IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

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

ZYMOGENETICS, INC.'S OPPOSITION TO BRISTOL-MYERS SQUIBB CO.'S MOTION FOR SUMMARY JUDGMENT OF NO WILLFULNESS

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Plaintiff Zymogenetics, Inc. ("ZymoGenetics") respectfully requests that the Court deny Defendant Bristol-Myers Squibb Co.'s ("Bristol") Motion for Summary Judgment of No Willfulness because discovery as to willfulness has not been completed and, in addition to proving Bristol's willful infringement, there are actual issues of genuine fact precluding summary disposition.[1] D.I. 175, 177.

I. INTRODUCTION

Bristol's Motion for Summary Judgment of No Willfulness (the "Motion") marks the culmination of Bristol's long-running attempt to defeat ZymoGenetics' willfulness claim through obstructive discovery tactics and self-serving misstatements of the law and facts of this case. Despite being repeatedly prevented from taking discovery relating to Bristol's actions after becoming aware of the ZymoGenetics Patents, ZymoGenetics has identified evidence sufficient to survive summary judgment demonstrating that, at the time it commenced infringement, Bristol acted in an objectively reckless manner.

While Bristol has asserted that its current noninfringement defenses constitute some sort of "Get Out of Jail Free" card as to willfulness, ZymoGenetics has clearly established in this filing and in other filings in this matter that Bristol's noninfringement defenses are meritless and that Bristol's faith in its noninfringement and invalidity defenses was unreasonable. Contrary to Bristol's assertions, the law governing this Court's examination of objective recklessness does not allow Bristol to avoid a finding of willful infringement simply by stating that it currently has substantial noninfringement defenses and setting out those defenses. This Court must examine

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[1] ZymoGenetics respectfully references the Court to its June 2, 2008 Response Statement of Material Facts as to which there is a Genuine Issue to be Tried and Legal Issues in Opposition to Defendant Bristol-Myers Squibb Company's Motion for Summary Judgment of No Willfulness for a detailed description of the disputed facts on this issue. *See* D.I. 206.

the totality of the circumstances, including Bristol's actual conduct upon becoming aware of the ZymoGenetics Patents and determine whether or not there is sufficient evidence such that a reasonable jury could find in favor of ZymoGenetics on the issue of willfulness. Upon such an examination, it is clear that the evidence strongly weighs in favor of a finding of objective recklessness such that Bristol's Motion must be denied.

II. BACKGROUND

ZymoGenetics is the assignee of United States Patent No. 5,843,725 (the "'725 Patent") bearing the title "Methods for Producing Secreted Receptor Analogs and Biologically Active Dimerized Polypeptide Fusions." *See* D.I. 169, Ex. 1. The '725 Patent issued on December 1, 1998. *Id.* The United States Patent and Trademark Office ("USPTO") issued a reexamination certificate affirming the validity of the '725 Patent on August 29, 2006. *Id.* ZymoGenetics is the assignee of United States Patent No. 6,018,026 (the "'026 Patent" and with the '725 Patent, the "ZymoGenetics Patents") bearing the title "Biologically Active Dimerized and Multimerized Polypeptide Fusions." *See* D.I. 169, Ex. 2. The '026 Patent issued on January 25, 2000. *Id.* The USPTO issued a reexamination certificate affirming the validity of the '026 Patent on July 4, 2006. *Id.* The reexamination procedure resulted in amendments to certain claims of the ZymoGenetics Patents. *See id.*, Exs. 1-2. However, the language of the amendments does not serve as the basis for Bristol's noninfringement defenses. D.I. 177 at 9-10. Furthermore, all the alleged prior art Bristol raises in this case was previously considered by the USPTO. *See* Declaration of Meghan A. Wharton in Support of ZymoGenetics, Inc.'s Opposition to Bristol-Myers Squibb Co.'s Motion for Summary Judgment of No Willfulness ("Wharton Decl."), ¶ 10, Ex. 9 at ZG001230-38, ZG001646, ZG000340-49, ZG000745.

ZymoGenetics made Bristol aware of the existence of the ZymoGenetics Patents shortly after the '026 Patent issued. Specifically, on January 17, 2001, Michael Kuran, ZymoGenetics' Director of Business Development, sent a letter to Stephen McAndrew, Bristol's Director of Biotechnology Licensing, informing Bristol of the ZymoGenetics Patents. *See* Wharton Decl., ¶ 2, Ex. 1. Bristol received the letter on or about January 17, 2001. *Id.*, ¶ 3, Ex. 2 at First Supplemental Response to Interrogatory No. 3. Bristol had filed an Investigational New Drug Application ("IND") on October 6, 2000, prior to receiving ZymoGenetics' letter, and subsequently in 2004 filed a Biologic License Application ("BLA") with the exact same infringing molecule and methods as the IND, which was well after it received notice of the ZymoGenetics Patents in early 2001. Wharton Decl., ¶ 13, Ex. 12; *id.*, ¶ 12, Ex. 11; *id.*, ¶ 2, Ex. 1. Thus, Bristol did not change its infringing conduct with respect to Orencia® after receiving notice of the ZymoGenetics Patents. Defendant Bristol began selling the pharmaceutical product known as Orencia® on February 9, 2006. *See id.*, ¶ 4, Ex. 3 at Response to Interrogatory No. 15.

ZymoGenetics first requested discovery relating to willfulness in October 2006. On October 31, 2006, ZymoGenetics propounded an interrogatory requesting that Bristol:

> Describe in detail when and under what circumstances you first became aware of the existence of each of the Patents-in-Suit or the applications that resulted in each of the Patents-in-Suit, what actions you took upon becoming aware of each of the Patents-in-Suit or applications, the identity of all persons with knowledge of such facts and circumstances, and the identity of all documents reflecting such facts and circumstances.

Wharton Decl., ¶ 5, Ex. 4 at Interrogatory No. 3. The full substance of the response ZymoGenetics received in January 2007 was:

[redacted]

Wharton Decl., ¶ 6, Ex. 5 at Response to Interrogatory No. 3. Subsequently, just prior to the close of fact discovery, on September 17, 2007 Bristol provided the following supplemental response:



Wharton Decl., ¶ 3, Ex. 2 at First Supplemental Response to Interrogatory No. 3. Bristol has not provided any further response to this interrogatory.

ZymoGenetics further requested discovery relating to willfulness by listing several topics on the issue as part of its February 12, 2007 Amended Notice of Deposition of Defendant Bristol-Myers Squibb Co. Pursuant to Fed. R. Civ. P. 30(b)(6). D.I. 203, Ex. 1. Specifically, ZymoGenetics requested that Bristol designate one or more persons to testify regarding the following topics:

> "14. Any and all communications referring to relating to the patents-in-suit.
>
> . . .
>
> 18. Any studies, analyses, opinions of counsel, or communications regarding infringement or validity of the patents-in-suit, or any foreign counterpart patents, and reliance by Bristol-Myers on such documents and/or communications.
>
> . . .
>
> 24. Bristol-Myers' knowledge and awareness of the patents-in-suit."

Id. at 4-5. Bristol has repeatedly refused to provide a witness to testify on these topics or otherwise provide discovery relating to the topics. *See* D.I. 203, Exs. 2, 3, 4, 5, 6, 7. As of the date of this Opposition, the only outstanding discovery to be completed in the case relates to

Bristol's ongoing refusal to provide discovery relating to ZymoGenetics' claim of willful infringement.

Early in the litigation, Bristol requested that ZymoGenetics state "facts which Plaintiff relies upon for their contention that this is an exceptional case under 35 U.S.C. § 285." D.I. 178, Ex. 5 at Interrogatory No. 7. At the time of the response, ZymoGenetics had not yet obtained discovery from Bristol regarding willfulness. As such, ZymoGenetics objected to the interrogatory on the grounds that it called for information outside the knowledge of ZymoGenetics. D.I. 178, Ex. 6 at Response to Interrogatory No. 7. While ZymoGenetics briefly answered the Interrogatory, it has not supplemented its response because Bristol has obstructed all of ZymoGenetics' attempts to take discovery relating to Bristol's actions after becoming aware of the ZymoGenetics Patents - evidence that is in Bristol's control and directly relates to objective recklessness.

In late 2007, Bristol effectively stayed all ZymoGenetics' attempts to obtain discovery on the issue of willfulness. Just prior to the close of discovery in October 2007, Bristol persuaded Magistrate Judge Thynge to allow Bristol until the end of November 2007, well after the close of fact discovery, in which to allow ZymoGenetics discovery on the issue of willfulness. D.I. 108, 109, 112. During an October 4, 2007 hearing, Magistrate Judge Thynge ordered Bristol to provide discovery as to willfulness during December 2007. Wharton Decl., ¶ 7, Ex. 6 at 20:1-5. However, Magistrate Judge Thynge suggested that Bristol could avoid having to provide such discovery by requesting bifurcation of discovery and trial as to willfulness and damages. *Id.*, ¶ 7, Ex. 6 at 19:24-20:1, 23:9-23:20. Less than two weeks after the hearing, Bristol filed a request for bifurcation of the issues of willfulness and damages for the purposes of discovery and trial. D.I. 116.

During the subsequent hearing on Bristol's request, Magistrate Judge Thynge stayed all discovery on willfulness and "punted" the decision as to bifurcation of the willfulness and damages issues for the purposes of discovery and trial to the new judge. Wharton Decl., ¶ 8, Ex. 7 at 23:22-24:24. In order to continue the stay of discovery, Bristol renewed its request that the Court bifurcate the issues of willfulness and damages for the purpose of discovery and trial shortly after the transfer of the case to this Court. D.I. 155. This renewed request is still pending. Such action by Bristol effectively prohibited further discovery as to willfulness until this Court issues a decision as to whether or not to bifurcate the issue of willfulness for purposes of discovery and trial. To date, ZymoGenetics has not yet been able to obtain discovery as to willfulness.

The willfulness discovery Bristol has denied ZymoGenetics is much broader than just discovery relating to Bristol's reliance on opinions of counsel. As is clearly demonstrated by Bristol's supplemental response to ZymoGenetics interrogatory on willfulness, the scope of discovery that Bristol has obstructed includes *all* discovery relating to Bristol's conduct following [redacted] Wharton Decl., ¶ 3, Ex. 2 at First Supplemental Response to Interrogatory No. 3. For example, during the November 8, 2007 hearing, in response to a question from Magistrate Judge Thynge, ZymoGenetics' counsel set forth the type of discovery that ZymoGenetics believed would relate to objective recklessness:

> I think what we want to see is what measures the company took, whether they considered the patents in trying to come up with a design-around. The other factors, the *Reed* factors that the court can look at that show how a company is reasonable, and take discovery into those issues.

Id., ¶ 8, Ex. 7 at 17:12-18:4.[2] Accordingly, Bristol's assertion during the June 29, 2008 hearing that "all discovery has been completed on the objective element" was false. Wharton Decl. ¶ 9, Ex. 8 at 131:4-5. Bristol clearly made it impossible for ZymoGenetics to complete discovery as to the objective element because it obstructed ZymoGenetics' efforts to obtain discovery as to what Bristol considered or did, if anything, after it became aware of the ZymoGenetics Patents. *See* Wharton Decl., ¶ 3, Ex. 2 at First Supplemental Response to Interrogatory No. 3.

III. ARGUMENT

A. Bristol Repeatedly Misstates ZymoGenetics' Required Burden of Proof to Survive Summary Judgment.

Bristol would have this Court believe that in order to survive summary judgment on the issue of willfulness, ZymoGenetics must prove willfulness by clear and convincing evidence. D.I. 177 at 2, 6, 9 (n.10), 12 (indicating that to survive summary judgment ZymoGenetics must "prove, by clear and convincing evidence, that there is a high likelihood that Bristol's actions were infringing" (n.10)). However, Bristol does not cite to, and ZymoGenetics is not aware of, any cases that support Bristol's position. Federal Rule of Civil Procedure 56(c) establishes the burden of proof for summary judgment. Fed. R. Civ. P. 56(c). Specifically, Rule 56(c) mandates that Bristol is not entitled to summary judgment on the issue of willfulness unless the Court determines from its examination of "the pleadings, the discovery and disclosure materials on file, and any affidavits" that there are no genuine issues of material fact as to the question of willfulness and that Bristol is entitled to judgment as a matter of law. *Id.* Bristol bears the

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[2] At the time of the November 8, 2007 hearing, the Federal Circuit's opinion in *Seagate* had been out for less than three months. *In re Seagate Tech., LLC*, 497 F.3d 1360 (Fed. Cir. Aug. 20, 2007).

burden of proving that no genuine issue of material fact exists. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 n.10 (1986).

While ZymoGenetics' burden of proof at trial for its claim of willfulness is "clear and convincing evidence," such a showing by ZymoGenetics is not required to survive summary judgment. *See* Fed. R. Civ. P. 56(c). Rather, on summary judgment, ZymoGenetics need only put forth evidence demonstrating *a genuine issue of material fact* as to whether or not Bristol acted despite an objectively high likelihood that its actions constituted infringement of a valid patent and that such objective risk was either known or so obvious that it should have been known to the accused infringer. *In Re Seagate Tech., LLC*, , 497 F.3d 1360, 1371 (Fed. Cir. Aug. 20, 2007), *cert. denied*, 128 S. Ct. 1445 (2008).[3] In doing so, ZymoGenetics need only assert sufficient evidence of objective recklessness such that a jury could reach a determination that willfulness was demonstrated by clear and convincing evidence. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248-49 (1986).

B. A Genuine Issue of Material Fact Exists as to whether Bristol's Actions were Objectively Reckless.

1. Bristol has Prevented ZymoGenetics from Obtaining Discovery Relating to Bristol's Actions After Becoming Aware of the Patents.

As discussed in detail above, Bristol has systematically obstructed ZymoGenetics' repeated attempts to obtain discovery on the issue of willfulness. Wharton Decl., ¶ 3, Ex. 2 at First Supplemental Response to Interrogatory No. 3; *id.*, ¶ 8, Ex. 7 at 23:22-24:24; D.I. 116; D.I. 203, Exs. 2, 3, 4, 5, 6, 7; D.I. 155. Bristol refused to provide ZymoGenetics with any discovery

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[3] Bristol's Motion in no way addresses the second prong of the *Seagate* analysis. *See* D.I. 177. Therefore, ZymoGenetics does not address the second prong herein. ZymoGenetics maintains, and presumably Bristol agrees, that further discovery will demonstrate that there is a genuine issue of material fact as to whether or not the objective risk of infringement "was either known [to Bristol] or so obvious that it should have been known" to Bristol. *Seagate*, 497 F.3d at 1371.

relating to its conduct after [redacted] and effectively stayed discovery as to willfulness by filing requests for bifurcation. *Id.* Other than Bristol's affirmative assertions in the present Motion, ZymoGenetics is without knowledge as to Bristol's internal conduct after [redacted] or any defenses known to Bristol before February 2006 when it commenced infringing sales of Orencia®, as Bristol prevented ZymoGenetics from taking discovery into these matters. Such information directly relates to the objectively reckless analysis. Inexplicably, without having provided ZymoGenetics any discovery relating to such conduct, Bristol now seeks to rely on ZymoGenetics' alleged lack of evidence as to Bristol's actions as "justify[ing] the entry of summary judgment against" ZymoGenetics on the issue of willfulness. D.I. 177 at 8.

While the Federal Circuit in *Seagate* noted that the "state of mind of the accused infringer is not relevant" to the analysis under the objective prong, such statement does not mandate that Bristol's *conduct* is not relevant to the objective prong. *Seagate*, 497 F.3d at 1371. The objective prong requires that ZymoGenetics demonstrate that Bristol "acted despite an objectively high likelihood that its actions constituted infringement of a valid patent." Evidence of Bristol's actions after it became aware of the ZymoGenetics Patents is directly relevant to this question. *See Rhino Assocs. L.P. v. Berg Mfg. & Sales Corp.*, 531 F. Supp. 2d 652, 658 (M.D. Pa. 2007) (examining specific evidence of the accused infringer's conduct and, based on that conduct, finding that the accused infringer did not "act with an objectively high likelihood that its actions constituted infringement of a valid patent") (quotation omitted); *see also Abbott Labs. v. Sandoz, Inc.*, 532 F. Supp. 2d 996, 1000 (N.D. Ill. 2007) (noting that to avoid a finding of objective recklessness, that the accused infringer must "show there was a reasonable basis for him to believe his actions were legitimate") (citations omitted); *ResQNet.com, Inc. v. Lansa, Inc.*,

533 F. Supp. 2d 397, 420 (S.D.N.Y. 2008) (considering infringement and invalidity arguments known by defendant at the time of first infringement in examining whether or not there was objective recklessness); *Trading Technologies Intern., Inc. v. eSpeed, Inc.*, No. 04 C 5312, 2008 WL 63233, at *1 (N.D. Ill. Jan. 3, 2008) (noting that defendant's conduct upon finding out about the patents-in-suit relevant to the objective recklessness analysis).

In the present case, ZymoGenetics has obtained little information from Bristol that directly relates to the question of objective recklessness including information relating to the very actions that Bristol is relying on to claim that its actions were not objectively reckless. Wharton Decl. ¶ 3, Ex. 2 at Supplemental Response to Interrogatory 3. For example, ZymoGenetics does not know what actions Bristol took after becoming aware of the ZymoGenetics Patents. 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? Each of these exemplary questions relates to Bristol's internal actions and is relevant to whether or not those actions were objectively reckless. By refusing to allow discovery relating to Bristol's internal actions after [redacted] Bristol refuses to allow ZymoGenetics to obtain answers to issues that directly go to the objective recklessness analysis.

In fact, Magistrate Judge Thynge acknowledged that staying discovery as to willfulness may effect the summary judgment process. During the October 4, 2007 hearing, Magistrate Judge Thynge specifically addressed the question of how a stay of discovery as to willfulness would effect the parties' summary judgment motions. D.I. 108, 109, 112. At that time, Bristol informed Magistrate Judge Thynge that it sought to prevent ZymoGenetics' discovery as to the

first (objective) prong of the *Seagate* analysis. At that time, Bristol did not inform the Court that it contemplated filing a motion for summary judgment as to willfulness. *Id.* On the issue of summary judgment as to willfulness, Judge Thynge stated as follows:

> I also recognize that it is highly unlikely, even under the new Seagate standard, I put it probably in the less than one percentile, that a defendant realistically could expect to have a willfulness argument be or lack of willfulness be necessarily an argument for summary judgment because it's potentially so factually intense under both the *objective* and subjective inquiry.

Wharton Decl., ¶ 7, Ex. 6 at 19:15-21 (emphasis added). Judge Thynge subsequently specifically stated "I don't think [willfulness is] generally an appropriate issue for summary judgment." *Id.*, ¶ 7, Ex. 6 at 20:7-9.

During the June 29, 2008 claim construction and summary judgment hearing, this Court specifically commented as to the inherent conflict presented by Bristol's present motion. Specifically, the Court noted: "it does strike me as remarkable that I'm facing a motion for summary judgment" on an issue where discovery had been stayed. *Id.*, ¶ 9, Ex. 8 at 129:24-130:6. For that very reason, a grant of summary judgment of no willfulness as requested by Bristol would be tantamount to rewarding Bristol for successfully obstructing discovery on the issue. Further, such a decision would be premature because the Court has not been presented with the *totality of the evidence* regarding willfulness. *Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmbH v. Dana Corp.*, 383 F.3d 1337, 1346-47 (Fed. Cir. 2004) (noting that courts are to look at the "totality of the circumstances" in examining questions of willfulness).

2. Despite Bristol's Attempts to Prevent Discovery on the Issue of Willfulness, there is Sufficient Evidence in the Record that Bristol Acted with Objective Recklessness After Becoming Aware of the ZymoGenetics Patents.

In *Seagate*, the Federal Circuit established a new standard for patentees asserting willful infringement that requires a plaintiff demonstrate that the defendant acted despite an objectively

high likelihood that its actions constituted infringement of a valid patent. *Seagate*, 497 F.3d at 1371. However, the Federal Circuit in *Seagate* explicitly noted that it was not specifying what type of evidence a plaintiff would be required to present in order to demonstrate objective recklessness. *Id.* ("We leave it to future cases to further develop the application of this standard.").

As discussed above, ZymoGenetics has been prevented from obtaining discovery relating to the issue of willfulness. However, this Court's examination of the facts in the record will reveal evidence of Bristol's objectively reckless conduct sufficient to allow ZymoGenetics to survive summary judgment on the issue. It is undisputed that [redacted] Wharton Decl., ¶¶ 2-3, Exs. 1-2. It is also undisputed that at all times between [redacted] and Bristol's commencement of infringing sales in February 2006, the ZymoGenetics Patents were valid and enforceable. D.I. 169, Exs. 1-2. It is further undisputed that Bristol did not change the structure of CTLA4-Ig in Orencia® between the time that it received notice of the ZymoGenetics Patents and the present date. Wharton Decl., ¶ 11, Ex. 9 (Deposition of Dr. David Smolin at 71:3-72:7). The undisputed facts before the Court in the present case are similar to the facts before other courts that have examined the objective recklessness prong of the *Seagate* analysis.

For example, a district court held that the non-moving party's demonstration that the accused infringer had knowledge of the patents at the time of infringement is a sufficient evidentiary showing to survive summary judgment. *Ball Aerosol & Specialty Container, Inc. v. Limited Brands, Inc.*, 553 F. Supp. 2d 939, 956-57 (N.D. Ill. 2008) (refusing to grant summary judgment where court found that facts demonstrated that defendant acted in an infringing manner despite knowledge of the patents-in-suit). In the present case, it is undisputed that Bristol had

knowledge of the ZymoGenetics Patents when it commenced infringing sales. D.I. 169, Exs. 1-2. As such, under *Ball*, Bristol's knowledge is sufficient to satisfy the objective element of *Seagate*. *Ball*, 553 F. Supp. 2d at 953.

In the *Church & Dwight* case, the district court in New Jersey set forth facts that a court may view as evidence of objective recklessness. *Church & Dwight, Co. v. Abbott Labs.*, Civ. No. 05-2142 (GEB)(JJH), 2008 WL 2565349, at * 10 (D.N.J. June 24, 2008). Specifically, the court noted that the fact that the patents when issued were considered valid constituted evidence supporting a finding of objective recklessness. *Id.* In the present case, not only were the ZymoGenetics Patents presumed valid by the USPTO at issue, the ZymoGenetics Patents were twice-blessed and affirmed by the USPTO during the reexamination proceedings. D.I. 169, Exs. 1-2. Such an affirmed determination of validity serves as particularly strong evidence that Bristol's infringement of the valid ZymoGenetics Patents was objectively reckless. This is particularly true because Bristol's validity challenge is based on the very same references that the USPTO already determined did not affect the validity of the ZymoGenetics Patents. Wharton Decl., ¶ 10, Ex. 9 at ZG001230-38, ZG001646, ZG000340-49, ZG000745. As explained by the Federal Circuit:

> When no prior art other than that which was considered by the PTO examiner is relied on by the attacker, he has the ***added burden*** of overcoming the deference that is due to a qualified government agency presumed to have properly done its job, which includes one or more examiners who are assumed to have some expertise in interpreting the references and to be familiar from their work with the level of skill in the art and whose duty it is to issue only valid patents.

American Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1359 (Fed. Cir. 1984) (emphasis added); *see also Hewlett-Packard Co. v. Bausch & Lomb, Inc.*, 909 F.2d 1464, 1467 (Fed. Cir. 1990) ("[W]e note that the claims . . . are entitled to a presumption of validity, and that

[Bausch & Lomb] faces the burden of showing, by clear and convincing evidence, the invalidity of the claims. This burden is ***especially difficult*** when the prior art was before the PTO examiner during prosecution of the application.") (citation omitted) (emphasis added).

Another court in the Northern District of California has found that it is evidence of objective recklessness when the facts demonstrate that an accused infringer proceeded with infringing activities despite having a long period of time between issuance of the patents and commencement of infringement in which to examine the patents-in-suit. *Depomed, Inc. v. Ivax Corp.*, 532 F. Supp. 2d 1170, 1185-86 (N.D. Cal. 2007) (denying summary judgment of no willfulness and finding sufficient evidence of objective recklessness where a patent issued two years before the commencement of infringing activities and noting that a reasonable party would "have had ample time to investigate and discover the relevant patent").[4] In the present case, similar to the facts presented in *Depomed*, there is evidence of objective recklessness because there was a gap of over five years between Bristol's first knowledge of the ZymoGenetics Patents and the commencement of Bristol's infringing activities. It is undisputed that the ZymoGenetics patents issued in 1998 and 2000. D.I. 169, Exs. 1-2. It is also undisputed that [redacted] Wharton Decl., ¶¶ 2-3, Exs. 1-2. Bristol began selling the accused product in February 2006. *See* Wharton Decl., ¶ 4, Ex. 3 at Response to Interrogatory No. 15. As such, Bristol had over five years between becoming aware of the ZymoGenetics Patents in which to investigate the ZymoGenetics Patents and avoid infringement by securing a license to the ZymoGenetics Patents or designing around

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[4] *Compare with Veritas Operating Corp. v. Microsoft Corp.*, No. C06-0703-JCC, --- F. Supp. 2d ---, 2008 WL 495658, at *75-76 (W.D. Wash. Feb. 20, 2008) (finding no evidence of objective recklessness where "no one at Microsoft actually knew of [the patent], much less considered the patent in connection with any commercial activities involving the accused products").

the ZymoGenetics Patents. 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. In fact, an examination of the evidence reveals that Bristol proceeded recklessly with its infringing conduct, as is demonstrated by Bristol's decision to proceed without changes to Orencia® after receiving notice of the ZymoGenetics Patents. Bristol's failure to take such action is evidence of objective recklessness.

C. Bristol's Self-serving Assertion of Substantial Defenses should be Disregarded.

1. Self-serving Assertions of Likelihood of Success Carry Little Weight in this Court.

The law of this Court advises that the Court should disregard Bristol's self-serving assertions of noninfringement in its analysis of objective recklessness.[5] D.I. 177 at 9. This Court has generally refused to allow self-serving statements by parties regarding likelihood of success to serve as the basis of granting relief. *Fisher-Price, Inc. v. Safety 1st, Inc.*, 279 F. Supp. 2d 526, 529 (D. Del. 2003) (rejecting argument in brief based on naked assertion of success where "[t]here [was] no persuasive evidence that the defendant's appeal carrie[d] a likelihood of success on the merits."). In a similar vein, another court addressing *Seagate*'s objective recklessness factor, recently stated that a party's "glowing assessment of its own dispositive motion" should not be accepted in evaluating questions under *Seagate*. *See Intervet Inc. v.*

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[5] ZymoGenetics strongly contests Bristol's assertions of the likelihood of success of its noninfringement defenses. ZymoGenetics' opening brief in support of its Motion for Summary Judgment of Infringement and statement of facts in support sets forth ZymoGenetics' infringement claims and discusses the undisputed evidence supporting those claims. D.I. 167, 168, 169. ZymoGenetics' response to Bristol's statement of allegedly undisputed facts filed in support of Bristol's Motion for Summary Judgment of Noninfringement, D.I. 205, is further evidence of the material issues of disputed facts now before the Court. Finally, ZymoGenetics Opposition to Bristol's Motion for Summary Judgment of Noninfringement filed concurrently with this opposition directly addresses the specific noninfringement positions raised in Bristol's willfulness motion at pages 9-12.

Merial Ltd., Civ. No. 06-658 (HHK/JMF), 2008 WL 2411276, at *2 (D.D.C. June 11, 2008) (declining to bifurcate issues of willfulness and damages and disregarding defendant's argument that it is likely to succeed on summary judgment on the issue).

2. Bristol's Assertion that it is Entitled to Summary Judgment because it has Alleged Substantial Noninfringement Defenses should be Disregarded because Bristol's Assertion is Based on an Incorrect Reading of the Law Regarding Willfulness.

Bristol's unilateral statement that it has raised "credible, substantial defenses to" ZymoGenetics' infringement claims and that Bristol should therefore be entitled to a finding of no willful infringement as a matter of law is without merit. D.I. 177 at 9. Simply put, when the assertion of willfulness relates to the accused infringers pre-litigation conduct, the current law of willful infringement does not permit the accused infringer to avoid a finding of willful infringement, much less obtain summary judgment of no willfulness, simply by stating a defense to the underlying infringement claim. *See Eaton Corp. v. ZF Meritor LLC*, No. 03-74844, 2008 WL 920128, at *2 (E.D. Mich. Apr. 3, 2008).

ZymoGenetics' willfulness claim is first and foremost based on Bristol's conduct after [redacted] including its decision to make infringing sales of Orencia® starting in February 2006 - conduct prior to the date ZymoGenetics filed the lawsuit in August 2006. *See* Wharton Decl., ¶ 4, Ex. 3 at Response to Interrogatory No. 15. Neither *Seagate* nor any opinion handed down following *Seagate* stands for the proposition that a party can avoid a finding of willfulness as to pre-filing conduct merely by stating a defense to infringement. *Seagate* merely held that a "substantial question about invalidity or infringement is likely sufficient to avoid . . . a charge of willfulness based on *post-filing* conduct." *Seagate*, 497 F.3d at 1374 (emphasis added).

The Federal Circuit has specifically rejected the legal position taken by Bristol that Bristol's alleged "substantial defenses" to ZymoGenetics' infringement claims allows Bristol to avoid a willfulness finding as to Bristol's pre-litigation conduct. In *Knorr-Bremse*, the Federal Circuit specifically answered "no" to the question as to whether or not "the existence of a substantial defense to infringement [is] sufficient to defeat liability for willful infringement." *Knorr-Bremse*, 383 F.3d at 1347. *Seagate* does not change this approach. *See Eaton*, 2008 WL 920128, at *2. In *Eaton*, the district court specifically rejected the defendants' assertion that "their invalidity positions reveal the opposite of objective recklessness." *Id.* (citation omitted). The court noted as to the alleged substantial defense that because "the jury has yet to address the defense [], the Court is unable to say that no jury could find that there was an objectively high likelihood that the defendant infringed a valid patent." *Id.*

In the present case, Bristol asserts that its noninfringement defenses as described in their motion require summary judgment of no willfulness. D.I. 177 at 9-12. In fact, in discussing its infringement defenses, Bristol specifically claims that "[r]ather 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 . . . [and] point[s] away from the alleged 'high likelihood'" that Bristol infringed. *Id.* at 9. However, as *Eaton* clearly demonstrates, Bristol's position is directly contrary to the law on this issue. The defendants in *Eaton* took an identical position to Bristol's position in this case arguing that their defense proved the opposite of objective recklessness. *Eaton*, 2008 WL 920128, at *2. As the Court in *Eaton* noted, such a defense does not obviate the fact that the jury, not the Court, is to determine whether "there was an objectively high likelihood that the defendant infringed a valid patent." *Id.* As in *Eaton*, this

Court should reject Bristol's attempt to obtain summary adjudication on the issue and allow the jury to examine Bristol's conduct and decide the issue of willfulness.

D. ZymoGenetics Put Forth Sufficient Evidence that Bristol's Noninfringement Defenses are Unreasonable such that there is a Genuine Issue of Material Fact as to the Question of Objective Recklessness.

As discussed above, the Federal Circuit in *Seagate* declined to explain what types of evidence would go to show objective recklessness. *Seagate,* 497 F.3d at 1371. However, in his concurring opinion, Judge Gajarsa stated 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." *Seagate,* 497 F.3d at 1384 (Gajarsa, J., concurring). In the present case, Bristol has asserted both invalidity and noninfringement defenses. Bristol asserts that its noninfringement defenses are of the sort to be considered by this Court to be a defense that avoids a finding of willfulness. D.I. 177 at 9 ("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' [infringement] allegations."). On the other hand, Bristol does not assert that its invalidity defense is of the sort to be considered by this Court to be a defense that avoids a finding of willfulness. D.I. 175.

Bristol argues that there is not a "high likelihood" that Orencia® infringes the patents-in-suit and that therefore it is entitled to summary judgment on willfulness. D.I. 177 at 9. However, the objective evidence shows that Bristol's reliance on its noninfringement theory in proceeding with the release of Orencia® was objectively reckless because there is substantial objective evidence that Bristol's theory was incorrect and unreasonable.[6] Contrary to Bristol's

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[6] For a complete discussion of the evidence undermining Bristol's assertion that there is a "high likelihood" that Orencia® does not infringe the ZymoGenetics Patents, ZymoGenetics refers the

characterization of the evidence, the objective evidence, including peer-reviewed publications, as well as Bristol's own submissions to the FDA and USPTO, show that the mutated Ig portion of Orencia® is a "dimerizing protein" and that native CTLA4 is a protein "requiring dimerization for biological activity." *See* ZymoGenetics' Opposition to Bristol's Motion for Summary Judgment of Noninfringement.

1. The Mutated Ig In Orencia® is a "Dimerizing Protein".

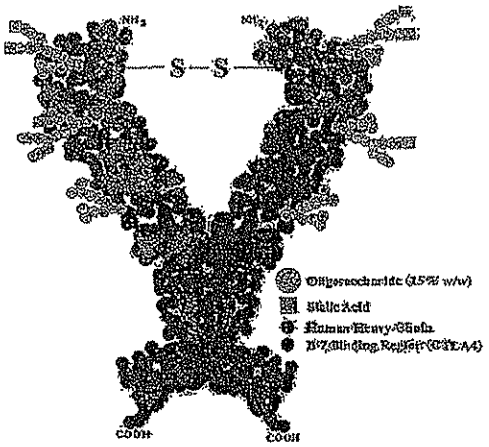
ZymoGenetics' claim construction for the term "dimerizing protein" is "a polypeptide chain having affinity for a second polypeptide chain, such that the two chains associate under physiological conditions to form a dimer. The second polypeptide chain may be the same or a different chain."[7] *See* D.I. 169, Ex. 1 at col. 9, ll. 30-35. Based on this claim construction, Orencia® infringes the ZymoGenetics Patents because the modified Ig portion of Orencia® "associate[s] under physiological conditions to form a dimer."

As an initial matter, the CTLA4-Ig contained in Orencia® is a dimer. The description of Orencia® that Bristol provided to the U.S. Food and Drug Agency states that Orencia® is a dimer. *See* D.I. 169, Ex. 5 at BMS001290162 ("[Orencia®] exists as a covalent homodimer…"]. Furthermore, in response to an interrogatory posed by ZymoGenetics, Bristol specifically stated that Orencia® is a dimer. *See* D.I. 171, Ex. 17. There is no doubt, based on Bristol's representations, that Orencia® is a dimer.

Court to ZymoGenetics' opening brief in support of its Motion for Summary Judgment of Infringement and associated statement of facts, D.I. 167, 168, 169, as well as ZymoGenetics Opposition to Bristol's Motion for Summary Judgment of Noninfringement, filed concurrently with the present Opposition.

[7] ZymoGenetics rejects Bristol's assertion that claim constructions it presumes "ZymoGenetics considered when making its allegations of willfulness" is relevant to the issue of willfulness. D.I. 177 at 4 n.4. Whether or not the Court adopts ZymoGenetics' proposed claim construction, Bristol's proposed claim construction or some hybrid of the two, Bristol infringes the ZymoGenetics Patents. Moreover, willfulness does not turn on claim construction - an issue for the Court to decide. Willfulness is a separate analysis to be performed by the finder of fact.

Not only is Orencia® a dimer, but the modified Ig portion of Orencia® associates under physiological conditions to form a dimer. This was confirmed by one of ZymoGenetics' experts, who isolated the modified Ig portion from a sample of Orencia® and observed that the modified Ig portion forms a dimer. *See* D.I. 171, Ex. 14 at 262:24-264:1. Furthermore, as shown in Zymogenetics' Opposition to Bristol's Opening Brief in Support of Its Motion For Summary Judgment of Noninfringement, Bristol repeatedly identified to the FDA that the modified Ig portion of Orencia® is a dimer. One example of Bristol's representation that the modified Ig is a dimer is in the following figure, in which the Ig portion at the bottom of the image is shown as a dimer.



Declaration of Lisa Kobialka in Support of ZymoGenetics' Opposition to Bristol-Myers Squibb Co.'s Motion for Summary Judgment of Noninfringement ("Kobialka Decl."), ¶ 6, Ex. 5 (in a Bristol document entitled "CTLA4Ig Development History"); *see also id.*, Ex. 5 (submitted to the FDA); *id.*, Ex. 7 (submitted to the FDA). Bristol cannot plausibly argue a "high likelihood" exists that the modified Ig portion of Orencia® does not dimerize when the both the objective evidence and Bristol's own statements show that the modified Ig portion of Orencia® is a dimerizing protein.

2. CTLA4 Requires Dimerization for Biological Activity

Contrary to Bristol's claims, there is a high likelihood, if not dispositive evidence, that CTLA4 requires dimerization for biological activity in the biological context. The specifications of the ZymoGenetics Patents 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). Biological activities may include the induction of an extracellular matrix secretion from responsive cell lines, the induction if hormone secretion, the induction of chemotaxis, the induction of mitogenesis, the induction of differentiation, or the inhibition of cell division of responsive cells. A recombinant protein or peptide is considered to be biologically active if it exhibits one or more biological activities of its native counterpart."[8]

See D.I. 169, Ex. 1 at col. 9, ll. 35-45. The overwhelming majority of scientific evidence shows that CTLA4 exists in the body only as a dimer, and that the dimer form of CTLA4 is the only form that is biologically active in the human body. D.I. 157, Ex. 9 at ¶ 108; D.I. 169, Ex. 8 at ¶ 112; D.I. 174, Ex. 12 at 604; D.I. 178, Ex. 13 at ZG054281. In fact, the scientific evidence relied upon by Bristol's own experts confirms that CTLA4 exists in nature as a dimer. D.I. 174, Ex. 12 at 607, 609, fig. 3. This is in agreement with both Zymogenetics' experts and the larger scientific community, all of which state the CTLA4 must be a dimer in order to have biological activity in the body. D.I. 157, Ex. 9 at ¶ 108 (native CTLA4 exists as a dimer); D.I. 169, Ex. 8 at ¶112 (CTLA4 is naturally a dimer); *see also* D.I. 171, Ex. 11 at 85:13-20 (CTLA4 is biologically active as a dimer in humans); D.I. 174, Ex. 12 at 607 (CTLA4 exists as "an obligate dimer"); Declaration of Nicholas R.J. Gascoigne, Ph.D. in Support of ZymoGenetics, Inc.'s Opposition to

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[8] Despite Bristol's assertion that it "is applying ZymoGenetics' proposed constructions, where possible" and despite Bristol's acknowledgement that the term "biological activity" is explicitly defined in the ZymoGenetics Patents, Bristol uses its own proposed construction for this term. At the least, the parties agree that the construction of the term should include the first sentence of the explicit definition, *i.e.*, "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)."

Bristol-Myers Squibb Co.'s Motion for Summary Judgment of Noninfringement ("Gascoigne Decl.") at ¶¶ 24, 27-28; Declaration of David A. Ostrov, Ph.D. in Support of ZymoGenetics, Inc.'s Opposition to Bristol-Myers Squibb Co.'s Motion for Summary Judgment of Noninfringement ("Ostrov Decl."), ¶¶ 6, 17. A monomeric form of native CTLA4 has not been identified that functions in the biological context. Gascoigne Decl., ¶¶ 24-28; Ostrov Decl., ¶¶ 14-15, 17; D.I. 178, Ex. 13 at ZG054281. Further discussion of CTLA4's biological activity as a dimer, and only as a dimer in the biological context is contained in ZymoGenentics' Opposition to Bristol's Opening Brief In Support of Its Motion for Summary Judgment of Noninfringement at pages 18-27.

Bristol's only support for its contention that native CLTA4 does not require dimerization for biological activity consists of binding assay studies performed on a non-native form of CTLA4. D.I. 177 at 9-12. These studies are insufficient to support Bristol's claim for two reasons. First, the cited studies contain experiments that were not performed with native CTLA4, but rather with a truncated artificial form of CTLA4 that does not exist in nature. D.I. 174, Ex. 12 at 604; Ostrov Decl., ¶¶ 5, 15, 17, 21. The ability of a shortened, artificial, monomeric form of a portion of CTLA4 to bind a ligand does not relate to the question of whether or not native CTLA4 requires dimerization to have biological activity. Second, these studies only show that a modified, non-native version of CTLA4 has the ability to bind to a ligand. *Id.* Binding ligand, by itself, does not meet the definition of "biological activity" as it relates to CTLA4 as defined by the ZymoGenetics Patents. *See* D.I. 174, Ex. 22 at 48:24-49:17; Kobialka Decl., Ex. 11 at 111:24-112:2, 116:11-117:11; D.I. 174, Ex. 28 at 153:4-10; Gascoigne Decl., ¶ 28; Ostrov Decl., ¶¶ 5, 15, 17. In addition, as noted in ZymoGenetics' Opposition to Bristol's Motion for Summary Judgment of Noninfringement, binding ligand is only the first step

in the cell-signaling process of CTLA4 and is not, by itself, suffient to be considered biological activity. *See* ZymoGenetics' Opposition to Bristol's Motion for Summary Judgment of Noninfringement at 21-22.

In summary, Bristol cannot reasonably argue that there is a "high likelihood" that Orencia® does not infringe the ZymoGenetics Patents based on the inclusion of the terms "dimerizing protein" and "requiring dimerization for biological activity" in the relevant claims of the Zymogenetics Patents. The objective evidence, as discussed above, included a substantial body of objective evidence that Bristol's theory regarding these terms was incorrect. The Court should therefore not entertain Bristol's summary judgment argument on this point.

E. The Undisputed Evidence Demonstrates that Bristol's Invalidity Defense was Unreasonable.

Any contention that Bristol's invalidity defense is a "substantial" defense to ZymoGenetics' assertion of willful infringement is without merit. First, 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" the invention. *Bard Peripheral Vascular, Inc. v. W.L. Gore & Assocs., Inc.*, No. CV 03-0597-PHX-MHM, 2008 WL 2958968, at *2 (D. Ariz. July 29, 2008). In the present case, Bristol asserts that several patents and other references invalidate the ZymoGenetics Patents. D.I. 171, Ex. 9 at ¶ 68. However, during the initial examination and the reexamination, the USPTO specifically reviewed these references and found them not to invalidate the ZymoGenetics Patents. Wharton Decl., ¶ 10, Ex. 9 at ZG001230-38, ZG001646, ZG000340-49, ZG000745.[9] As such, under

[9] The USPTO did not specifically examine each of the four Capon patents, U.S. Patent Nos. 5,336,603, 5,565,335, 6,117,655 and 6,710,169. A detailed review of each of these patents was unnecessary because, as Dr. Capon acknowledges in his report, the specifications for each of

Bard, Bristol's invalidity defense does not preclude a finding of objective recklessness. Id.; *see also Depomed*, 532 F. Supp. 2d at 1185-86 (finding objective recklessness where defendant unreasonable in believing that the patents-in-suit are invalid).

Second, Bristol's remaining basis for its invalidity defense relates to alleged inadequacies in ZymoGenetics' conception and reduction to practice of the inventions. The facts of this defense were not known to Bristol at the time infringement began, as it is based on ZymoGenetics' internal activities. *See* D.I. 161 at 3-4. Such a theory of invalidity cannot serve as evidence of no objective recklessness for pre-litigation conduct because Bristol could not have relied on this defense at the time Bristol commenced infringing sales of Orencia® in February 2006.

F. Cases Relied Upon by Bristol in its Motion are Easily Distinguished.

While it is true that several Courts have granted summary judgment of no willfulness, the cases relied upon by Bristol in its motion are easily distinguished from the facts now before the Court. For example, in *Franklin* the court was presented with the fact that the court had once granted summary judgment of noninfringement, a ruling later overturned by the Federal Circuit. *Franklin Elec. Co. v. Dover Corp.*, No. 05-C-598-S, 2007 WL 5067678, at *8 (W.D. Wis. Nov. 15, 2007). Under such circumstances, the Court found that its early noninfringement analysis supported a grant of summary judgment on the willfulness issue because the analysis revealed "significant support in the language of the patent, the specification and prosecution history for defendant's non-infringement position." *Franklin*, 2007 WL 5067678, at *8; *see also Lucent Techs., Inc. v. Gateway, Inc.*, No. 04-CV-2000-H, 2007 U.S. Dist. LEXIS 95934, at *20-*21

these patents are identical. D.I. 171, Ex. 10 at ¶ 74. Bristol can not plausibly argue that the USPTO was required to provide a separate analysis for each of these patents when Dr. Capon himself did not provide a separate analysis. *Id.* [redacted]

(S.D. Cal. Oct. 30, 2007) (granting summary judgment of no willfulness where "the court [had] already ruled in Defendants' favor on several threshold issue required to establish an invalidity defense"). In the present case, this Court has engaged in no such analysis and has in no way examined Bristol's noninfringement defense much less made a finding that Bristol's noninfringement position has merit or could have served as a reasonable basis for proceeding with the sale of Orencia®. As such, *Franklin* does not counsel a grant of summary judgment in the present case.

Similarly, *Trading Technologies* is easily distinguished from this case by the facts before the Court in that case. *Trading Technologies*, 2008 WL 63233, at *1. Specifically, in *Trading Technologies*, the court granted summary judgment of no willfulness where the patent at issue had not yet issued prior to the defendant's first sale of the accused product. *Id.* (citations omitted). The court noted that "[w]hile defendants knew of the plaintiff's patent application, this knowledge alone is not enough to demonstrate willfulness." *Id.* In the present case, at the time of the first infringing sale, Bristol had been aware of the ZymoGenetics Patents for over five years. As such, the *Trading Technologies* court's basis for granting summary judgment is simply not present in this case and should not serve as a basis for granting summary judgment in this case.

IV. CONCLUSION

For all of the foregoing reasons, ZymoGenetics respectfully requests that this Court deny Bristol's Motion for Summary Judgment of No Willfulness.

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CERTIFICATE OF SERVICE

I, Philip A. Rovner, hereby certify that on August 25, 2008, the within document was filed with the Clerk of the Court using CM/ECF which will send notification of such filing(s) to the following; that the document was served on the following counsel as indicated; and that the document is available for viewing and downloading from CM/ECF.

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