IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ZYMOGENETICS, INC., a Washington Corporation,	)	
Plaintiff,	)	C. A. No: 06-500-SLR-MPT
v.	)	
BRISTOL-MYERS SQUIBB CO., a Delaware Corporation, and DOES 1 through 100,	)	**REDACTED PUBLIC VERSION**
Defendants.	)	

BRISTOL-MYERS SQUIBB COMPANY'S OPENING BRIEF IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT OF NO WILLFULNESS

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Defendant Bristol-Myers Squibb Company ("Bristol") moves, pursuant to Rule 56 of the Federal Rules of Civil Procedure ("Rule 56"), for summary judgment that any alleged infringement of U.S. Patent Nos. 6,018,026 ("the '026 Patent") and U.S. Patent No. 5,843,725 ("the '725 Patent") (collectively the "patents-in-suit") is not willful. In accordance with the Court's March 13, 2008 Order (D.I. 148 at 1), Bristol has concurrently filed "Bristol-Myers Squibb Company's Statement of Undisputed Facts in Support of Its Motion for Summary Judgment of No Willfulness" providing a short and concise statement of the material facts as to which there is no genuine issue to be tried, along with citations to the record supporting each contention.

INTRODUCTION

On August 29, 2006, Plaintiff ZymoGenetics, Inc. ("ZymoGenetics") sued Bristol, alleging that Bristol's CTLA4-Ig and the method for producing CTLA4-Ig infringe the patents-in-suit.[1] (Exh. 1 and Exh. 2).[2] ZymoGenetics' Complaint includes an allegation that the purported infringement is "willful", and that therefore this case is exceptional and ZymoGenetics is entitled to enhanced damages and attorneys' fees pursuant to 35 U.S.C. §§ 284 and 285.[3] (D.I. 1 at 3-5).

The Federal Circuit recently laid out in detail the requirements for establishing willfulness. *In re Seagate Tech., LLC*, 497 F.3d 1360, 1371 (Fed. Cir. 2007) (en banc). The

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[1] The asserted claims of the '026 Patent (Exh. 1) (Claims 1-4, 7, and 30) are generally directed to specific types of fusion proteins and the asserted claims of the '725 Patent (Exh. 2) (Claims 1-3, 5, 6, 21, 22, 24, 25, 50, and 51) are directed to methods of producing the specific type of fusion proteins that are the subject of the '026 patent.

[2] The exhibits reference herein are exhibits to the Declaration of John W. Kirkland In Support of Bristol-Myers Squibb Company's Motion for Summary Judgment of No Willfulness.

[3] ZymoGenetics' infringement allegations include inducement of infringement and contributory infringement.

necessary proofs for willfulness consist of two parts: an objective element (Part 1) and a subjective element (Part 2). If the patentee cannot prove objective Part 1 by clear and convincing evidence, the analysis need go no further, and willfulness cannot be found. To satisfy the threshold element of Part 1, ZymoGenetics must prove -- by clear and convincing evidence -- that the objective facts establish a "high likelihood" that Bristol's actions constituted infringement of a valid patent.

ZymoGenetics has not set forth sufficient evidence of objective recklessness, nor can they do so, as Bristol has substantial litigation defenses. In fact, the objective evidence proves that there is no likelihood that Bristol's CTLA4-Ig and method for producing CTLA4-Ig meets several of the limitations required by the claims. Therefore, pursuant to Rule 56, Bristol respectfully requests the Court grant its motion for summary judgment of no willfulness and dismiss ZymoGenetics' claims for enhanced damages and attorneys fees. For a complete explication of the absence of any viable infringement claim, Bristol respectfully invites the Court's attention to the summary judgment motion and memorandum in support thereof on that issue, filed concurrently.

BACKGROUND

Bristol provided the Court with a technical tutorial on October 17, 2007 in the form of a CD-ROM (D.I. 122), and also provided technical background on much of the technology described in this motion in Bristol's Opening Claim Construction Brief ("Bristol's Cl. Constr. Br.") filed concurrently. Bristol respectfully invites the Court's attention to the technical background provided on pages 2 through 11 in Bristol's Cl. Constr. Br. as context for the present motion.

I. The Patents-In-Suit

The '026 Patent was filed as U.S. Appl. No. 08/980,400 on November 26, 1997 and names Andrzej Z. Sledziewski, Lillian Anne Bell, and Wayne R. Kindsvogel as inventors. The '026 Patent issued on January 25, 2000. On March 16, 2004, ZymoGenetics filed a Request for Reexamination, citing seven prior art patents and articles that, by its admission "raise[d] a substantial question of patentability for each of the 29 claims of the '026 patent . . . ." (Exh. 3 Request for Reexamination Under 35 U.S.C. §302 and 37 C.F.R. §1.510 at BMS004260620). A Reexamination Certificate was issued on July 4, 2006 after ZymoGenetics narrowed its independent claims. Approximately 6 weeks later, on August 14, 2006, ZymoGenetics filed the present lawsuit alleging Bristol's CTLA4-Ig infringes the '026 Patent.

The '725 Patent was filed as U.S. Appl. No. 08/475,458 on June 7, 1995 and names Andrzej Z. Sledziewski, Lillian Anne Bell, and Wayne R. Kindsvogel as inventors. The '725 Patent issued on December 1, 1998. On March 16, 2004, ZymoGenetics filed a Request for Reexamination stating that the same prior art "raise[d] a substantial question of patentability for each of the 49 claims of the '725 patent . . . ." (Exh. 4, Request for Reexamination Under 35 U.S.C. §302 and 37 C.F.R. §1.510 at BMS004261270). A Reexamination Certificate was issued on August 29, 2006 after ZymoGenetics narrowed its independent claims. Several weeks prior to issuance of the reexamination certificate, ZymoGenetics had already filed the present lawsuit alleging Bristol's process of making CTLA4-Ig infringes the '725 Patent.

A. Each Asserted Claim Requires a "Dimerizing Protein"

Each asserted claim of the patents-in-suit requires a "dimerizing protein". (Exh. 1, Claims 1-4, 7, and 30; Exh. 2, Claims 1-3, 5, 6, 21, 22, 24, 25, 50, and 51). ZymoGenetics alleges that this claim term should be construed to mean:

> A polypeptide chain having affinity for a second polypeptide chain, such that the two chains associate under physiological conditions to form a dimer. The second polypeptide chain may be the same or a different chain.

(D. I. 153, Exh. A at 3-4).[4] The claims also require that the "dimerizing protein" be:

> selected from the group consisting of yeast invertase, at least a portion of an immunoglobulin light chain comprising at least an immunoglobulin light chain constant region domain, and at least a portion of an immunoglobulin heavy chain comprising at least an immunoglobulin heavy chain constant region domain

(Exh. 1, Claim 1 at ZG000003) (Exh. 2, Claims 1 and 21 at ZG000844). ZymoGenetics alleges that the mutated immunoglobulin ("Ig") portion of Bristol's CTLA4-Ig is a "dimerizing protein."[5]

B. Each Asserted Claim Requires a Non-Immunoglobulin Polypeptide or Ligand-Binding Domain of a Receptor "Requiring Dimerization for Biological Activity"

Each asserted claim requires either a non-immunoglobulin polypeptide or a ligand-binding domain of a receptor "requiring dimerization for biological activity". (Exh. 1, Claims 1-4, 7, and 30; Exh. 2, Claims 1-3, 5, 6, 21, 22, 24, 25, 50, and 51). As addressed in Bristol's Cl. Constr. Br., the term "requiring dimerization for biological activity" should be construed to mean: [6]

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[4] For purposes of this present motion only, Bristol is applying ZymoGenetics' proposed construction, where possible, as this is presumably the construction that ZymoGenetics considered when making its allegations of willfulness.

[5] Bristol's Memorandum in Support of its Motion for Summary Judgment Motion of Noninfringement, filed concurrently, contains a discussion of Bristol's mutated Ig at pages 10-15.

[6] Bristol intended to address the present motion in the context of ZymoGenetics' purported construction of this claim term, but ZymoGenetics made that impossible. In the joint claim construction chart, ZymoGenetics refused to provide any construction of "requiring dimerization for biological activity" stating only that it has an "ordinary meaning within context of claims" without providing a construction for its alleged ordinary meaning. (D.I. 153, Exh. A at 2).

> needing to be dimerized to have biological activity, *i.e.*, (a) unless a dimer, it has no biological activity; and (b) will not dimerize on its own

(D.I. 153, Exh. A at 2-3) (Bristol's Cl. Constr. Br at 20-28). ZymoGenetics alleges that the "CTLA4" portion of Bristol's CTLA4-Ig is "requiring dimerization for biological activity."[7]

II. ZymoGenetics' Alleged Evidence of Willfulness

On October 17, 2006, Bristol propounded an interrogatory requesting that ZymoGenetics:

> State with particularity all facts which Plaintiff relies upon for their contention that this case is an exceptional case under 35 U.S.C. § 285, and identify the persons most knowledgeable about, and all documents and things relating to, such contention.

(Exh. 5, Bristol-Myers Squibb Company's First Set of Interrogatories to ZymoGenetics, Inc., Interrogatory No. 7 at 4).

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Despite ZymoGenetics' promise (and its obligation under Fed. R. Civ. P. 26(e)) to supplement "as additional information becomes known to it", it has not done so.

[7] Bristol's Memorandum in Support of its Motion for Summary Judgment Motion of Noninfringement, filed concurrently, contains a discussion of CTLA4 at pages 10-11.

ARGUMENT

III. Legal Standards

A. Willfulness

The Federal Circuit prescribed a two-part test, each element of which must be proven by clear and convincing evidence, for a patentee to establish willfulness. *Seagate*, 497 F.3d at 1371. This two-part test requires "at least a showing of objective recklessness" and consists of an objective threshold element (Part 1) and a subjective element (Part 2). *Id.*

To satisfy the "objective" threshold of the *Seagate* test, the patentee must establish by clear and convincing evidence that there was a "high likelihood" that the accused infringer's actions constituted infringement of a valid patent.[8] *Id.* If the patentee cannot prove Part 1, *i.e.*, the threshold objective, the claim of willfulness necessarily fails.[9] *Id.* As the concurring opinion of *Seagate*, authored by Judge Gajarsa and joined by Judge Newman, explained: "If Convolve is unable to show [Part 1 of the Seagate test], Seagate cannot be found to have willfully infringed. . . ." *Id.* at 1384 (Gajarsa, J., concurring).

B. Summary Judgment Is Appropriate Here

Courts should enter summary judgment when there is no genuine dispute of material fact and judgment can be entered as a matter of law. Fed. R. Civ. P. 56(c); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986).

"Summary judgment is as appropriate in a patent case as in any other." *Barmag Barmer Maschinenfabrik AG v. Murata Mach., Ltd.*, 731 F.2d 831, 835 (Fed. Cir. 1984). Where there is no genuine issue of material fact "and the movant is entitled to judgment as a matter of

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[8] The accused infringer's state of mind is irrelevant to the objective element. *Id.*

[9] If this threshold is met, ZymoGenetics must also prove that the objectively defined risk was either known or so obvious that it should have been known. *Id.*

law, the court should utilize the salutary procedure of Fed. R. Civ. P. 56 to avoid unnecessary expense to the parties and wasteful utilization of the jury process and judicial resources." *Id.* Where the nonmoving party bears the burden of persuasion at trial, as in the present instance, the moving party's burden "may be discharged by 'showing' -- that is, pointing out to the district court -- that there is an absence of evidence to support the nonmoving party's case." *Celotex Corp. v. Catrett*, 477 U.S. 317, 325 (1986).

Disputes regarding material facts are "genuine" only "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson*, 477 U.S. at 248. "If the evidence is merely colorable, or is not significantly probative, summary judgment may be granted." *Id.* at 249-50 (citations omitted). The evidence must be viewed through the prism of the evidentiary standard of proof applicable at a trial on the merits which, as noted above, is by clear and convincing evidence. *Id.* at 252-54.

Applying the *Seagate* standards, courts have granted summary judgment of no willful infringement. *See, e.g., Franklin Elec. Co., Inc. v. Dover Corp.*, No. 05-C-598-S, 2007 U.S. Dist. LEXIS 84588 (W.D. Wis. Nov. 15, 2007); *Lucent Techs., Inc. v. Gateway, Inc.*, No. 07-CV-2000-H, 2007 U.S. Dist. LEXIS 95934 (S.D. Cal. Oct. 30, 2007); *see also Trading Techs. Int'l, Inc. v. eSpeed, Inc.*, No. 04-C-5312, 2008 U.S. Dist. LEXIS 295 (N.D. Ill. Jan. 3, 2008).

Bristol's Motion for Summary Judgment of No Willfulness is ripe and appropriate for decision because ZymoGenetics has not and cannot prove that there was a "high likelihood" that Bristol's actions constituted infringement.

IV. ZymoGenetics Has Not Set Forth Evidence That Bristol's Activities Were Objectively Reckless, and Relies on Overruled Case Law In Support of Its Positions

Despite the voluminous factual record developed in this case between filing of the Complaint in August of 2006 and the close of fact discovery in October of 2007, ZymoGenetics

has not identified any evidence of objective recklessness -- let alone clear and convincing evidence of objective recklessness.

The only factual basis ZymoGenetics provided for its exceptional case allegations was its bare, conclusory interrogatory response concerning exceptional case provided in December of 2006 stating:

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If those conclusions were considered to be "facts" at all, they are legally insufficient for a finding of willfulness.

First, the standard ZymoGenetics relies on -- an affirmative duty to exercise due care – was expressly overruled by *Seagate*, as a basis for a finding of willfulness. *Seagate*, 497 F.3d at 1371 (overruling the "affirmative duty to exercise due care" standard). Second, "knowledge of the existence of the patents-in-suit", if true, is an irrelevant subjective fact. *See id.* (holding the accused infringer's state of mind is irrelevant to the objective element); *Franklin Elec.*, 2007 U.S. Dist. LEXIS 84588, at *22-23 (finding patentee could not meet the burden of proving objective recklessness by clear and convincing evidence when all of the evidence proffered by the patentee was subjective).

Fact discovery in this case closed on October 12, 2007, more than seven months ago. And, despite both the promise to supplement its interrogatory response when more information became known, and its clear obligation to do so under Fed. R. Civ. P. 26(e), ZymoGenetics has not identified any other facts. (Ex. 6 at 13). The lack of evidence of "objective recklessness" identified by ZymoGenetics justifies the entry of summary judgment against it on that issue.

V. Bristol Has Credible, Substantial Defenses to the Lawsuit, and the Objective Evidence Shows No Evidence of a "High Likelihood" of Infringement

Bristol respectfully invites the Court's attention to Bristol's Motion for Summary Judgment of Noninfringement filed concurrently for several of Bristol's substantial defenses to ZymoGenetics' allegations. *Seagate*, 497 F.3d at 1374 ("[a] substantial question about invalidity or infringement is likely sufficient . . . to avoid . . . a charge of willfulness based on post-filing conduct").[10]

Rather than a "high likelihood" that Bristol infringes the patents-in-suit prior to the commencement of the litigation, the record of objective facts supports the opposite conclusion. Bristol summarizes below several key facts relevant to the objective analysis below, which point away from any alleged "high likelihood" that (a) Bristol's mutated Ig is a "dimerizing protein" and (b) that CTLA4 is a polypeptide "requiring dimerization for biological activity".

A. The Objective Evidence Shows No "High Likelihood" That Bristol's Mutated Ig Is A "Dimerizing Protein" As Required By The Claims

ZymoGenetics alleges that the mutated Ig portion of Bristol's CTLA4-Ig is a "dimerizing protein". ZymoGenetics' proposed construction of "dimerizing protein" is:

> a polypeptide chain having affinity for a second polypeptide chain, such that the two chains associate under physiological conditions to form a dimer. The second polypeptide chain may be the same or a different chain.

[10] While Bristol believes it is entitled to summary judgment of noninfringement, a finding of noninfringement is not a prerequisite to concluding that ZymoGenetics has failed to bring forth sufficient evidence to prove, by clear and convincing evidence, that there is a high likelihood that Bristol's actions are infringing.

(D.I. 153, Exh. A at 3-4). Therefore, in order to infringe, the two polypeptide chains of mutated Ig in Bristol's CTLA4-Ig must "associate under physiological conditions to form a dimer". The salient objective facts concerning Bristol's mutated Ig are as follows:

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- It is understood among scientists who work with Igs that a single amino acid change at a dimer interface can affect the ability of an Ig to form a dimer.

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Therefore, contrary to proving a "high likelihood" that Bristol's mutated Ig region forms a dimer, the objective evidence leads one away from that conclusion.[11]

B. The Objective Evidence Shows No "High Likelihood" That CTLA4 is "Requiring Dimerization for Biological Activity"

All claims of the asserted patents either require either a "non-immunoglobulin *requiring dimerization for biological activity*" or a "ligand-binding domain of a receptor *requiring dimerization for biological activity*". As discussed in Bristol's Opening Claim Construction Brief, the proper construction for "requiring dimerization for biological activity" is

> needing to be dimerized to have biological activity, *i.e.*, (a) unless a dimer, it has no biological activity; and (b) will not dimerize on its own

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(D.I. 153, Exh. A at 2-3) (Bristol's Cl. Constr. Br., at 20-28).

Stated otherwise, if the polypeptide has biological activity as a monomer, it does not meet the "requiring dimerization" limitation.

The objective evidence supports the fact that CTLA4 does not require dimerization for biological activity. The relevant objective evidence is as follows:

- The patents-in-suit define "biological activity" as "a function or set of activities performed by a molecule in a biological context (*i.e.*, in an organism or an in vitro facsimile thereof)". (Exh. 1 at ZG000031, Col. 9, ll. 54-56).

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- Years before the patents-in-suit issued, Bristol scientists demonstrated in scientifically peer reviewed publications that CTLA4, as a monomer, binds to B7 with high affinity in a ligand binding assay, and that CTLA4-Ig competitively binds B7 in a competition binding assay:

    - In an article authored by Bristol scientists entitled "Binding Stoichiometry of the Cytotoxic T Lymphocyte-associated Molecule-4 (CTLA-4)" in 1995, it was reported that: "Each monomeric polypeptide chain of CTLA4 contains a high affinity binding site for B7 molecules" and "monomeric and dimeric forms of CTLA-4 bound CD80 and CD86 [both forms of B7]". (Exh. 12, Linsley *et al.*, *Binding Stoichiometry of the Cytotoxic T lymphocyte-associated Molecule (CTLA-4)*, J. BIOL. CHEM. 270:15417 at 15417, 15421 (1995)).

    - In another article authored by Bristol scientists entitled "CD28/CTLA4 Receptor Structure, Binding Stoichiometry and Aggregation During T-Cell Activation" in 1995, it was reported that: "CTLA4 was stably

expressed as a monomer . . . and monomeric CTLA4 contained a high affinity binding site for B7 molecules." (Exh. 13, Linsley *et al.*, *CD28/CTLA-4 receptor structure, binding stoichiometry and aggregation during T-cell activation*, RESEARCH IN IMMUNOL. at 146:130 at 133 (1995)).

- Bristol also demonstrated in peer reviewed publications that monomeric CTLA4 "competitively" binds to B7: "The relative avidities of monomeric and dimeric CTLA-4 were compared by competitive binding assay in the experiment . . . . Monomeric CTLA-4 was a more effective competitor than multimeric CD28Ig . . . ." (Exh. 12 at 15421-22).

The objective evidence shows that the CTLA4 monomer was biologically active and did not "require dimerization for biological activity" and therefore proves there was no high likelihood of infringement. As a result, ZymoGenetics has not and cannot meet its burden of proving objective recklessness by clear and convincing evidence.

CONCLUSION

For the foregoing reasons, Bristol respectfully requests the Court find no willfulness as a matter of law and dismiss ZymoGenetics' claims for enhanced damages and attorneys fees pursuant to 35 U.S.C. §§ 284 and 285.

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DISTRICT OF DELAWARE

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