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

PETITIONER'S REPLY BRIEF

NICHOLAS GROOMBRIDGE
ERIC ALAN STONE
PETER SANDEL
JENNY C. WU
JOSEPHINE YOUNG
PAUL, WEISS, RIFKIND, WHARTON & GARRISON LLP
1285 Ave. of the Americas
New York, NY 10019
(212) 373-3000

JEFFREY A. LAMKEN
Counsel of Record
MOLOLAMKEN LLP
The Watergate, Suite 500
600 New Hampshire Ave., N.W.
Washington, D.C. 20037
(202) 556-2000
jlamken@mololamken.com

Counsel for Petitioner

CORPORATE DISCLOSURE STATEMENT

Pursuant to this Court's Rule 29.6, Petitioner Biogen MA Inc. states that the corporate disclosure statement included in the petition remains accurate.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

IN THE

Supreme Court of the United States

NO. 20-1604

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

REPLY FOR PETITIONER

INTRODUCTION

This case squarely presents a clear and purely legal question—the propriety of the Federal Circuit's unprecedented application of product-by-process law to claims covering methods of treatment. The ordinary rule is that, for a patent claim to be anticipated, all elements of the claim must be found in the prior art. Contravening that well-settled principle, the Federal Circuit held below that a breakthrough, never-before-performed method of treatment requiring the use of a *recombinant* protein was anticipated by prior-art treatments using the *native*,

human version of that protein. To reach that result, it applied so-called product-by-process law, under which existing *products* do not become patentable merely because the inventor identifies a novel means of producing them. But product-by-process law—as its name implies—concerns *products*, not *methods* of treatment like the one at issue here. The Federal Circuit's application of product-by-process law to claims covering methods of treatment conflicts with this Court's decision in *Association for Molecular Pathology* v. *Myriad Genetics, Inc.*, in which this Court recognized that methods of treatment are patentably distinct from the products administered in those methods. 569 U.S. 576, 595 (2013).

The relevant facts are clear and completely undisputed. The claimed method of administering recombinant interferon-β had never been done before. Yet the Federal Circuit held that the claim was anticipated anyway by prior-art treatments that did not use recombinant interferon-β, but rather used native, human interferon-β.

If allowed to stand, the Federal Circuit's decision threatens to preclude patent protection for lifesaving treatments that use recombinant technologies, placing at risk the patients that depend on these treatments and removing an important incentive for biopharmaceutical companies to invest the billions of dollars required to develop such treatments.

This Court should grant review to confirm that methods of treatment using recombinant versions of naturally occurring substances are not anticipated by prior-art treatments using the native, human versions of those substances. The answer to this pure question of law is of enormous importance to both the patients that need such treatments and the biopharmaceutical companies that

dedicate countless resources to discovering innovative ways to help those in need of these treatments.

I. THIS CASE PRESENTS A PURE QUESTION OF LAW

Rather than address the propriety of the Federal Circuit's novel test for anticipation, Serono attempts to conjure factual disputes where there are none. There is no dispute that the method of the '755 Patent can be practiced only by using recombinant interferon-β. Pet. 22. It is undisputed that no prior-art reference disclosed treatment using recombinant interferon-β. Pet. 19. The issue presented by this case is thus a purely legal one: Whether, as a matter of law, the Federal Circuit properly applied product-by-process law to method claims when it held that a method of treatment using recombinant interferon-β was anticipated by prior-art treatment using native, human interferon-β—even though such treatment with the native protein would not infringe the '755 Patent if performed after the patent issued.

Neither Serono nor the Federal Circuit identify any prior decision ever holding that a prior-art treatment method that would not infringe a patent can nevertheless anticipate it. There is no basis in this Court's precedent to apply product-by-process law to method claims, as the Federal Circuit did for the first time in the decision below. Instead, Serono merely asserts that "a source limitation cannot alone confer novelty." Br. in Opp. 2. Yet every case invoked by Serono in support of this proposition involves source limitations in *product* claims, not *method* claims. *See* Br. in Opp. 2, 13-14; *Cochrane* v. *Badische Anilin & Soda Fabrik*, 111 U.S. 293, 311 (1884) (claim directed to "artificial alizarine"); *Gen. Elec. Co.* v. *Wabash Appliance Corp.*, 304 U.S. 364, 368 (1938) (claims directed to a "filament for electric incandescent lamps"); *Leggett* v. *Standard Oil Co.*, 149 U.S. 287, 289-290 (1893)

(claim directed to "a barrel, cask, etc."). This petition squarely presents the purely legal question whether the rule in those cases should be applied to method claims.

II. THE FEDERAL CIRCUIT'S DECISION CONFLICTS WITH THIS COURT'S PRECEDENTS, INCLUDING *MYRIAD*

Urging that refusing to apply this Court's product-by-process precedents to method claims would lead to "absurdity," Br. in Opp. 17, Serono attempts to distinguish this Court's decision in *Association for Molecular Pathology* v. *Myriad Genetics, Inc.*, 569 U.S. 576 (2013). In *Myriad*, Serono urges, the Court merely acknowledged that an "innovative" method for making or using a product may have been patentable. Br. in Opp. 16. Serono then argues that the method of the '755 Patent cannot be innovative under *Myriad* because the prior art disclosed the therapeutic administration of *native*, *human* interferon-β.

That, however, merely assumes the answer to the question presented here: Whether treatment with native, human interferon-β anticipates claims directed to a method treatment with recombinant interferon-β. Under *Myriad*, the answer to this question is clear: A never-before-performed *method* of treatment—such as the one at issue here—is patentably distinct from the *products* administered in that method. *Myriad*, 569 U.S. at 595.

Before the '755 Patent, no one had ever treated any disease with recombinant interferon-β. The best minds in the world were racing to see if that was even possible. Pet. 18. Dr. Fiers won that race and was awarded the '755 Patent for his work creating this advance that made it possible to treat multiple sclerosis. The Federal Circuit, however, deemed that leap forward unprotectable because the prior art recognized treatments using native,

human interferon-β—even though prior to the invention of the '755 Patent the scarcity and impurity of native, human interferon-β meant that effective treatment of patients with interferon-β was not possible on a practical basis. C.A. App. 119 ("the antitumor and anticancer applications of IFN-β have been severely hampered by lack of an adequate supply of purified IFN-β"). The difficulty of obtaining and using interferon-β in the methods of the prior art led to enormous efforts to make recombinant interferon-β and to prove that it could indeed be used in place of the native protein; it was Dr. Fiers's breakthrough that solved these problems and made treatment possible.[1]

The goal of the patent system is to protect and encourage innovations like this one. This Court should grant review to protect such innovations and confirm that the existence of a naturally occurring substance does not preclude methods of treatment using a previously non-existent recombinant version of that substance.

---

[1] Serono suggests that the work of Dr. Tadatsugu Taniguchi, which led to patents on both the DNA that encodes for interferon-β and the interferon-β protein itself, supports its assertion that the method of the '755 Patent cannot be innovative. Br. in Opp. 4-5, 28-29. But the Patent Office considered that work during prosecution of the '755 Patent and rejected any argument that it anticipated or rendered obvious the methods of treatment claimed in the '755 Patent. C.A. App. 99, 101. And the Federal Circuit nowhere considered that argument. After hearing extensive testimony, including from Dr. Taniguchi himself, the jury rejected Serono's argument that Dr. Taniguchi's work rendered the '755 Patent obvious, and Serono did not challenge that finding on appeal. C.A. App. 68294. Serono's arguments regarding Dr. Taniguchi's work are thus entirely irrelevant to the legal issue presented or its resolution.

III. This Case Is An Excellent Vehicle For Deciding These Hugely Important Issues

Innovation is how our society makes medicines broadly available—and develops new methods to treat previously untreatable diseases. Whether it be the ability to recombinantly make therapeutically useful insulin, Factor VIII, erythropoietin, monoclonal antibodies to treat Covid-19, or—as here—to make therapeutically useful recombinant interferon-β, these advances are critical to human health. As a result, the question before the Court in this case is of enormous importance to both the patients in need of innovative treatments and the biopharmaceutical companies that depend on robust and predictable patent protection to recoup their multi-billion-dollar investments in developing lifesaving treatments. Pet. 28.

Serono suggests that the significance of the issue presented has diminished because products such as recombinant insulin have been marketed now for several decades. Br. in Opp. 29. But Serono never challenges the facts laid out in the petition—that recombinant therapies are a huge and ever-growing part of modern medical treatment. And the fact that some methods of treatment using recombinant versions of natural proteins are now well-established in no way undermines the need for new ones to be developed. On the contrary, as the frontiers of biomedical research advance, the potential for therapeutic use of proteins that were not previously well understood likewise grows.

There is no dispute here that the lifesaving treatment made possible by the '755 Patent did not exist in the prior art. This case thus presents an undisputed set of facts on which this Court can confirm that methods of treatment using recombinant versions of naturally occurring sub-

stances are not anticipated by prior-art treatments using the native, human versions of those substances.

CONCLUSION

For the foregoing reasons and those set forth in the petition for a writ of certiorari, the petition should be granted.

Respectfully submitted,

NICHOLAS GROOMBRIDGE
ERIC ALAN STONE
PETER SANDEL
JENNY C. WU
JOSEPHINE YOUNG
PAUL, WEISS, RIFKIND, WHARTON & GARRISON LLP
1285 Ave. of the Americas
New York, NY 10019
(212) 373-3000

JEFFREY A. LAMKEN
Counsel of Record
MOLOLAMKEN LLP
The Watergate, Suite 500
600 New Hampshire Ave., N.W.
Washington, D.C. 20037
(202) 556-2000
jlamken@mololamken.com

Counsel for Petitioner

AUGUST 2021