IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ZYMOGENETICS, INC., a Washington Corporation,	)	
Plaintiff,	)	Civil Action 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 REPLY BRIEF IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT OF NO WILLFULNESS

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Pursuant to the Court's Order dated August 4, 2008, Bristol-Myers Squibb Company ("Bristol") submits this reply brief in Support of its Motion for Summary Judgment of No Willful Infringement. (D.I. 175)

INTRODUCTION

ZymoGenetics Inc. ("ZymoGenetics") has failed to raise a genuine issue of material fact as to willfulness. Instead, ZymoGenetics makes baseless allegations that Bristol obstructed discovery, and ZymoGenetics distorts the test for willfulness set forth by the Federal Circuit in the *Seagate* decision. *In re Seagate Tech., LLC*, 497 F.3d 1360, 1371 (Fed. Cir. 2007). To prove willful infringement according to *Seagate*, ZymoGenetics must make "at least a showing of objective recklessness" by clear and convincing evidence. *Id.* In order to make this minimum showing, it must first satisfy a threshold objective inquiry, which involves showing an "objectively high likelihood" that Bristol's actions constituted infringement of a valid patent. *Id.* If ZymoGenetics cannot satisfy the threshold inquiry, the analysis stops and there can be no willfulness. That is, there is no need to address the second subjective prong of willfulness if the threshold objective element is not met. *Id.*

In its opposition brief, ZymoGenetics attempts to avoid the threshold objective element of willfulness: (1) by claiming discovery on the objective prong is not complete (contrary to ZymoGenetics' representations to the Court and contrary to the Court's directive), (2) by conflating the objective and subjective standards of *Seagate*, and (3) by arguing there is a question of objective recklessness because Bristol's defenses are "incorrect and unreasonable"

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Each of ZymoGenetics' assertions is either incorrect, irrelevant, or insufficient.

ZymoGenetics attempts to avoid the threshold objective portion of the *Seagate* test because it cannot make a sufficient evidentiary showing. None of ZymoGenetics' alleged evidence of objective recklessness is germane to the first hurdle it must surmount -- whether there was an "objectively high likelihood" of infringement. If anything, it only speaks to the subjective standard of *Seagate*, which need not be addressed unless the first prong is first established. *Id.* The record is clear, there is no "objectively high likelihood" of infringement.

ZymoGenetics bears the burden to prove willfulness by clear and convincing evidence. It has not shown any facts that would meet that standard and support the conclusion that there was an "objectively high likelihood" of infringement. Its claim of willful infringement cannot survive summary judgment.

ARGUMENT

I. Legal Standard -- Bristol Applies the Correct Burden of Proof

Bristol applies the correct burden of proof on its Motion for Summary Judgment of No Willful Infringement (D.I. 177 at 6-7, "Opening Brief"), and ZymoGenetics' assertions to the contrary are wrong. In its brief, ZymoGenetics refers to Bristol's citation of the *Seagate* standard for proving the ultimate conclusion of willfulness, which requires a patentee satisfy both the "objective" and "subjective" prongs of the *Seagate* test by clear and convincing evidence. (ZymoGenetics' Opposition Brief, D.I. 240 at 7-8). *Seagate*, 497 F.3d at 1371. On summary judgment, courts take into account the applicable evidentiary standard of proof. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 252-54 (1986). Therefore, it is proper for Bristol to refer to the evidentiary standard for willfulness. ZymoGenetics' own brief acknowledges that it must show "sufficient evidence of objective recklessness such that a jury could reach a

determination that willfulness was demonstrated by clear and convincing evidence." (D.I. 240 at 8) (emphasis added).

II. Because ZymoGenetics has No Evidence an "Objectively High Likelihood" of Infringement Exists, ZymoGenetics Attempts to Avoid the Threshold Objective Inquiry of *Seagate*

ZymoGenetics attempts to avoid the threshold objective element of willfulness in three ways: (1) by incorrectly claiming discovery on the objective element of *Seagate* is not complete, (2) by conflating the objective and subjective standards of *Seagate*, and (3) by arguing there is a question of objective recklessness because Bristol's defenses are "incorrect and unreasonable." Each of these attempts fails.

A. ZymoGenetics Mischaracterizes the Record: Discovery on the Objective Element of *Seagate* is Complete

ZymoGenetics claims that Bristol has stayed "all" discovery on willfulness, including the objective element, despite the fact that (1) ZymoGenetics told the Court that it had taken discovery on the objective element and the remaining discovery largely concerned opinions of counsel, and (2) the Court directed ZymoGenetics to complete its discovery on the objective element.

1. ZymoGenetics Told the Court It Had Taken Discovery on the Objective Element and that Most of the Remaining Discovery was Related to Opinions of Counsel

Bristol requested a stay of discovery related to advice of counsel, but there was no stay of discovery on the objective inquiry. In a teleconference with the Court on November 8, 2007, ZymoGenetics' counsel confirmed that it was permitted to take discovery on the objective prong of willfulness, and that the remaining discovery was primarily related to opinions of counsel:

> The Court: What it sounds like to me, and you correct me if I'm wrong, Paul, about this, the only thing that is left on willfulness

> from your viewpoint I guess is the opinion of counsel aspect and whether or not you get it now and/or have you been prevented to take discovery on other willfulness aspects? You know, other evidence of willfulness.
>
> Mr Andre: At this point, Your Honor, they have not provided us ***We have had issues of willfulness and written discovery and there have been objections to that. But mostly it has focused on the opinions of counsel***
>
> The Court: Yes, but I mean I'm trying to find out what are their objections to the other discovery, the other discovery outside of opinion of counsel
>
> Mr. Andre: Sitting here off the top of my head, I don't know that there has been additional objections on that discovery. We have been able to discover certain issues that would factor into the showing of objective recklessness. ***I think probably most of the discovery has been denied on the idea of the opinion of counsel.***
>
> The Court: Okay.
>
> Ms. Farnan: Your Honor, that is my understanding as well. That it's only the waiver issue that is left.

(Declaration of Meghan Wharton in Support of ZymoGenetics' Opposition to Bristol's Motion for Summary Judgment of No Willfulness, D.I. 241, Exh. 7, 22:8-23:6) (emphasis added). To now argue that it was not permitted to take discovery concerning the objective standard is incorrect.

2. The Court Directed Discovery Concerning the Objective Element be Completed

During the November 8, 2007 teleconference, the Court made clear that only discovery relating to the opinions of counsel and subjective standard of *Seagate* would be stayed, not "all discovery" as ZymoGenetics incorrectly asserts. In fact, the Court directed discovery to be completed on the objective standard.

> The Court: . . ***To the extent that discovery was not allowed or prevented or reduced on the initial objective argument that has to***

> ***be obviously reached . . . I really do think discovery should be allowed to go forward.***
>
> * * *
>
> ***. . . because what has been said to me is there has been some discovery taken on willfulness at this point on the objective standard. I'm saying that that discovery should be allowed to go forward and get completed.*** On the more subjective standard on opinion of counsel, quite frankly, I'm punting it a bit . . . .
>
> * * *
>
> Ms. Farnan: Just to be clear, our position would be on the objective portion, that that has been completed and what would be left to be decided later would be our waiver [of privilege concerning opinions of counsel] and the discovery on that.
>
> The Court: I'm not certain of that because, like I said, I have not seen the discovery, Kelly, ***but to the extent it hasn't been responded or hasn't been finished up, I want that to be completed*** . . . .

(D.I. 241, Exh. 7, 23:11-15; 24:9-15; 26:4-11) (emphasis added). Recognizing that fact discovery had just closed the Court went on to state that this should not prevent completion of discovery on the objective element. (*See* D.I. 241, Exh. 7, 26:11-23 ("So there could be some [discovery] . . . but that is, to me, extremely limited in any event.").

Following the November 8, 2007 teleconference, Bristol never received a single complaint from ZymoGenetics alleging that it needs further discovery concerning the objective element of willful infringement.

ZymoGenetics is wrong in belatedly asserting that it was prevented from completing discovery on the objective element. The only discovery that was stayed was on the subjective element as it relates to the opinion of counsel. Therefore, ZymoGenetics should have completed all the discovery it needs to present its evidence concerning the objective standard. But because ZymoGenetics has not identified any such evidence, no reasonable jury could find willfulness.

a) The Additional Discovery that ZymoGenetics Seeks Does Not Relate to Whether an "Objectively High Likelihood" of Infringement Exists

ZymoGenetics is unable to show an "objectively high likelihood" of infringement -- the core of the objective inquiry. ZymoGenetics repeatedly fails to address this issue, and claims instead that additional discovery is needed to address this issue. However, aside from the fact that discovery is closed and the Court made clear discovery on the objective prong should be completed, the additional discovery that ZymoGenetics seeks does not relate to whether or not an "objectively high likelihood" of infringement exists as required by *Seagate*.

The additional discovery that ZymoGenetics belatedly claims is necessary to address willfulness is:

- "Did Bristol consider changing the molecule to design around the ZymoGenetics patents?"
- "When did Bristol come up with its alleged 'substantial noninfringement and/or invalidity defenses'?"
- "Did Bristol have any other basis for believing that its actions were legitimate?"

(D.I. 240 at 10). However, each of these questions relates to Bristol's state of mind, *i e* , the subjective inquiry, not the objective inquiry

For example, ZymoGenetics considers Bristol's actions after it became knowledgeable of the patents-in-suit relevant to the objective inquiry -- "the infringer acted despite an objectively high likelihood . . . ." *Seagate*, 497 F.3d at 1371. However, consideration of how the accused infringer "acted" is only in the context of a separately established "objectively high likelihood".[1] The analysis requires first establishing the "objectively high

[1] ZymoGenetics mistakenly construes the word "acted" in the objective prong to mean any action taken by an alleged infringer. However, as the *Seagate* standard involves proving an "objectively high likelihood" of infringement, the only "actions" relevant to the objective inquiry are those that go to the alleged infringement.

likelihood", and only after that threshold has been met does the court consider how the infringer acted in the face of those objective facts.

Therefore, apart from the fact that ZymoGenetics had full opportunity to take whatever discovery it needed on the objective standard, the new discovery it now says it needs would be irrelevant to the requisite "objective high likelihood" criterion.

b) The Decisions ZymoGenetics Relies On Do Not Support the Proposition that Bristol's Actions Can Be Evidence of an "Objectively High Likelihood" of Infringement

ZymoGenetics cites *Rhino Assocs.* for the proposition that actions are relevant to the objective prong. (D.I. 240 at 9, citing *Rhino Assocs. L.P. v. Berg Mfg. & Sales Corp.*, 531 F. Supp. 2d 652, 658 (M.D. Pa. 2007)). However, *Rhino* did not state that evidence of particular actions is relevant to determining whether there is a "high likelihood of infringement". *Rhino*, 531 F. Supp. 2d at 658. In *Rhino*, after finding infringement, the court addressed willfulness by examining the defendant's attempt to design around the patents-in-suit. *Id.* The conduct of attempting to design around was considered relevant because the record was clear that the defendant explicitly based its design on the patent-in-suit. *Id.* There has been no such allegation in the present suit.[2] Further, as the *Rhino* court reasoned, attempts to design around are cogent evidence of an absence of willfulness. *Id.* at 658-59. In other words, as discussed above, ZymoGenetics must show an objectively high likelihood that Bristol's sale of Orencia® constituted infringement independently of whether or not there is evidence that Bristol tried to avoid this alleged infringement.[3]

[redacted]

[3] Evidence of Bristol's conduct to avoid infringement would only further support a conclusion of no willfulness.

ZymoGenetics also cites *Abbott Labs. v. Sandoz*, but this case does not support the contention that Bristol's actions can evidence an "objectively high likelihood" of infringement. (D.I. 240 at 9, citing *Abbott Labs. v. Sandoz, Inc.*, 532 F. Supp. 2d 996, 1000 (N.D. Ill. 2007)). ZymoGenetics cites *Abbott* for the proposition "the accused infringer must 'show there was a reasonable basis for [it] to believe [its] actions were legitimate.'" (D.I. 240 at 9) (emphasis added). *Abbott* does not place such a burden on the accused infringer. As noted *supra* at 2, ZymoGenetics bears the burden of proving willfulness by clear and convincing evidence. According to *Abbott*, Bristol can show no willfulness by demonstrating "objective reasonableness" -- *i.e.*, that "there was a reasonable basis for [Bristol] to believe [its] actions were legitimate".[4] *Abbott*, 532 F. Supp. 2d at 999-1000. And Bristol has made a showing on summary judgment that its noninfringement defense is objectively reasonable.[5]

ZymoGenetics also cites to *ResQNet*, but this case does not support the contention that particular actions are evidence of an "objectively high likelihood" of infringement. (D.I. 240 at 9-10, citing *ResQNet.com, Inc. v. Lansa, Inc*, 533 F. Supp. 2d 397, 420 (S.D.N.Y. 2008)). The *ResQNet* decision does not address this issue. In fact, despite finding infringement, the court concluded defendant's "arguments [on infringement and validity] were substantial, reasonable, and far from the sort of easily-dismissed claims that an objectively reckless infringer would be forced to rely upon." *ResQNet*, 533 F. Supp. 2d at 420. Likewise, in light of the record, Bristol's noninfringement defenses are equally substantial, reasonable, and not easily-dismissed

[4] But ZymoGenetics has provided no evidence of even the objective threshold of *Seagate*.

[5] While Bristol believes it is entitled to summary judgment of noninfringement, a finding of noninfringement is not a prerequisite to concluding 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.

Lastly, ZymoGenetics cites *Trading Technologies*, but this decision makes clear that conduct is not relevant to a plaintiff's showing "the likelihood of infringement could be considered objectively high", rather it is only relevant to showing that a "defendants acted despite that likelihood." (D.I. 240 at 10, citing *Trading Tech. Int'l, Inc. v. eSpeed, Inc.*, 2008 WL 63233, at *1 (N.D. Ill. Jan. 3, 2008)). In *Trading Tech.*, the defendants stopped any allegedly infringing conduct when they found out about the patents. *Trading Tech.*, 2008 WL 63233 at *1-2. The court did not identify this as pertinent to whether there was an "objectively high likelihood" of infringement. In fact, just the opposite occurred. The court stated "even if the likelihood of infringement could be considered objectively high, plaintiff adduced no evidence that defendants acted despite that likelihood."[6] *Id.* at *1. (emphasis added).

B. ZymoGenetics Fails to Raise a Genuine Issue of Material Fact on the Objective Element of *Seagate* and Improperly Muddles the Subjective Element of *Seagate* with the Objective Element

ZymoGenetics fails to raise a genuine issue of material fact on the objective element of *Seagate*. In its effort to overcome Bristol's Motion for Summary Judgment of No Willfulness, ZymoGenetics continually muddles the subjective element of *Seagate* with the objective element. In the entirety, ZymoGenetics' "evidence" of objective recklessness includes assertions that go only to the subjective element of *Seagate* and a mere statement of law that is not evidence of willfulness.

1. Bristol's Knowledge of the Patents Goes to the Subjective Element

ZymoGenetics' first alleged piece of evidence, "Bristol had knowledge of the ZymoGenetics Patents when it commenced [allegedly] infringing sales" (D.I. 240 at 12-13), goes only to the subjective element despite its incorrect assertion that "Bristol's knowledge is

[6] Additionally, this case supports Bristol's construction of "acted" discussed above (*i.e.*, there was no evidence the defendant "acted" when it stopped the allegedly infringing activity).

sufficient to satisfy the objective element of *Seagate*" (D.I. 240 at 13). *Seagate* made clear that "[t]he state of mind of the accused infringer is not relevant to this objective inquiry." *Seagate*, 497 F.3d at 1371. Knowledge of the patents is part of the subjective prong

ZymoGenetics erroneously cites *Ball Aerosol* for the proposition that "knowledge of the patents at the time of infringement is a sufficient evidentiary showing to survive summary judgment" of no willfulness. (D.I. 240 at 12, citing *Ball Aerosol & Specialty Container, Inc. v. Limited Brands, Inc.*, 553 F. Supp. 2d 939, 956-57 (N.D. Ill. 2008)). *Ball Aerosol* does not support the proposition that knowledge is sufficient to overcome summary judgment. And unlike the present litigation, the *Ball Aerosol* court had already granted summary judgment of infringement. *Ball Aerosol*, 553 F. Supp. 2d at 942. In fact, the court rested its decision not on the knowledge of the patent, but on the fact that the plaintiff and defendant "enjoyed a business relationship" and "[defendant] utilized the advice, support, and expertise of [plaintiff] to help create and market the infringing product." *Id.* at 953-954. Defendant specifically had the infringing product manufactured only after obtaining this information and based on this information. *Id.* Notably, the *Ball Aerosol* court also based its decision on the fact that the defendant "continued to produce and sell the [infringing product] ***for almost a year after a court found that the [infringing product] infringed*** . . . .". *Id.* at 956.

2. The Length of Time Bristol has Known About the Patents-In-Suit Goes to the Subjective Element

ZymoGenetics' second alleged piece of evidence also goes to the subjective element of *Seagate*: "Bristol had over five years between becoming aware of the ZymoGenetics Patents in which to investigate the ZymoGenetics Patents and avoid [the alleged] infringement by securing a license the ZymoGenetics Patents or designing around the ZymoGenetics Patents"

(D.I. 240 at 14-15). As discussed above, knowledge of the patents goes to the subjective element.

ZymoGenetics erroneously cites *Depomed* for the proposition that knowing about a patent for a long time is evidence of willfulness. (D.I. 240 at 14, citing *Depomed, Inc. v Ivax Corp.*, 532 F. Supp. 2d 1170, 1185-86 (N.D. Cal. 2007)). However, it is not evidence that relates to the objective prong of willfulness. And unlike the present litigation, the *Depomed* court had already granted summary judgment of infringement. *Depomed,* 532 F. Supp. 2d at 1183. In fact, the defendant "***[had] not present[ed] any evidence of non-infringement.***" *Id.* at 1181 (emphasis added).

In making its argument about the length of time Bristol had known about the patents-in-suit, ZymoGenetics again confuses who bears the burden of proof by stating "Bristol has not put forth any evidence that it investigated the ZymoGenetics Patents, changed the molecule in an attempt to design around the ZymoGenetics Patents or sought out and obtained a license from ZymoGenetics." (D.I. 240 at 15). Bristol does not have the burden. ZymoGenetics bears the burden of proving willfulness and must first identify evidence under the objective element of *Seagate*. In fact, courts have explicitly held that activities such as licensing only relate to the subjective element of *Seagate*. *See, e.g., Franklin Electric Co., Inc. v. Dover Corp.*, 2007 WL 5067678, at *8 (W.D. Wis. Nov. 15, 2007) ("That . . . defendant sought a license has no bearing on whether there was an objectively high likelihood that its product infringed. ***It goes to the defendant's knowledge and state of mind,*** which *Seagate* holds irrelevant to the objective inquiry.") (emphasis added).

3. A Mere Statement of Law Is Not Evidence of Willfulness

ZymoGenetics' final alleged piece of evidence is a statement of law: "[T]he ZymoGenetics Patents are presumed valid . . . ." (D.I. 240 at 13). This is not record evidence of

willfulness and cannot raise a genuine issue of material fact. Even if the patents are presumed valid, it is not relevant to the issue of whether there was an "objectively high likelihood" of infringement -- nor is it relevant to the subjective element.

ZymoGenetics' citation to *Church & Dwight* is misleading because ZymoGenetics suggests that the court found sufficient evidence of objective recklessness based on the presumption of validity given to issued patents. (D.I. 240 at 13, citing *Church & Dwight, Co. v Abbott Labs.*, 2008 WL 2565349, at *10 (D.N.J. June 24, 2008)). However, ZymoGenetics ignores much of what the *Church & Dwight* court relied on in its objective inquiry determination under *Seagate*. In addition to noting that the patents were presumed valid, the *Church & Dwight* court stated the evidence for objective recklessness included: "that Abbott did not contest infringement of the '982 Patent at trial", and "the infringement arguments as to the other patents were not convincing." *Church & Dwight*, 2008 WL 2565349, at *10. Thus, the *Church & Dwight* court based its objective inquiry on the strength of the defendant's arguments. As Bristol noted in its Opening Brief, Bristol's defenses are credible and substantial. (D.I. 177 at 9-12).

Instead of addressing whether there was an "objectively high likelihood of infringement" -- a threshold step that necessarily must be addressed -- ZymoGenetics assumes an "objectively high likelihood" of infringement and believes it merely needs to show Bristol knew about the patents. ZymoGenetics cannot survive Bristol's motion for summary judgment on that basis.

C. Substantial Defenses of Noninfringement and/or Invalidity Can Provide a Basis for a Finding of No Willfulness

Seagate has established that in determining the objectively-defined risk under the objective inquiry a court should look to "the record developed in the infringement proceeding".[7] *See Seagate*, 497 F.3d at 1371; *see, e.g., ResQNet.com*, 533 F. Supp. 2d at 420 (reviewing the record on infringement and invalidity and finding no willfulness because defendant's "arguments in these areas were substantial, reasonable, and far from the sort of easily-dismissed claims that an objectively reckless infringer would be forced to rely on.")

Courts have determined that a review of the summary judgment record serves as an appropriate tool to evaluate whether there was an objectively high likelihood of infringement. *See, e.g., Franklin Electric*, 2007 WL 5067678, at *8. The *Franklin* Court determined that "the infringement analysis in the first summary judgment decision goes to the objective inquiry of the likelihood of infringement." It found "significant support in the language of the patent, the specification and prosecution history for the defendant's non-infringement position . . . ." *Id.* Based on this the *Franklin* court held "defendants' conduct . . . was not reckless in the sense that there was an 'objectively high likelihood'" of infringement. *Id.*

Similarly, Bristol's noninfringement defense draws significant support from the claim language, specification, and prosecution history. (*See* Bristol's Opening Brief in Support of its Motion for Summary Judgment of Noninfringement, D.I. 173; Bristol's Brief in Opposition to ZymoGenetics' Motion for Summary Judgment of Infringement, D.I. 248; *see also* Bristol's Reply Brief in Support of its Motion for Summary Judgment of Noninfringement filed

[7] ZymoGenetics states that "this Court has engaged in no such analysis and has in no way examined Bristol's noninfringement defenses . . . ." (D.I. 240 at 25). But currently pending before the Court is Bristol's summary judgment briefing on noninfringement. The Court heard preliminary oral arguments concerning the parties' opening summary judgment briefs, and ordered the completion of this briefing

concurrently with this brief ("Noninfringement Reply Brief")). It also finds support from ZymoGenetics' own admissions and admissions of its experts. (*See id.*)

ZymoGenetics acknowledges that a review of evidence of Bristol's noninfringement defense is a proper basis for evaluating willfulness.[8] (D.I. 240 at 18). ZymoGenetics cites *Seagate* for the proposition that "in order to show objective recklessness, a plaintiff must show that a defendant's 'theory of noninfringement/invalidity, was not only incorrect, but was objectively unreasonable.'" (*Id.*, citing *Seagate*, 497 F.3d at 1384 (Gajarsa, J., concurring)). ZymoGenetics has not shown that Bristol's defenses are objectively unreasonable.

So as not to revisit all of its arguments here, Bristol refers the Court to its full briefing on noninfringement and notes that the invalidity record on summary judgment is incomplete as it addresses only conception and reduction to practice as it pertains to two references. Below, Bristol briefly addresses the points raised in ZymoGenetics' No Willfulness answering brief.

1. **Bristol's Noninfringement Defense is Substantial and Reasonable**

a) **CTLA4 Does Not "Require Dimerization for Biological Activity"**

Under ZymoGenetics' claim construction, the CTLA4 portion of CTLA4-Ig does not "require dimerization for biological activity". A full discussion is provided in Bristol's Opening and Reply Briefs in Support of its Motion for Summary Judgment of Noninfringement, the latter of which has been concurrently filed with this brief, as well as Bristol's Brief in

[8] ZymoGenetics is wrong that Bristol based its Motion for Summary Judgment of No Willfulness on "self-serving assertions" and by "merely stating a defense to infringement". (D.I. 240 at 15-17). In fact, consistent with *Seagate*, Bristol respectfully invited the Court to review the record on infringement in its Opening Brief. (D.I. 177 at 9). Now that summary judgment briefing is complete, the entire record for noninfringement/infringement summary judgment briefing is available.

Opposition to ZymoGenetics' Motion for Summary Judgment of Infringement (D.I. 173; Noninfringement Reply Brief; D.I. 248). Below, Bristol briefly addresses ZymoGenetics' arguments set forth in its opposition to the present motion:

- ZymoGenetics attempts to confuse the issue by arguing that CTLA4 exists naturally only as a dimer. Not only is this incorrect (as CTLA4 also exists naturally as a monomer), but more importantly, it is irrelevant to whether CTLA4 requires dimerization for biological activity (*See* D.I. 173 at 27-33; D.I. 248 at 5, 19-20; Noninfringement Reply Brief at 8-11).

- ZymoGenetics makes incorrect assertions about Bristol's evidence that CTLA4 does not require dimerization for biological activity, stating: (1) Bristol relies on studies using a "non-native form of CTLA4", and (2) studies showing that CTLA4 monomer binds to its natural ligand does not show the monomer has "biological activity". However, as Bristol's noninfringement briefing makes clear, the scientific evidence proves CTLA4 exists naturally in the body as both a monomer and dimer and is biologically active as both a monomer and a dimer, even under ZymoGenetics' claim construction (*See* D.I. 173 at 27-33; D.I. 248 at 5, 20-24; Noninfringement Reply Brief at 2-6, 8-11).

Because it is ZymoGenetics' burden to prove that CTLA4 requires dimerization for biological activity, and it has not done so, Bristol's noninfringement defense is substantial and reasonable.

b) The Mutated Ig is Not a "Dimerizing Protein"

ZymoGenetics only discusses its own claim construction for "dimerizing protein". Bristol's mutated Ig is not a "dimerizing protein" under this claim construction which requires each mutated Ig in CTLA4-Ig to have affinity for each other "such that the two associate under physiological conditions to form a dimer . . ." (*See* Joint Claim Construction Chart, D.I. 153 at 3) (emphasis added). Despite its assertions, ZymoGenetics has no proof that the mutated Ig in Orencia® forms a dimer. A full discussion of why the mutated Ig in Bristol's CTLA4-Ig is not a "dimerizing protein" is provided in Bristol's Opening and Reply Briefs in Support of its Motion for Summary Judgment of Noninfringement, the latter of which has been concurrently filed with

this brief, as well as Bristol's Brief in Opposition to ZymoGenetics' Motion for Summary Judgment of Infringement. (D.I. 173; Reply Brief; D.I. 248).

Below, Bristol briefly addresses why the evidence ZymoGenetics relies on is not proof that Bristol's mutated Ig forms a dimer:

- ZymoGenetics states the entire CTLA4-Ig molecule is a dimer. However, evidence that CTLA4-Ig is a dimer does not prove that the mutated Ig portion is a dimer. In fact, the CTLA4 portion of Bristol's CTLA4-Ig is what forms the dimer of CTLA4-Ig, not the mutated Ig portion. (*See* D.I. 173 at 22-27, 33-35; D.I. 248 at 27-28; Noninfringement Reply Brief at 7-8).



- ZymoGenetics references a picture in an FDA submission allegedly showing Bristol's mutated Ig as a dimer. None of this evidence proves that the mutated Ig in Orencia® forms a dimer. In fact, Bristol told the FDA that the picture was based on unmutated Ig. (*See* Noninfringement Reply Brief at 13-14).

ZymoGenetics has no evidence that the mutated Ig in Bristol's CTLA4-Ig forms a dimer. Thus, the record evidence shows that Bristol's noninfringement defense is substantial and reasonable.

2. Bristol's Invalidity Defense is Substantial and Reasonable

As noted, Bristol's invalidity defenses are sufficient to avoid a finding of willfulness. However, the reason Bristol did not refer to its invalidity defenses as a basis for no willfulness in its Opening Brief is because neither party has moved for summary judgment on the entirety of invalidity and there is only an incomplete record before the Court on this issue. However, so as to not leave ZymoGenetics' assertions on invalidity unaddressed, Bristol briefly does so below.

ZymoGenetics improperly cites *Bard* for the proposition that "Bristol's invalidity defense cannot serve as a basis to preclude a finding of objective recklessness because the defense is based on 'the same references . . . previously found not to invalidate.'" *Bard Peripheral Vascular, Inc. v. W.L. Gore & Assocs., Inc.*, 2008 WL 2958968, at *2 (D. Ariz. July 29, 2008). *Bard* does not state such a broad proposition. The *Bard* court merely failed to find any basis by which to conclude the patent examiner made errors during the examination. It is untenable for ZymoGenetics to argue that Bristol's invalidity defense is "unreasonable" merely because there is a rebuttable presumption that the patent examiner did his job correctly. *See, e.g., N. Am. Container, Inc., v. Plastipak Packaging, Inc.*, 415 F.3d 1335, 1349-50 (Fed. Cir. 2005) (Defendant asserted that "the patent examiner misapplied the recapture rule, and thus any presumption that the examiner properly did his job was rebutted."). Although, the record has not been fully established, Bristol has substantial evidence the patent examiner made patentability errors during the prosecution of ZymoGenetics' patents. (*See* Expert Report of Jeffrey V. Ravetch, M.D., Ph.D., D.I. 135 at 43-45, 55-56, 64-65, 69).

During the prosecution of the patents-in-suit, ZymoGenetics did not allege or provide any evidence that it had made its invention prior to the Seed and Capon patents. It obtained allowance only because the examiner misconstrued the disclosures of those prior references, and failed to appreciate that they anticipated. Now, in asserting in its motion seeking a summary determination that its claims are not invalidated by Seed and Capon, ZymoGenetics implicitly concedes the examiner erred, because it nowhere disputes that the references do disclose the same subject matter as the claims in issue here and, instead, tries to circumvent them by making unsupportable assertions of prior invention.

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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Dated: August 25, 2008

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CERTIFICATE OF SERVICE

I hereby certify that on August 25, 2008, I electronically filed the foregoing document with the Clerk of the Court using CM/ECF which will send notification of such filing to the following and which has also been served as noted:

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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