Case: 19-1133 Document: 97 Page: 1 Filed: 11/13/2020

No. 19-1133

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Biogen MA Inc.,

Plaintiff-Appellee,

v.

EMD Serono, Inc., Pfizer Inc.,

Defendants-Appellants,

Bayer Healthcare Pharmaceuticals, Inc., Novartis Pharmaceuticals Corporation,

Defendants.

Appeal From The United States District Court For The District of New Jersey, Case No. 2:10-cv-02734-CCC-MF, Hon. Claire C. Cecchi

RESPONSE TO PETITION FOR REHEARING

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FORM 9. Certificate of Interest

Form 9 (p. 1) July 2020

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

CERTIFICATE OF INTEREST

Case Number	19-1133
Short Case Caption	Biogen MA Inc. v. EMD Serono, Inc.
	EMD Serono, Inc. and Pfizer Inc.

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EMD Serono, Inc.		Merck KGaA
Pfizer Inc.		None

 \square Additional pages attached

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ARGUMENT

"Anticipation is a question of fact that is ultimately for the jury to decide." Lighting Ballast Control LLC v. Philips Elecs. N. Am. Corp., 790 F.3d 1329, 1340 (Fed. Cir. 2015). After a five-week trial, the properly instructed jury found the asserted claims anticipated based on undisputed evidence that the recombinant "polypeptide" of the claims—defined in the patent as "a linear array of amino acids"—is identical to native IFN-β polypeptides in the prior art. Applying Amgen Inc. v. Hoffman-La Roche Ltd., 580 F.3d 1340 (Fed. Cir. 2009), the panel concluded that "[t]he jury ... had sufficient evidence to find" anticipation. Slip op. 19.

In its petition for rehearing, Biogen does not dispute that the polypeptides are identical, or that the anticipation verdict is supported by legally sufficient evidence under Amgen. Instead, Biogen argues that the verdict should be set aside based on unclaimed structural differences in the glycosylation of native and recombinant IFN- β proteins. But the trial record contains substantial evidence that there are no such differences; moreover, the jury was instructed to compare only the polypeptides, not the proteins, in deciding anticipation. As the panel explained, "[n]either Biogen nor the district court can reframe the anticipation inquiry on JMOL to focus on [an] unclaimed ... structure, where the jury was instructed, without objection, to decide anticipation based on the linear amino acid sequence." Slip op. 18.

The goalposts can't be moved after the verdict. Rehearing should be denied.

I. The Anticipation Verdict Is Supported by Legally Sufficient Evidence

U.S. Patent No. 7,588,755 "is directed to a method of treating [viral conditions] by administration of a pharmaceutically effective amount of a recombinant *polypeptide* related to human interferon-β ('IFN-β')." Slip op. 3 (emphasis added); see Appx142 (49:59-50:12). The recited "polypeptide" is defined in the specification as a linear array of amino acids. Appx121 (8:62-64).

At trial, the sole question of novelty was whether the recombinant "polypeptide" of the claims is identical to the native IFN-β polypeptides administered in the prior art for the same antiviral purposes. Biogen's expert admitted that "there's no new information about treatment in the '755 patent that wasn't already in the prior art" (Appx81050 (Green)), forcing Biogen to concede that "no one is suggesting that Dr. Fiers [the named inventor] came up with a new way of treating some disease with beta interferon that had never been known before." Appx81424 (summation). Thus, as Biogen told the jury, "if we do want to get into the facts, … the natural human interferon would have to be exactly the same as recombinant" to support a finding of anticipation. 2/22/18 Trial Tr. 44:10-13 (summation).

The trial evidence was undisputed that the native and recombinant polypeptides are identical. *See*, *e.g.*, Appx79720 (Lodish) ("[T]he beta interferon made [recombinantly] is ... the same interferon polypeptide as natural human interferon");

Appx79721 (Lodish) ("[I]t's exactly the same polypeptide"); Appx50501 (Inter-Pharm Study) ("The amino acid sequence of [recombinant IFN- β] ..., when compared to the amino acid sequence of [native IFN- β] ..., demonstrates that the sequences of both proteins are identical"). Indeed, to prove direct infringement, *Biogen* relied on evidence that "[t]he amino acid sequence of Rebif is identical to that of natural fibroblast derived human interferon beta." Appx66914 (Rebif label).

The jury accordingly made the *factual finding* that "the claims of the '755 patent are invalid as anticipated by prior art uses of native human interferon-beta." Appx68295 (verdict form). After reviewing the trial record, the panel concluded that the jury "had sufficient evidence to find that native IFN-β polypeptide is identical to recombinant IFN-β polypeptide, was administered in therapeutically effective amounts, and showed antiviral activity in the prior art. The district court thus erred in granting JMOL of no anticipation." Slip op. 19.

Biogen does not challenge the panel's conclusion that the trial record contains sufficient evidence to support the jury's verdict. Moreover, Biogen does not object to the admission or exclusion of any evidence at trial, or the giving or refusing of any jury instruction. And Biogen does not dispute that the jury's finding that the native and recombinant polypeptides are identical, or the panel's conclusion that this factual finding is legally sufficient to establish anticipation under the controlling legal framework. *See Amgen*, 580 F.3d at 1370.

Under these circumstances, Rule 50 does not authorize judgment as a matter of law for Biogen. McGinley v. Franklin Sports, Inc., 262 F.3d 1339, 1355 (Fed. Cir. 2001) ("When the jury is supplied with sufficient valid factual information to support the verdict it reaches, that is the end of the matter. In such an instance, the jury's factual conclusion may not be set aside by a JMOL order."). Surprisingly, Biogen argues that the panel erred in "rejecting the district court's JMOL findings," and goes so far as to argue that those "finding[s]" should have been reviewed for "clear error." PFR 14-15. But this was a jury trial, not a bench trial. As a matter of law, the district court had no power to substitute its view of the facts for that of the jury (Reeves v. Sanderson Plumbing Prods., Inc., 530 U.S. 133, 153 (2000)); and the panel properly reviewed the sufficiency of the evidence supporting the verdict de novo (Lightning Lube, Inc. v. Witco Corp., 4 F.3d 1153, 1166 (3d Cir. 1993)), with no deference to the district court's post-verdict order.

II. The Verdict Cannot Be Disturbed Based on "Unclaimed Structures" That the Jury Was Not Charged to Consider

The principal basis for the district court's post-verdict JMOL on anticipation was its conclusion that the recombinant "source limitation" was alone sufficient to confer novelty as a matter of law. *See* Appx20-22, Appx33-36. The panel ruled that this reasoning is precluded by *Amgen* (slip op. 10-16), and Biogen "does not seek rehearing" of that ruling. PFR 9.

Biogen asserts that "the panel disregarded the district court's independent, alternative basis for JMOL of no anticipation, set out in a separate section of the opinion entitled 'JMOL Of No Anticipation Is Appropriate Even Applying Product-By-Process Law." PFR 10. That is false: The panel expressly recognized that "[i]n the alternative, the district court held that no reasonable jury could have found anticipation even applying a product-by-process analysis" (slip op. 8), and then devoted an entire section of its opinion to explaining the district court's errors (*see id.* at 16-19). Biogen's petition for rehearing repackages those same errors.

1. Biogen contends that "the record evidence showed that the amino acids themselves *are not the same* in recombinant and native interferon-beta." PFR 12 (citing Appx24 n.11 (JMOL order)). The only "record evidence" cited in that footnote was the InterPharm Study, which concluded that the amino acid sequences are "identical" (Appx50501), and the testimony of Dr. Lodish, who opined that the polypeptides are "exactly the same" (Appx79721). In addition, Biogen's own expert testified at the claim construction stage that the term "polypeptide' (or 'polypeptide chain') tends to be used to refer to a sequence of amino acids linked by peptide bonds ... without any chemical modifications to the amino acids and with no implication about its three-dimensional conformation." Appx2538 (Jackson) (emphasis added). There is no "record evidence" that the polypeptides are not the same.

As the panel explained, "the district court concluded that just because recombinant and native IFN-β 'share the same linear amino acid sequence is not enough for purposes of anticipation." Slip op. 16 (quoting JMOL order). Rather, "[t]he district court took the position that native polypeptide anticipates the 'recombinant polypeptide' only if their respective folded three-dimensional proteins share identical structure and function." *Id.* As the panel concluded, "[t]his was error." *Id.*

The panel recognized that "[t]he 'product' administered in the claimed method is the 'polypeptide." Slip op. 16 (quoting Claim 1). Under *Amgen*, "the key question for anticipation is whether the native 'polypeptide' is identical to the 'polypeptide' 'produced by' the recited recombinant process." *Id.* "Biogen explicitly defined 'polypeptide' in the '755 patent" as "[a] linear array of amino acids." *Id.* (quoting specification). "The district court charged the jury with this definition," and "Biogen did not object to this charge." *Id.* at 17 (citing jury instructions).

The panel continued: "As the district court recognized on summary judgment, 'Biogen does not dispute that the sequential order of the amino acid residues for native IFN- β is the same as the sequential order of the amino acid residues for recombinant IFN- β ." Slip op. 17 (quoting summary judgment order). "Thus, the native IFN- β polypeptide and the claimed recombinant IFN- β polypeptide are identical for purposes of the instant claim." *Id.* (emphasis added).

On appeal, "Biogen argue[d] that the district court was correct in requiring identity not just of the polypeptide, but also of the folded proteins." Slip op. 17. The panel rejected that contention, concluding that "Biogen is incorrect." *Id.* The panel explained that "Biogen's argument fails to give effect to Biogen's explicit definition of 'polypeptide' in the specification. We must respect this lexicographic choice. Biogen does not attempt to square its theory with the definition in the specification." Slip op. 17 (citations omitted). The panel continued:

[I]mportantly, Biogen did not ask for a jury instruction on anticipation that required comparing the three-dimensional protein structures of prior art IFN-β and the claimed recombinant IFN-β. *Neither Biogen nor the district court can reframe the anticipation inquiry on JMOL to focus on the unclaimed three-dimensional protein structure, where the jury was instructed, without objection, to decide anticipation based on the linear amino acid sequence. See Finjan, Inc. v. Blue Coat Sys., Inc., 879 F.3d 1299, 1306 (Fed. Cir. 2018) ("[I]t is too late at the JMOL stage to ... adopt a new and more detailed interpretation of the claim language and test the jury verdict by that new and more detailed interpretation.") (quoting <i>Hewlett-Packard Co. v. Mustek Sys., Inc.*, 340 F.3d 1314, 1321 (Fed. Cir. 2003)).

Slip op. 18 (emphasis added). The same reasoning disposes of Biogen's rehearing arguments.

Biogen argues that "[t]he panel's failure to consider the structure of the recombinant polypeptide that was the actual *product* of the claimed process, the test articulated in *Amgen*, was error." PFR 11; *see also* PFR 9 (quoting slip op. 14). But in *Amgen*, the claimed product was a "glycoprotein"—that is, a three-dimensional protein including its associated carbohydrate structures. 580 F.3d at 1360; *see* slip

op. 12 n.2. The product of the claimed method here is the *polypeptide* (a linear sequence of amino acids), regardless of any glycosylation—as Biogen's own claim construction expert admitted. ECF No. 522-19 at 17 ("Whether it's glycosylated or not, th[e] beta interferon is the same polypeptide, applying the [patent's] definition") (quoting Jackson Dep. Tr. 161:10-16). As the panel correctly recognized, the claims encompass the "administration of *any* three-dimensional protein with a linear amino acid sequence identical to the claimed recombinant 'polypeptide." Slip op. 18 (emphasis added).

Biogen does not dispute that, under *Amgen*, "the key question for anticipation is whether the native 'polypeptide' is identical to the 'polypeptide' 'produced by' the recited recombinant process." Slip op. 16. Rather, Biogen complains that the panel failed to correctly "answer" this question. PFR 10; *see also* PFR 4 ("Biogen seeks rehearing because the panel *failed to apply* the test for novelty it announced"). That argument has no basis in the trial record, since the evidence was *undisputed* that the native and recombinant *polypeptides* are identical. *See* SeronoBr. 14-15 (citing Appx66914; Appx50438, Appx50501).

2. Biogen accuses the panel of making "scientific errors that led to a misunderstanding of the structure of interferon-beta." PFR 8. To support this accusation, Biogen says that the panel "mistakenly cited the district court as having stated that 'the attached carbohydrate groups in native IFN-β protein were glycosylated, and

the attached carbohydrate groups in recombinant IFN-β were *not* glycosylated." PFR 13 (quoting slip op. 8). But in that sentence fragment, the panel was merely summarizing the district court's order regarding the alleged differences in "structural identity" between "the three-dimensional structure of the protein[s]" due to glycosylation. Slip op. 8. The panel went on to explain in detail why any such differences are irrelevant to the anticipation inquiry in this case. *Id.* at 16-19 & n.3. Biogen points to no error in that analysis, and there is none.

Biogen asserts that "there was no record evidence from which a reasonable jury could find that that the amino acids in recombinant interferon-beta are identical to the amino acids in native, human interferon-beta." PFR 14 (citing Appx22). Biogen ignores the *undisputed* evidence that the recombinant polypeptide of the claim—the linear array of amino acids—is identical to the native polypeptides. Indeed, even if the anticipation inquiry could be "reframed" to focus on the complete proteins, there was substantial evidence in the trial record from which a reasonable jury could find structural identity—none of which Biogen acknowledges in its petition.

For example, the InterPharm Study expressly "concluded that recombinant beta interferon CHO cells (RBIF) *is identical to* human fibroblast interferon (HFIF)." Appx50559 (emphasis added). This conclusion was based on 13 separate measures of structural identity, including a detailed explanation that "the two protein

molecules ... have *the same three-dimensional structure*." Appx50541 (emphasis added). Serono's expert, Dr. Lodish, testified that the InterPharm Study showed that "clearly the *protein was identical*." Appx79722 (emphasis added); *see also* 2/9/18 Trial Tr. 103:6-10 (Lodish) ("I was asked the direct question of whether I had seen data that if protein made by recombinant CHO cells was or was not identical to native beta human interferon, and I answered in the affirmative"). The jury also heard evidence that "[h]amster cells glycosylate proteins identically to human cells" (Appx51578 (Revel Patent)) and that the vast majority of glycosylated native IFN-β molecules are identical to glycosylated IFN-β molecules produced recombinantly in CHO cells (Appx51646 (Kagawa Table III))—which is important because these are "comprising" claims.

To be sure, Biogen put up an expert who offered a contrary opinion. *See* Appx80513-80517 (Garcia). But the jury was not required to credit that testimony over Serono's contrary evidence. *Med. Instrumentation & Diagnostics Corp. v. Elekta AB*, 344 F.3d 1205, 1225 (3d Cir. 2003) ("[W]here, as here, there is an evidentiary basis for the jury's verdict, the jury is free to discard or disbelieve whatever facts are inconsistent with its conclusion") (citation omitted). The Court must give Serono, "as verdict winner, the benefit of all logical inferences that could be drawn from the evidence presented, resolve all conflicts in the evidence in [its] favor and,

in general, view the record in the light most favorable to [it]." *Williamson v. Consolidated Rail Corp.*, 926 F.2d 1344, 1348 (3d Cir. 1991) (citation omitted).

More importantly, the panel recognized that the disputed evidence regarding structural identity is not relevant because the anticipation inquiry cannot be "reframed" after the verdict. "Because the proper construction of the claims does not require comparison of the three-dimensional structure of prior art native IFN- β and recombinant IFN- β , we need not consider the parties' contested readings of the InterPharm study or the evidence or lack thereof of structural identity." Slip op. 19 n.3. Biogen's entire rehearing argument founders on this ruling.

3. As the panel emphasized, "the jury was instructed, without objection, to decide anticipation based on the linear amino acid sequence." Slip op. 18. In light of this instruction, the resulting verdict cannot be set aside *regardless* of what the trial evidence showed regarding other supposed differences between native and recombinant IFN-β, on which Biogen never requested an instruction. *See id.* at 7. Biogen responds that "[t]he anticipation instructions contain no reference to 'polypeptide'"; and that "nowhere was the jury asked to decide anticipation by comparing 'linear amino acid sequences." PFR 14-15. That misrepresents what transpired below.

The anticipation instruction explained to the jury that "to be entitled to a patent, the invention must actually be 'new," and that "[a]n invention is not new if it

was known to or used by others in the United States before the priority date of the '755 patent." Appx47665; *see also* Appx47663 (defining "anticipating prior art"). The verdict form asked the jury: "Do you find, by clear and convincing evidence, that the claims of the '755 patent are invalid as anticipated by prior art uses of native human interferon-beta?" Appx68295. And the court instructed the jury on a number of claim terms, including "polypeptide": "The term 'polypeptide' means 'a linear array of amino acids connected one to the other by peptide bonds between the α -amino and carboxy groups of adjacent amino acids." Appx47651.

Biogen says that the definitional instruction "did not concern anticipation." PFR 14. In fact, the jury was expressly instructed:

You will first need to understand what each claim covers in order to decide whether or not there is infringement and to decide whether or not the claim is invalid. ... I have determined the meaning of certain claim terms and I will provide to you my definition of those certain claim terms. You must accept my definitions of these words in the claims as being correct. It is your job to take these definitions and apply them to the issues that you are deciding, including the issues of infringement and validity.

ECF No. 968, Instr. No. 14 (emphases added). Thus, the jury was *required* to apply the district court's definition of "polypeptide" in deciding the anticipation question on the verdict form.

Because the asserted claims of the '755 patent recite a recombinant "polypeptide," none of Biogen's post-verdict arguments regarding glycosylation or three-dimensional structure—in the district court, on appeal, and now on rehearing—can

justify setting aside the jury's verdict. The undisputed evidence that "the native IFN- β polypeptide and the claimed recombinant IFN- β polypeptide are identical for purposes of the instant claim" (slip op. 18) is legally sufficient to sustain the verdict under *Amgen*. None of Biogen's arguments to the contrary even remotely warrants rehearing by the panel, let alone the en banc Court.

III. Biogen's New Trial Argument Is Contrary to Third Circuit Law

In support of its alternative request for a new trial, Biogen asserts that the panel erred by failing to "view the verdict in 'the overall setting of the trial" rather than "analyz[ing] individual considerations in isolation." PFR 17 (citing *Lind v. Schenley Indus., Inc.*, 278 F.2d 79, 89 (3d Cir. 1960), and *Wilburn v. Maritrans GP Inc.*, 139 F.3d 350, 354, 363-64 (3d Cir. 1998)). But the panel reviewed *all* of the "additional considerations noted by the district court" and found them insufficient under Third Circuit law to warrant a new trial. Slip op. 19. That record-intensive conclusion does not warrant rehearing.

Biogen's principal authority actually stressed that "it is the duty of the appellate tribunal to exercise a *closer degree of scrutiny and supervision*" when a new trial is granted on evidentiary grounds, because of the risk that the trial judge has "substituted his judgment of the facts and the credibility of the witnesses for that of the jury." *Lind*, 278 F.2d at 90 (emphasis added). That is exactly what happened here. And Biogen's other authority makes clear that "new trials because the verdict

is against the weight of the evidence are proper *only* when the record shows that the jury's verdict resulted in a *miscarriage of justice* or where the verdict, on the record, cries out to be overturned or *shocks our conscience*." *Wilburn*, 139 F.3d at 364-65 (citation omitted and emphases added). The district court never made these findings.

In its petition for rehearing, Biogen does not even attempt to actually weigh the evidence. That is because the evidence was *undisputed* that native and recombinant polypeptides are *identical*, and Biogen's own expert conceded at trial that the patent disclosed no new method of treatment. The district court made no finding that the anticipation verdict was a miscarriage of justice or shocks the conscience, and on this record no court could make such a finding.

The trial here was long and complex, requiring the jury to consider issues of infringement, validity, and damages. Since there was legally sufficient evidence of anticipation, the mere presence of other issues is no basis for a new trial. The evidence that Biogen invented nothing new *pervaded* the five-week trial, from the very first witness onwards. ReplyBr. 3, 9-14; *see also* SeronoBr. 14-30. Serono made the same point, repeatedly, during its summation. *E.g.*, 2/22/18 Trial Tr. 61, 83-85, 93-94. Several jury instructions addressed anticipation and subsidiary issues. *See*, *e.g.*, Appx47665, Appx47651, Appx47662-47663. The jurors asked at least two written questions—one during trial and one during deliberations—that bore on an-

ticipation before rendering their verdict. *See, e.g.*, Appx47701-47702. Biogen myopically focuses on the word "anticipation" (*e.g.*, PFR 4) in an effort to deflect attention from the fact that much of the trial concerned *novelty*—including clear and convincing evidence that Biogen invented *nothing*.

Moreover, the district court's new trial order—like its JMOL order—rested on "refram[ing]" the anticipation inquiry after the verdict was rendered—a *legal* error, not an evidentiary determination. *See* slip op. 19 ("The district court's grant of a new trial was based on the same legal errors supporting its grant of JMOL"). "The Third Circuit reviews the conditional grant of a new trial against the weight of the evidence for an abuse of discretion, 'unless the court's [ruling] is based on the application of a legal precept, in which case the standard of review is plenary." Slip op. 9-10 (quoting Lightning Lube, 4 F.3d at 1167 (emphasis added)). The panel properly applied that standard, which Biogen does not even address in its petition for rehearing.

IV. If Rehearing Were Granted on Anticipation, Serono Would Be Entitled to Judgment on Other Grounds

Because the Court reinstated the anticipation verdict, it did not address the other grounds asserted by Serono on appeal. Slip op. 3, 19. If the Court were to reframe the anticipation inquiry as Biogen proposes in its petition for rehearing, the

Court would necessarily have to reach those other issues. *See* SeronoBr. 32-65; ReplyBr. 15-31. Moreover, Biogen's rehearing arguments, if accepted, would require judgment for Serono on one or more alternative grounds:

First, it is axiomatic that claims must be construed the same for infringement as for validity. As the panel recognized, Biogen's "three-dimensional structure" argument would require a different "construction" of the claims. Slip op. 19 n.3. Such a changed construction would require reversal or vacatur of the judgment of infringement. See, e.g., CVI/Beta Ventures, Inc. v. Tura LP, 112 F.3d 1146, 1161-62 (Fed. Cir. 1997).

Second, before the asserted priority date Dr. Fiers worked only in *E. coli* bacteria, which inarguably do not glycosylate; thus, the inventor was never in possession of—and certainly did not disclose in the patent—any invention related to glycosylation patterns or three-dimensional structures. If the Court were to accept that theory for purposes of anticipation, it would necessarily render the patent invalid for failure to meet the enablement and written description requirements of 35 U.S.C. § 112.

Finally, Biogen now concedes that its claims are drawn to an "abstract idea" (PFR 12), and thus they fail step one of the patent-eligibility framework. And at step two, the patent claims *nothing* that was not well known, conventional, or routine—as Dr. Fiers himself acknowledged in sworn testimony to the Canadian Patent Office.

Appx47826-47829 (¶¶ 93(a), (c)); Appx47830. The patent is therefore ineligible under 35 U.S.C. \S 101.

CONCLUSION

Biogen's petition for rehearing should be denied.

Respectfully submitted.

/s/ Mark A. Perry
Mark A. Perry

Counsel for Defendants-Appellants EMD Serono, Inc. and Pfizer Inc.

CERTIFICATE OF SERVICE

I, Mark A. Perry, hereby certify that that I caused the foregoing to be filed via the Court's CM/ECF system and served on counsel of record who have registered for such service on November 13, 2020.

/s/ Mark A. Perry
Mark A. Perry

CERTIFICATE OF COMPLIANCE

The undersigned counsel certifies that this brief complies with the type-vol-

ume limitation of Federal Rule of Appellate Procedure 32(a) because this brief con-

tains 3,887 words, excluding parts of the brief exempted by Federal Rule of Appel-

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/s/ Mark A. Perry

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