Case No. 26-1581

IN THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

ARBUTUS BIOPHARMA CORPORATION and GENEVANT SCIENCES, GMBH,

Plaintiffs - Appellees,

v.

MODERNA, INC., and MODERNATX, INC.,

Defendants - Appellants.

On Appeal from the U.S. District Court for the District of Delaware,
The Honorable Joshua D. Wolson, Case No. 1:22-cv-00252-JDW

***AMICUS CURIAE* BRIEF OF THE EAGLE FORUM EDUCATION & LEGAL DEFENSE FUND IN SUPPORT OF PLAINTIFFS-APPELLEES AND IN SUPPORT OF AFFIRMANCE**

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CERTIFICATE OF INTEREST

Counsel for Eagle Forum Education & Legal Defense Fund certifies under Federal Circuit Rule 47.4 that the following information is accurate and complete to the best of his knowledge:

1. **Represented Entities.** Provide the full names of all entities represented by undersigned counsel in this case.

Eagle Forum Education & Legal Defense Fund.

2. **Real Parties in Interest.** Provide the full names of all real parties in interest for the entities.

Eagle Forum Education & Legal Defense Fund.

3. **Parent Corporation and Stockholders**. Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities.

None.

4. **Legal Representatives**. List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court.

Andrew L. Schlafly, Attorney at Law. No other law firms, partners, or associates have appeared below or are expected to appear in this Court on behalf of this amicus.

5. **Authorship and Funding**.

Pursuant to Rule 29(a)(4)(E) of the Federal Rules of Appellate Procedure, the undersigned counsel certifies that (1) no party's counsel authored this brief in whole or in part, (2) no party or party's counsel contributed money that was intended to fund preparing or submitting the brief, and (3) no person—other than the amicus curiae, its members, or its counsel—contributed money that was intended to fund preparing or submitting the brief.

6. **Related Cases**. Provide the case titles and numbers of any case known to be pending in this court or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. Do not include the originating case number(s) for this case.

None known.

7. **Organizational Victims and Bankruptcy Cases**. Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees).

Not applicable.

/s/ Andrew L. Schlafly
Andrew L. Schlafly
Counsel for Eagle Forum Education & Legal Defense Fund

Dated: July 14, 2026

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IDENTITY, INTEREST AND AUTHORITY TO FILE[1]

Amicus curiae Eagle Forum Education & Legal Defense Fund ("Eagle Forum ELDF") is a non-profit corporation founded in 1981. For more than two decades, Eagle Forum ELDF has supported continuation of the strong patent protection for innovation by pharmaceutical companies and all other inventors. Eagle Forum ELDF has previously filed many amicus briefs in federal courts in defense of robust patent rights. *See, e.g.*, *Bilski v. Kappos*, 561 U.S. 593 (2010).

The decision in this appeal could have an enormously detrimental impact on research and development in the pharmaceutical industry, by sharply reducing the value of their patents as obtained based on massive investments and efforts. Frustrating the right of a patent-holder to seek recovery and remedies from an infringer has the undeniable effect of reducing the value of the patent, and of all other patents like it. Moreover, the expansive interpretation sought here by Appellants of a little-used statutory provision, which was first enacted to protect military suppliers during World War I, could have a particularly devastating impact on the ability of pharmaceutical companies to recoup their immense investments toward developing beneficial new medications.

[1] All parties have consented to the filing of this brief.

As a longtime defender of strong patent rights by those who invent, including pharmaceutical companies, Eagle Forum ELDF has direct and vital interests in the issues presented here.

INTRODUCTION

Patents are the lifeblood of the pharmaceutical industry, where an investment of more than a billion dollars is often necessary to develop a new drug or vaccine today.[2] The principles underlying patent law apply with special force to pharmaceutical inventions, because there are tremendous public benefits from new treatments while the costs of innovation and development are extraordinarily high. This industry has unique characteristics that make strong patent protection especially important. Invention in the pharmaceutical industry entails long development timelines, large capital investment requirements, stringent regulatory approval hurdles, and high failure rates. Undermining patent protection and remedies for pharmaceutical creativity cannot be responsibly taken lightly. Congress has declined to reduce incentives for the pharmaceutical industry; this Court should decline to do likewise and should not reinterpret a World War I-era

[2] Congressional Budget Office, "Research and Development in the Pharmaceutical Industry" (April 2021) ("The expected cost to develop a new drug—including capital costs and expenditures on drugs that fail to reach the market—has been estimated to range from less than $1 billion to more than $2 billion," and inflation since then boosts that higher).

statute to foreclose patent remedies in the pharmaceutical context, as urged here by Defendants-Appellants Moderna, Inc., and ModernaTx, Inc. ("Moderna") based on 28 U.S.C. §1498(a) ("Section 1498(a)").

The Supreme Court has determined that Section 1498(a) was originally enacted with:

> [t]he intention and purpose of Congress in the Act of 1918 … to stimulate contractors to furnish what was needed for the War, without fear of becoming liable themselves for infringements to inventors or the owners or assignees of patents. The letter of the Assistant Secretary of the Navy, upon which the Act of 1918 was passed, leaves no doubt that this was the occasion for it.

Richmond Screw Anchor Co. v. United States, 275 U.S. 331, 345 (1928). What was "needed for the War" in 1918 is far afield from what Moderna seeks here.

Section 1498(a) states that:

> (a) Whenever an invention described in and covered by a patent of the United States ***is used or manufactured by or for the United States*** without license of the owner thereof or lawful right to use or manufacture the same, the owner's remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture. …
>
> For the purposes of this section, the use or manufacture of an invention described in and covered by a patent of the United States by a contractor, a subcontractor, or any person, firm, or corporation ***for the Government*** and with the authorization or consent of the Government, shall be construed as use or manufacture for the United States. …

28 U.S.C. § 1498(a) (emphasis added). By these express terms, the use must be ***for*** the Government, not merely funded by it.

The effect of Section 1498(a) is to convert a valuable patent infringement claim against a private infringer into a weaker claim against the federal government, similar to the concept of eminent domain except without an analogous notice and opportunity to be heard. By foreclosing remedies ordinarily available to a patent-holder, Section 1498(a) substantially reduces the value of the patent. As explained by one scholar:

> Evidence that the purpose of 1498 is distinct from that of the Patent Act lies in the different remedies available. The Patent Act in Title 35 of the United States Code, allows for adequate compensation for patent infringement in various forms, including but not limited to, lost profits, reasonable royalty, treble damages, injunctions, and attorney fees. In contrast, the remedy under 28 U.S.C. § 1498 is limited to "reasonable and entire compensation," which disfavors awarding lost profits, and punitive damages, and injunctions are generally unavailable. Thus, the remedies alone make recovery under 28 U.S.C. § 1498 different from that under 35 U.S.C. § 271.

Lt. Col. Katherine E. White, "Contract and Fiscal Law Developments of 2006—The Year in Review: Special Topics: Intellectual Property," 2007 Army Law. 136, 138-39 (Jan. 2007) (footnotes omitted). Application of Section 1498(a) thereby removes liability from certain types of patent infringers, leaving as the only remedy for the patent-holder a limited right to sue the federal government in the United States Court of Federal Claims.

The district court properly rejected Moderna's attempt to evade its liability through Moderna's proposed expansive interpretation of Section 1498(a). Relying

on a well-reasoned decision by the Claims Court – which this Court has cited favorably – the district court held that:

> The Court Of Claims' decision in *Larson* is particularly instructive. In [*Larson v. United States*, 26 Cl. Ct. 365, 369 (1992)], the Court Of Claims refused to approve a Section 1498 defense where the Government paid for medical splints and casts for patients participating in certain government programs. Rejecting the argument that the use of infringing splints and casts to treat patients was for the Government, the Court Of Claims stated that "[m]edical care is provided for the benefit of the patient, not the [G]overnment." *Id.*
>
> In this case, [Moderna's] C-100 Contract, for the most part, did not authorize the manufacture or use of vaccines for the Government. Instead, it authorized their manufacture and use for ***residents*** of the United States.

Arbutus Biopharma Corp. v. Moderna, Inc., No. 1:22-cv-00252-JDW, 2026 U.S. Dist. LEXIS 20889, at *19 (D. Del. Feb. 2, 2026) (emphasis added). This reasoning was correct and should be affirmed here.

SUMMARY OF ARGUMENT

Pharmaceutical products, including Moderna's product at issue here, are not typically designed for government consumption, in contrast with military weaponry and other goods provided especially to the government under a contract with it. Moderna's product here was plainly made for the public, which does not fall within the scope of the liability-shifting provision of Section 1498(a). This statutory provision has not been generally applied to pharmaceutical products as sought by Moderna here, for very good reasons. In addition to Moderna's product not being within the meaning of this statutory provision, Moderna's arguments

would undermine the patent protection needed for billion-dollar investments in innovative drugs and vaccines.

To allow Moderna to get a free ride while their competitors and others play by the rules of making licensing payments would be highly disruptive and would create a disincentive to pharmaceutical invention. The patent infringers themselves – in this case Moderna – are in the best position to assess the claims of others and negotiate royalty arrangements as may be warranted. The federal government is in no position to do that, which means that limiting remedies for infringement and shifting liability to the federal government in these circumstances would inflict an unjustified distortion on the development of new drugs. Congress could even enact a specific denial of an appropriation for this, leaving the patent-holder such as Plaintiffs with no recovery at all.

The Appropriations Clause of the U.S. Constitution grants the "power of the purse" exclusively to Congress, and grave constitutional separation-of-powers issues are implicated if another branch of government attempts to override that. *See* U.S. CONST. art. I, § 9, cl. 7. The extraordinary $1.3 billion in patent infringement liability which Moderna seeks to shift on to the back of the U.S. government, without an express, specific assumption of such liability by any Act of Congress, implicates a constitutional difficulty that would be best avoided by rejecting Moderna's interpretation of Section 1498(a). If Moderna's arguments were

accepted here, then the executive branch could bypass Congress by entering into contracts for the benefit of a favored contractor, in an attempt to shift liability on to the federal government in unexpected ways never authorized by Congress.

A straightforward textualist approach to statutory interpretation requires rejecting any argument to construe the "United States" as something broader than the federal government here, meaning the military and federal agencies. The phrase "manufactured by … the United States" plainly means made by the United States government. Section 1498(a) broadened this to include "manufactured … for the United States," and "used … by or for the United States," but this context of the term "United States" must remain the same in this same clause: the federal government and not the general public. The vast majority of Moderna's sales were for administration to millions of private individuals rather than for governmental use. No textualist or any other canon of statutory interpretation permits stretching the same term used in the context for "manufactured by … the United States" government to include the many millions of units of Moderna's product distributed to private persons unrelated to the federal government.

To the extent that legislative intent may dictate the outcome here, this statute was enacted to protect military contractors who sold their goods directly to the United States government for wartime use. Moderna's attempt to shift their own liability for patent infringement, which arose from its own sales of its own product

for public consumption, is not within the ambit of this statutory provision.

If Moderna's arguments on appeal were accepted to deny relief to Plaintiffs against Moderna as the patent infringer, this would open a Pandora's box of other liability-shifting on to the government whenever the patent infringer may coincidentally have a contract with it. This would undermine long-established enforcement remedies for patent infringement, and thereby reduce the value of patents issued by the United States. This would come at an unfortunate time when patent applications in the United States are already sharply declining, and have fallen far less than in China. In 2025, "U.S. patent applications headed sharply downward, dropping 9% from 2024, the lowest level since 2019." IFI CLAIMS Patent Services, "U.S. Patent Applications Decrease Dramatically One Year After Reaching Record High, Falling 9%; 2025 U.S. Patent Grants Also Down" (Jan. 13, 2026).[3] Annual patent applications are now three times higher in China than in the United States, as patent enforceability diminishes here. *See* "World Intellectual Property Indicators by Country 2026."[4] Moderna proposes denying remedies inherent in a patent, including the right to recover damages directly from the

[3] https://www.ificlaims.com/news/u-s-patent-applications-decrease-dramatically-one-year-after-reaching-record-high-falling-9-2025-u-s-patent-grants-also-down/ (viewed June 21, 2026).

[4] https://worldpopulationreview.com/country-rankings/world-intellectual-property-indicators-by-country (viewed June 21, 2026).

infringer based on a jury trial, and Moderna's proposed deprivation of this right would cause a harmful decrease in the value of U.S. patents while creating a disincentive for undertaking the substantial investments in inventing and then applying for patent protection.

ARGUMENT

Amicus presents three compelling reasons to affirm. First, Moderna's approach would open the door to a variety of harmful patent infringements without compensation to pharmaceutical companies, thereby undermining the patent protections upon which this industry depends to innovate. Second, shifting this liability without an explicit authorization by Congress would raise grave separation-of-powers concerns under the Appropriations Clause. The constitutional avoidance canon, also known as the avoidance doctrine or constitutional-doubt canon, requires interpreting a statute to avoid constitutional difficulties because Congress is presumed not to have transgressed the Constitution. Third, a textualist interpretation of Section 1498(a) requires rejecting Moderna's arguments, because "for the United States" in this context means for the government of the United States, not its many millions of individual residents for whom Moderna's product was intended and to whom it was primarily distributed.

Affirmance here may be on grounds not reached below. "Although the district court did not reach this issue, we may affirm on any grounds for which

there is a record sufficient to permit conclusions of law, even grounds not relied upon by the district court. *Simio, LLC v. Flexsim Software Prods.*, 983 F.3d 1353, 1365 (Fed. Cir. 2020) (inner quotation marks omitted). *See also Luv N' Care, Ltd. v. Laurain*, 98 F.4th 1081, 1094 (Fed. Cir. 2024) ("We may affirm on any grounds that are adequately supported by the evidence in the record ….").

I. Section 1498 Has Not Been Applied to Pharmaceutical Products as Sought by Moderna Here, and Its Argument Would Undermine the Patent Protection Needed to Protect Billion-Dollar Investments in New Drugs and Vaccines.

Moderna's unprecedented argument for applying Section 1498 expansively against pharmaceutical patents strikes at the heart of the incentive necessary for innovation in this important field. Pharmaceutical companies need to be able to rely on secure, robust patent rights before they and their investors will commit the extraordinary resources required to research, invent, and obtain regulatory approval for beneficial new drugs. The 20-year baseline protection of the patent term, 35 U.S.C. § 154, is undermined if Section 1498 is interpreted here to allow infringement during this period without full recourse by the patent-holder against the infringer. For pharmaceutical products, much of the 20-year term can be consumed by development and regulatory review, further frustrating the ability to recoup the massive investments necessary in this field.

Congress has indicated that patent protection for pharmaceutical innovation needs to be stronger than for other types of inventions, such as machinery used in war which was the motivation for enacting Section 1498 during World War I. Congress, for example, enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (commonly known as the Hatch-Waxman Act), to allow pharmaceutical companies to extend the term of their patents in order to be able to recoup the larger investment and longer regulatory process required for these inventions. *See* 35 U.S.C. § 156.

Moderna's argument to allow infringement on pharmaceutical patents such that there would be only a limited remedy in the Court of Federal Claims against the federal government would be a harmful step backwards, contrary to what Congress has enacted to strengthen patent rights for this industry. Weakening pharmaceutical patent protection, as urged by Moderna for its unique benefit here, would create a disincentive that discourages investment in the most challenging and important therapeutic areas. Companies would thereby have an incentive to copy and infringe, rather than incur the investment expenses needed to discover and develop new treatments against complex diseases. The result would be fewer breakthrough therapies and diminished progress against illnesses.

Moderna argues that its actions, which include its patent infringement, were for the good of the country. (Moderna Br. 50-51) But that is an argument Moderna

could have made, and could still make, to Congress while lobbying for an appropriation. Assuming infringement, Moderna had other options for resolving patent liability, including licensing, redesign, or pricing for expected royalties.

The reasoning by this Court in invalidating a law by the District of Columbia to lower medication costs is instructive here. This Court explained that:

> the District has chosen to re-balance the statutory framework of rewards and incentives insofar as it relates to inventive new drugs. In the District's judgment, patents enable pharmaceutical companies to wield too much exclusionary power, charging prices that are "excessive" for patented drugs. The [District of Columbia's Prescription Drug Excessive Pricing Act of 2005] is a clear attempt to restrain those excessive prices, in effect diminishing the reward to patentees in order to provide greater benefit to District drug consumers. This may be a worthy undertaking on the part of the District government, but it is contrary to the goals established by Congress in the patent laws.

Biotechnology Indus. Org. v. District of Columbia, 496 F.3d 1362, 1374 (Fed. Cir. 2007). The bottom line is that Congress has chosen to reward pharmaceutical companies for innovation through the full and robust protections provided by the Patent Act, as amended, and this Court has consistently abided by this clear congressional intent particularly for this life-saving industry.

Some have already sought to misuse Section 1498 as a "powerful tool" for lowering drug prices, in a manner analogous to Moderna's arguments here. *See* Letter from Senator Elizabeth Warren to Xavier Becerra, Sec'y, U.S. Dep't of

Health & Human Servs. (Apr. 22, 2022).[5] Under this approach, the federal government would simply enter into a contract with a generic producer of an innovative pharmaceutical drug, include an authorization and consent clause similar to what Moderna cites in its brief, and – *voila* – the patent rights of the pharmaceutical company that invested a billion dollars in inventing this drug would be eviscerated. Misusing Section 1498 in this manner, without any additional congressional action, has been expressly suggested by at least one senator and former presidential candidate already. *See id.* at 1 (urging a "directed use" of Section 1498 to "help the government obtain fair prices for prescription drugs").

Moderna's expansive interpretation of Section 1498 would undermine the incentives in the Patent Act for all pharmaceutical innovation, far beyond the patents relevant to this case. As emphasized by this Court:

> [T]he Patent Act creates an incentive for innovation. The economic rewards during the period of exclusivity are the carrot. The patent owner expends resources in expectation of receiving this reward. Upon grant of the patent, the only limitation on the size of the carrot should be the dictates of the marketplace.

[5] https://www.warren.senate.gov/wp-content/uploads/media/doc/2022.4.22%20Letter%20to%20Becerra%20on%20Drug%20Pricing%20Executive%20Authorities.pdf?utm_source=chatgpt.com (viewed July 10, 2026).

Biotechnology Indus. Org., 496 F.3d at 1372-73 (quoting *King Instruments Corp. v. Perego*, 65 F.3d 941, 950 (Fed. Cir. 1995)).

This Court has explained on multiple occasions, in the pharmaceutical context at issue here, how important encouraging innovation is to the patent system:

> We have long acknowledged the importance of the patent system in encouraging innovation. Indeed, the "encouragement of investment-based risk is the fundamental purpose of the patent grant, and is based directly on the right to exclude." *Patlex Corp. v. Mossinghoff*, 758 F.2d 594, 599 (Fed. Cir. 1985). The district court relied on the testimony of Dr. Hausman in finding that the average cost of developing a blockbuster drug is $800 million. Importantly, the patent system provides incentive to the innovative drug companies to continue costly development efforts. We therefore find that the court did not clearly err in concluding that the significant public interest in encouraging investment in drug development and protecting the exclusionary rights conveyed in valid pharmaceutical patents tips the scales in favor of Sanofi.

Sanofi-Synthelabo v. Apotex, Inc., 470 F.3d 1368, 1383-84 (Fed. Cir. 2006) (inner quotation marks omitted). *See also Biotechnology Indus. Org.*, 496 F.3d at 1372 (quoting the same passage from *Sanofi-Synthelabo*).

This Court has found that the goal of Congress in its patent legislation has been to encourage innovation and invention. As this Court held:

> Congress, too, has acknowledged the central role of enhanced profits in the statutory incentive scheme it has developed. In the legislative history of the Drug Price Competition and Patent Term Restoration Act of 1984 (popularly known as the "Hatch-Waxman Act"), the House Committee on Energy and Commerce observed:
>
> > Patents are designed to promote innovation by providing the right to exclude others from making, using, or selling an invention. They enable

> innovators to obtain greater profits than could have been obtained if direct competition existed. These profits act as incentives for innovative activities.
>
> H.R. Rep. No. 98-857, at 17 (1984); *see also id.* at 15 ("The purpose of Title II of the bill is to create a new incentive for increased expenditures for research and development.").

Biotechnology Indus. Org., 496 F.3d at 1373.

If adopted by this Court, Moderna's argument would create harmful incentives in favor of infringement on pharmaceutical patents, and against further innovation in this field contrary to basic principles and goals of patent statutes. Victims would include everyone who stands to benefit from future innovation in this industry.

II. Shifting This Immense Liability on to the Federal Government Would Intrude on the Exclusive Congressional Authority Under the Appropriations Clause, and Constitutional Avoidance Doctrine Requires Steering Clear of Moderna's Interpretation.

Moderna seeks to shift an unprecedented billion-dollar liability on to the federal government that is far greater than any other award ever granted under Section 1498(a), and which would eliminate the guardrails that have successfully limited application of this provision to narrow circumstances. Congress has never authorized such a vast, unbounded expansion in liability by the United States government, and the separation of powers doctrine prohibits transgressing this exclusive authority of Congress.

"It is well understood that when there are two reasonable constructions for a statute, yet one raises a constitutional question, the Court should prefer the interpretation which avoids the constitutional issue." *Legal Servs. Corp. v. Velazquez*, 531 U.S. 533, 545 (2001) (citing *Gomez* v. *United States,* 490 U.S. 858, 864 (1989), and *Ashwander* v. *TVA,* 297 U.S. 288, 346-48 (1936) (Brandeis, J., concurring)). Moderna's request that this Court shift a vast liability on to taxpayers, without specific congressional authorization, implicates grave constitutional separation-of-powers issues that are best avoided by rejecting Moderna's request for an expansive interpretation of the scope of Section 1498(a).

The Supreme Court has repeatedly emphasized that:

> It has long been an axiom of statutory interpretation that "where an otherwise acceptable construction of a statute would raise serious constitutional problems, the Court will construe the statute to avoid such problems unless such construction is plainly contrary to the intent of Congress."

Pub. Citizen v. United States Dep't of Justice, 491 U.S. 440, 466 (1989) (quoting *Edward J. DeBartolo Corp.* v. *Florida Gulf Coast Building & Construction Trades Council*, 485 U.S. 568, 575 (1988), additional citations omitted). The Supreme Court added, "Our reluctance to decide constitutional issues is especially great where, as here, they concern the relative powers of coordinate branches of government." *Pub. Citizen*, 491 U.S. at 466.

Moderna asks this Court to do what Congress has so far declined to do: appropriate more than a billion dollars to pay for patent infringement by Moderna. Separation of powers doctrine prevents either the executive or the judicial branch from appropriating funds because this authority is vested exclusively in Congress: "No Money shall be drawn from the Treasury, but in Consequence of Appropriations made by Law." U.S. CONST. Art. I, Sec. 9, cl. 7. Moderna's requested relief would infringe on this exclusive power of the purse by Congress under the Constitution, and thereby overstep the separation of powers.

Congress cannot properly delegate this authority to another branch of government, because it is Article I, Section 9, not its Section 8, which requires Congress alone to appropriate funds:

> Since legislative appropriations power is rooted in article I, section 8, we may infer that a primary significance of the appropriations clause in section 9 lies in what it takes away from Congress: the option *not* to require legislative appropriations prior to expenditure. If the Constitution thus strictly forbids "executive appropriation" of public funds, the exercise by Congress of its power of the purse is a structural imperative.

Kate Stith, "Congress' Power of the Purse," 97 Yale L.J. 1343, 1349 (June 1988) (footnotes omitted).

The Supreme Court has explained:

> [T]he power of the purse belongs to Congress, and Congress has determined that the price for greater fairness is not too high. The agencies, unlike the aliens, have ready and persuasive access to the legislative ear and if error is

made by including them, relief from Congress is a simple matter. *Wong Yang Sung v. McGrath*, 339 U.S. 33, 46-47 (1950) (superseded by statute).

Moderna emphasizes that the COVID-19 pandemic was a "worldwide emergency" (Moderna Br. 5-6), but that reinforces the significance of silence by Congress in never assuming this specific, colossal liability of Moderna. Congress did enact laws with overwhelming bipartisan support to address the COVID-19 pandemic, but never authorized payment for patent infringement by Moderna related to its vaccine. For example, Congress passed the CARES Act (Coronavirus Aid, Relief, and Economic Security Act, Pub. L. 116-136, enacted March 27, 2020) (passed by a voice vote in the House and 96-0 in the Senate), to fund $10 billion initially allocated toward Operation Warp Speed ("OWS") efforts, including countermeasure development and research. This allocation was in support of advanced development, large-scale manufacturing contracts, and related efforts. Additional COVID-19 appropriations included the Families First Coronavirus Response Act, Paycheck Protection Program and Health Care Enhancement Act, and Consolidated Appropriations Act (2021) (all enacted with overwhelming majorities), which further supplied funding that OWS drew upon. Overall, through several appropriations, Congress funded OWS efforts with

approximately $18 billion for vaccine development, manufacturing, and procurement, predominantly for the later stages of product development.[6]

In its brief here, Moderna cites to an Authorization and Consent clause in some (not all) of its contracts. (Moderna Br. 12-13) But the executive branch cannot bypass the Appropriations Clause any more than the judiciary should. Moreover, under the seminal decision in *Loper Bright*, this Court and not the executive branch has the sole responsibility for interpreting a statute when it is ambiguous:

> [W]hen a particular statute delegates authority to an agency consistent with constitutional limits, courts must respect the delegation, while ensuring that the agency acts within it. But courts need not and under the APA may not defer to an agency interpretation of the law simply because a statute is ambiguous.

Loper Bright Enters. v. Raimondo, 603 U.S. 369, 413 (2024). Section 1498(a) does not delegate any authority to an agency, and thus the executive branch lacks authority to relieve Moderna of a massive liability for its patent infringement.

Neither the executive nor the judicial branch can compel Congress to spend what it did not authorize, which in this case is an obligation in excess of a billion

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[6] "OWS has invested an estimated US$18 billion mostly in the late-stage clinical development and early manufacturing of COVID-19 vaccines …." Winch, G. M., Cao, D., Maytorena-Sanchez, E., Pinto, J., Sergeeva, N., & Zhang, S., Operation Warp Speed: Projects responding to the COVID-19 pandemic, *Project Leadership and Society*, *2*, (2021) https://doi.org/10.1016/j.plas.2021.100019 (viewed July 10, 2026).

dollars. As then-Judge Kavanaugh observed, the Appropriations Clause is "a bulwark of the Constitution's separation of powers" that gives Congress "exclusive power over the federal purse." *United States Dep't of the Navy v. Fed. Labor Rels. Auth.*, 665 F.3d 1339, 1346, 1347 (2012). "If not for the Appropriations Clause, 'the executive would possess an unbounded power over the public purse of the nation; and might apply all its monied resources at his pleasure.'" *Id.* (quoting 3 Joseph Story, Commentaries on the Constitution of the United States § 1342, at 213-14 (1833)). The Framers established Congress as the branch most directly and frequently accountable to the People, and it is entirely consistent with this structure that Congress alone can authorize expenditures from the public fisc. For the executive or judicial branch to impose a billion-dollar liability on taxpayers without direct authorization by Congress would be contrary to the separation of powers inherent in the Constitution.

Instances where Congress has consented to suit, as in Section 1498(a), the Tucker Act, and the Federal Tort Claims Act, are thus to be construed narrowly and strictly, and have been. For example, in rejecting an attempt to overcome sovereign immunity, the Supreme Court explained:

> A waiver of the Federal Government's sovereign immunity must be unequivocally expressed in statutory text, see*, e. g.*, *United States v. Nordic Village, Inc.*, 503 U.S. 30, 33-34, 37 (1992), and will not be implied. Moreover, ***a waiver of the Government's sovereign immunity will be strictly construed, in terms of its scope, in favor of the sovereign***. See, *e. g.*, *United*

> *States v. Williams*, 514 U.S. 527, 531 (1995) (when confronted with a purported waiver of the Federal Government's sovereign immunity, the Court will "construe ambiguities in favor of immunity"); *Library of Congress v. Shaw*, 478 U.S. 310, 318 (1986); *Lehman v. Nakshian*, 453 U.S. 156, 161 (1981) ("Limitations and conditions upon which the Government consents to be sued must be strictly observed and exceptions thereto are not to be implied").

Lane v. Pena, 518 U.S. 187, 192 (1996) (emphasis added, citations trimmed or deleted). The Court explained further that "[t]o sustain a claim that the Government is liable for awards of monetary damages, the waiver of sovereign immunity must extend ***unambiguously*** to such monetary claims." *Id.* (emphasis added, citation omitted).

The Supreme Court concluded there, as this Court should hold here:

> In light of our established practice of construing waivers of sovereign immunity narrowly in favor of the sovereign, however, we decline [plaintiff's] invitation to read the statutory language so broadly.

Id. at 195.

Because Congress, not the judiciary, has the authority and responsibility to decide how to allocate scarce resources for public benefit, judicial restraint is warranted before imposing a colossal new obligation on the federal government for the benefit of a private company. Statutes are narrowly interpreted to avoid compelling expenditures which Congress has not specifically authorized. Fiscal policy is properly determined by Congress, not the courts. This approach preserves

the constitutional structure for the three branches of government, without disrupting its delicate balance.

III. A Textualist Interpretation of Section 1498(a) Requires Rejecting Moderna's Arguments, as Do Sound Policy Considerations.

The textualist approach looks to the ordinary meaning of a phrase in the context in which it is used. As explained by Justice Scalia, "Words that can have more than one meaning ***are given content … by their surroundings***, and in the context of [the statutory section] this second definition makes no sense." *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 466 (2001) (Scalia, J., citing *FDA* v. *Brown & Williamson Tobacco Corp.,* 529 U.S. 120, 132-33 (2000); *Jones* v. *United States,* 527 U.S. 373, 389 (1999), emphasis added).

By using "United States" with the phrase "manufactured by … the United States," Section 1498(a) is plainly referring to the federal government and not the American public. Private patients, who have been the consumers of Moderna's product, do not "manufacture" the good. So the use of "United States" in this context cannot possibly be referring to patients in the United States but must refer to the federal government itself.

Similarly, the explanatory provision in Section 1498(a) reinforces that the context of the use of the term "United States" refers to the federal government. As quoted in the Introduction above and set forth again here for convenience, the

statute explains that this term should be interpreted as meaning "for the Government":

> For the purposes of this section, the use or manufacture of an invention described in and covered by a patent of the United States by a contractor, a subcontractor, or any person, firm, or corporation ***for the Government*** and with the authorization or consent of the Government, shall be construed as use or manufacture ***for the United States***.

28 U.S.C. §1498(a) (emphasis added).

This meaning of "United States" as the federal government is eminently reasonable in this context, as the federal government is not in a position to assess and negotiate royalty obligations for a product manufactured privately for consumption by the general public, as in this case. Moderna alone was in the position to know that it was infringing on patented technology, and whether it could innovate in a way to avoid this infringement. The federal government had no way of knowing that. Moderna alone was in the position to set the price of its COVID-19 vaccine dependent on any royalty obligations that might be owed on the product, which is not something the federal government could do for it.

The incoherence of Moderna's argument is evident in multiple ways. It would be unfair to competitors who play by the rules, and who negotiate and pay royalty fees for their patent infringement. Moderna's arguments, if adopted, could encourage companies to proceed with an unaffordable product in the hope of profiting only by shifting an enormous infringement liability on to the government.

It is unfair to the federal government to have a liability in excess of a billion dollars sprung on it years after the fact. In high-tech products the developer alone, not the federal government, is or should be aware of possible infringement, and should take prompt steps to address that risk or otherwise factor it into its pricing. Surprises later of this magnitude, which Moderna's arguments here would encourage, should not be allowed. In sum, Moderna's approach would encourage patent infringement, not invention.

The context for interpreting Section 1498 may be gleaned further from its history. Congress enacted Section 1498(a) for a wartime purpose as a narrow exception to the general rule that liability for a wrongful or infringing act remains with the person who committed it, thereby discouraging more unauthorized infringement. Decoupling liability for infringement from the entity that commits the infringement was for this military procurement context, and discarding that context would open the floodgates to a taking of the inventions of others without their permission.

Moderna relies heavily in its brief on the application of Section 1498 to protect a government contractor in "the cleanup of a lead-contaminated parcel of land near Colonie, New York ('the Colonie site') that is owned by the United States and managed by the U.S. Army Corps of Engineers." *Sevenson Envtl. Servs. v. Shaw Envtl., Inc.*, 477 F.3d 1361, 1363 (Fed. Cir. 2007) (cited by Moderna Br.

26, 33, 46, 47). But in sharp contrast with Moderna's product at issue there, in *Sevenson* the "use of the accused method [was in defendant's] capacity as a government contractor and pursuant to its contract for the benefit of the government." *Id.* at 1366. Moderna's admitted patent infringement here was not merely "as a government contractor and pursuant to its contract for the benefit of the government," as it was in *Sevenson*. *Id.*

The decisions distinguished by this Court in *Sevenson* are much closer to the facts here, and those precedents are what should control here:

> [I]n *Riles v. Amerada Hess Corp.*, a district court concluded that where an offshore oil drilling operation leased drilling rights from the government for a 12.5% royalty and was required to get government approval for its drilling platform installation methods, the infringement of a patent on those methods was not part of a use "for the Government." 999 F. Supp. 938, 940 (S.D. Tex. 1998). The government received some benefit from the infringement, to be sure, but the drilling was not a "governmental function" that the government had sought or required the driller to carry out. *Id. Riles* noted that "[c]learly, Defendant did not agree to drill *for* the Government simply because the Government receives some monetary benefit as a byproduct of the activity." *Id.*

Sevenson Envtl. Servs., 477 F.3d at 1365-66.

This Court then explained with full approval of the *Larson* precedent relied on below, which Moderna disparages in its brief as having been rendered merely by an Article I Claims Court (Moderna Br. 40 n.4):

> Similarly, in *Larson v. United States*, the United States Claims Court held that use of infringing medical devices by Medicare and Medicaid providers did not fall within § 1498 because the use of those particular devices, though

> funded by the government, was not required by it, nor were the providers under the government's control. 26 Cl. Ct. 365, 369-70 (1992).

Sevenson Envtl. Servs., 477 F.3d at 1366. As in *Larson*, the mere use by the government of Moderna's product does not qualify Moderna's patent infringement for protection under Section 1498.

If accepted, Moderna's sweeping new approach would create an unprecedented new incentive for patent infringement by nearly any company that does business with the federal government, and introduce new impediments for patent-holders to obtain appropriate and timely remedies. A statute designed narrowly to facilitate a wartime effort would thereby be turned into an incentive to steal intellectual property from others without the infringing party ever paying for it. Such an incentive to misappropriate is not what Congress enacted in Section 1498, and Moderna's interpretation would be significantly detrimental to the value of our patent system.

CONCLUSION

For the foregoing reasons and those stated in Plaintiffs-Appellees' brief, the decision below should be affirmed.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

1. This brief has been prepared using 14-point, proportionately spaced, serif typeface, in Microsoft Word.

2. This brief complies with FED. R. APP. P. 29(a)(5) and 32(a)(7)(B) because it contains a total of 6,113 words, excluding material not counted under Rule 32(f).

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