; there must be enough evidence to enable a jury reasonably to find for the non-moving party on that issue. *Anderson*, 477 U.S. at 249.

When a party challenges a patent's validity, the court begins with the statutory presumption of validity. 35 U.S.C. § 282 ("A patent shall be presumed valid."). Accordingly, "[t]he burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity." *Id*. Invalidity must be shown by clear and convincing evidence. *Robotic Vision Sys., Inc. v. View Eng'g, Inc*., 189 F.3d 1370, 1377 (Fed. Cir. 1999). This evidentiary standard is relevant in the context of a motion for summary judgment because "the judge must view the evidence presented through the prism of the substantive evidentiary burden." *Anderson*, 477 U.S. at 254. As the Court elaborated,

> [W]here the . . . 'clear and convincing' evidence requirement applies, the trial judge's summary judgment inquiry as to whether a genuine issue exists will be whether the evidence presented is such that a jury applying that evidentiary standard could reasonably find for either the plaintiff or the defendant. Thus, where the factual dispute concerns [a material issue]. . . the appropriate summary judgment question will be whether the evidence in the record could support a reasonable jury finding either that the [movant]

> has shown [that material issue] by clear and convincing evidence or that the [movant] has not.

Id. at 255-56. Thus, the defendants must show that there is no genuine issue as to any material fact that is necessary for a finding, by clear and convincing evidence, of invalidity. If the defendants make such a showing, Talecris may withstand summary judgment by adducing "specific facts" sufficient to create a genuine issue of material fact as to an essential element of Baxter's defense of invalidity. Fed. R. Civ. P. 56(e); *see also Int'l Ass'n of Heat & Frost Insulators & Asbestos Workers Local Union 42 v. Absolute Envtl. Serv., Inc., et al.*, 814 F. Supp. 392, 401-02 (D. Del. 1993) (explaining summary judgment standard and burdens).

IV. DISCUSSION

Baxter contends that all of the "asserted claims of the '191 patent are invalid as indefinite because the claim terms 'acceptable level [of anticomplement activity] suitable for intravenous administration,' 'increased level of anticomplement activity,' and 'then incubating the solution of step a)'/'the increased anticomplement activity of the solution' are insolubly ambiguous." (D.I. 231 at 2.) Title 35 of the United States Code, Section 112, provides that "the specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." 35 U.S.C. § 112, ¶ 2. As the construer of patent claims, it is the court's duty to determine whether patent claims are indefinite. *Personalized Media Commc'ns, LLC v. Int'l Trade Comm'n*, 161 F.3d 696, 705 (Fed. Cir. 1998). Determining whether a claim is definite requires an analysis of "whether one skilled in the art would understand the bounds of the claim when read in light of the specification. . . . If the claims read in light of the specification reasonably apprise those skilled in the art of the scope of

the invention, § 112 demands no more." *Miles Lab., Inc. v. Shandon, Inc.*, 997 F.2d 870, 875 (Fed. Cir. 1993).

"acceptable level suitable for intravenous administration"

The thrust of Baxter's argument is that the patent fails to define "acceptable level suitable for intravenous administration," and no objective measure or numeric cutoff point for "acceptability" is provided in the patent's specification. As evidence of this point, Baxter points to the inability of the Patent Office examiner, inventor, prosecuting patent attorney, and experts to define this claim term. Baxter thus concludes that, "[w]ithout clear boundaries, potential infringers cannot determine whether or not they infringe the '191 patent."

During the prosecution of the '191 patent, the examiner did in fact initially reject Claim 1 on the ground that the phrase "an acceptable level" of anticomplement activity was indefinite because "[t]he metes and bounds of what is defined by . . . an 'acceptable level' cannot be determined." (D.I. 161, Joint Appendix 35.) Bayer responded to the examiner's rejection by explaining that the acceptable level of ACA generally depends on the concentration of the IGIV. *Id*. Bayer pointed to the example in the specification for 5 and 10% IGIV solutions. *Id*. (*citing* the '191 patent, 5:57-64.) Based on Bayer's explanation, the examiner withdrew the rejection, acknowledging that "'an acceptable level' is not vague because it depends on the concentration of IGIV." (D.I. 161, Joint Appendix 83.)

Baxter also highlights the deposition testimony of the inventor and prosecuting attorney of the '191 patent, and Talecris's experts, as support for its contention that the claim term "acceptable level" renders the claims of the '191 indefinite. In summary, the deposition testimony of these witnesses reveals to the court a reluctance to assign any specific definition of "acceptable level" of ACA because acceptability is dependent upon a number of variables, which

may include the assay used to measure ACA, the properties of a given IGIV solution, and the individual characteristics of the patient. (*See, e.g.*, D.I. 231 at 14.)

Baxter argues that "the variety of methods available to measure ACA, but which have not been defined by the patentee, can result in infringement or non-infringement depending on which method is chosen." (D.I. 23 at 19.) The defendants consequently view this uncertainty and lack of boundaries in the '191 patent as grounds for a finding of indefiniteness. Baxter principally relies on two cases from the Federal Circuit Court of Appeals, and one case from the Eastern District of Texas, as the legal foundation for its argument.

In *Honeywell Int'l, Inc. v. Int'l Trade Comm'n*, the Federal Circuit affirmed a decision of the United States International Trade Commission that invalidated a patent due to indefiniteness. 341 F.3d 1332, 1338 (Fed. Cir. 2003). The patent in *Honeywell* concerned the production of synthetic yarn. The claim term at issue recited "thereby obtaining a drawn yarn with a terminal modulus of at least 20 g/d and a melting point elevation [MPE] of 10 C. to 14 C." The claims did not recite the method used for measuring MPE or preparing samples. The Federal Circuit held the claim "insolubly ambiguous, and hence indefinite … [in that] the claims, the written description, and the prosecution history fail to give [the Court], as the interpreter of the claim term, any guidance as to what one of ordinary skill in the art would interpret the claim to require."

In *Datamize, LLC v. Plumtree Software, Inc*., the Federal Circuit considered the claim term "aesthetically pleasing," which the district court had found to be "hopelessly indefinite" in a utility patent claiming a software program. 417 F.3d 1342, 1347 (Fed. Cir. 2005). Affirming the district court, the Federal Circuit stated that "the scope of claim language cannot depend solely on the unrestrained, subjective opinion of a particular individual purportedly practicing the

invention. … Some objective standard must be provided in order to allow the public to determine the scope of the claimed invention." *Id*. at 1350.

In *Halliburton Energy Servs, Inc. v. MI, LLC*., the district court considered a patented invention directed to using drilling fluids that contain "fragile gels" or exhibit "fragile gel behavior" in drilling operations. 456 F. Supp. 2d 811 (E.D. Tex. 2006). The court determined that any possible construction of "fragile gel" would include subjective terms that render the claims indefinite. *Id*. at 816. The court opined that neither the specification nor any other evidence provided an objective standard for determining the scope of the amorphous terms. *Id*. at 817.

In view of these cases, Baxter argues that 1) as in *Honeywell*, neither the method of measuring ACA nor the level of ACA that is "acceptable" is taught by the '191 patent; 2) as in *Datamize,* the '191 patent provides no standard by which to measure "acceptability;" and 3) as in *Halliburton,* no objective measure or numeric cutoff point for "acceptability" is provided in the '191 patent. (D.I. 231 at 9.) Talecris distinguishes the claim at issue in *Honeywell* from Claim 1 of the '191 patent, stating that "the *Honeywell* claim contained a specific numeric range and it therefore required a specific test method to yield a precise numeric value." Conversely, Claim 1 of the '191 patent does not contain a numeric range; rather, it requires the measurement of ACA to determine relative ACA levels—an increase followed by a reduction. As such, Talecris argues that it is not necessary for Claim 1 to recite numeric limits of acceptability based on a particular test for a particular product as it would unfairly and unnecessarily limit Claim 1. The court agrees.

Talecris distinguishes *Datamize* and *Halliburton* from this case by pointing out that those cases involved the purely subjective terms "aesthetically pleasing" and "fragile gel,"

respectively. In both instances, the claim terms were judged as lacking an "objective anchor" that identified the bounds of the claims for one skilled in the art. *Datamize*, 417 F.3d at 1350; *Halliburton*, 456 F. Supp. 2d at 817. Here, the court is persuaded that "acceptable level suitable for intravenous administration" is not purely subjective, and therefore not analogous to *Datamize* and *Halliburton*. To the contrary, the record reflects that the phrase has meaning to those of ordinary skill in the art, albeit the determination of that meaning may depend on a number of variables, and the ultimate determination of acceptability may be temporally distant from the time in which the inventive steps of the claim are performed. (*See, e.g.*, D.I. 239, Ex. 7 at 135 (relating the testimony of Baxter's infringement expert, Dr. Snape, in which he admits that the FDA release limits are indicative of what the regulatory authority and manufacturer have agreed are ***acceptable*** to give a human patient, for release of a particular product, and that everyone in his field would know as much).)

The court finds the Federal Circuit's guidance in *SmithKline Beecham Corp. v. Apotex Corp*. to be instructive here. 403 F.3d 1331 (Fed. Cir. 2005.) The Court explained that "[t]he test for indefiniteness does not depend on a potential infringer's ***ability to ascertain the nature of its own accused product to determine infringement***, but instead on whether the claim delineates to a skilled artisan the bounds of the invention." *Id*. at 1341 (emphasis added). What the Federal Circuit observed in *SmithKline*, the court finds especially applicable here: "[b]readth is not indefiniteness." *Id*. (*citing In re Gardner*, 427 F.2d 786, 788 (C.C.P.A. 1970).

"increased level of anticomplement activity," "then incubating the solution of step a)" and "increased anticomplement activity of the solution"

The court has reviewed and considered Baxter's arguments that the claim terms "increased level of anticomplement activity," "then incubating the solution of step a)," and

"increased anticomplement activity of the solution" are indefinite because they are ambiguous or "nonsensical" under the court's claim construction. Applying the legal principles discussed above, the court finds no issue of indefiniteness with these claim terms. Baxter's arguments are essentially reargument of claim construction with a view towards its non-infringement defense. The plain and ordinary meaning of these claim terms are sufficiently definite such that one skilled in the art would understand the bounds of the claim when read in light of the specification.

Effect of the Court's Denial of Summary Judgment on an Issue of Law

For the reasons discussed herein, the court rejects Baxter's assertion that summary judgment of indefiniteness is appropriate in this case. Unlike the common circumstance of a denial of summary judgment due to a dispute of material fact, the court reaches its conclusion having agreed with Baxter that this case does not present any disputes of material fact that affect the legal determination of whether the claims at issue are indefinite. (*See* Baxter's Reply Br., D.I. 242 at 16 ("None of these issues is 'material' to a determination of indefiniteness, and some of these issues are undisputed for purposes of this motion.").)

A district court may grant summary judgment in favor of a non-movant where it believes that the movant has had adequate notice of the grounds for that judgment, and where there is clear support for such judgment. *Banks v. Lackawanna County Comm'rs***,** 931 F. Supp. 359, 363 (M.D. Pa. 1996). Although there are no genuine issues of material fact, Baxter is not entitled to a judgment in its favor. Talecris, however, is so entitled, despite its assertion that material facts preclude summary judgment.[1] Where one party has invoked the power of the court to render a

[1] A fact is material if it might affect the outcome of the legal determination to be made. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986) ("Only disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment." In its answering brief, Talecris contends that

summary judgment against an adversary, Fed. R. Civ. P. 54(c) and 56, when read together, give the court the power to render a summary judgment for the adversary if it is clear that the case warrants that result, even though the adversary has not filed a cross-motion for summary judgment. *See, e.g., Peiffer v. Lebanon School Dist.,* 673 F. Supp. 147, 152 (M.D. Pa. 1987), *affirmed*, 848 F.2d 44 (3d Cir.1988); 10A Charles Alan Wright, Arthur R. Miller & Mary Kay Kane, *Federal Practice and Procedure*, § 2720 at 29-35 (1983).

Whether the asserted claims of the '191 patent are indefinite ultimately amounted to the question of whether one of ordinary skill in the art would know what it means—not when or how it is determined—that ACA is at an "acceptable level suitable for intravenous administration."[2] The deposition testimony of the experts from both parties confirm to the court that those of ordinary skill in the art understand what it means for ACA to have an "acceptable level suitable for intravenous administration." Where, with that understanding, the claims set forth the boundaries of the patent, that is all the statute requires to satisfy 35 U.S.C. § 112, paragraph two. There is no factual issue for the jury to decide that would warrant a trial on the issue of indefiniteness. As such, the court will grant, *sua sponte*, summary judgment that the claims of

---

six issues of fact preclude summary judgment. (*See* Talecris's Answering Br., D.I. 238 at 29-30.) The court has considered each one, and finds that none of them constitute facts that affect whether the claims at issue are indefinite.

[2] The issues of when it is determined that ACA is at an "acceptable level" or how it is determined that ACA is at an "acceptable level" are essentially different, potentially triable, issues of fact, applicable to other areas of patent law. The court is not foreclosing the parties from litigating whether other requirements for patentability were met or whether infringement occurred, with respect to the acceptability limitation. The court's conclusion on indefiniteness is a determination that the claim language is sufficiently definite and apprises those of ordinary skill in the art of its boundaries. Accordingly, the court will not foreclose expert testimony as to the meaning of the acceptability limitation from either Baxter or Talecris, as long as such meanings do not attempt to re-litigate a claim construction to the jury that the court has foreclosed as a limitation on the claim language.

the ‘191 patent are not indefinite. The undisputed facts, viewed as Baxter urges, fail to show that the asserted patent claims are indefinite as a matter of law.

V. CONCLUSION

For the foregoing reasons, Baxter’s motion for summary judgment will be denied. The court finds that Talecris is entitled to a judgment in its favor that the asserted claims of the ‘191 patent are not indefinite as a matter of law.

Dated: June 18, 2007

/s/ Gregory M. Sleet
UNITED STATES DISTRICT JUDGE

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TALECRIS BIOTHERAPEUTICS, INC., Plaintiff v. BAXTER INTERNATIONAL INC., et al., Defendants	C.A. No. 05-349 GMS
BAXTER HEALTHCARE CORP., Counterclaimant v. TALECRIS BIOTHERAPEUTICS, INC. and BAYER HEALTHCARE LLC, Counterdefendants	

ORDER

For the reasons set forth in the court's memorandum of this same date, IT IS HEREBY ORDERED that:

1. Baxter's motion for summary judgment on the issue of indefiniteness (D.I. 230) is DENIED.
2. Summary judgment in favor of Talecris that the asserted claims of the '191 patent are not indefinite is GRANTED.
3. The parties are permitted to adduce expert testimony at trial as to the meaning of the phrase "acceptable level suitable for intravenous administration," as long as such

testimony does not include claim construction positions, or limitations on the claim language, that the court has foreclosed in its claim construction order.

Dated: June 18, 2007

/s/ Gregory M. Sleet
UNITED STATES DISTRICT JUDGE