No. 20-1604

IN THE
# Supreme Court of the United States

BIOGEN MA INC.,

*Petitioner,*

v.

EMD SERONO, INC., PFIZER INC.,

*Respondents.*

**On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit**

## BRIEF IN OPPOSITION


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## QUESTION PRESENTED

After a five-week trial, the jury made the factual finding (based on agreed instructions) that the asserted patent claims were anticipated by the prior art. The Federal Circuit, applying settled precedent, concluded that the verdict was supported by legally sufficient evidence. The sole question presented is whether the court of appeals' evaluation of the sufficiency of the evidentiary record at trial was correct.

## RULE 29.6 STATEMENT

The parent corporation of Respondent EMD Serono, Inc. is Merck KGaA, which is publicly held. Respondent Pfizer Inc. has no parent corporation, and no publicly traded corporation owns 10% or more of its stock.

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## BRIEF IN OPPOSITION

Respondents EMD Serono, Inc. and Pfizer Inc. (collectively, "Serono") respectfully submit that the petition for a writ of certiorari filed by Biogen MA Inc. ("Biogen") should be denied.

## INTRODUCTION

The only question presented by the Federal Circuit's judgment is whether the jury's verdict on the factual question of anticipation is supported by legally sufficient evidence. Biogen accused Serono of infringing U.S. Patent No. 7,588,755, which claims a method of administering a composition comprising recombinant "polypeptides" related to interferon beta ("IFN-β") to treat certain diseases. Serono responded that there is nothing novel in the claims, relying on undisputed evidence showing that native IFN-β polypeptides were used in the prior art to treat the same diseases in the same way. Biogen did not object to either the jury instructions or the verdict form on anticipation, and the jury made the factual finding that all asserted claims were anticipated by the prior art. This verdict, which Biogen all but ignores in its petition, was sustained by the Federal Circuit.

The Federal Circuit recognized that "[t]he key question for anticipation here, as in [*Amgen Inc. v. F. Hoffman-La Roche Ltd.*, 580 F.3d 1340, 1365 (Fed. Cir. 2009)], is … whether the recombinant *product* is identical to the prior art *product*—not whether the prior art product was made recombinantly." Pet. App. 14a. It is undisputed that native and recombinant IFN-β "polypeptides" are identical. Pet. App. 18a; *see* Pet. 29. Biogen conceded at trial that its patent dis-

closes no new methods of administration or treatment, and instead reiterates information about treatment disclosed in the prior art. Accordingly, the Federal Circuit held that the jury's verdict of anticipation was supported by legally sufficient evidence including two prior art references that disclosed every element of the claims. Pet. App. 20a.

Before this Court, Biogen concedes that the *Amgen* framework applies to product-by-process claims, but argues that this same framework should not apply to treatment method claims with a nested product-by-process limitation. Pet. 19–22. As the Federal Circuit recognized, however, where (as here) "the novelty of the method of administration rests *wholly* on the novelty of the composition administered, which in turn rests on the novelty of the [recombinant] source limitation, the *Amgen* analysis will necessarily result in the same conclusion on anticipation for both forms of claims." Pet. App. 16a (emphasis added). The court reasoned that it would "defy all reason" and produce an "absurd result" if the *Amgen* analysis were not applied to Biogen's claims, which recite a method of treatment using a product made by a particular process. Pet. App. 14a–15a. This is a principle of novelty, not claim drafting; and it accords with a long line of precedent holding that a source limitation cannot alone confer novelty. *See*, *e.g.*, *Cochrane v. Badische Anilin & Soda Fabrik*, 111 U.S. 293, 311 (1884) ("*BASF*"); *see also Gen. Elec. Co. v. Wabash Appliance Corp.*, 304 U.S. 364, 373 (1938); *Leggett v. Standard Oil Co.*, 149 U.S. 287, 289–90 (1893).

Based on this well-established framework for evaluating novelty, the Federal Circuit correctly concluded that legally sufficient evidence supported the

jury verdict of anticipation in this case. There is no basis to review that patent-specific and fact-bound decision.

## STATEMENT OF THE CASE

Biogen accused Serono of infringing the '755 patent, which claims a method of administering a therapeutically effective amount of a composition comprising recombinant polypeptides related to IFN-β to treat viral diseases and other conditions. Pet. App. 2a, 4a–5a. The claim term "polypeptide" is defined in the patent as a "linear array" or sequence of amino acids. *See* Pet. App. 17a–18a. It was undisputed below that the amino acid sequence of recombinant IFN-β polypeptides is identical to that of native IFN-β polypeptides (i.e., IFN-β harvested from cultured human cell lines), and that the prior art—including the Kingham and Sundmacher references—disclosed successfully treating viral diseases with native IFN-β. *See*, *e.g.*, Pet. App. 18a. After a five-week trial, a jury made the factual finding that the claims are invalid for anticipation, relying on jury instructions and a verdict form to which Biogen did not object. *See* Pet. App. 7a. On Biogen's motion, the district court set aside the verdict. Pet. App. 7a–9a. In a unanimous opinion, the Federal Circuit reinstated the verdict of anticipation as supported by legally sufficient evidence. Pet. App. 10a–20a.

### I. FACTUAL BACKGROUND

1. Before the June 1980 priority date asserted by Biogen, several different clinicians successfully administered native IFN-β polypeptides to treat patients with various viral diseases. *See*, *e.g.*, C.A. App. 118 (2:53–55); *id.* at 47748, 47752; *id.* at 47827, 47829; *id.*

at 79711–79712 (77:16–78:18); *id.* at 79080–79081 (33:15–34:11); *id.* at 79090–79093 (43:9–46:25); *id.* at 79138–79139 (91:21–92:14); *id.* at 79141 (94:5–9); *id.* at 77874–77875 (25:13–26:25); *id.* at 81047–81049 (173:24–175:22); *id.* at 81050 (176:18–22). For instance, beginning in the 1970s, Serono collaborated with Dr. Michel Revel to develop a native IFN-β product called Frone, which was marketed to treat viral and other diseases. C.A. App. 80079–80080 (8:4–9:6); *id.* at 80083 (12:23–25); *id.* at 80086–80087 (15:13–16:19).

Due to the clinical successes with native IFN-β, scientists sought a cheaper way to produce IFN-β in larger quantities. Before 1980, scientists had transformed *E. coli* bacterial host cells and induced them to produce numerous recombinant human proteins. C.A. App. 78648–78649 (35:19–36:20); *id.* at 51689–51693; *id.* at 79693–79694 (59:16–60:9); *id.* at 79695 (61:14–24); *id.* at 79698–79699 (64:19–65:11); *id.* at 47784–47787 (¶¶ 58, 60); *id.* at 48120–48124. Scientists applied those existing recombinant DNA techniques to isolate from human cells the particular DNA sequence encoding IFN-β, insert that DNA into *E. coli* bacterial host cells, and induce the transformed cells to produce IFN-β. C.A. App. 78648–78649 (35:19–36:20); *id.* at 79693–79694 (59:16–60:9); *id.* at 79695 (61:14–24); *id.* at 79698–79699 (64:19–65:11); *id.* at 47784–47787 (¶¶ 58, 60); *id.* at 48120–48124; *id.* at 51689–51693.

2. In 1980, Dr. Walter Fiers and Biogen filed the first of a series of IFN-β-related patent applications that they would prosecute for the next three decades. Biogen sought to patent IFN-β DNA, but the invention was instead awarded to Tadatsugu Taniguchi and his colleagues. *See Fiers v. Revel*, 984 F.2d 1164, 1166–

67, 1171–72 (Fed. Cir. 1993). Biogen also sought to patent the IFN-β protein itself, but this invention was also awarded to Dr. Taniguchi and his team. *See Biogen MA, Inc. v. Japanese Found. for Cancer Research*, 785 F.3d 648, 650–51, 657–60 (Fed. Cir. 2015). Consistent with the award of those patents, evidence was presented at trial showing that Dr. Taniguchi and his colleagues were the first to clone the DNA sequence for human IFN-β and produce biologically active IFN-β polypeptides. C.A. App. 48089; *id.* at 78647–78650 (34:10–37:12); *Fiers*, 984 F.2d at 1166–67.

The '755 patent issued on September 15, 2009, with claims to a method of administering a composition comprising IFN-β-related "polypeptides" produced in non-human hosts transformed by a recombinant DNA molecule. Pet. App. 4a–5a. "Polypeptide" is defined in the patent as a linear array of amino acids. *See* Pet. App. 17a–18a. This sequence is the backbone of IFN-β proteins, which fold into a three-dimensional structure. C.A. App. 79703–79705 (69:14–71:6); *id.* at 79709 (75:20–21).

3. In 1993, sixteen years before the '755 patent issued, Serono's product Rebif became the first recombinant IFN-β product approved anywhere in the world for treating human patients. C.A. App. 79379 (10:9–23). Biogen's infringement allegations against Serono, first made in 2010, are based on the sale and marketing of Rebif in the United States for treatment of multiple sclerosis, where it has been approved since 2002. Pet. App. 2a; C.A. App. 79385 (16:22–25).

## II. PROCEEDINGS BELOW

1. A five-week jury trial began on January 18, 2018. Pet. App. 46a. At issue was whether Serono

infringed the '755 patent claims and whether the claims are invalid as anticipated, obvious, or for lack of enablement and/or written description. Pet. App. 2a–3a. Serono also challenged whether the claims are patent-eligible. Pet. App. 51a–52a.

The '755 patent claims are directed to administering a composition comprising recombinant IFN-β "polypeptides." Pet. App. 4a–5a. The patent specification defines "polypeptide" as an amino acid sequence, i.e., 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." Pet. App. 17a–18a. The jury heard undisputed evidence that the "polypeptide," or "linear array of amino acids," of native IFN-β is *identical* to that of recombinant IFN-β, including Serono's accused product, Rebif. For instance, the jury heard undisputed evidence that "[t]he amino acid sequence of Rebif® is identical to that of natural fibroblast derived human interferon beta." C.A. App. 66914. Both parties also presented evidence concerning a "very detailed analytical chemistry" study (the "InterPharm Study"), which concluded that 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." C.A. App. 80515–80516 (101:11–102:2); *id.* at 50438, 50501.

Notably, the jury heard evidence of several prior art clinical studies, including particularly the Kingham and Sundmacher references, that disclosed treatment of patients with IFN-β before the asserted priority date of the '755 patent. C.A. App. 51651–51654, 52134–52138. The jury also heard explicit admissions from Biogen that the '755 patent discloses no new

method of treatment with IFN-β beyond what was already known in the prior art. *See*, *e.g.*, C.A. App. 77727–77728 (7:1–8:3); *id.* at 79090 (43:2–8); *id.* at 81047–81050 (173:22–176:25); *see also id.* at 47826–47829. For example, Biogen's technical expert agreed that "compositions with native or naturally-occurring interferon beta" "had long been used by" 1979 "to treat human tumors and viruses." C.A. App. 77727 (7:14–21). He also agreed that "all of the information about treatment … that is in the '755 Patent comes from the understanding of clinicians and scientists about how native interferon-beta was used in the 1970s." C.A. App. 81048–81049 (174:23–2). Biogen's expert likewise agreed that it was "the expectation of Dr. Fiers and everyone else" that "recombinant interferon-beta could be used in the same way as native interferon-beta had been used in the prior art … in the 1970s." C.A. App. 81049 (175:3–10). This testimony was consistent with additional evidence disclosing the prior use of native IFN-β, including polypeptides identical to the claimed recombinant IFN-β, to treat the same viral conditions referred to in the claims. *See*, *e.g.*, C.A. App. 52134–52138; *id.* at 51651–51654; *id.* at 51605–51619; *id.* at 118–119 (2:53–4:13).

The jury was instructed that "to be entitled to a patent, the invention must actually be 'new.'" C.A. App. 81262 (109:6–12). The jury also was instructed that a "polypeptide" is 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," as that term is defined in the specification. Pet. App. 7a, 17a–18a. After receiving its charge, the jury was asked to decide whether Serono had proved 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." C.A. App. 68295. Biogen did not object to any of these instructions, including the definition of "polypeptide," or to the verdict form. Pet. App. 7a, 18a–19a.

After two days of deliberation, the jury returned a verdict making the factual finding that the '755 patent claims are all invalid as anticipated. Pet. App. 2a–3a, 7a, 46a.

2. On September 7, 2018, the district court overturned the jury verdict of anticipation, and granted judgment as a matter of law of no anticipation on two grounds. Pet. App. 62a–81a.

First, the district court held that "[d]efendants failed to present as evidence a single prior-art reference that describes the therapeutic use of a recombinant interferon-β polypeptide," and that the prior art only "employed native, human interferon-β." Pet. App. 62a–63a. The court stated that the production of IFN-β using recombinant technology constitutes a "source limitation," which *alone* conferred novelty (and thus overcame an anticipation defense), even if the native and recombinant IFN-β polypeptides are identical. Pet. App. 77a–81a. The court recognized that precedent from both this Court and the Federal Circuit requires that, for novelty, a claimed product or method must itself be new—regardless of whether a claim recites a source limitation. The court agreed with Biogen's contention that this precedent was applicable only to "product-by-process" claims and not treatment method claims with a product-by-process limitation. Pet. App. 79a–80a.

Second, the district court ruled that the anticipation analysis depends not on the "linear array of amino acids" that defines the claimed IFN-β "polypeptide," but instead on the "three-dimensional structure" of the entire IFN-β *protein*, including any carbohydrate groups and glycosylation patterns. Pet. App. 65a–66a. On that premise, the court purported to analyze whether the three-dimensional structures of native and recombinant IFN-β are structurally and functionally identical, and concluded that they are not. Pet. App. 64a–77a. The court held that native and recombinant IFN-β are not structurally identical because "the proteins differ structurally in terms of their attached carbohydrate (or sugar) groups, also referred to as glycosylation patterns." Pet. App. 65a. The court ruled that native and recombinant IFN-β are not functionally identical because "recombinant IFN-β can be made in much larger quantities and much more easily than native, human interferon-β can be obtained." Pet. App. 73a.

3. On September 28, 2020, a unanimous panel of the Federal Circuit reversed the district court's grant of judgment as a matter of law, and reinstated the jury's verdict of anticipation. Pet. App. 21a, 25a. The court recognized that the record evidence included prior art, specifically the Kingham and Sundmacher references, that a reasonable jury could find disclosed every element of the claims. The court further explained that the district court's bases for setting aside the jury verdict were legally erroneous.

a. As to the district court's "source limitation" ruling, the court of appeals relied on longstanding precedent from this Court—which the Federal Circuit had previously applied in the context of recombinant DNA

technology—to hold that "[t]he district court's refusal to consider the identity of recombinant and native IFN-β runs afoul of the longstanding rule that 'an old product is not patentable even if it is made by a new process.'" Pet. App. 12a (quoting *Amgen*, 580 F.3d at 1366; and citing *Wabash*, 304 U.S. at 373, and *BASF*, 111 U.S. at 311).

The court of appeals held that "[t]he nature of the origin or source of the composition recited in the claims at issue in this case is, in all relevant respects, identical to" the claim to a recombinant EPO (erythropoietin) at issue in *Amgen*. Pet. App. 13a. The court explained that "[a]s in *Amgen*, the recombinant origin of the recited composition cannot alone confer novelty on that composition if the product itself is identical to the prior art non-recombinant product." Pet. App. 13a–14a. The court stated, "[t]he key question for anticipation here, as in *Amgen*, is thus whether the recombinant *product* is identical to the prior art *product*—not whether the prior art product was made recombinantly." Pet. App. 14a.

The court of appeals rejected Biogen's argument that "*Amgen* is limited to composition claims and is not applicable to the method of treatment claims at issue here." Pet. App. 14a. The court stated that "Biogen's only basis for novelty" of the claims was "the novelty of the recombinant IFN-β composition that is administered," which "is claimed in terms of the process by which it is manufactured." *Id.* The court explained:

> If the novelty of the recombinant IFN-β *composition* requires comparing its structure to the structure of native IFN-β, as *Amgen* requires, it would *defy all reason* to excuse that

> analysis for a method of administration claim using that composition. Such a rule could have the *absurd result* that a recombinant composition could be non-novel, the method of administration could be non-novel, but the method of administration of the composition defined by the process of its manufacture would be novel as a matter of law.

Pet. App. 14a–15a (second and third emphases added); *see also* Pet. App. 15a ("There is no logical reason why the nesting of a product-by-process limitation within a method of treatment claim should change how novelty of that limitation is evaluated").

The court of appeals held that, accordingly, the "district court erred in concluding that the mere absence of *recombinantly* produced IFN-β in the prior art was sufficient to grant JMOL of no anticipation." Pet. App. 16a–17a (emphasis added).

b. The Federal Circuit additionally held that the district court's "three-dimensional structure" ruling was erroneous. Pet. App. 17a–20a. The court explained that the "'product' administered in the claimed method is the 'polypeptide,'" and thus "the key question for anticipation is whether the native 'polypeptide' is identical to the 'polypeptide' 'produced by' the recited recombinant process." Pet. App. 17a. The court reasoned that "Biogen explicitly defined 'polypeptide' in the '755 patent" "by reference to its 'linear' array, without regard to its folded protein structure." Pet. App. 17a–18a. The Federal Circuit also recognized that the "district court charged the jury with this definition," and that "Biogen did not object to this charge and did not ask the court for a jury

instruction requiring identity of the folded protein structures." Pet. App. 18a.

The Federal Circuit held that it was "undisputed that the prior art here teaches the administration of native IFN-β that has a linear amino acid sequence identical to the linear amino acid sequence of the recited recombinant IFN-β and that shows antiviral activity." Pet. App. 20a; *see also* Pet. App. 18a. The court held that the "jury thus 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," and thus that the district court "erred in granting JMOL of no anticipation." Pet. App. 20a.

## REASONS FOR DENYING THE PETITION

The jury made the factual finding that the '755 patent claims are invalid for anticipation, based on instructions to which Biogen did not object and under longstanding precedent that Biogen does not challenge. Biogen's attempts to transform that fact-specific application of settled legal principles into something worthy of this Court's review all fail.

### I. THE FEDERAL CIRCUIT DECISION IS CONSISTENT WITH LONGSTANDING PRECEDENT

The question before the Federal Circuit was whether legally sufficient evidence supported the jury verdict that Biogen's '755 patent claims are invalid for anticipation; specifically, whether the claimed method of administering an old product (IFN-β polypeptides) made by an artificial process (recombinant DNA technology) to treat certain diseases was anticipated by

prior art uses of native IFN-β polypeptides to treat the same diseases in the same way.

The Federal Circuit reinstated the jury's anticipation verdict under established precedent holding that claiming an old product made by a new process, including specifically by recombinant DNA technology, is insufficient to confer novelty where the products are identical. Biogen accepts this framework as a correct interpretation of the Patent Act, yet contends that method claims should be exempt from the rules of novelty applicable to all other patent claims. Biogen does not even attempt, however, to grapple with the Federal Circuit's conclusion that it would "defy all reason" and produce an "absurd result" if the anticipation analysis articulated in product-by-process cases did not apply to treatment method claims that use a product made by a particular process. Pet. App. 14a–15a; *see also* Pet. App. 16a. In this respect and others, Biogen's arguments ignore or misapply the relevant precedent and should be rejected.

1. This Court has long recognized that simply specifying that an old product is made by a new process is insufficient to confer novelty. *See*, *e.g.*, *BASF*, 111 U.S. at 311 ("While a new process for producing [a product] was patentable, the product itself could not be patented, even though it was a product made artificially for the first time"); *Wabash*, 304 U.S. at 373 ("[A] patentee who does not distinguish his product from what is old except by reference … to the process by which he produced it, cannot secure a monopoly on the product by whatever means produced"). This precedent applies to method claims reciting the use of an old product made by a new process. *Leggett*, 149 U.S.

at 294–95 (holding that a method claim directed to lining barrels with an old glue made by a new process was "clearly anticipated").

This principle specifically applies where, as here, a "recombinant" source limitation is the sole basis for novelty. In *Amgen*, the Federal Circuit considered whether the production of the human protein erythropoietin ("EPO") "by recombinant technology resulted in a new product, so that [Amgen's claim to recombinant EPO] was not anticipated by the urinary EPO" in the prior art. 580 F.3d at 1367. Like the '755 patent claims, Amgen's claim recited a "source limitation" requiring the claimed protein (EPO) to be "purified from mammalian cells grown in culture," i.e., made recombinantly. *Id.* at 1364. The Federal Circuit applied this Court's longstanding novelty law and held that reciting a process limitation (recombinant technology) does *not* in and of itself confer novelty; rather, the claimed product or method must *itself* be new. *Id.* at 1365 ("[A] claimed product shown to be present in the prior art *cannot be rendered patentable solely by the addition of source or process limitations*") (quoting *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1354 n.20 (Fed. Cir. 2003)) (emphasis added); *see also*, *e.g.*, *Purdue Pharma L.P. v. Epic Pharma, LLC*, 811 F.3d 1345, 1354 (Fed. Cir. 2016); *SmithKline Beecham Corp. v. Apotex Corp.,* 439 F.3d 1312, 1317 (Fed. Cir. 2006); *In re Thorpe*, 777 F.2d 695, 697–98 (Fed. Cir. 1985).

In this case, the Federal Circuit explained that the "rule in *Amgen* is a necessary outgrowth of the black-letter legal principle that an old product made by a new process is not novel and cannot be patented." Pet. App. 16a. Biogen does not argue that the legal

standard articulated in *Amgen* is incorrect; in fact, in its petition for rehearing before the Federal Circuit, Biogen explicitly stated that it was *not* challenging the panel's ruling that the *Amgen* analysis applies to treatment method claims like those of the '755 patent. C.A. Dkt. 95 at 4. Nor does Biogen argue that the Federal Circuit misinterpreted *Amgen* in applying that standard. Indeed, Biogen ignores the relevant portion of *Amgen* entirely in its petition for a writ of certiorari.

Biogen's only answer to the longstanding precedent discussed above is to assert that it applies only to "*products*, not methods of using products." Pet. 19; *see also id.* at 6–7. Biogen contends that the application of this precedent to method claims "runs headlong into this Court's decision in *Association for Molecular Pathology* v. *Myriad Genetics, Inc.*, 569 U.S. 576, 595 (2013), which recognizes that methods of treatment are patentably distinct from the products administered in those methods." Pet. 6; *see also id.* at 21 ("This Court recognized the fundamental distinction between method claims and product claims in [*Myriad*]"). Biogen's entire argument turns on this purported distinction between product and method claims. Pet. 6–7.

In *Myriad* (which involved eligibility, not anticipation), this Court held that claims to naturally occurring DNA segments related to the BRCA1 and BRCA2 genes were unpatentable, whereas a synthetic product (cDNA) was patent-eligible because it differed from the naturally occurring genetic information. 569 U.S. at 595; *see also In re BRCA1- & BRCA2-Based Hereditary Cancer Test Pat. Litig.*, 774 F.3d 755, 760 (Fed. Cir. 2014) (confirming that "neither naturally occurring compositions of matter, nor synthetically

created compositions that are structurally identical to the naturally occurring compositions, are patent eligible"). The Court noted that there were "no method claims" before it, and explained that "[h]ad Myriad created an *innovative* method of manipulating genes while searching for the BRCA1 and BRCA2 genes, it could possibly have sought a method patent." *Myriad*, 569 U.S. at 595 (emphasis added).

In its decision, the Federal Circuit acknowledged that "the scope of composition and method of treatment claims is generally subject to distinctly different analyses." Pet. App. 16a. But the court explained that:

> [W]here, as here, the novelty of the method of administration rests wholly on the novelty of the composition administered, which in turn rests on the novelty of the of the [recombinant] source limitation, the *Amgen* analysis will necessarily result in the same conclusion on anticipation for both forms of claims.

*Id.* Had Biogen invented an "innovative method" for making or using recombinant IFN-β, it may well have been entitled to a patent on those inventions, just as this Court stated in *Myriad*. 569 U.S. at 595. (Indeed, Biogen sought a patent on a method for making recombinant IFN-β, but the PTO and the Federal Circuit concluded that this method was invented by someone else.) Here, the product is old *and* the method is old, and so the jury was entitled to find that there was nothing "new" about Biogen's claims. Pet. App. 16a ("an old method of administration of an old product made by a new process is not novel and cannot be patented"). Indeed, that is the holding of this Court's decision in *Leggett*, which involved method

claims (*see* 149 U.S. at 289–90); Biogen's submission cannot be reconciled with that authority.

The Federal Circuit further explained that "[i]f the novelty of the recombinant IFN-β *composition* requires comparing its structure to the structure of native IFN-β, as *Amgen* requires, it would defy all reason to excuse that analysis for a method of administration claim using that composition." Pet. App. 14a–15a. The court stated that "[s]uch a rule could have the absurd result that a recombinant composition could be non-novel, the method of administration could be non-novel, but the method of administration of the composition defined by the process of its manufacture would be novel as a matter of law." *Id.*; *see also id.* at 16a.

Biogen does not even acknowledge (much less attempt to explain) the absurdity that would ensue from the distinction it asks this Court to draw between method and other claims. The jury made the factual finding that the claimed recombinant IFN-β polypeptide is identical to the native IFN-β polypeptide, and thus is an old product. And there was no dispute that the claimed treatment method (or method of administration) was old as well. Indeed, Biogen's technical expert admitted at trial that the '755 patent claims offer "no new method of treatment" and "no new methods of administration" of IFN-β, and that all of the information about treatment in the patent comes from the prior art. C.A. App. 81048–81049 (174:11–175:14); *id.* at 81050 (176:2–4, 176:18–22); *id.* at 81077 (203:13–15); *id.* at 81078 (204:15–18); *id.* at 81049–81050 (175:15–22, 175:23–176:7).

Even Biogen's own inventor, Dr. Fiers, affirmed under oath that native IFN-β was "well known before

1979 and had long been used by that date to treat human tumors and viruses" (as the '755 patent confirms, C.A. App. 118–119 (2:53–4:13)) and that it was "straightforward" for recombinant IFN-β to "be used to prepare compositions for use in treating human tumors and viruses *just as native* [or natural] beta interferon had been used to prepare those compositions for many years." C.A. App. 47749, 47826–47829 (¶ 93(a), (c)), 47830 (emphasis added). Thus, Biogen asks this Court to hold that Biogen is entitled to a patent on an old way of using an old product for the same old purpose, simply because Biogen's claims include a source limitation—in direct contravention of binding precedent and common sense. *See*, *e.g.*, *BASF*, 111 U.S. at 311; *Leggett*, 149 U.S. at 289–90.

2. Biogen's reliance on the general notion that anticipation requires all elements to be present in the prior art (Pet. 18–19) misses the point. The jury was correctly instructed that "all the requirements of the claim must have been disclosed" so that a person of skill in the art "could make and use the claimed invention" based on a single prior art reference. *See* Pet. App. 57-58a. The Federal Circuit expressly acknowledged that "[a] claim is anticipated only if 'each and every [limitation] is found within a single prior art reference.'" Pet. App. 10a (quoting *Summit 6, LLC v. Samsung Elecs. Co.*, 802 F.3d 1283, 1294 (Fed. Cir. 2015)) (second alteration in original). That standard is entirely consistent with the cases cited by Biogen. *See* Pet. 18 (citing *Woodbury Pat. Planing-Mach. Co. v. Keith*, 101 U.S. 479, 489 (1880); *Le Roy v. Tatham*, 63 U.S. (22 How.) 132, 139 (1860)).

What Biogen fails to acknowledge is that the jury found that two separate prior art references—Kingham and Sundmacher—disclosed every element of the asserted claims. Pet. App. 2a-3a. Instead, Biogen insists that the verdict should be disregarded because a source limitation (*e.g.*, recombinant production) *alone* can confer novelty over the prior art. Pet. 19. This argument, which Biogen failed to preserve in its pre-verdict motion for judgment as a matter of law (*see* Pet. App. 12a), is meritless: A source limitation alone cannot confer novelty unless the product itself is novel.

As the Federal Circuit has consistently recognized, the question for anticipation analysis is whether recited source characteristics *actually distinguish* the claims from the prior art such that the claims are novel. *See Purdue*, 811 F.3d at 1354; *Greenliant Sys., Inc. v. Xicor LLC*, 692 F.3d 1261, 1268 (Fed. Cir. 2012); *Amgen*, 580 F.3d at 1370; *SmithKline Beecham*, 439 F.3d at 1317; *see also Cubist Pharms., Inc. v. Hospira, Inc.*, 75 F. Supp. 3d 641, 668–69 (D. Del. 2014), *aff'd*, 805 F.3d 1112 (Fed. Cir. 2015) (stating that, to avoid anticipation, the claim's "composition … must be structurally and functionally different from the [prior art] compositions, such that it is something novel").

Contrary to Biogen's submission, merely specifying such a source limitation has *never* been held sufficient to save otherwise non-novel claims from invalidity for anticipation. Thus, Biogen's theory "that the '755 Patent provided a new element not found in the prior art" merely because it claims treatment with "*recombinant* interferon-β made by non-human cells" (Pet. 19 (emphasis added)) would require overturning

a long and unbroken line of contrary precedent. Biogen's position that the "recombinant" limitation is an element not found in the prior art for purposes of a method claim would apply equally to product claims; there is no principled distinction that would require otherwise.

The Federal Circuit's conclusion that "a reasonable jury could find the claims of the '755 patent anticipated on the record presented in this case" (Pet. App. 3a) is entirely consistent with the Patent Act, as construed by this Court and the Federal Circuit. Biogen's petition asks this Court to rule for the first time that the prior art use of a native product for a specific purpose can never, as a matter of law, anticipate the claimed use of an identical recombinant version of that native product for that very same purpose. That request would require overturning more than a century of precedent. There is no basis to do so, and no basis for review.

## II. THE FEDERAL CIRCUIT CORRECTLY CONCLUDED THAT THE JURY'S VERDICT OF ANTICIPATION IS SUPPORTED BY LEGALLY SUFFICIENT EVIDENCE

This Court has recognized that anticipation is a question of fact, and that factual questions are reviewed for legally sufficient evidence. *See Microsoft Corp. v. Biscotti, Inc.*, 878 F.3d 1052, 1068 (Fed. Cir. 2017) ("[C]ase law from the Supreme Court and this court has stated for decades that anticipation is a factual question.") (citations omitted); *Busch v. Jones*, 184 U.S. 598, 604 (1902) ("Anticipation is a question of fact"); *see also E.I. du Pont De Nemours & Co. v. Unifrax I LLC*, 921 F.3d 1060, 1067 (Fed. Cir. 2019)

("Judgment as a matter of law is 'sparingly invoked' and 'granted only if, viewing the evidence in the light most favorable to the nonmovant and giving it the advantage of every fair and reasonable inference, there is sufficient evidence from which a jury reasonably could find' for the nonmovant") (quoting *Marra v. Phila. Hous. Auth.*, 497 F.3d 286, 300 (3d Cir. 2007); *Lighting Ballast Control LLC v. Philips Elecs. N. Am. Corp.*, 790 F.3d 1329, 1340 (Fed. Cir. 2015) ("Anticipation is a question of fact that is ultimately for the jury to decide")).

Here, there was a trial on the factual question of whether "the claims of the '755 patent are invalid as anticipated by prior art uses of native human interferon-beta." C.A. App. 68295 (verdict form). That question was submitted to the jury on instructions to which Biogen did not object, and the jury made the factual finding (on a verdict form to which Biogen also did not object) that Biogen's patent claims are invalid for anticipation. After reviewing the trial record, the Federal Circuit 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." Pet. App. 20a. Nothing about this case-specific, fact-bound decision warrants review.

1. The '755 patent claims recite administering "composition[s] comprising" recombinant IFN-β "polypeptides." Pet. App. 17a ("The 'product' administered in the claimed method is the 'polypeptide.'"). Thus, under *Amgen*, "the key question for anticipation is whether the native 'polypeptide' is identical to the 'polypeptide' 'produced by' the recited recombinant

process." *Id.* As discussed, the patent specification defines "polypeptide" as "[a] linear array of amino acids connected one to the other by peptide bonds." Pet. App. 18a (citing '755 patent, col. 8, ll. 62–64). "The district court charged the jury with this definition," and "Biogen did not object to this charge." *Id.*

The jury heard undisputed evidence that the "linear array of amino acids" (i.e., the "polypeptide") of native IFN-β is *identical* to recombinant IFN-β, including Serono's accused product, Rebif. Biogen admits as much in its petition. Pet. 23 ("Recombinant interferon-β has the same amino-acid sequence" as native). The jury then made the *factual* finding that all claims of the '755 patent were anticipated by prior art uses of native IFN-β for the treatment of viral diseases. C.A. App. 68203. There is no basis to disturb that verdict.

2. Before the Federal Circuit, Biogen defended the district court's JMOL order on the ground that no reasonable jury could find that the recombinant product was identical to the native product. C.A. Dkt. 54 at 23. Biogen reiterated the district court's post-verdict redefinition of the claims as reciting IFN-β *proteins*—as opposed to the "polypeptides" recited in the claims. Biogen then argued that these proteins differ from native IFN-β *proteins* in terms of their three-dimensional structure, including carbohydrate groups and glycosylation. *Id.* at 23–27. Biogen focused its argument on the proteins in order to redefine the claims to include glycosylation, which is not part of the recited "polypeptide," i.e., the "linear array of amino acids." *Id.*; Pet. App. 17a–18a. Biogen repeats the same argument here. Pet. 22–23.

The '755 patent, however, does not claim the use of *proteins*, but rather the use of "polypeptides." It

was *Biogen* that chose to draft its claims in that way, and to expressly define "polypeptide" in the patent as an amino acid sequence. Yet, from the very beginning of its petition, Biogen continues to misrepresent the scope of its own claims, repeatedly referring to the claims as reciting "protein[s]." Pet. i (Question Presented) (referring three times to recombinant and human "*proteins*"); *id.* at 7 ("The '755 Patent is directed to a treatment that was not previously possible—administering a new recombinant *protein*"); *id.* at 22 ("Here, the claimed method can only be practiced by the use of a recombinant *protein*"); *id.* at 24 ("the express claim language requiring that the *protein* to be used for treatment be 'recombinant'"); *id.* at 29 ("By holding that a method of treatment with a recombinant *protein* is anticipated by treatment with non-identical native, human protein …") (emphases added). Biogen's attempt to redraft the claims to gain litigation advantage is impermissible as a matter of both law and patent practice, and cannot be reconciled with the actual language of the claims, specification, and jury instructions. The '755 patent claims clearly and indisputably recite the use of a "polypeptide."

Biogen's choice to claim the "polypeptide" and define that term in both the '755 patent and the jury instructions has consequences. It is the "polypeptide" recited in the claims that must be compared to the polypeptides in the prior art, *not* the unclaimed protein. *See In re Qapsule Techs., Inc.*, 759 F. App'x 975, 981 (Fed. Cir. 2019) ("Unclaimed differences do not avoid anticipation"). Furthermore, as the Federal Circuit noted: "[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." Pet. App. 19a. The court continued, "[n]either 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." Pet. App. 19a–20a (citing *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 *Hewlett-Packard Co. v. Mustek Sys., Inc.*, 340 F.3d 1314, 1321 (Fed. Cir. 2003)).

The Federal Circuit correctly rejected Biogen's and the district court's attempt to rely on a different, post-verdict re-definition of "polypeptides" that incorporated the three-dimensional structure of the IFN-β protein and effectively converted the claims to recite the use of *proteins* rather than "polypeptides." *See* Pet. App. 17a–20a. Strikingly, Biogen seeks to do the same thing in its petition to this Court without even attempting to argue that the Federal Circuit erred in its analysis below. The Federal Circuit correctly decided that the jury verdict cannot be overturned on a basis that the jury itself was not asked to consider.

3. Even if the three-dimensional protein structure were relevant to whether the '755 patent claims were anticipated (it is not), there was ample evidence from which a jury could have found that native and recombinant IFN-β proteins are the same—had Biogen requested an instruction to that effect (which it did not).

Contrary to Biogen's unadorned assertion, it is not "undisputed" that the "molecule[s]" are different. Pet. 16. Rather, there was ample evidence that the recombinant and native molecules are both structurally and functionally *identical*. A comprehensive study on which both parties relied at trial explicitly concluded that "RECOMBINANT BETA INTERFERON DERIVED FROM CHO CELLS (RBIF) IS IDENTICAL TO HUMAN FIBROBLAST INTERFERON (HFIF)" (C.A. App. 50559), and that "the two protein molecules … have the same three-dimensional structure." C.A. App. 50541; *see also id.* at 50459, 50466, 50472, 50484, 50501, 50529, 50531, 50535, 50545, 50553, 50558 (each detailing ways in which the two proteins are "identical"). Additional evidence confirmed that "hamster [CHO] cells glycosylate proteins identically to human cells." C.A. App. 51578 (9:56–58); *see also id.* at 66993, 67003. And contrary to Biogen's argument (at 13) that no "witness testif[ied] that recombinant interferon-β and native, human interferon-β are themselves identical," Serono's expert Dr. Lodish testified that he had seen evidence of such identicality. C.A. App. 79721–79722 (87:24–88:3).

In addition, a second comparative study specifically analyzed the glycosylation patterns of native and recombinant IFN-β proteins and concluded that each has a population of IFN-β molecules with multiple carbohydrate structures, two of which are common to both native and CHO recombinant IFN-β and which account for more than eighty percent of native IFN-β molecules. C.A. App. 51643–51650; *see also id.* at 79720–79723 (86:2–89:5). Accordingly, the prior art described patients whose viral conditions were

treated with native IFN-β, and those patients *necessarily* received "a composition *comprising*" native polypeptides that are atomically identical to recombinant polypeptides recited in the '755 patent claims. *Brown v. 3M*, 265 F.3d 1349, 1351 (Fed. Cir. 2001) ("When a claim covers several structures or compositions, … the claim is deemed anticipated if any of the structures or compositions within the scope of the claim is known in the prior art"). This evidence was undisputed below.

Furthermore, the jury heard substantial evidence that native IFN-β functions in the same way as recombinant IFN-β. The '755 patent claims require recombinant IFN-β with antiviral activity. C.A. App. 142–143. Native IFN-β has antiviral activity. *See*, *e.g.*, C.A. App. 119 (3:4–14); *id.* at 77872 (23:15–19); *id.* at 48089 (native IFN-β "has potent antiviral activity"); *see also id.* at 77905 (56:7–24); *id. at* 66993–67011; *id.* at 66773. The evidence at trial also showed that recombinant IFN-β has "the same physical properties and specific antiviral activity as the human product." C.A. App. 51574 (1:57–62); *id.* at 50556; *see also id.* at 50556 (InterPharm Study concluded that "pure RBIF [recombinant IFN-β] and HFIF bulks [native IFN-β] have identical antiviral potency").

Accordingly, even under the district court's erroneous post-verdict approach requiring a comparison of the three-dimensional *proteins* and their glycosylation structures, there was more than ample evidence from which a jury could have concluded that native and recombinant IFN-β *proteins* are identical, and thus that the asserted claims are anticipated even under Biogen's rubric.

## III. THIS CASE IS AN EXCEEDINGLY POOR VEHICLE FOR THIS COURT'S REVIEW

The jury made the factual finding that the particular patent claims asserted here are invalid as anticipated, and the Federal Circuit concluded that this verdict was supported by legally sufficient evidence. Biogen's assertions that this patent-specific outcome, rendered after a trial on a unique set of disputed facts, will have wide-ranging ramifications are unsupported and wrong.

1. Biogen argues that the Federal Circuit's decision will disincentivize drugmakers from producing new recombinant therapeutics. This argument—which Biogen did not make in either the district court or the court of appeals—is undermined by the fact that not a single company or person has filed an *amicus* brief agreeing with Biogen's submission. It also lacks factual or logical support.

Biogen spends several pages discussing drugs on the market today that contain recombinant proteins. Pet. 24–28. In particular, Biogen notes that half the leading drugs by sales volume are recombinant biologics. But what Biogen fails to inform the Court is that *every single one them includes a novel recombinant protein not appearing in nature*. *See* Pet. 25 n.4 (identifying Humira (mouse-derived monoclonal antibody ("MAb")); Keytruda (mouse-derived humanized MAb); Stelara (MAb created using transgenic mice); Eylea (artificial fusion protein created from fragments of multiple human proteins); and Opdivo (MAb created using transgenic mice)).

For example, the active ingredient of Humira (the top-selling drug for many years) is a monoclonal antibody generated by "guided selection" from a mouse antibody using phage-display technology. *See* Ole Henrik Brekke & Inger Sandlie, *Therapeutic Antibodies for Human Diseases at the Dawn of the Twenty-First Century*, 2 Nature Reviews: Drug Discovery 52, 56 (2002). A novel technology (phage-display) was used to create a novel drug (Humira) to treat disease (rheumatoid arthritis) that was previously untreated by the drug. That is in stark contrast to the purported invention of the '755 patent: a technology invented by others (recombinant DNA technology), used to copy a natural polypeptide (human IFN-β), to treat the same condition that IFN-β was already known to treat (viral disease) in exactly the same way.

For none of these bestselling drugs does a natural protein exist that would (or could) provide the basis on which the jury found the '755 patent invalid. Thus, the Federal Circuit's routine application of settled novelty law in this case would have had *no effect at all* on the incentives to develop any of these drugs. Nor will it have any effect on the incentives for drugmakers to develop new drugs like these in the future that contain proteins, polypeptides, or other biological products not found in nature.

Biogen's logic does not even apply to this case. According to the view Biogen espouses, the incentive provided by "robust and predictable patent protection is essential" to development of important new drugs. Pet. 28. Biogen's logic demands that a drugmaker would not take the risk of developing a drug that merely copies a natural protein. But Biogen developed its product, Avonex (a copy of human IFN-β),

long before it ever received the '755 patent. Nor had Biogen received patents covering the DNA, polypeptide, or the protein of the IFN-β in Avonex, or the method of producing it; those patents were awarded to others. And the original patents on insulin, human growth hormone, Factor VIII, and other naturally occurring proteins are long expired, yet as Biogen notes the recombinant versions of those proteins are still made by numerous drugmakers and used by millions of patients. *See* Pet. 24–26.

Only one example Biogen cites is relevant to this case: recombinant EPO. Patents concerning recombinant EPO were, like the '755 patent, challenged as not novel. The legal framework resulting from the application of long-established novelty law in that case, *Amgen*, is the very framework the Federal Circuit applied here. Under that framework, the dispositive factual question is whether the native and recombinant products at issue are identical—a question that the jury in this case answered in the affirmative. This framework has long provided drugmakers the "settled expectation[]" (Pet. 28) that they cannot patent a copy of a natural product if the recombinant product is identical to the natural one. It is Biogen's petition—not the Federal Circuit's opinion in this case—that asks this Court to "upend this careful balance" (*id.*) that this Court's law and its application by the Federal Circuit have established.

In the approximately 40-year history of genetically engineered pharmaceuticals, the question of whether a native product can anticipate a recombinant product has reached the appellate courts only twice, in this case and in *Amgen.* As Biogen does not

dispute, the Federal Circuit applied the same framework in those two cases, and that framework is consistent with this Court's anticipation precedents. There is accordingly no basis for this Court's review.

2. Review is not warranted for another reason that Biogen entirely ignores: Biogen's attempts to avoid the anticipation verdict by recasting the scope of its own claims renders those claims invalid for lack of written description and enablement. 35 U.S.C. § 112. Biogen neither described nor enabled the three-dimensional structure or glycosylation of any recombinant IFN-β protein that Biogen now argues is not identical to the native IFN-β protein. Indeed, the '755 patent's disclosure as of the asserted priority date is limited to work conducted in a single bacterial host cell (*E. coli*), which does not glycosylate proteins at all. C.A. App. 79094 (47:12–21); *id.* at 79680–79681 (46:17–47:3); *id.* at 79719–79720 (85:11–86:21); *id.* at 80473 (59:20–24).

In fact, the U.S. Patent and Trademark Office ("PTO") recently reached a similar conclusion. Claim 1 of the '755 patent is the subject of a pending *ex parte* reexamination. In that reexamination, Biogen proposed claims that, unlike the issued '755 patent claims, explicitly recite "recombinant, biologically active folded protein [that] has glycosylation that is not identical to that of authentic human interferon (HuIFN β) protein." U.S. Reexamination Application No. 90/014,423, May 12, 2021, Final Rejection at 13 (emphasis in original). On May 12, 2021, the PTO issued a final rejection stating that, among other deficiencies, these claims that cover the three-dimensional structure and glycosylation of IFN-β have no

written description support in the application on which Biogen relies here for priority. *Id.*

Biogen's '755 patent also does not demonstrate how to make IFN-β in CHO cells, which is how Serono's accused product (Rebif) is made. This is also the position of the PTO. *See id.* at 30 ("The recombinant production of IFN-β in CHO cells (i.e., CHO cells as the choice of host cells to produce IFN-β) … [was] not contemplated in the present '755 patent specification"). Biogen's own inventor said the same under oath, admitting "[t]he *only* hosts that were available [in early 1980] for the expression of cloned DNA sequences were bacterial hosts." C.A. App. 47788 (emphasis in original).

Accordingly, in the unlikely event the Court were to reverse the finding below on anticipation, the court of appeals would have to address these Section 112 challenges and would undoubtedly hold the patent invalid on that ground. And even if Biogen could overcome that hurdle, the Federal Circuit would have to decide patent-eligibility, direct infringement, and indirect infringement. These issues were all fully briefed below but not reached in light of the anticipation verdict. Biogen has thus brought to this Court just one of many litigation-ending problems with its patent.

3. Biogen's bid for de novo appellate review (Pet. 29) entirely ignores the trial and verdict. Contrary to Biogen's assertion, this case does not involve an "undisputed set of facts." *Id.* There was a trial on the issue of anticipation, and the jury—the fact finder—found against Biogen based on the evidence presented and instructions to which Biogen did not object. Pet. App. 2a–3a. This Court rarely reviews the sufficiency

of evidence underlying such a jury verdict, which is the only question that the judgment in this case presents. *See* Robert L. Stern et al., Supreme Court Practice at 4-46 (11th ed. 2019) ("Today, a petition that presents no more than a question whether the evidence was sufficient to support the jury verdict … stands little or no chance of being granted"). Fatally, Biogen does *not* argue in its petition that the verdict is unsupported by legally sufficient evidence.

As the Federal Circuit explained, "Biogen's only basis for novelty" of the claims was "the novelty of the recombinant IFN-β composition that is administered," which "is claimed in terms of the process by which it is manufactured." Pet. App. 14a; *id.* at 15a (describing the claims as "nesting … a product-by-process limitation within a method of treatment claim"). Put another way, Biogen's claims recite an old method of using an old product whose only asserted novelty was a recombinant product-by-process limitation nested within the claim. The jury's verdict of anticipation, sustained by the Federal Circuit, thus "protects the public from attempts to excise old products from the public domain." Pet. App. 16a.

Biogen has not identified even one other patent that utilizes the unusual claim structure of the '755 patent, and thus its assertion that the Federal Circuit's opinion will have wide-ranging consequences is totally unsupported. More generally, the notion that the Federal Circuit's fact-bound decision in this case will "imperil[] … the scientific investments needed to develop … promising new therapies" (Pet. 4) is simply not plausible. *Cf. Diamond v. Chakrabarty*, 447 U.S. 303, 317 (1980). While Biogen postulates a parade of

horribles, there is simply no parade at all—as the absence of any *amici* supporting Biogen confirms. The jury's factual finding that Biogen's patent claims are invalid as anticipated—a finding that, as the Federal Circuit correctly concluded, is supported by legally sufficient evidence—does not warrant further review.

## CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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