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**

PLAINTIFF ZYMOGENETICS, INC.'S REPLY IN SUPPORT OF MOTION TO EXCLUDE TESTIMONY OF BRISTOL-MYERS SQUIBB CO.'S EXPERTS

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I. INTRODUCTION

ZymoGenetics, Inc.'s ("ZymoGenetics") motion to exclude the testimony of Bristol-Myers Squibb Co.'s ("Bristol") experts, Dr. Jeffrey Ravetch ("Dr. Ravetch"), Dr. Daniel Capon ("Dr. Capon"), and Dr. John Kuriyan ("Dr. Kuriyan") presented compelling reasons and argument for why exclusion is proper. Bristol's opposition brief fails to actually counter ZymoGenetics' specific arguments. Additionally, much of Bristol's opposition discusses only Dr. Ravetch's opinions, and only in conclusory statements; Bristol does not respond ***at all*** to ZymoGenetics' specific challenges to Dr. Capon's and Dr. Kuriyan's opinions. The end result of Bristol's arguments is a series of one absurd conclusion after the other, *e.g.*, that the verbatim passages among Bristol's experts' reports somehow reflect that their opinions are [redacted] Bristol took the risk of drafting its expert reports in the manner it did, and any consequence resulting from Bristol's actions is entirely its own responsibility. ZymoGenetics respectfully requests the Court to exclude the testimony of Bristol's experts.

II. ARGUMENT

A. BRISTOL'S EXPERT QUALIFICATIONS HAVE NEVER BEEN AT ISSUE

Bristol claims that ZymoGenetics made [redacted] and has presented [redacted] D.I. 212 at 4. Such an argument is not relevant because ZymoGenetics is not raising the issue of whether any or all of Bristol's experts possess the requisite "knowledge, skill, experience, training, or education" under Federal Rule of Evidence 702 to proffer an expert opinion. FED. R. EVID. 702. *See* D.I. 158. Bristol's opposition, which touts the [redacted] of its experts, fails to address the actual issues raised in ZymoGenetics' motion.

It is not enough that Bristol's experts are qualified; that does not end inquiry of admissibility. Though an expert may be qualified, if his opinion fails to trace back to his qualifications, then his qualifications are relegated to nothing more than fancy packaging in

which to present an idea. The danger of admitting an opinion, divorced from an expert's qualifications and reliance of facts, is that any opinion may be presented to the trier of fact based solely on a resume—resumes which, incidentally, [redacted] The Court must instead assess whether the methodology underlying the testimony is scientifically valid, and whether it has been properly applied to the facts. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 592-93 (1993).

An expert's opinion ***must*** draw from his unique qualifications because it is an expert's specialized knowledge which qualifies him to testify as an expert in the first place. FED. R. EVID. 702. Thus, an expert's failure to utilize his special qualifications in forming an opinion negates the only reason why his opinion would be considered helpful to the trier of fact in the first instance, precluding the admissibility of such an opinion. In this case, Bristol's experts admit [redacted] Such methodology—opinion not based on the factual evidence but rather on speculative positions taken by the opposing par—cannot survive *Daubert* review.

Here, [redacted] which is that Bristol's experts did not draw on what they believed the science to be in formulating their opinions. *See* Fed. R. Civ. P. 26(a)(2)(B) (the expert opinion shall contain a complete statement of all opinions the witness will express and the basis and reasons for them). Instead, Bristol's scientific experts attempted to use legal arguments they claim ZymoGenetics was making as a basis and starting point for their opinions.[1] *See* D.I. 158 at 4-16. Such methodology does not satisfy Rule 702's requirement that to be helpful, there must

[1] As described in ZymoGenetics' opening brief, the claims that these are the legal positions that ZymoGenetics is taking is often incorrect or an assumption improperly made by Bristol's experts. This will not be revisited here as Bristol did not even address these arguments in its opposition.

be a "valid scientific connection to the pertinent inquiry." *Daubert*, 509 U.S. at 592. ZymoGenetics pointed out ***specific deposition testimony*** and excerpts of Bristol's experts' reports ***by paragraph*** where its experts failed to apply their own knowledge, skill, and experience in formulating their opinions. Bristol ***completely*** failed to address these specifically identified sections of its experts' "opinions." Thus, Bristol does not dispute that these portions of its experts' opinions lack any basis in or connection to the "knowledge, skill, experience, training, or education" which are prerequisites to assisting the trier of fact, and thus admissibility. FED. R. EVID. 702. Thus, the opinions will not assist the trier of fact and are inadmissible under Rule 702.[2]

B. BRISTOL'S EXPERT OPINIONS ARE NOT BASED UPON FACTS AND DATA AS REQUIRED BY RULE 702

As ZymoGenetics demonstrated in its underlying motion, the opinions of Bristol's experts lack any basis in "facts and data," as required by Rule 702. Bristol's response to this charge is completely insufficient. [redacted] D.I. 212 at 5. The fact of an element-by-element analysis says nothing about the sufficiency of such analysis or the methodology behind it. *See Heller v. Shaw Indus. Inc.*, 167 F.3d 146, 153 (3d. Cir. 1999) (holding that courts "must examine the expert's conclusions to determine whether they could reliably follow from the facts known to the expert and the methodology used."). Additionally, Bristol's citations to bulk paragraphs of its experts' reports (*i.e.*, paragraphs 33-182, paragraphs 42-158, paragraphs 67-329, and paragraphs 68-164) encompass essentially the entirety of the reports minus the background sections. D.I. 212 at 5. These citations are too unspecific to be helpful to the trier of fact, and thus also do not sufficiently demonstrate that Bristol's experts' opinions are grounded in scientific facts and data. *See Daubert*, 509 U.S. at 591-92.

[2] For the specific testimony of Bristol's experts on which ZymoGenetics seeks to preclude, ZymoGenetics respectfully requests the Court to refer to its underlying motion. *See* D.I. 158.

As ZymoGenetics specifically explained in its motion, it was incorrect methodology for Bristol's experts to abandon their independent scientific judgment about the technology at issue to form their "opinion" and instead base their opinions on speculative non-scientific legal arguments allegedly made by ZymoGenetics. *See Daubert*, 509 U.S. at 589-90 (holding that opinions must be grounded in the "methods and procedures of science", and not on speculation).

To divert the focus away from Bristol's experts' improper reliance on ZymoGenetics' alleged arguments, Bristol accuses ZymoGenetics' experts of [redacted] However, reference is precisely the extent of it; ZymoGenetics' experts refer to Bristol's positions in order to refute them, but they do not rely on them. For instance, the following language from the expert report of ZymoGenetics' expert, Dr. David Ostrov ("Dr. Ostrov"), is quoted by Bristol in order to suggest that the report is improper for referencing Bristol's positions: [redacted] D.I. 212 at 7; Declaration of Paul J. Andre in Support of ZymoGenetics' Reply in Support of Motion to Exclude Testimony of Bristol-Myers Squibb's Experts ("Andre Decl."), Ex. 3, ¶ 16. Bristol, however, omits the sentence immediately following, which states, [redacted] *Id.* Therefore, while Bristol's experts' opinions rely and build on positions allegedly taken by ZymoGenetics, ZymoGenetics' experts actually rebut and break down the positions taken by Bristol. *See Daubert*, 509 U.S. at 589-90 (opinion may not be based on speculation.) ZymoGenetics' experts' mere reference to Bristol's positions does not violate the standards of admissibility because their opinions are based on the scientific principles , unlike Bristol's experts' reliance on legal argument and speculation.

Finally, Bristol also attempts to mischaracterize ZymoGenetics' motion [redacted] D.I. 212 at 5-6. Without directing the Court to any specific section or sections of ZymoGenetics' underlying motion, however, such a generalized allegation is too vague to comprehend. Bristol's failure to point to any specific [redacted]

[redacted] actually demonstrates that ZymoGenetics' motion does not raise such a dispute in its motion. *Id.* ZymoGenetics could not reach such a point given that Bristol's experts' reports are not based in facts and data, but rather fail under *Daubert* because the opinions are based on speculation. *See Daubert*, 509 U.S. at 589-90.

C. BRISTOL'S EXPERT OPINIONS ARE NOT SUPPORTED BY CITATIONS TO PEER-REVIEWED PUBLICATIONS

Bristol alleges [redacted] D.I. 212 at 6. Examining the specific citations to scientific journal articles in Bristol's expert reports, it becomes clear that such citations are utterly lacking with respect to the opinions specifically challenged in ZymoGenetics' motion, *i.e.*, [redacted] *See* D.I. 158.

For example, no citations are provided to support Dr. Ravetch's opinion that [redacted] *See* Declaration of Amy Sun in Support of ZymoGenetics' Motion to Exclude Testimony of Bristol-Myers Squibb's Experts ("Sun Decl."), Ex. 1, ¶ 39. No citations are provided to support Dr. Capon's opinion [redacted] *See* Sun Decl., Ex. 7, ¶ 90. No citations are provided to support Dr. Kuriyan's opinion [redacted] *See* Sun Decl., Ex. 8, ¶ 48. The reason is that all of these opinions were explicitly reached [redacted] and [redacted] *See* Sun Decl., Ex. 1, ¶ 39; Sun Decl., Ex. 7, ¶ 90; Sun Decl., Ex. 8, ¶ 48.[4] Therefore, Bristol does not demonstrate that the opinions actually challenged by

[3] In fact, Dr. Ravetch states in his report that [redacted] *See* D.I. 158 at 5.

[4] As set forth in ZymoGenetics' opening brief, ZymoGenetics never actually took the positions Bristol imputes to it.

ZymoGenetics in its motion are reliable by virtue of being supported by citations to peer-reviewed publications. The fact that other portions of its experts' reports contain such citations does not establish the reliability of all of the opinions expressed in the expert reports. Because Bristol has failed to establish that the opinions challenged by ZymoGenetics are reliable, their testimony on these subjects should be excluded.[5]

D. BRISTOL, NOT ZYMOGENETICS, HAS TAKEN CONTRADICTORY POSITIONS REGARDING THE MEANING OF CLAIM TERMS IN ORDER TO BE ABLE TO REACH CONCLUSIONS OF BOTH NONINFRINGEMENT AND INVALIDITY

Bristol attempts to attribute its experts' contradictory opinions to ZymoGenetics' allegedly contradictory positions, but such an argument is problematic for several reasons. First, there is no reason why Bristol's experts had to be bound by ZymoGenetics' alleged contradictory positions as a premise for their analyses. To use the example given in ZymoGenetics' motion, a rebuttal damages expert would need to base his opinion on the infringement position of the plaintiff; absent such a presumption, there would be no need to assess damages. However, whether [redacted]

To base an opinion concerning a matter of science on alleged legal arguments made by a party to the litigation is flawed methodology, and fails under *Daubert*. *See Daubert*, 509 U.S. at 589-90. The very reason for an expert's involvement in a case is to provide his or her own independent and objective scientific opinion, detached from and not contingent upon the positions of either party.

Second, ZymoGenetics has not actually taken contradictory opinions. [redacted] D.I. 212 at 8.

[5] *See supra* note 2.

For instance, [redacted] U.S. Patent No. 5,843,725 ("the '725 patent") and U.S. Patent No. 6,018,026 ("the '026 patent") because [redacted] Bristol broadly extrapolates , without any basis in science, into the contradictory conclusion [redacted] and at other times is not. Experts cannot take contrary or alternative positions; their opinions must be based solely on science. If an expert opinion is based on sound scientific principles and methodology, then it will not result in contrary or alternative opinions, as is the case with Bristol's expert opinions in this case.

Such sweeping conclusions and the unscientific reasoning from which they stem are proper grounds for exclusion of Bristol's expert testimony. As the Supreme Court articulated in *General Electric. Co. v. Joiner*, 522 U.S. 136, 146 (1997):

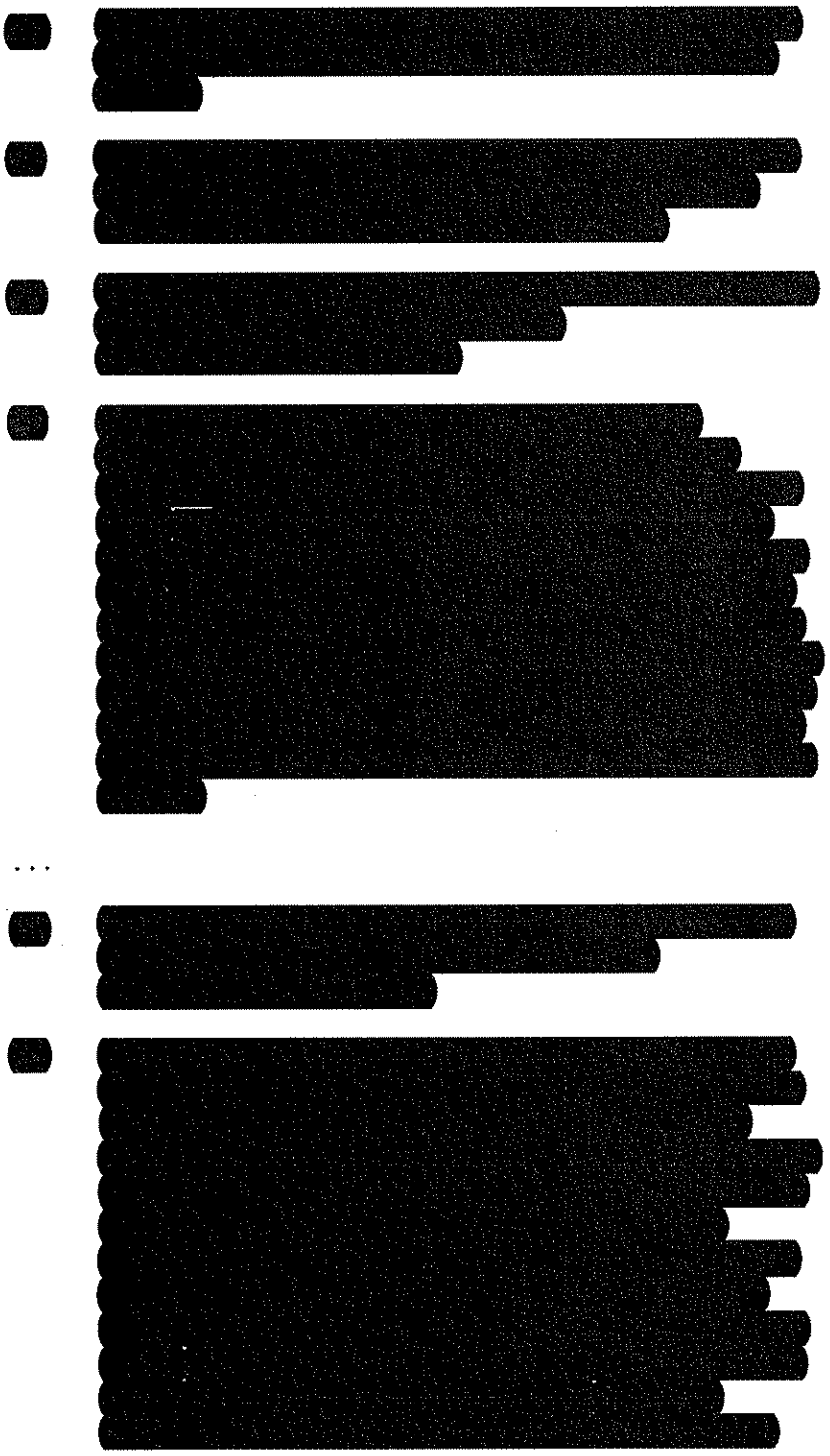
> [C]onclusions and methodology are not entirely distinct from one another. Trained experts commonly extrapolate from existing data. But nothing in either Daubert or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert. A court may conclude that there is simply ***too great an analytical gap between the data and the opinion proffered.***

General Electric, 522 U.S. at 146 (citations omitted) (emphasis added).

Bristol's experts' broad extrapolation from the narrow positions taken by ZymoGenetics opens a vast analytical gap between such positions and their ultimate conclusions, bridged only by the *ipse dixit* of its experts. Such testimony is inadmissible. *Id.*

Third, Bristol still offers no explanation for why its experts chose to [redacted] Such alternative positions can not

possibly assist the trier of fact. *See Daubert*, 509 U.S. at 591-92. In deposition, Bristol's experts strained to avoid this issue of duplicity. Dr. Ravetch testified:



[redacted]

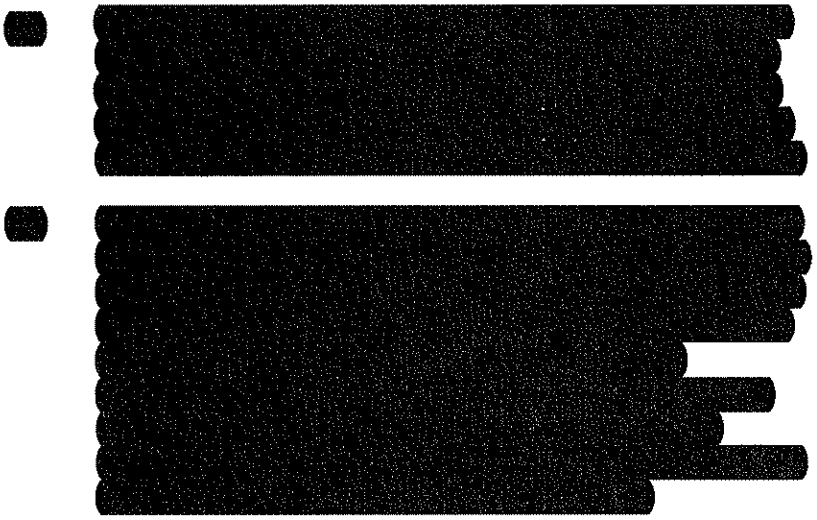
Andre Decl., Ex. 1 at 60:24-64:20 (emphasis added) (objections omitted); *see also id.* at 64:21-67:23 (objections omitted).[6]

Dr. Capon testified in his deposition:

[redacted]

[6] Dr. Ravetch's deposition occurred after the filing of ZymoGenetics' motion to exclude. Therefore, it was not possible until now to cite to Dr. Ravetch's deposition testimony.

. . .



Andre Decl., Ex. 2 at 212:22-216:20 (objections omitted).

What Bristol and its experts strenuously avoided stating in deposition, in the expert reports, and in Bristol's opposition brief is obvious: Bristol cannot establish both noninfringement and invalidity under a single definition of certain claim terms. For purposes of finding infringement, Bristol's experts state [redacted] At the same time, for purposes of finding invalidity, Bristol's experts state [redacted] If Bristol's experts had utilized a single, consistent definition, it would not have been possible to reach a conclusion of both noninfringement and invalidity. Bristol's experts' alternative, contradictory positions should be excluded because they are not helpful to the trier of fact and fail to satisfy Rule 26(a)(2)(B)'s requirement that an expert disclose the basis for his opinion.

E. BRISTOL'S EXPERT OPINIONS ARE BASED ON PRESENT DAY LITIGATION POSITIONS, NOT THE UNDERSTANDING OF PERSONS OF ORDINARY SKILL IN THE ART AT THE TIME OF THE INVENTION

As a means to divert attention from the fact that none of its experts possessed or disclosed their own independent scientific understanding of various claim terms, Bristol argues that [redacted] *See* D.I. 212 at 11-12. Bristol's argument is irrelevant because the fact is that [redacted] Moreover, Bristol's experts admitted that [redacted]

Dr. Ravetch testified at his deposition that he had no independent understanding of certain claim terms:

- [redacted]
- [redacted]

. . .

- [redacted]
- [redacted]
- [redacted]

[redacted]

Andre Decl., Ex. 1 at 67:24-69:20 (objections omitted). Dr. Capon and Dr. Kuriyan testified similarly and their testimony is quoted in ZymoGenetics' underlying motion, which Bristol does not address or explain. *See* D.I. 158 at 12, 14-15. Therefore, Bristol's argument that [redacted] Such "expertise" cannot assist the trier of fact. *Daubert*, 509 U.S. at 592-93.

Moreover, although Bristol acknowledges that [redacted] For example, Dr. Ravetch and Dr. Kuriyan relied on ZymoGenetics' alleged definition of the term [redacted] *i.e.*, [redacted] Sun Decl., Ex. 1, ¶ 35; Sun Decl., Ex. 8, ¶ 46. [redacted] Therefore, Bristol's experts admit [redacted]

Further, it is Bristol, not ZymoGenetics, who has relied on present day interpretations of the claim terms. For instance, Dr. Ravetch's and Dr. Capon's opinion that [redacted] Dr. Ravetch states in his report:

[redacted]

Sun Decl., Ex. 2, ¶¶ 83, 85 (emphasis added). Dr. Capon states, substantially identically, in his report:

[redacted]

Sun Decl., Ex. 7, ¶ 86 (emphasis added); *see also id.* ¶¶ 26, 68 [redacted] (emphasis added). Thus, Bristol's experts' opinions depend on ZymoGenetics' present positions "in this litigation" rather than the scientific understanding that existed among persons skilled in the art at the time of the invention, roughly 20 years ago. *See Daubert*, 509 U.S. at 589-90.

Dr. Capon further confirmed in deposition that [redacted]

[redacted]

Andre Decl., Ex. 2 at 166:12-169:6 (objections omitted) (emphasis added).

In sum, Bristol's argument that [redacted] *See* Fed. R. Civ. P. 26(a)(2)(B) (requiring basis and reasons for opinions). Further, Bristol's experts admitted that [redacted] Lastly, Bristol's experts' opinions are improperly based on [redacted] For these reasons, Bristol's experts' testimony will not assist the trier of fact and should be excluded. *Daubert*, 509 U.S. at 589; Fed. R. Civ. P. 26(a)(2)(B).

F. BRISTOL'S EXPERTS ARE NOT INDEPENDENT AND OBJECTIVE

Bristol does not dispute that [redacted] Instead, Bristol argues that [redacted]

[redacted] D.I. 212 at 13. Such a statement is as strained a justification as could be made based on [redacted] *Id.* Bristol bears the burden of proving admissibility. *See Daubert,* 509 U.S. 593 n.10. According to Bristol's argument, [redacted] Such a result is obviously impermissible. Bristol's suggestion [redacted]

In a further effort to downplay the fact that [redacted] Moreover, Bristol did not file a *Daubert* motion by the time set by the Court for filing such motions. Thus, any arguments made in Bristol's opposition to ZymoGenetics' *Daubert* motion regarding the alleged inadmissibility or exclusion of ZymoGenetics' experts' testimony should be disregarded.

G. DR. RAVETCH'S CONCEPTION TESTIMONY SHOULD BE EXCLUDED

Dr. Ravetch's testimony regarding dates of conception should be excluded for the following reasons. First, [redacted] Sun Decl., Ex. 2, ¶ 24. There is no

factual basis provided to show how he reached his finding. *See* Fed .R. Civ. P. 26(a)(2)(B). Second, Dr. Ravetch improperly supplemented his *de minimis* conception opinion ***after*** the close of fact discovery and ***after*** his deposition. He attempted to do so by submitting a declaration in summary judgment briefing accompanying Bristol's answer to ZymoGenetics' statement of undisputed facts in support of its motion for summary judgment of validity of the patents-in-suit ("Ravetch Declaration"). *See* Andre Decl., Ex. 4.[7] Third, during deposition Dr. Ravetch's answers consisted of [redacted] Andre Decl., Ex. 1 at 30:22-36:2. [redacted]

Dr. Ravetch's expert report does not mention [redacted] *See* Fed. R. Evid. 702; Daubert, 509 U.S. at 589-90. It merely espouses his unsupported legal conclusion. Dr. Ravetch claims that he [redacted]

The Ravetch Declaration purports to provide [redacted]

[7] Dr. Ravetch submitted his invalidity report on December 4, 2007 and his noninfringement report on January 29, 2008. Expert discovery closed on May 12, 2008. On May 16, 2008, the parties filed their opening claim construction briefs and summary judgment motions. On this date ZymoGenetics also filed its motion to exclude. Dr. Ravetch was deposed after the close of expert discovery on May 20, 2008, [redacted] On June 2, 2008, each party submitted its response to the other party's statement of undisputed facts in connection with the summary judgment motions. The Ravetch Declaration was submitted on this date in support of Bristol's response to ZymoGenetics' statement of undisputed facts. D.I. 208.

[redacted] The excerpt below shows the [redacted]

[redacted]

Andre Decl. Ex. 4, ¶ 9. In contrast, [redacted]

[redacted]

Sun Decl., Ex. 2, ¶ 24. Allowing Dr. Ravetch to testify regarding the information in the Ravetch Declaration would be unfairly prejudicial since it was drafted ***after*** the close of expert discovery, ***after*** the postponed deposition of Dr. Ravetch,[8] and ***after*** the deadline for filing a motion for summary judgment. Bristol should not be permitted to attempt to cure its deficient expert opinions after the expert discovery cutoff.

[8] The deposition of Dr. Ravetch originally scheduled for April 24, 2008 was postponed by Bristol until May 20, 2008, 4 days after the deadline for filing a motion for summary judgment.

Dr. Ravetch's testimony during deposition was not as illuminating [redacted] Dr. Ravetch's replies to inquiries regarding [redacted] *See, e.g.*, Andre Decl., Ex. 1 at 30:22-32:14. Even as late as Dr. Ravetch's deposition, which was postponed until after the close of fact discovery, ZymoGenetics still had not been provided with the Ravetch Declaration and thus could not depose him regarding its contents.

Based on the above reasons, the testimony from Dr. Ravetch regarding conception in his report, his deposition, the Ravetch Declaration should be excluded.

H. THE SCOPE OF DR. CAPON'S TESTIMONY CONCERNING OBVIOUSNESS SHOULD BE LIMITED TO HIS DISCUSSION CONCERNING ANTICIPATION

Dr. Capon should be precluded from offering an obviousness opinion for the reasons stated in its underlying motion. *See* D.I. 158 at 23-25. Dr. Capon refused [redacted] Sun Decl., Ex. 7 at 38. Moreover, Dr. Capon's cursory obviousness opinion, consisting of only [redacted] D.I. 158 at 23-25D.. Finally, Dr. Capon's confusion over the [redacted] *See id.*

Both Dr. Capon's expert report and deposition testimony show that because [redacted] Sun Decl., Ex. 7, Sun Ex. 7 E ¶ 163; Andre Decl., Ex. 2 at 239:16-244:20. This is the only rationale Dr. Capon provides for his obviousness conclusion. Therefore, if Dr. Capon is permitted to provide an obviousness opinion at trial, he should be excluded from testifying regarding any of the other criteria for evaluating obviousness because [redacted] Thus, he should be disallowed from testifying regarding obviousness according to the legal standard [redacted]

[redacted] Sun. Decl., Ex. 7, ¶ 31. Furthermore, Dr. Capon should be excluded from testifying about any other indicia of obviousness as well, such as the following *Graham* factors: (1) the scope and content of the prior art, (2) the level of ordinary skill in the art, (3) the differences between the prior art and the claimed invention, and (4) objective evidence of nonobviousness including items such as commercial success, long felt but unsolved needs, and failure of others. *See Graham v. John Deere Co. of Kansas City,* 383 U.S. 1, 17-18 (1966). In sum, the only obviousness opinion Dr. Capon should be allowed to testify to, if at all, is that the asserted claims of the '725 and '026 patents are obvious by virtue of their being allegedly anticipated.

III. CONCLUSION

In light of the foregoing, ZymoGenetics respectfully requests the Court to grant its motion and exclude the testimony of Dr. Ravetch, Dr. Capon, and Dr. Kuriyan at trial.

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CERTIFICATE OF SERVICE

I, Philip A. Rovner, hereby certify that on June 20, 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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