

UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY

IN RE BIOGEN '755 PATENT  
LITIGATION

Civil Action No.: 10-2734 (CCC)(JBC)  
(consolidated)

MEMORANDUM OPINION  
AND ORDER

**CECCHI, District Judge.**

Before the Court are motions *in limine* by Biogen MA, Inc. (“Biogen”) (ECF Nos. 670, 672, 674, 676, 678, 680, 684, 686), by EMD Serono, Inc. and Pfizer Inc. (“Serono”) (ECF Nos. 692, 694, 695, 696, 697), and by Bayer Healthcare Pharmaceuticals Inc. (“Bayer”) (ECF Nos. 710, 712).<sup>1</sup> Also before the Court is a *Daubert* motion by Serono (ECF No. 699). Having considered all of the submissions filed in connection with these motions, and having heard oral argument and held conferences concerning the motions on December 12, 2017, December 13, 2017, and December 15, 2017, the Court makes the following determinations with respect to the motions.

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<sup>1</sup> Pursuant to this Court’s Order dated November 7, 2017, Biogen’s Motion *in Limine* No. 1 (ECF No. 668) and Serono’s Motion *in Limine* No. 2 (ECF No. 693) are granted. ECF No. 759. In addition, pursuant to this Court’s Order dated December 5, 2017, Biogen’s Motion *in Limine* No. 11 (ECF No. 688) and Bayer’s Motions *in Limine* Nos. 1, 3, and 7-10 (ECF Nos. 701, 706, 714, 715, 716, 718) are administratively terminated without prejudice. ECF No. 866. Biogen’s Motion *in Limine* Nos. 8 and 12 (ECF Nos. 682, 690) and Serono’s joining proviso to Bayer’s Motion *in Limine* No. 2 (ECF No. 730) will be addressed in a separate Order. Furthermore, on January 12, 2018, Serono withdrew Bayer’s Motion *in Limine* No. 4 (ECF No. 708) as to Serono. ECF No. 903. Therefore, Bayer’s Motion *in Limine* No. 4 is also administratively terminated without prejudice.

## I. LEGAL STANDARDS

A motion *in limine* is designed to narrow evidentiary issues for trial and to eliminate unnecessary interruptions during trial. *Bradley v. Pittsburgh Bd. of Educ.*, 913 F.2d 1064, 1069 (3d Cir. 1990). The purpose of a motion *in limine* is to bar “irrelevant, inadmissible, and prejudicial issues from being introduced at trial, thus narrow[ing] the evidentiary issues for trial.” *Id.* (internal quotation marks omitted). However, “[t]he Federal Rules of Evidence embody a strong and undeniable preference for admitting any evidence having some potential for assisting the trier of fact.” *Holbrook v. Lykes Bros. Steamship Co., Inc.*, 80 F.3d 777, 780 (3d Cir. 1996) (internal quotation marks omitted). “An *in limine* motion is not a proper vehicle for a party to ask the Court to weigh the sufficiency of the evidence to support a particular claim or defense, because that is the function of a motion for summary judgment, with its accompanying and crucial procedural safeguards.” *Bowers v. NCAA*, 563 F. Supp. 2d 508, 532 (D.N.J. 2008) (internal quotation marks omitted).

“Under the Federal Rules of Evidence, a trial judge acts as a ‘gatekeeper’ to ensure that any and all expert testimony or evidence is not only relevant, but also reliable.” *Fineda v. Ford Motor Co.*, 520 F.3d 237, 243 (3d Cir. 2008) (quoting *Kannankeril v. Terminix Int’l, Inc.*, 128 F.3d 802, 806 (3d Cir. 1997)). The admissibility of such expert testimony is governed by *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993) and Federal Rule of Evidence 702. For expert testimony to be admitted: “(1) the proffered witness must be an expert, i.e., must be qualified; (2) the expert must testify about matters requiring scientific, technical or specialized knowledge, i.e., reliability; and (3) the expert’s testimony must assist the trier of fact, i.e., fit.” *United States v. Schiff*, 602 F.3d 152, 172 (3d Cir. 2010) (internal citation, quotation marks, and brackets omitted). In evaluating the reliability of a proffered expert’s testimony, the Third Circuit

has emphasized that “an expert’s testimony is admissible so long as the process or technique the expert used in formulating the opinion is reliable.” *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 742 (3d Cir. 1994) (internal citation omitted). An expert must base his or her opinion “on the ‘methods and procedures of science’ rather than on ‘subjective belief or unsupported speculation.’” *Id.* (quoting *Daubert*, 509 U.S. at 590). The party offering the expert testimony bears the burden of proving that the testimony is admissible, which requires proof, by a preponderance of the evidence, that the testimony is reliable. *Id.* at 744.

## **II. BIOGEN’S MOTIONS IN LIMINE**

### **A. Biogen’s Motion *in Limine* No. 2 (ECF No. 670)**

Biogen’s Motion *in Limine* No. 2 seeks to exclude evidence or arguments that any inference can be drawn against Biogen because of the absence at trial of Dr. Walter Charles Fiers—the sole named inventor on U.S. Patent No. 7,588,755 (the “755 patent”). For the following reasons, Biogen’s motion is granted.

“When a party knows of witnesses on a material issue and they are within his control to produce, if the party chooses to not call the witnesses, the fact finder may draw the inference that the testimony would have been unfavorable.” *A.B. Dick Co. v. Burroughs Corp.*, 798 F.2d 1392, 1400 n.9 (Fed. Cir. 1986) (citation omitted). An unfavorable inference may be drawn against a party from a witness’s absence where the witness is “peculiarly within [the party’s] power to produce,” *Graves v. United States*, 150 U.S. 118, 121 (1893), but may not be drawn from the lack of testimony by one who is equally available to be called by either party, *A.B. Dick*, 798 F.2d at 1400 n.9 (citation omitted). *See also United States v. Keplinger*, 776 F.2d 678, 702-03 (7th Cir. 1985) (noting that “where the witness appears to be equally available or unavailable to both sides” it is “well within the district court’s discretion to refuse to allow” argument on the significance of the witness’s absence). Moreover, an adverse inference applies in circumstances where “one can

infer from a party's conduct . . . a particular state of mind (i.e., a fear or belief that the evidence would be unfavorable to his or her position on an issue).” *United States v. Molina-Guevara*, 96 F.3d 698, 703 n.1 (3d Cir. 1996).

Biogen asserts that Dr. Fiers, who has refused to testify by deposition and at trial and is beyond the Court's subpoena power, is equally unavailable to all parties and not peculiarly within Biogen's power to produce. ECF No. 671 at 4-6. Biogen also contends that it does not have the requisite state of mind to support an adverse inference. *Id.* at 6-7. Biogen argues that any arguments based on Dr. Fiers's unavailability are irrelevant under Federal Rule of Evidence 402 and unfairly prejudicial under Federal Rule of Evidence 403. In response, Serono and Bayer contend that Dr. Fiers is not equally unavailable to all parties; rather, unlike Serono and Bayer, Biogen has a long-standing relationship with Dr. Fiers and a contractual right to require Dr. Fiers to assist in enforcing the '755 patent (including by testifying), yet has refused to invoke its right. ECF No. 765 at 12-14; ECF No. 776 at 6-8. Serono and Bayer seek to comment on Dr. Fiers's absence at trial; Bayer argues that the Court should also instruct the jury in Bayer's trial that it may draw an inference against Biogen from Dr. Fiers's absence. ECF No. 776 at 6; ECF No. 888 at 1.

This Court finds that Dr. Fiers appears to be equally unavailable to all parties. Although Serono and Bayer rely on Dr. Fiers's June 29, 1979 consulting agreement to support their argument that Dr. Fiers is peculiarly within Biogen's power to control, that agreement appears to merely require Dr. Fiers to execute documents for use in enforcing patents, and does not go as far as to obligate him to testify at trial. *See* ECF No. 829 at 3; ECF No. 703, Ex. 41 at BIMA0219089-219090. *See also Minebea Co., Ltd. v. Papst*, 370 F. Supp. 2d 302, 308-10 (D.D.C. 2005) (cautioning that jury would be instructed that adverse inference may be drawn from party's failure to produce inventors at trial where inventors' assignment agreements *explicitly* required them to

testify at the party's request). Moreover, Biogen has sufficiently detailed its efforts to obtain Dr. Fiers's testimony, efforts which appear to undercut a suggestion that Biogen "fear[ed] or belie[ved] that the [testimony] would be unfavorable to [its] position." *Molina-Guevara*, 96 F.3d at 703 n.1. Furthermore, were the Court to deny Biogen's motion, both sides presumably would argue at trial that Dr. Fiers's testimony would have been unfavorable to the other party, "which at least in a complex case like this one would allow the jury to speculate about the meaning of a great deal of non-evidence." *Keplinger*, 776 F.2d at 703. The Court "see[s] no constructive purpose to be served by such a procedure." *Id.*

Accordingly, Serono and Bayer are precluded from introducing at their respective trials evidence or arguments that any inference may be drawn against Biogen because of the absence of Dr. Fiers. In addition, Bayer's request for a missing witness instruction is denied.

**B. Biogen's Motion *in Limine* No. 3 (ECF No. 672)**

Biogen's Motion *in Limine* No. 3 seeks to exclude evidence or arguments regarding foreign language proceedings under Federal Rules of Evidence 402 and 403. For the following reasons, Biogen's motion is granted-in-part and denied-in-part.

The Federal Circuit has instructed that because the theories and laws of patentability and examination practices vary from country to country, district courts should exercise caution in extrapolating any consequences arising out of actions taken in a foreign proceeding. *See, e.g., Medtronic, Inc. v. Daig Corp.*, 789 F.2d 903, 907-08 (Fed. Cir. 1986) (rejecting as "specious" the argument that the Court should "adopt the conclusion of a German tribunal holding the . . . German counterpart patent obvious"); *Lindemann Maschinenfabrik GMBH v. Am. Hoist & Derrick Co.*, 730 F.2d 1452, 1458 n.2 (Fed. Cir. 1984) (finding it "meaningless" as to the issue of validity in the United States the fact that foreign counsel, who was prosecuting foreign counterpart, allegedly conceded that prior art anticipated foreign counterpart's claims); *In re Dulberg*, 472 F.2d 1394,

1398 (C.C.P.A. 1973).

Biogen asks the Court to preclude Serono and Bayer “from offering evidence or arguments regarding the foreign patent proceedings involving Dr. Fiers’s work.” ECF No. 673 at 2. Specifically, Biogen asserts that “legal assertions from foreign proceedings under foreign laws, and arguments about the significance of foreign procedures and foreign decisions,” including assertions in Dr. Fiers’s affidavit that Biogen submitted to the Canadian Patent Office in 2001 in connection with a Canadian patent proceeding (the “Fiers Affidavit”) and “other documents that necessarily depend on an application of foreign law as to what is ‘obvious,’ ‘inventive,’ or the like,” are irrelevant, prejudicial, and risk confusing the jury. *Id.* at 2-3. By contrast, Serono contends that Biogen’s statements in foreign legal tribunals, such as the Fiers Affidavit, are admissible and binding party admissions and “admissions of universal scientific fact” that directly relate to the issues in this case. ECF No. 766 at 1-8. Serono also argues that decisions by foreign patent offices, while not dispositive of the validity of U.S. counterparts, are nonetheless relevant, (*id.* at 9-10), and that the prejudice to Serono from granting Biogen’s motion would outweigh any potential prejudice to Biogen from denying the motion, (*id.* at 11-13). Bayer adopts and makes similar arguments to those presented in Serono’s opposition. ECF No. 779.

As discussed in the Court’s Opinion regarding Serono’s motion for summary judgment of invalidity under 35 U.S.C. § 103, there are genuine issues of material fact as to whether the Fiers Affidavit constitutes an admission by Biogen of the obviousness of the ’755 patent claims. ECF No. 892 at 9. The Court is disinclined to preclude sections of the Fiers Affidavit that Biogen characterizes as legal argument. Rather, a properly-instructed jury can decide what weight to give to, and what conclusions to draw from, the Fiers Affidavit or any other alleged prior admissions and/or inconsistent statements made by Dr. Fiers or Biogen, which this Court will permit Serono

and Bayer to present at their respective trials if otherwise permitted by the Federal Rules of Evidence. The Court agrees with Biogen, however, that informing the jury of the outcomes of foreign legal proceedings involving, and determinations reached by foreign tribunals regarding, Biogen's other patents and patent applications would risk unduly prejudicing Biogen. Therefore, Biogen's motion is granted in this respect for purposes of Serono's trial.<sup>2</sup> Nevertheless, evidence that is otherwise relevant and admissible or otherwise permitted by the Federal Rules of Evidence, for example, portions of the prosecution history developed before the U.S. Patent and Trademark Office ("PTO") or prior inconsistent testimony, is not excluded by this Order solely because such evidence may also have been part of a foreign patent proceeding.

**C. Biogen's Motion *in Limine* No. 4 (ECF No. 674)**

Biogen's Motion *in Limine* No. 4 seeks to exclude evidence or argument to the jury regarding inequitable conduct or other alleged misconduct before the PTO. For the following reasons, Biogen's motion is granted.

The Federal Circuit has made clear that inequitable conduct, "being entirely equitable in nature, is not an issue for a jury to decide." *Paragon Podiatry Labs., Inc. v. KLM Labs., Inc.*, 984 F.2d 1182, 1190 (Fed. Cir. 1993). "Nevertheless, district courts occasionally delegate aspects of the inequitable conduct inquiries to juries." *Rothman v. Target Corp.*, 556 F.3d 1310, 1322 (Fed. Cir. 2009).

Biogen asks this Court to restrict evidence and arguments about alleged inequitable conduct outside the presence of the jury, including evidence and arguments about the manner in

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<sup>2</sup> On December 8, 2017, Biogen withdrew its allegation of willful infringement against Serono. ECF No. 870. Biogen maintains its willfulness case against Bayer. Bayer contends that the disputed evidence at issue in Biogen's Motion *in Limine* No. 3 "is directly relevant to Bayer's state of mind in defense" of Biogen's willfulness claim. 12/12 Tr. at 111:12-15. Accordingly, the Court may address Bayer's contention prior to Bayer's trial.

which Biogen submitted information, particularly the Fiers Affidavit, to the PTO (i.e., Biogen's intent in prosecuting the '755 patent, alleged violations of PTO rules, and the PTO examiner's not having considered the Fiers Affidavit before issuing the patent). ECF No. 675 at 1, 12-13. Biogen contends that such evidence and arguments are highly prejudicial and irrelevant to invalidity. In response, Serono argues that nearly all of the evidence and arguments underlying its claim of inequitable conduct are directly relevant to its invalidity defense. ECF No. 767 at 1. Serono also contends that the Court in its discretion should ask the jury for an advisory verdict on inequitable conduct. *Id.* at 8-11. Serono further argues that any prejudice to Biogen may be addressed by a limiting jury instruction. *Id.* at 11-12. Bayer adopts Serono's arguments and emphasizes that even if evidence or arguments of inequitable conduct *per se* were excluded, "evidence of the conduct underlying the inequitable conduct defense should nonetheless be admitted," particularly the circumstances under which the Fiers Affidavit was submitted to the PTO. ECF No. 782 at 1.

Although the Court recognizes the advantages of using an advisory jury, on balance the Court finds that this option risks contaminating the jury's consideration of infringement and validity and would likely result in more time during the jury phase of the trial spent discussing limiting instructions. *See Patent Case Management Judicial Guide, Third Edition* § 8.1.1.1.1 (2016) ("[A]llegations of inventor misconduct before the USPTO relevant to an inequitable conduct defense, while irrelevant to infringement, may influence a jury's decision on that issue by suggesting that the inventor is untrustworthy."). In making their invalidity case at their respective trials, Serono and Bayer may argue to the jury that certain materials were or were not before the PTO during prosecution of the '755 patent. This ruling is consistent with the Supreme Court's discussion in *Microsoft Corp. v. i4i Ltd. Partnership*, 564 U.S. 91, 111 (2011) ("When warranted, the jury may be instructed to consider that it has heard evidence that the PTO had no opportunity



to evaluate before granting the patent.”). The issue of validity does not, however, “warrant findings of whether the examiner ‘really did understand what he was ruling,’” and “[i]ntrospection and speculation into the examiner’s understanding of the prior art or the completeness or correctness of the examination process is not part of the objective review of patentability.” *Norian Corp. v. Stryker Corp.*, 363 F.3d 1321, 1329 (Fed. Cir. 2004) (finding that district court erred in “instructing the jury that the presumption of validity varied with the jury’s view of whether the examiner . . . did not properly focus on the prior art”) (internal quotation marks omitted).

Accordingly, as stated above, in presenting their cases on invalidity, Serono and Bayer may argue to the jury that certain materials, including the Fiers Affidavit, were or were not before the PTO during prosecution of the ’755 patent. However, Serono and Bayer are precluded from introducing at their respective trials evidence or arguments to the jury regarding inequitable conduct or other alleged misconduct before the PTO, including, *inter alia*, arguments that Biogen allegedly withheld certain information from the PTO, including the fact that Dr. Cate was not a person of ordinary skill in the art (“POSA”), evidence or arguments about the state of mind and intent of Biogen and its prosecuting attorneys in prosecuting the ’755 patent, and evidence or arguments about alleged violations or non-compliance with PTO rules by Biogen’s prosecuting attorneys or other witnesses. During each trial, on dates to be decided by the Court and the parties, the Court will hear evidence and argument regarding inequitable conduct after the jury has been dismissed for the day.

**D. Biogen’s Motion *in Limine* No. 5 (ECF No. 676)**

Biogen’s Motion *in Limine* No. 5 seeks to preclude expert testimony on the governing law or ultimate conclusions of law. For the following reasons, Biogen’s motion is denied.

“Although Federal Rule of Evidence 704 permits an expert witness to give expert testimony that ‘embraces an ultimate issue to be decided by the trier of fact,’ an expert witness is prohibited

from rendering a legal opinion.” *Berkeley Inv. Grp., Ltd. v. Colkitt*, 455 F.3d 195, 217 (3d Cir. 2006). Moreover, “[a]lthough courts typically forbid parties from calling ‘legal experts’ to testify about the requirements of the law, technical experts are not forbidden from offering opinions on technical matters that lead them to particular conclusions that bear on ultimate issues in the case,” and “patent law experts are frequently permitted to testify about matters such as general practices and procedures employed by the PTO in examining or reexamining patents.” *Sonos, Inc. v. D&M Holdings Inc.*, No. 14-1330, 2017 WL 4969328, at \*4 (D. Del. Nov. 1, 2017).

Biogen contends that testimony from experts regarding the law or what legal conclusions the fact-finder should reach is irrelevant, unhelpful, prejudicial, and would usurp the role of the Court to instruct the jury on the law. ECF No. 677. Biogen does not seek to exclude testimony regarding PTO standards and practices. ECF No. 833 at 5; 12/12 Tr. at 161:8-12. Serono opposes Biogen’s request as vague, overbroad, and unworkable, and contends that expert testimony regarding the legal standards and concepts applied in reaching the experts’ opinions is admissible and helpful to the jury. ECF No. 768. Bayer adopts Serono’s arguments. ECF No. 784.

As an initial matter, the parties appear to agree that expert testimony regarding PTO standards and practices is not precluded. The parties also appear to agree that no one will seek to introduce expert testimony “tell[ing] the jury what to conclude.” ECF No. 768 at 2. Beyond that, the Court rejects the notion that witnesses cannot, if otherwise appropriate, opine on an ultimate issue. *See* Fed. R. Evid. 704(a). Biogen’s motion is unduly broad and general, and a blanket pretrial ruling applying Federal Rule of Evidence 403 to all potential ultimate issue testimony would be inappropriate and unworkable. Rather, objections to particular proffers of evidence could be appropriate and will be assessed as raised at trial. Accordingly, the Court denies Biogen’s motion subject to appropriate renewals at trial.

**E. Biogen's Motion *in Limine* No. 6 (ECF No. 678)**

Biogen's Motion *in Limine* No. 6 seeks to exclude evidence or arguments that regulatory standards are relevant to or probative of patentability. For the following reasons, Biogen's motion is denied.

Biogen moves the Court to preclude Serono and Bayer from introducing evidence or argument that compliance with U.S. Food and Drug Administration ("FDA") or other regulatory standards for safety, efficacy, and purity are relevant to or probative of patentability, and that Dr. Fiers did not develop a polypeptide that is suitable for administration to human patients or conduct a clinical trial, on the ground that such evidence and argument "has a substantial likelihood of confusion, undue delay, and unfair prejudice." ECF No. 679 at 4, 9. Specifically, Biogen seeks to preclude evidence or argument that fusion proteins are immunogenic, that Dr. Fiers did not conduct clinical trials, that Dr. Fiers failed to meet Goal 5 of Biogen's and Dr. Fiers's Project Agreement, and regarding Serono's and Bayer's independent development of their products. *See* 12/12 Tr. at 59:2-65:9.

In response, Serono argues that such evidence is relevant to validity because, *inter alia*, "[e]vidence that the claims cover therapeutically *ineffective* polypeptides," where the claims require administering polypeptides in a "therapeutically effective amount," shows that the specification "fails to enable an ordinarily-skilled person to make and use the claimed invention." ECF No. 765 at 4 (emphasis in original). Serono also contends that evidence that "Dr. Fiers failed to make a protein that could be used for clinical trials, let alone sold commercially," is relevant to the damages inquiry. *Id.* at 4-5. Bayer adopts Serono's arguments and explains how the evidence Biogen seeks to preclude is relevant to its own invalidity and damages defenses. ECF No. 787.

As an initial matter, the parties appear to agree that no one may argue to the jury that FDA

approval, or meeting FDA or other regulatory standards, is dispositive of the legal requirements of patentability. The Court is persuaded, however, that the probative value of the disputed evidence—namely, that fusion proteins are immunogenic, that Dr. Fiers did not conduct clinical trials, that Dr. Fiers failed to meet Goal 5 of Biogen’s and Dr. Fiers’s Project Agreement, and regarding Serono’s and Bayer’s independent development of their products—to various issues in this case, including written description, enablement, secondary considerations of non-obviousness (e.g., long-felt need and commercial success), and damages, outweighs the purported prejudice to Biogen. Biogen’s concerns may be more appropriately addressed through cross-examination and limiting jury instructions, rather than a blanket pretrial ruling.

**F. Biogen’s Motion *in Limine* No. 7 (ECF No. 680)**

Biogen’s Motion *in Limine* No. 7 seeks to exclude evidence or arguments regarding Serono’s and Bayer’s patents that purport to cover their accused products. For the following reasons, Biogen’s motion is denied.

“[T]he existence of one’s own patent does not constitute a defense to infringement of someone else’s patent.” *Bio-Tech. Gen. Corp. v. Genentech, Inc.*, 80 F.3d 1553, 1559 (Fed. Cir. 1996). A defendant’s own patent on its accused product is “evidence not material to the issue of infringement.” *Fiskars, Inc. v. Hunt Mfg. Co.*, 221 F.3d 1318, 1324 (Fed. Cir. 2000). However, such evidence may serve legitimate purposes. For example, “the figures or description contained in an accused infringer’s patent may help the jury understand aspects of the accused products better than any other piece of evidence available,” which “may be important where the technology is particularly complex or abstract.” Patent Case Management Judicial Guide, Third Edition § 7.5.1.3 (2016).

Biogen moves to preclude evidence and arguments about Serono’s and Bayer’s patents covering accused products Rebif<sup>®</sup>, Betaseron<sup>®</sup>, and Extavia<sup>®</sup> on the ground that such evidence is

irrelevant to the question of whether those products infringe the '755 patent claims. ECF No. 681 at 1. Biogen also contends that such evidence would be distracting and likely create jury confusion. *Id.* at 6. Biogen further asserts that the “same information underlying scientific work” by Serono and Bayer “can be presented through other means without creating confusion, distraction, and prejudice.” ECF No. 850 at 2.

In response, Serono contends that its own patents are relevant to secondary considerations of non-obviousness, written description, enablement, damages, and indirect infringement. ECF No. 769 at 2-6, 7-9. Serono also argues that Serono’s patents are “inextricably linked to Serono’s work on the product Biogen accuses of infringement,” Rebif<sup>®</sup>, and that Serono would be prejudiced by the exclusion of evidence regarding those patents. *Id.* at 6. Serono further contends that the probative evidentiary value of its patents outweighs any potential for prejudice or confusion, and that any prejudice or confusion can be overcome by a limiting instruction. *Id.* at 9. Bayer adopts Serono’s arguments and presents similar arguments. ECF No. 790.

The Court finds that a blanket pretrial ruling precluding evidence or argument regarding Serono’s and Bayer’s patents for any and all purposes is inappropriate. Both Serono and Bayer have identified legitimate purposes for introducing their own patents, including with respect to secondary considerations of non-obviousness, and neither intends to argue at its trial that patents on its product(s) constitute a defense to infringement. The Court can head off any jury confusion by employing appropriate jury instructions. In particular, the parties should include in their proposed final jury instructions an instruction that ensures the jury will not mistakenly conclude that Serono and Bayer cannot infringe the '755 patent claims solely because they have their own patents.

**G. Biogen's Motion *in Limine* No. 9 (ECF No. 684)**

Biogen's Motion *in Limine* No. 9 seeks to exclude evidence or arguments regarding Biogen not seeking injunctive relief.<sup>3</sup> For the following reasons, Biogen's motion is granted as to Serono.

Biogen seeks an order precluding "Defendants from presenting evidence or arguments about (1) Biogen not seeking, or being unwilling to seek, an injunction against Defendants' infringing activity; (2) Biogen's willingness to license the '755 Patent rather than enjoin Defendants' infringing activity; and (3) the harm to the patient community and Biogen's reputation amongst doctors and patients if Biogen were to exclude Defendants' accused products from the marketplace." ECF No. 685 at 9. Biogen contends that such evidence and arguments are irrelevant to the determination of lost profits and a reasonable royalty, prejudicial to Biogen, would lead to jury confusion, and would waste time.

Serono does not oppose Biogen's motion pertaining to "Biogen not seeking, or being unwilling to seek, an injunction against Defendants' infringing activity" or "the harm to the patient community and Biogen's reputation amongst doctors and patients if Biogen were to exclude Defendants' accused products from the marketplace." 12/12 Tr. at 195:14-196:3. Serono "reserves the right to assert all other evidence and arguments not the subject of Biogen's Motion *in Limine* No. 9," such as "those regarding the parties' Nonsuit and Option Agreement, including but not limited to the fact that Biogen could not have taken Serono's product off the market because it was under a binding obligation to grant Serono a license under the Nonsuit and Option

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<sup>3</sup> Biogen's Motions *in Limine* Nos. 9 and 10 are administratively terminated as to Bayer. ECF No. 866. Previously, by agreement of the parties, Bayer did not file oppositions to these motions because they "apply differently to Serono and Bayer such that the Court should defer consideration of the motion as to Bayer." ECF Nos. 740, 817.

Agreement.”<sup>4</sup> ECF No. 771 at 1.

Following oral argument, it appears that the dispute focuses on whether Serono may present argument regarding “Biogen’s willingness to license the ’755 Patent rather than enjoin Defendants’ infringing activity” as part of its damages defense based on the Nonsuit and Option Agreement. As discussed below regarding Biogen’s Motion *in Limine* No. 10, the Court will permit Serono to introduce evidence and argument regarding the parties’ Nonsuit and Option Agreement. Accordingly, the Court grants Biogen’s motion, and the parties may propose a limiting jury instruction on this subject in light of the Court’s ruling on Biogen’s Motion *in Limine* No. 10.

**H. Biogen’s Motion *in Limine* No. 10 (ECF No. 686)**

Biogen’s Motion *in Limine* No. 10 seeks to exclude evidence or arguments regarding the Nonsuit and Option Agreement. For the following reasons, Biogen’s motion is denied as to Serono.

Biogen moves to preclude Serono and Bayer from offering evidence or argument regarding the Nonsuit and Option Agreement in connection with the jury’s assessment of lost profits or calculation of a reasonable royalty. ECF No. 687 at 1. With respect to the lost-profits analysis, Biogen relies on the arguments made in its opposition to Serono’s summary judgment motion on lost profits. With respect to the reasonable-royalty analysis, Biogen contends that the Nonsuit and Option Agreement is not “comparable to [licenses and agreements] that which would be negotiated in the hypothetical negotiation.” *Id.* at 5. Biogen also asserts that allowing Serono and Bayer to

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<sup>4</sup> During oral argument, Serono reiterated that it “wants to make sure that it can offer or argue that Biogen would not have been able to keep Serono off the market because of the Nonsuit and Option Agreement,” which in Serono’s view “goes to the ability to seek an injunction.” 12/12 Tr. at 195:19-23. *See also id.* at 196:7-10 (“Serono just wants to argue that Biogen was willing to license every potential infringer, which is directly relevant to the reasonable royalty analysis . . .”).

present such evidence and arguments “would cause substantial danger of unfair prejudice, confusion, misleading the jury and waste of time, all in violation of Federal Rule of Evidence 403.” *Id.* at 8.

By contrast, Serono contends that it does not rely on the Nonsuit and Option Agreement as “comparable” to a license resulting from the hypothetical negotiation. ECF No. 772 at 4-6. Instead, according to Serono, its expert’s opinions are based “on the *established fact* that Serono and Biogen had already agreed in the 2000 Option Agreement that Serono would pay for a license to the ’755 patent,” and that Serono’s contractual right under the agreement to take a license is the “*single most important fact* in this case relating to damages.” *Id.* at 1-2 (emphasis added). Serono also contends that the jury must be explicitly instructed regarding Biogen’s alleged obligation to give Serono a license at Serono’s discretion, at a pre-negotiated rate. *Id.* at 6. Serono further asserts that the Nonsuit and Option Agreement is relevant to other issues, including induced infringement. *Id.* at 11.

In its Opinion denying Serono’s motion for partial summary judgment as to Biogen’s claim of lost profits, this Court indicated that Serono’s argument that a decision by Serono to exercise its option may constitute a non-infringing alternative is not foreclosed by case law and may proceed to trial. ECF No. 884 at 10. The Court finds that the Nonsuit and Option Agreement’s relevance to at least Serono’s damages defenses outweighs the purported prejudice to Biogen, and the case law upon which Biogen relies does not support the exclusion of such evidence.

### **III. SERONO’S MOTIONS IN LIMINE**

#### **A. Serono’s Motion *in Limine* No. 1 (ECF No. 692)**

Serono’s Motion *in Limine* No. 1 seeks to preclude Biogen from offering opinion testimony at trial from Biogen’s co-founder and fact witness Dr. Philip Sharp. Bayer joined Serono’s motion. ECF No. 726. For the following reasons, Serono’s motion is denied.



Federal Rule of Evidence 701 provides that “[i]f a witness is not testifying as an expert, testimony in the form of an opinion is limited to one that is: (a) rationally based on the witness’s perception; (b) helpful to clearly understanding the witness’s testimony or to determining a fact in issue; and (c) not based on scientific, technical, or other specialized knowledge within the scope of Rule 702.” Fed. R. Evid. 701.

Serono moves to preclude Biogen from eliciting “undisclosed opinion testimony” on “scientific or technical matters” by Dr. Sharp. ECF No. 692-1 at 1, 4. According to Serono, Dr. Sharp was never designated as an expert witness, did not provide an expert report, and did not sit for an expert deposition in this case. *Id.* at 1. Serono also contends that it will be “especially prejudiced by opinion testimony from Dr. Sharp, because a jury will be particularly susceptible to influence when it hears scientific testimony from a Nobel Prize-winning scientist.” *Id.* at 3. Serono further asserts that Dr. Sharp should be precluded from testifying about the “state of the art outside Biogen in the 1980s.” ECF No. 832 at 5. Biogen contends that it will not elicit expert opinion testimony from Dr. Sharp, who will instead testify solely as a fact witness regarding what he himself perceived, knew, or otherwise witnessed. ECF No. 760 at 1. Biogen also asserts that it may be proper for fact witnesses to testify about facts known to them personally even if they involve “scientific, technical, or other specialized knowledge.” *Id.* at 5.

Pursuant to Rule 701, no party may introduce at trial opinion testimony of a non-expert witness on scientific matters. Each party shall instruct its fact witnesses that they are not to offer opinion testimony. Although the Court understands Serono’s concern that some of the testimony Biogen may intend to elicit through examination of Dr. Sharp would constitute impermissible expert testimony, this is an issue best addressed in specific circumstances as they arise during trial. Accordingly, Serono’s motion is denied without prejudice to Serono or Bayer objecting to

individual questions of Dr. Sharp at their respective trials.

**B. Serono's Motion *in Limine* No. 3 (ECF No. 694)**

Serono's Motion *in Limine* No. 3 seeks to exclude evidence and argument concerning any allegation that Serono withheld data from the FDA, or any other alleged misconduct or malfeasance in Serono's dealings with the FDA. For the following reasons, Serono's motion is granted.

Serono contends that Biogen will seek to present at trial evidence and argument "falsely accusing Serono of withholding from FDA data" from the two-year extension of the PRISMS<sup>5</sup> clinical study, which was conducted prior to approval of Serono's Rebif<sup>®</sup> in 2002, for the purpose of "stain[ing] Serono's character." ECF No. 694-1 at 1-2. Serono asserts that such evidence and argument are irrelevant to any issue in the case, unduly prejudicial to Serono, would cause undue delay, and would waste time at trial. *Id.* at 2-3; ECF No. 834 at 2-4. Serono also points out that the disputed data has been publicly available since 2001 and that Serono made the FDA aware of the data in 2001. 12/15 Tr., ECF No. 899 at 59:22-25, 68:19-69:6, 71:21-25. Serono further contends that Biogen has not identified any fact witnesses to testify concerning, and none of its damages experts have opined about, Serono's alleged withholding of data. *Id.* at 60:2-7, 63:15-22.

In response, Biogen contends that evidence concerning Serono's alleged withholding of data from the FDA is relevant to Biogen's lost-profits damages claim. ECF No. 761 at 1-2. According to Biogen, if in support of its defense against lost profits Serono argues that the FDA found that Rebif<sup>®</sup> is "clinically superior" to Biogen's Avonex<sup>®</sup>, then Biogen should be permitted

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<sup>5</sup> PRISMS stands for "Prevention of Relapses and Disability of Interferon- $\beta$ -1a Subcutaneously in Multiple Sclerosis." ECF No. 761 at 3.

to “tell the jury the whole story.” *Id.* at 8.

The Court finds that granting Biogen’s motion would likely result in the jury speculating as to whether the allegedly-withheld data would have impacted or changed the FDA’s “clinical superiority” findings regarding Rebif®. The Court sees no constructive purpose to be served by proceeding in such a manner. In addition, any probative value of the disputed evidence to Biogen’s lost-profits claim is substantially outweighed by the prejudice to Serono and undue delay that would likely result from its introduction. Fed. R. Evid. 403.

**C. Serono’s Motion in Limine No. 4 (ECF No. 695)**

Serono’s Motion in Limine No. 4 seeks to preclude Biogen from introducing or relying on statements by Dr. Fiers in a 2009 journal article entitled “Cloning and Expression of Human Interferon-β: From BC to AC” published by the Royal Academy of Medicine in Belgium (the “Fiers Retrospective”) to prove the truth of those statements. Bayer joined Serono’s motion. ECF No. 726. For the following reasons, Serono’s motion is denied.

Federal Rule of Evidence 801(c) defines hearsay as “a statement, other than one made by the declarant while testifying at the trial or hearing, offered in evidence to prove the truth of the matter asserted.” Fed. R. Evid. 801(c). Federal Rule of Evidence 703 provides, in relevant part, that “[a]n expert may base an opinion on facts or data in the case that the expert has been made aware of or personally observed” and that “[i]f experts in the particular field would reasonably rely on those kinds of facts or data in forming an opinion on the subject, they need not be admissible for the opinion to be admitted.” Fed. R. Evid. 703.

Serono contends if Biogen seeks to offer the statements in the Fiers Retrospective for the truth of the matters asserted, those statements are “textbook hearsay” to which no exception applies. ECF No. 695-1 at 1. Serono asserts that it would be unfair to permit Biogen, through its experts, to rely on Dr. Fiers’s unsworn, out-of-court statements directly pertaining to the ’755

patent's validity in an article that Serono cannot cross-examine. *Id.* at 2. In opposition, Biogen points out that Serono seeks to admit hundreds of journal articles without calling their authors to testify at trial while only objecting to the admissibility of the Fiers Retrospective. ECF No. 762 at 6. Biogen also asserts that pursuant to Federal Rule of Evidence 703, its experts can, "within the scope of their expertise, rely on the Fiers Retrospective as one piece of evidence supporting their opinions." *Id.* at 8.

Biogen does not seek to admit the Fiers Retrospective into evidence. 12/15 Tr., ECF No. 899 at 88:13-19. In addition, Serono does not dispute that the Fiers Retrospective is a document that would be reasonably relied upon by experts in the field, and does not seek to exclude the expert opinions that are based on the Fiers Retrospective. *Id.* at 90:25-91:1. The Court finds that the disputed expert testimony falls within the ambit of Rule 703 in that the experts would reasonably rely on the Fiers Retrospective in forming their opinions. Accordingly, expert testimony in reliance on and pertaining to the Fiers Retrospective is admissible.

**D. Serono's Motion *in Limine* No. 5 (ECF No. 696)**

Serono's Motion *in Limine* No. 5 seeks to preclude evidence and argument regarding the validity of the '755 patent in Biogen's case-in-chief. Bayer joined Serono's motion. ECF No. 726. For the following reasons, Serono's motion is granted.

Serono contends that evidence regarding the validity of the '755 patent is "properly presented in the first instance in Serono's case-in-chief, not Biogen's" given that Serono bears the burden of proving invalidity at trial. ECF No. 696-1 at 1. Serono asserts that it would be fundamentally unfair and prejudicial to Serono, and confusing to the jury, if Biogen were permitted to introduce rebuttal evidence to Serono's invalidity case prior to Serono presenting its invalidity case to the jury. *Id.* at 1, 3. Serono asks specifically that the work of non-Biogen scientists, including Drs. Goeddel and Taniguchi, that is not explicitly set forth in the '755 patent

specification be excluded from Biogen's case-in-chief.

In response, Biogen contends that, although it does not intend to present rebuttal evidence of validity in its case-in-chief, "[s]ome of the evidence that bears on validity, however, also bears on infringement and on damages," issues that Biogen will present first at trial. ECF No. 763 at 1. Biogen also asserts that it will need to "provide the jury with a technical background of the invention, to explain what the claims cover, to explain why Serono infringes those claims through its sales of Rebif, and to explain the importance of the '755 Patent invention to Rebif and its therapeutic use." *Id.* at 3.

The Court grants Serono's motion and will preclude Biogen from offering evidence or argument regarding the validity of the '755 patent in its case-in-chief. However, nothing in this Order shall preclude Biogen from introducing evidence or argument in its case-in-chief regarding the production of recombinant interferon- $\beta$  in *E. coli* and other work by non-Biogen scientists and other background information that is described in the '755 patent specification. During oral argument, Serono indicated its agreement that Biogen may present in its case-in-chief evidence and argument regarding non-Biogen scientists' work and other information set forth in the patent. 12/15 Tr., ECF No. 899 at 104:24-105:1, 106:20-22.

**E. Serono's Motion *in Limine* No. 6 (ECF No. 697)**

Serono's Motion *in Limine* No. 6 seeks to exclude evidence and argument that contradicts certain prior sworn statements by Biogen. Bayer joined Serono's motion. ECF No. 726. For the following reasons, Serono's motion is denied.

Serono contends that Biogen should not be permitted to present evidence or argument that contradicts Biogen's prior sworn statements, specifically the statements in the Fiers Affidavit. ECF No. 697-1. Serono takes the position that "[a] patentee specifically cannot, in U.S. litigation, contradict prior submissions made in foreign tribunals." *Id.* at 3. In opposition, Biogen contends

that it has “no intention of contradicting the factual assertions” in the Fiers Affidavit, (ECF No. 764 at 2), and reiterates the arguments it made in opposition to Serono’s summary judgment motion regarding obviousness.

As the Court discussed in its Opinion denying Serono’s motion for summary judgment under 35 U.S.C. § 103, (ECF No. 892 at 9), and above with respect to Biogen’s Motion *in Limine* No. 3, there are genuine issues of material fact regarding whether the Fiers Affidavit is a binding admission by Biogen of the obviousness of the ’755 patent claims. For the same reasons discussed in the Court’s prior Opinion, Serono’s motion is denied.

**F. Serono’s *Daubert* Motion (ECF No. 699)**

Serono’s *Daubert* Motion seeks to exclude the testimony of Biogen’s damages expert, Dr. Kevin M. Murphy.<sup>6</sup> For the following reasons, Serono’s motion is denied.

Serono contends that Dr. Murphy’s opinions are unreliable because he failed to consider the Nonsuit and Option Agreement and Serono’s ongoing right to exercise its option as part of his damages analyses. ECF No. 699-1. Specifically, Serono asserts that Dr. Murphy’s lost-profits opinions should be excluded because, in reconstructing the hypothetical market that would have existed absent infringement, he assumes that Serono would have removed Rebif<sup>®</sup> from the market when the ’755 patent issued in September of 2009. *Id.* at 9. According to Serono, such an assumption is contrary to the Federal Circuit’s decision in *Grain Processing Corp. v. Am. Maize-Products Co.*, 185 F.3d 1341 (Fed. Cir. 1999), and therefore renders his market reconstruction “factually and legally erroneous.” *Id.* at 10. Serono also contends that Dr. Murphy’s alternative reasonable-royalty opinions should be excluded because he disregarded the parties’ pre-

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<sup>6</sup> Biogen retained another damages expert, Dr. Fintan Walton. Serono does not seek to preclude Dr. Walton’s opinions. ECF No. 780 at 8-9.

determined royalty rates in the Nonsuit and Option Agreement and instead “recasts” Biogen’s lost profits as a reasonable royalty. *Id.* at 11 n.8. Serono further asserts that Dr. Murphy’s damages analyses impermissibly attempt to punish Serono, in contravention of “fundamental damages law.” *Id.* at 13.

By contrast, Biogen reiterates the arguments it made in opposition to Serono’s lost-profits summary judgment motion—namely, that the Nonsuit and Option Agreement does not preclude, and is irrelevant to, Biogen’s lost-profits claim. ECF No. 780 at 3-4. Biogen also contends that Dr. Murphy’s reasonable-royalty analysis employed the same methodology endorsed by Federal Circuit precedent and previously used by Serono’s own expert, Dr. Christopher Velturo, in a separate patent litigation. *Id.* at 6-8. Biogen further contends that, contrary to Serono’s assertion, and unlike the expert whose testimony regarding a reasonable royalty was excluded in *Intellectual Ventures I LLC v. Xilinx, Inc.*, No. 10-1065, 2014 WL 1814384 (D. Del. Apr. 14, 2014), Dr. Murphy did, in fact, consider the Nonsuit and Option Agreement as part of his damages analysis—namely, he determined that the agreement was not a “comparable agreement” to be included in a hypothetical negotiation analysis. *Id.* at 8.

As the Court held in its Opinion denying Serono’s summary judgment motion, whether the Nonsuit and Option Agreement provides a non-infringing alternative is a disputed issue to be decided at trial. ECF No. 884 at 10-11. Serono’s disagreement with Dr. Murphy’s damages opinions goes to the weight to be afforded to those opinions, not to their admissibility. Both sides may present testimony in support of their positions on lost profits and reasonable-royalty damages. Accordingly, Serono’s *Daubert* motion is denied.

#### **IV. BAYER’S MOTIONS IN LIMINE**

##### **A. Bayer’s Motion *in Limine* No. 5 (ECF No. 710)**

Bayer’s Motion *in Limine* No. 5 seeks to exclude evidence or argument by Biogen that

various facts relating to PTO proceedings in any way bear on the validity of the '755 patent. Serono joined Bayer's motion. ECF No. 727. For the following reasons, Bayer's motion is granted-in-part and denied-in-part.

Expert opinion that is inconsistent with the governing law is not admissible. *Herbert v. Lisle Corp.*, 99 F.3d 1109, 1117 (Fed. Cir. 1996). In addition, experts may not testify as to a patent examiner's state of mind. *Abbott Biotech. Ltd. v. Centocor Ortho Biotech, Inc.*, No. 09-40089, 2014 WL 7330777, at \*8 (D. Mass. Dec. 19, 2014).

Bayer contends that Biogen should not be allowed to argue that the PTO's April 15, 1982 restriction requirement<sup>7</sup> on U.S. Application No. 06/250,609 (the "'609 application"), to which the '755 patent claims priority, is substantive evidence of validity of the '755 patent claims. ECF No. 710-1 at 2. According to Bayer, the Federal Circuit in *Biogen MA, Inc. v. Japanese Foundation for Cancer Research*, 785 F.3d 648 (Fed. Cir. 2015), *cert. denied*, No.15-607, 136 S. Ct. 1450 (Mar. 21, 2016), rejected Biogen's argument that the restriction requirement is evidence that the subject matter in one restriction group is patentably distinct from subject matter in a different restriction group. *Id.* Bayer also contends that evidence or argument regarding the restriction requirement would prolong and complicate the trial, prejudice Bayer, and mislead the jury. *Id.* at 6. Bayer further argues that evidence or arguments that the declaration or non-declaration of interference proceedings is relevant to validity should similarly be excluded. *Id.* at 6-7. Bayer

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<sup>7</sup> Section 121 of Title 35 of the U.S. Code provides, in relevant part: "If two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions." 35 U.S.C. § 121. *See also* 37 C.F.R. § 1.142(a) ("If two or more independent and distinct inventions are claimed in a single application, the examiner in an Office action will require the applicant in the reply to that action to elect an invention to which the claims will be restricted, this official action being called a requirement for restriction (also known as a requirement for division).").



also contends that evidence or argument suggesting that the PTO examiner considered information or prior art not cited in the '755 patent's prosecution history (for example, laboratory notebooks documenting other scientists' work on interferon- $\beta$ ) should be excluded. According to Bayer, Biogen's experts should not be "permitted to speculate concerning what [the PTO examiner] considered beyond the materials in the prosecution history," and that there is a risk the jury may be misled to believe that the examiner considered and rejected certain of Bayer's invalidity defenses that are based on such materials. *Id.* at 7-12. Serono echoes Bayer's arguments but, unlike Bayer, Serono does not seek to exclude from evidence any portion of the '755 patent's prosecution history, including the restriction requirement or interference proceedings. ECF No. 841; 12/13 Tr. at 144:13-17.

In response, Biogen asserts that it "will not argue that the restriction requirement is itself proof of patentable distinctness" or that the restriction requirement is "substantive evidence that the separately restricted claims are, as a matter of law, patentably distinct." ECF No. 791 at 7. Instead, Biogen states that it will argue, consistent with the Federal Circuit's *Biogen* decision, that the restriction requirement evidences that the PTO examiner, who is deemed to be a POSA, believed that the claims to the DNA, claims to the protein, and claims to the methods of treatment "can support separate patents." *Id.* at 6-7. Biogen also argues that *Biogen* does not preclude an argument that the fact that the PTO did not declare an interference to determine who was the first to invent method-of-treatment claims evidences that the PTO believed that Dr. Fiers was the first to invent those claims. *Id.* at 11-12. Biogen further contends that given the PTO examiner who prosecuted the '755 patent was also involved in prosecuting the other scientists' patent applications, and that the '755 patent lists several references regarding the other scientists' work that were cited by the examiner, Biogen may argue that the examiner was aware of those scientists'

work. *Id.* at 12-13.

The Court will not preclude from evidence any section of the '755 patent's prosecution history, including the PTO's April 1982 restriction requirement and interference proceedings. The restriction requirement is admissible for the purpose of explaining why Biogen subsequently filed separate divisional applications with respect to the method-of-treatment, polypeptide, and DNA claims. Beyond that, however, the Court agrees with Bayer and Serono that the risks of unfair prejudice and jury confusion outweigh the probative value of the disputed evidence. Accordingly, Biogen may not argue that the restriction requirement is itself proof of patentable distinctness or is "substantive evidence" that the separately restricted claims are patentably distinct. The parties should include in their proposed final jury instructions the purposes for which the jury may consider the restriction requirement and interference proceedings. Furthermore, Biogen shall not present any evidence or argument that the PTO examiner was aware of or considered materials that are not cited in the prosecution history of the '755 patent, including the work of third-party scientists.

**B. Bayer's Motion *in Limine* No. 6 (ECF No. 712)**

Bayer's Motion *in Limine* No. 6 seeks to preclude any suggestion at trial that the issuance of U.S. Patent No. 9,376,478 (the "'478 patent") on June 28, 2016 to Dr. Taniguchi's research group is evidence that the recombinant expression of the interferon- $\beta$  polypeptide is non-obvious over the DNA encoding interferon- $\beta$ .<sup>8</sup> Bayer contends that such evidence should be excluded under Federal Rules of Evidence 402 and 403. Serono joined Bayer's motion. ECF No. 727. For the following reasons, Bayer's motion is denied.

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<sup>8</sup> Bayer and Serono do not contend that the '478 patent itself should be excluded from evidence.

Bayer and Serono contend that evidence that the recombinant expression of the interferon- $\beta$  polypeptide is non-obvious over the DNA encoding interferon- $\beta$  is irrelevant and would likely confuse the jury. ECF No. 712-1; ECF No. 842. In their view, Biogen's alleged efforts to have the jury find non-obviousness "by analogy" or "by proxy" is improper. 12/13 Tr. at 183:1-14. In response, Biogen contends that the fact that the '478 patent (which claims the recombinant interferon- $\beta$  polypeptide) issued separately from another of Dr. Taniguchi's patents, U.S. Patent No. 5,326,859 (the "'859 patent") (which claims the DNA for interferon- $\beta$ ), is "compelling proof" that those are "independent inventions." ECF No. 794 at 1. Thus, according to Biogen, "if the protein is not obvious over the DNA, then a method of treatment using the protein likewise cannot be obvious over the DNA." *Id.*

The Court agrees with Biogen that the probative value of the evidence outweighs any prejudice to Bayer or Serono. The Court agrees with Biogen that evidence and argument regarding the '478 patent is relevant to Biogen's rebuttal on invalidity and may aid the jury in understanding the background of the development of recombinant interferon- $\beta$ . In addition, Biogen has indicated that its proposed discussion of the '478 patent will not unduly delay proceedings during trial. *See* 12/13 Tr. at 198:18-199:12. Biogen also indicated a desire to use the '478 patent to cross-examine third-party fact witness, Dr. Taniguchi, who Serono plans to bring to trial. *Id.* at 213:16-214:22. The Court finds that Bayer's and Serono's concerns about Biogen's potential arguments based on the '478 patent go to weight, not admissibility.

Accordingly,

**IT IS** on this 12<sup>th</sup> day of January, 2018,

**ORDERED** that Biogen's Motion *in Limine* No. 2 (ECF No. 670) is **GRANTED**; it is further

**ORDERED** that Biogen's Motion *in Limine* No. 3 (ECF No. 672) is **GRANTED-IN-PART** and **DENIED-IN-PART**; it is further

**ORDERED** that Biogen's Motion *in Limine* No. 4 (ECF No. 674) is **GRANTED**; it is further

**ORDERED** that Biogen's Motion *in Limine* No. 5 (ECF No. 676) is **DENIED**; it is further

**ORDERED** that Biogen's Motion *in Limine* No. 6 (ECF No. 678) is **DENIED**; it is further

**ORDERED** that Biogen's Motion *in Limine* No. 7 (ECF No. 680) is **DENIED**; it is further

**ORDERED** that Biogen's Motion *in Limine* No. 9 (ECF No. 684) is **GRANTED** as to Serono; it is further

**ORDERED** that Biogen's Motion *in Limine* No. 10 (ECF No. 686) is **DENIED** as to Serono; it is further

**ORDERED** that Serono's Motion *in Limine* No. 1 (ECF No. 692) is **DENIED**; it is further

**ORDERED** that Serono's Motion *in Limine* No. 3 (ECF No. 694) is **GRANTED**; it is further

**ORDERED** that Serono's Motion *in Limine* No. 4 (ECF No. 695) is **DENIED**; it is further

**ORDERED** that Serono's Motion *in Limine* No. 5 (ECF No. 696) is **GRANTED**; it is further

**ORDERED** that Serono's Motion *in Limine* No. 6 (ECF No. 697) is **DENIED**; it is further

**ORDERED** that Serono's *Daubert* motion to exclude the testimony of Dr. Murphy (ECF No. 699) is **DENIED**; it is further

**ORDERED** that Bayer's Motion *in Limine* No. 5 (ECF No. 710) is **GRANTED-IN-PART** and **DENIED-IN-PART**; and it is further

**ORDERED** that Bayer's Motion *in Limine* No. 6 (ECF No. 712) is **DENIED**.

**SO ORDERED.**



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**HON. CLAIRE C. CECCHI**  
**United States District Judge**