No. 26-1581

United States Court of Appeals for the Federal Circuit

ARBUTUS BIOPHARMA CORPORATION,
GENEVANT SCIENCES, GMBH,

Plaintiffs-Appellees,

v.

MODERNA, INC.,
MODERNATX, INC.,

Defendants-Appellants.

Appeal from the U.S. District Court for the District of Delaware, Case No. 22-cv-252, before the Honorable Joshua D. Wolson

BRIEF OF *AMICUS CURIAE* NORTHWESTERN UNIVERSITY IN SUPPORT OF APPELLEES AND IN SUPPORT OF AFFIRMANCE

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CERTIFICATE OF INTEREST

I certify the following information is accurate and complete to the best of my knowledge:

1. **Represented Entities**. Fed. Cir. R. 47.4(a)(1). Provide the full names of all entities represented by undersigned counsel in this case.

Northwestern University.

2. **Real Party in Interest**. Fed. Cir. R. 47.4(a)(2). Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities.

None/not applicable.

3. **Parent Corporations and Stockholders**. Fed. Cir. R. 47.4(a)(3). 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/not applicable.

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. Fed. Cir. R. 47.4(a)(4).

None/not applicable.

5. **Related Cases**. Other than the originating case(s) for this case, are there related or prior cases that meet the criteria under Fed. Cir. R. 47.5(a)?

Not applicable (amicus/movant).

6. **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). Fed. Cir. R. 47.4(a)(6).

None/not applicable.

July 15, 2026

/s/ Katherine E. Rhoades

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STATEMENT OF INTEREST OF AMICUS CURIAE

Amicus curiae Northwestern University is a private, not-for-profit research university. Each year, Northwestern is recognized as one of the top research institutions in the world. Northwestern is at the cutting edge of research in many fields, including biotechnology, bioengineering, chemistry, medicine, and other life and biomedical sciences.

Like many universities, Northwestern relies on funding from federal agencies to support its research. Of the $1.04 billion that Northwestern received in sponsored funding in 2025, over $660 million was awarded through the National Institutes of Health, National Science Foundation, Department of Defense, and Department of Energy. About $496 million came from the National Institutes of Health alone.

Northwestern sometimes patents and commercializes inventions developed by its faculty and then returns a portion of the proceeds of those activities to fund further education and research at the university. The U.S. Patent and Trademark Office has awarded thousands of patents to Northwestern, recognizing the many discoveries made by its researchers. Many of Northwestern's patents are based on groundbreaking research done at Northwestern's International Institute for Nanotechnology ("IIN"), which supports interdisciplinary nanoscience research to address the world's most pressing problems in medicine, energy, the environment, and advanced nanomaterials. Since its inception in 2000, the IIN has led to over 2,000 new commercial products and over 40 new startup companies.

Through collaboration between Northwestern's IIN and medical school, several researchers at Northwestern achieved a breakthrough in synthetic lipid nanoparticle technology and were awarded patents for their advancements. Northwestern has asserted those patents against Moderna in a related case in the U.S. District Court for the District of Delaware. That case is captioned *Northwestern University v. Moderna, Inc.*, No. 1:24-cv-01151 and is assigned to Judge John Campbell Barker, sitting by designation. Northwestern has accused Moderna's lipid nanoparticle platform in its COVID-19 vaccine (Spikevax), among other vaccines, of infringing Northwestern's patents on lipid nanoparticles.

This appeal will directly impact Northwestern's lawsuit against Moderna.[1] In that case, Moderna has raised the same 28 U.S.C. § 1498(a) defense based on the same C-100 contract and vaccine doses at issue in this appeal. Specifically, Moderna has alleged that Northwestern's infringement claims based on Moderna's manufacture and sale of COVID-19 vaccine doses pursuant to the C-100 contract are barred by § 1498(a). This Court's resolution of the § 1498(a) question in this appeal will therefore govern Moderna's identical defense in Northwestern's case against Moderna.

Northwestern submits this brief to ensure that the Court has the benefit of Northwestern's arguments that may not be fully developed in the parties' briefing.

[1] WilmerHale represents Moderna in the Northwestern case. WilmerHale, including one of the same lawyers, also represents amicus curiae Dr. Matthew Hepburn in this appeal.

RULE 29(A) STATEMENT OF AMICUS CURIAE

Pursuant to Federal Rule of Appellate Procedure 29(a)(2), all parties have consented to the filing of this brief.

No party's counsel authored this brief in whole or in part. No party or a party's counsel contributed money that was intended to fund the preparation or submission of this brief. No person other than amicus curiae, its members, or its counsel contributed money that was intended to fund the preparation or submission of this brief.

INTRODUCTION

In 1918, Congress enacted 28 U.S.C. § 1498(a) and waived sovereign immunity for patent owners to sue the United States in the Court of Federal Claims when their patented invention was "used or manufactured by or for the United States." When a government contractor (rather than the United States itself) infringes a patent, Congress waived immunity and shifted liability to the United States only when the contractor's conduct is "for the Government and with the authorization or consent of the Government." 28 U.S.C. § 1498(a). In that situation, the contractor's infringement "shall be construed as use or manufacture for the United States," *id.*, because it is "clothed with the authority of the eminent domain power" of the United States, *Decca Ltd. v. United States*, 640 F.2d 1156, 1167 (Ct. Cl. 1980).

Moderna argues that the statute immunizes Moderna from liability for any patent it infringed in manufacturing, selling, and profiting from over 500 million doses of its COVID-19 vaccine paid for by the U.S. Government. But only a small number of those doses went directly to the government. The rest went to the American public. Of course, § 1498(a) covers the doses that went directly to government employees. It does not cover the doses that were used to vaccinate private citizens.

The text, context, and history of § 1498(a) confirm that the statute's waiver of immunity only reaches a contractor's conduct when the government itself is the intended recipient or beneficiary. The government was not the intended recipient or beneficiary of the vaccine doses that went to the American public. Private citizens were.

Any liability for Moderna's patent infringement in manufacturing and selling vaccine doses under the C-100 contract that went to the American public lies with Moderna, not the United States. The Court should affirm the district court's judgment.

ARGUMENT

Applying § 1498(a) to Moderna's distribution of vaccine doses to the American public stretches the statute beyond its text and purpose. Section 1498(a) waives sovereign immunity for patent owners to bring infringement suits against the United States for a contractor's use or manufacture of a patented invention and assumes liability of the contractor's infringement only when the contractor's infringement was "*for the Government* and with the authorization or consent of the Government." 28 U.S.C. § 1498(a) (emphasis added); *see Richmond Screw Anchor Co. v. United States*, 275 U.S. 331, 343–44 (1928) (explaining that the statute "is more than a waiver of immunity and effects an assumption of liability by the government"). Vaccine doses manufactured by Moderna and administered to the American public were not for the *government*. Those vaccines were for the patients who received them.

I. Section 1498(a) Does Not Bar Direct Infringement Claims Against Moderna

A. The Text, Statutory Framework, and Legislative History Show That "For the Government" Means the Government Was the Intended Recipient or Beneficiary

"The starting point in every case involving construction of a statute is the language itself." *Santa Fe Indus., Inc. v. Green*, 430 U.S. 462, 472 (1977) (citation modified).

Since "Section 1498 waives the United States' sovereign immunity from suit," "it must be strictly construed in favor of the United States." *Zoltek Corp. v. United States*, 672 F.3d 1309, 1318 (Fed. Cir. 2012); *see Lane v. Pena*, 518 U.S. 187, 192 (1996) ("[A] waiver of the Government's sovereign immunity will be strictly construed, in terms of its scope, in favor of the sovereign."); *Lehman v. Nakshian*, 453 U.S. 156, 161 (1981) ("[L]imitations and conditions upon which the Government consents to be sued must be strictly observed and exceptions thereto are not to be implied." (quoting *Soriano v. United States*, 352 U.S. 270, 276 (1957))). Courts "may not enlarge the waiver beyond the purview of the statutory language" and should "discern the unequivocally expressed intent of Congress, construing ambiguities in favor of immunity." *United States v. Williams*, 514 U.S. 527, 531 (1995) (citation modified). The text, history, and judicial interpretation of "for the Government" in § 1498(a) show that Congress did not unequivocally express its intent to waive sovereign immunity for, and assume liability of, a private party's infringement of a patent in manufacturing vaccines for the American public.

1. The text of Section 1498(a)

The plain language of § 1498(a) does not say that Congress has waived sovereign immunity for, and assumed liability of, all patent infringement by the United States' contractors under a government procurement contract. The first paragraph of § 1498(a) provides that a patent owner may sue the "United States in the United States Court of Federal Claims" for "reasonable and entire compensation" when their patented invention "is used or manufactured by or for the United States." The second paragraph

then clarifies when use or manufacture of a patent by a contractor shall be construed as "use or manufacture for the United States":

> 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).

The statute thus waives immunity for, and assumes liability of, a contractor's infringement when that infringement is "*for the Government* and with the authorization or consent of the Government." *Id.* (emphasis added). If the contractor's use or manufacture was not "for the Government" or "with the authorization or consent of the Government," then the United States has not waived immunity and a patent owner's recourse is against the contractor.

The meaning of "for the Government" is clear from the text of the statute. Waiver is limited to use or manufacture "*for* the *Government* and with the authorization or consent of the *Government*." *Id.* (emphases added). In this context, the preposition "for" is used to indicate the recipient or beneficiary: the government. The language requires that the government—not the public at large—is the intended recipient or beneficiary. Only that use or manufacture is "for the *United States*." *Id.* (emphasis added).

The district court interpreted "for the Government" in the same way, explaining that "the Government, as an entity, must be the intended recipient of the infringing

product, as opposed to the public that the Government represents." Appx13. This is consistent with how the phrase "for the Government" would have been understood in 1942 when that language was added to the statute. *See* Act of October 31, 1942, ch. 634, 56 Stat. 1013, 1014 (1942). At that time, the word "for" "[i]ntroduc[ed] the intended recipient" or signaled "the purpose or result of benefiting or gratifying," such as who benefits. *For*, A New English Dictionary on Historical Principles at 410–11 (James A.H. Murray ed., Vol. IV, 1901) (also known as "The Oxford English Dictionary"); *For*, The Oxford English Dictionary at 410–11 (Vol. IV, 1933). And the word "government" referred to "the system of polity in a state," a "state," "the United States," or "the body of persons charged with the duty of governing." *Government*, A Law Dictionary at 544–45 (Henry Campbell Black, 2d ed., 1910) (also known as "Black's Law Dictionary"); *Government*, A New English Dictionary on Historical Principles at 320–21 (James A.H. Murray ed., Vol. IV, 1901); *see Government*, Webster's Practical Dictionary at 165 (Noah Porter ed., 1910) (similar). The statutory framework confirms this interpretation.

2. The statutory framework of Section 1498(a)

Section 1498(a)'s neighboring provisions waive sovereign immunity for other types of infringement and contain the same "for the Government" language. *See* 28 U.S.C. §§ 1498(b), (d). Sections 1498(b) and (d) provide that a copyright owner (§ 1498(b)) or owner of a certificate of plant variety protection (§ 1498(d)) may sue the United States for "reasonable and entire compensation" when their copyrighted work or certificate of plant variety protection is "infringed by the United States" or a

contractor "acting *for* the *Government* and with the authorization or consent of the Government." *Id.* § 1498(b) (emphases added); *see id.* § 1498(d). Each subsection of § 1498 is consistent: it waives the United States' sovereign immunity only when the United States itself, or someone acting with the authority of the United States and for its benefit, commits the infringement.

The broader statutory scheme confirms that Congress is specific and explicit when it waives sovereign immunity. Section 1498(a) appears in Chapter 91 of Title 28 of the U.S. Code, which governs the U.S. Court of Federal Claims. The chapter's opening provision grants that court jurisdiction over claims against the United States based on the Constitution, an Act of Congress or regulation, an express or implied contract with the United States, or for damages "in cases not sounding in tort." 28 U.S.C. § 1491 (a)(1). The sections that follow specify additional claims that may be brought against the United States pursuant to an Act of Congress based on an action by the United States or an action done for the United States (including for unsettled contractor accounts, *id.* § 1494, unjust convictions and imprisonment for federal offenses, *id.* § 1495, and damage to privately owned or leased oyster beds caused by federal dredging, *id.* § 1497). In each case, the waiver of sovereign immunity is precisely defined and tied to a specific act by or for the *government*. Section 1498(a) is not an exception. It fits that pattern. If Congress intended to waive immunity whenever a contractor used or manufactured a patented invention for the American population at large under a government procurement contract, it would have said so. It did not.

3. The legislative history of Section 1498(a)

The legislative history confirms that Congress only intended to waive sovereign immunity for a contractor's acts where the government itself is the intended recipient or beneficiary.

Congress enacted the precursor to § 1498(a) in 1910 to provide a way for patent owners to secure compensation from the United States for Takings Clause violations. *See* Act of June 25, 1910, ch. 423, 36 Stat. 851, 851–52 (1910); H.R. Rep. No. 61-1288, at 1, 3 (1910). Patents are property rights secured by the Takings Clause of the U.S. Constitution. *Cammeyer v. Newton*, 94 U.S. 225, 226 (1876). Once the United States grants a patent, it cannot appropriate or use the patented invention "without just compensation[] any more than it can appropriate or use without compensation land which has been patented to a private purchaser." *James v. Campbell*, 104 U.S. 356, 357–58 (1881). But before 1910, a patent owner could not seek just compensation from the United States for infringing their patent because the United States had not waived sovereign immunity for such suits.[2] U.S. Const. amend. V; *see Schillinger*, 155 U.S. at 167–69. The 1910 Act rectified that problem and waived sovereign immunity when a

[2] If a patent owner's claim was based on an express or implied contract, then their claim could proceed against the United States under contract law. *Schillinger v. United States*, 155 U.S. 163, 167–69 (1894). But "absent conduct by the United States from which a contract to license the patent could be inferred, a patent holder lacked a remedy for infringement by the United States." *Zoltek*, 672 F.3d at 1315.

patented invention was "used by the United States." Act of June 25, 1910, ch. 423, 36 Stat. 851, 851–52 (1910).

But the 1910 Act did not waive sovereign immunity when a patented invention was "used by" a government contractor, rather than the United States itself. The Supreme Court confirmed this in *William Cramp & Sons Ship & Engine Building Co. v. International Curtis Marine Turbine Co.*, 246 U.S. 28 (1918). There, the Cramp Company had contracted with the United States Navy during World War I to build torpedo boat destroyers for the Navy. *Id.* at 35. The Supreme Court held that the Cramp Company's infringement was not "use[] by the United States" because the Cramp Company was not "an official of the United States." *Id.* at 42–43 (citation modified).

Congress responded by extending waiver of immunity when a patented invention was "used or *manufactured* by or *for* the United States" after receiving a letter from the Acting Secretary of the Navy. *Richmond*, 275 U.S. at 342–43 (emphases added) (quoting Act of July 1, 1918, ch. 114, 40 Stat. 704, 705 (1918)). The Acting Secretary was concerned that the Supreme Court's decision would affect the Navy's ability to procure military supplies from its contractors during wartime. *Id.* Therefore, "[t]he intention and purpose of Congress in the act of 1918 was to stimulate contractors to furnish what was needed for the war, without fear of becoming liable themselves for" patent infringement. *Id.* at 345; *see* 65 Cong. Rec. 7948, 7960–61 (1918) (explaining that the amendment "would expedite the manufacture of war material" for the Navy).

In 1942, Congress further clarified when use or manufacture of a patented invention by a contractor constitutes "use or manufacture for the United States." Act of October 31, 1942, ch. 634, 56 Stat. 1013, 1014 (1942) (codified as amended in 28 U.S.C. § 1498(a)); *see* S. Rep. No. 77-1640, at 5 (1942). The 1942 amendment added the following language, which appears in the second paragraph of § 1498(a) today:

> [T]he use or manufacture of an invention described in and covered by a patent of the United States by a contractor . . . *for the Government* and with the authorization or consent of the Government, shall be construed as use or manufacture for the United States.

Act of October 31, 1942, ch. 634, 56 Stat. 1013, 1014 (1942) (emphasis added).

This history confirms that the "for the Government" qualifier is narrow and deliberate. Nothing in § 1498(a)'s text or history shows that Congress unequivocally expressed its intent to extend waiver beyond conduct where the *government* itself was the intended recipient or beneficiary.

B. The Government Was Not the Intended Recipient or Beneficiary of Vaccines That Went to the General Public

Section 1498(a) does not apply to Moderna's vaccine doses that went to the American public. Moderna was not the only company to develop a COVID-19 vaccine. Nor was it the first to receive approval. Pfizer's and BioNTech's vaccine was the first to receive Emergency Use Authorization on December 11, 2020.[3] Moderna received

[3] Andra Fortner & David Schumacher, *First COVID-19 Vaccines Receiving the US FDA and EMA Emergency Use Authorization*, 9(1) Discoveries e122 at 2 (Jan.–Mar. 2021), https://discoveriesjournals.org/discoveries/D.2021.01.FR-Fortner.pdf.

authorization a week later,[4] and Janssen's approval came in February 2021.[5] The U.S. government purchased over one billion doses to achieve its "overall goal of having sufficient adult vaccines for the American public."[6]

The overwhelming number of the 500,001,540 doses that Moderna supplied to the government under the C-100 contract "went to members of the general public" to vaccinate the American public against COVID-19. Appx8. A small number of vaccines went to government employees. *Id.* The C-100 contract defined these two classes of recipients or beneficiaries of Moderna's vaccine: "for the *United States Government* (USG) and the *US population*." Appx2796 (emphases added). While the doses that were "for the *United States Government*" are subject to § 1498(a), the doses "for . . . the *US population*" are not. The U.S. population was the intended recipient and beneficiary of those doses, not the government.

This is true even under Moderna's interpretation of "for" that means "on behalf of." Moderna Br. at 38–39. Moderna manufactured doses on behalf of the United States (the doses that went to government employees) and on behalf of the U.S. population (the doses that went to the American public).

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[4] *Id.*

[5] *Id.* at 3.

[6] U.S. Government Accountability Office, GAO-22-104453, *COVID-19: HHS and DOD Transitioned Vaccine Responsibilities to HHS, but Need to Address Outstanding Issues* 3, 36–37 (Jan. 2022), https://www.gao.gov/assets/gao-22-104453.pdf.

The Claims Court addressed a similar situation in *Larson v. United States*, 26 Cl. Ct. 365 (Cl. Ct. 1992). In that case, the court held that the use of infringing splints and casts by healthcare providers was not "for the Government" under § 1498(a), even though the government reimbursed the cost of the splints and casts under federal programs like Medicare and Medicaid. *Id.* at 367–69; *see Advanced Software Design Corp. v. Fed. Rsrv. Bank of St. Louis*, 583 F.3d 1371, 1378–79 (Fed. Cir. 2009) (citing *Larson* with approval); *Sevenson Env't Servs., Inc. v. Shaw Env't, Inc.*, 477 F.3d 1361, 1366 (Fed. Cir. 2007) (same). The *Larson* court explained that "[m]edical care is provided for the benefit of the patient, not the government" and rejected patentee's argument that use was for the benefit of the government:

> Any use of plaintiffs' casts and splints was for the benefit and convenience of the patient and provider, with no benefit to the government. The fact that the government has an interest in the program generally, or funds or reimburses all or part of its costs, is too remote to make the government the program's beneficiary for the purposes underlying § 1498.

Larson, 26 Cl. Ct. at 369. Since *Larson*, the Federal Circuit has reaffirmed that an "incidental benefit to the government is insufficient." *IRIS Corp. v. Japan Airlines Corp.*, 769 F.3d 1359, 1362 (Fed. Cir. 2014) (quoting *Advanced Software*, 583 F.3d at 1378). The use or manufacture must "be done 'for the benefit of the government.'" *Id.* (quoting *Advanced Software*, 583 F.3d at 1378).

The district court was correct that "[l]ike the patients receiving splints and casts in *Larson*, the patients receiving Moderna's mRNA vaccines were the beneficiaries."

Appx15. Moderna's agreement with the government makes this clear. The C-100 contract states that the government's partnership with Moderna is to "ensure development of [a] promising vaccine" and "improve *patient care*, thereby mitigating the impact of COVID-19 on the nation and its *people*." Appx2796 (emphases added). The fact that the government chose to subsidize the cost for the American people or help distribute vaccines does not convert the government into the recipient or beneficiary of those doses.

Moderna fails to distinguish *Larson*. Moderna's government procurement (C-100 contract) versus reimbursement (*Larson*) distinction is immaterial. Moderna Br. at 42–43. In both this case and *Larson*, the government funded the infringing products (vaccines or splints), but the use of the products was "for the benefit of the patient, not the government." *Larson*, 26 Cl. Ct. at 369. Whether "the infringing activity occurred with the government's authorization or consent" was a separate question that the court addressed. *Id.* But the court's determination that the splints were not "for the Government" rested on the nature of the use, not the absence of a government procurement contract, as Moderna suggests. Moderna Br. at 42–43.

C. Congress Did Not Waive Sovereign Immunity for All Procurement Contracts

Moderna argues that the "for the Government" requirement of § 1498(a) "turns on whether the contractor was doing what the Government hired the contractor to do." *Id.* at 46. According to Moderna, for procurement contracts, the "for the Government"

inquiry asks only whether the contractor was working within its scope. *Id.* If so, then Moderna argues that § 1498(a) would apply any time "the Government gave authorization or consent." *Id.* But Congress did not write the statute that way or make the government the arbiter of whether § 1498(a) applies.

Moderna's interpretation reads "for the Government" out of § 1498(a). "A statute should be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant." *Corley v. United States*, 556 U.S. 303, 314 (2009) (citation modified). Under § 1498(a), a contractor's infringement "shall be construed as use or manufacture for the United States" only when two conditions are met: (1) when the use or manufacture is "for the Government" and (2) "with the authorization or consent of the Government." 28 U.S.C. § 1498(a). Both requirements must be met or the contractor's activity falls outside of the statute. Nothing in the statute supports Moderna's bright-line rule that all procurement contracts fall within § 1498(a) regardless of their purpose.

Regardless, the Court need not decide whether the "for the Government" requirement is satisfied by every government procurement contract. That requirement is not met for the doses that went to the American public under Moderna's C-100 contract. Moderna was on notice from the outset about who would receive vaccines. The C-100 contract—a contract that Moderna negotiated and signed—specified that doses were intended for two distinct recipients or beneficiaries. Some doses were "for the *United States Government* (USG)" and others were "for . . . the *US population*."

Appx2796 (emphases added). Moderna's suggestion that the district court's interpretation would "turn[] on *post hoc* assessments about the downstream effects of" a government contract is not a concern here. Moderna Br. at 48; *see id.* at 37–38. The district court's interpretation properly prevents the extension of § 1498(a) immunity to cover commercial-scale distribution to the general public on the theory that the government contracted for and paid for the doses.

Nor does the district court's interpretation return § 1498(a) to its "pre-World War I scope." *Id.* at 37. Before 1918, Congress had only waived sovereign immunity when a patented invention was "used by the United States" and did not cover manufacture or use "for" the United States. Act of June 25, 1910, ch. 423, 36 Stat. 851, 851–52 (1910). Congress broadened the statute to cover situations where a patent is "used or *manufactured* by or *for* the United States." 28 U.S.C. § 1498(a) (emphases added). That broader scope captures Moderna's activities in manufacturing vaccines for government employees.

Moderna's manufacture of vaccines for private individuals is not the type of activity for which the United States has waived sovereign immunity and assumed liability. While Moderna equates supplying vaccines to private citizens during a pandemic to a contractor supplying military supplies to the government to fight a war, civilians do not receive torpedo boat destroyers. They do receive vaccines. Interpreting § 1498(a) to cover Moderna's infringement would convert every patent infringement lawsuit relating to drugs, medical devices, or other healthcare treatments involving a

government contractor into a suit for compensation against the government. The statute is not that broad.

This Court has never endorsed Moderna's bright-line rule "that government-authorized patent use to fulfill a government procurement contract is manufacture or use 'for the United States,'" Moderna Br. at 22, or held that mass distribution of patented goods to the American public is "for the Government" under § 1498(a). It should decline Moderna's invitation to do so here.

II. Moderna's Interpretation Is Inconsistent with the Bayh-Dole Act and Would Undermine University Patent Rights in Federally Sponsored Research

Moderna's proposed reading of § 1498(a) would not only expand the United States' waiver of sovereign immunity, it would also unravel a separate statutory scheme that Congress enacted to incentivize universities to pursue commercialization of innovations developed with federal support. The Bayh-Dole Act (Pub. L. 96-517, 94 Stat. 3019–28 (1980) (codified as amended at 35 U.S.C. § 200 *et seq.*), allows recipients of federal research funding like universities to retain title to patents resulting from federal funds. 35 U.S.C. § 202(a). In exchange, the United States receives non-exclusive, paid-up licenses to those patents. *Id.* § 202(c)(4).

A. The Bayh-Dole Act Is Intended to Strengthen Patent Rights for Universities

The Bayh-Dole Act "addresses patent rights in work funded by the federal government," "with a particular focus on government-funded research by universities

and small businesses." *Univ. of S. Fla. Bd. of Trs. v. United States*, 92 F.4th 1072, 1073, 1077 (Fed. Cir. 2024). Congress sought to "strengthen the patent rights of government-fund recipients" like universities by allowing them to retain title to inventions developed with the assistance of federal funding "in order to incentivize commercial development of patentable inventions into useful products." *Id.* at 1077. In exchange, the government receives a "nonexclusive, nontransferrable, irrevocable, paid-up license to practice or have practiced *for or on behalf of the United States* any subject invention."[7] 35 U.S.C. § 202(c)(4) (emphasis added). This language—"for or on behalf of the United States"—is virtually identical to the "by or for the United States" and "for the Government" language in 28 U.S.C. § 1498(a).

If "for the Government" in § 1498(a) were interpreted to cover mass public distribution (as Moderna urges), then "for or on behalf of the United States" in the Bayh-Dole Act would carry the same breadth. Under that interpretation, the government's paid-up Bayh-Dole license would itself authorize commercial-scale distribution to the American public. But a key purpose of the Bayh-Dole Act was to preserve enforceable patent rights for universities. *See Univ. of S. Fla.*, 92 F.4th at 1077; 35 U.S.C. § 200. A university's patent rights would be illusory if the scope of the government's Bayh-Dole licenses is extended to unlimited public distribution. Read

[7] "Subject invention" is broadly defined to include "any invention of the contractor conceived or first actually reduced to practice in the performance of work under a funding agreement." 35 U.S.C. § 201 (e).

together, § 1498(a) and the Bayh-Dole Act confirm that "for" the government cannot mean for distribution to the American public.

B. The Bayh-Dole Act Has a Separate Procedural Mechanism and Protections for Public Access to Inventions

Congress distinguished between the *government's* own use of a federally funded invention and *public* access to that invention in the Bayh-Dole Act. One objective of the Act is "to ensure that the *Government* obtains sufficient rights in federally supported inventions to meet the needs of the *Government* and protect the *public* against nonuse or unreasonable use of inventions." 35 U.S.C. § 200 (emphases added). The government's paid-up license in § 202 addresses those governmental needs. Public access is a separate question, addressed by a separate mechanism in § 203, referred to as the government's "march-in rights." This provision authorizes the government to compel a university to license an invention made in the course of previously funded research to a third party. *Id.* § 203(a). Congress knew how to provide for public access to patented inventions when that was its intent. It did so for the Bayh-Dole Act and chose not to do so in § 1498(a).

Moderna's interpretation of "for the Government" in § 1498(a) would render the Bayh-Dole Act's march-in rights provisions in § 203 superfluous. While Congress provided the government with march-in rights, it can only exercise them if a federal agency determines that a specific public need exists, such as because the university "has not taken, or is not expected to take within a reasonable time, effective steps to achieve

practical application of the subject invention," "to alleviate health or safety needs," or "action is necessary to meet requirements for public use specified by Federal regulations." 35 U.S.C. § 203(a). If the government could procure unlimited public access to any invention subject to a Bayh-Dole license through a procurement contract, it would not need to invoke its march-in rights. Congress does not enact surplusage. *See Corley*, 556 U.S. at 314.

Moderna's interpretation would also provide an end-run around Bayh-Dole's procedural safeguards. The Commerce Department, to which Congress gave rulemaking authority, 35 U.S.C. § 206, has promulgated regulations that specify that the federal agency must notify and consult with the university "before initiating any march-in proceeding," 37 C.F.R. § 401.6(a)(1). For example, if the agency initiates a march-in proceeding, the university is entitled to written notice stating "the reasons for the proposed march-in," and "to appear with counsel, submit documentary evidence, present witnesses" and to confront the agency's witnesses. 37 C.F.R. §§ 401.6(a)(2)–(4). The agency must make findings of fact and issue a determination of whether it will exercise march-in rights. *Id.* §§ 401.6(a)(4)–(5). And the university has the right to petition the Court of Federal Claims for review of that decision. 35 U.S.C. § 203(b).

That Congress included a specific mechanism in the Bayh-Dole Act for public access to federally funded inventions demonstrates that it viewed public access as a distinct question from the government's own access requiring procedural protection, not an issue to be resolved through a procurement contract.

C. Moderna's Interpretation of Section 1498(a) Would Weaken University Patent Rights and Undermine the Bayh-Dole Act

The consequence of Moderna's broad interpretation of § 1498(a) is one that Congress could not have intended. Any invention developed by a university with federal support that is later incorporated into a product manufactured under a government contract could be distributed to the American public in any amount without notifying or compensating the university, even if the manufacturer has no license from the university. That cannot be the correct outcome. Under § 1498(a), a university whose invention is used by a contractor "for the Government and with the authorization or consent of the Government" may seek compensation only against the government in the Court of Federal Claims. If the government raises a Bayh-Dole license defense in that proceeding, arguing it has a license under Bayh-Dole to the university's patent, the university would have no remedy anywhere: The university could not sue the contractor under § 1498(a) because, under Moderna's reading, the government has assumed liability. It could not recover from the government because of the Bayh-Dole license. The university receives nothing.

This is not merely a hypothetical. The government has Bayh-Dole licenses to Northwestern's patents on lipid nanoparticle technology at issue in Northwestern's related case against Moderna. Yet if "for the Government" covers Moderna's manufacturing of vaccine doses to the American public, the government's Bayh-Dole licenses would necessarily cover that distribution as well. Northwestern would have no

recourse for Moderna's infringement of hundreds of millions of doses. That result would turn the government's limited paid-up license for governmental use into de facto title for any government-contracted commercial distribution.

This concern extends well beyond Northwestern. The federal government funds over half of all "R&D expenditures at academic institutions."[8] Research universities like Northwestern foster commercialization by transferring federally funded inventions to the private sector through licensing and collaborations with industry partners, generating revenue that is reinvested in further research and development. Before Bayh-Dole, "fewer than 5 percent of the 28,000 patents being held by federal agencies had been licensed, compared with 25 percent to 30 percent of the small number of federal patents for which the government had allowed companies to retain title to the invention."[9] Since its passage in 1980, the Act has played an instrumental role in "stimulating the commercial development of discoveries emerging from government-sponsored research in universities."[10] An interpretation of § 1498(a) that allows the

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[8] National Science Foundation, 25-345, *Since the 1950s, Over Half of R&D Expenditures at U.S. Colleges and Universities Have Been Funded by the Federal Government* (July 10, 2025), https://ncses.nsf.gov/pubs/nsf25345.

[9] U.S. Government Accountability Office, GAO/RCED-98-126, *Technology Transfer: Administration of the Bayh-Dole Act by Research Universities* 3 (May 1998) ("GAO 1998"), https://www.gao.gov/assets/rced-98-126.pdf.

[10] Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82(8) Va. L. Rev. 1663, 1708 (1996) ("Eisenberg 1996"); *see* Stephen Ezell et al., *The Bayh-Dole Act's Role in Stimulating University-Led Regional Economic Growth*, Info. Tech. & Innovation Found. (June 2025), https://www2.itif.org/2025-bayh-dole-regional-growth.pdf.

government to nullify university patent rights for any quantity of public distribution through a procurement contract would directly undermine the incentive to accept federal funding and commercialize federally supported inventions, recreating the problem the Bayh-Dole Act was enacted to solve.[11] The Act's success in facilitating commercialization of federally funded inventions depends on limiting the scope of the government's license to true government uses.[12]

Nothing in the district court's decision prevents the government and its contractors from relying on § 1498(a) for legitimate *government* use. Government employees, military branches, contractors performing government work, and agencies operating government programs all remain protected. Indeed, Northwestern agrees that the vaccines that went directly to government employees, such as military personnel, are covered by § 1498(a). What the district court's decision prevents is the use of a government procurement contract to immunize the commercial exploitation of patented inventions at the expense of universities whose research made those inventions possible.

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[11] *See* Eisenberg 1996 at 1695–1700; GAO 1998 at 3; Goshen David Miteu, *Patenting: the Bayh-Dole Act and its transformative impact on science innovation and commercialization*, 86 Annals of Med. & Surgery 3192, 3193–94 (2024).

[12] *See* Eisenberg 1996 at 1698–1700, 1709.

III. Section 1498(a) Does Not Bar Indirect Infringement Claims

Section 1498(a)'s waiver extends only to infringement claims that are predicated on "use or manufacture" by the United States. Those are the same verbs that define direct infringement in 35 U.S.C. § 271(a). *See* 35 U.S.C. § 271(a) ("whoever without authority *makes*, *uses*, . . . any patented invention, within the United States . . . infringes the patent." (emphasis added)). As a result, "Section 1498 expressly waives the Government's sovereign immunity only with respect to governmental *direct* infringement of a patent." *Decca*, 640 F.2d at 1169 (emphasis added).

Section 1498(a) does not bar indirect infringement claims that are not predicated on any "use or manufacture" by the United States. Neither this Court nor its predecessor has held that § 1498(a) protects contractors from all indirect infringement claims. Moderna Br. at 55 (citing *Astornet Techs. Inc. v. BAE Sys., Inc.*, 802 F.3d 1271 (Fed. Cir. 2015) and *Decca*). In *Astornet*, the patentee alleged that the defendants induced the TSA to use the patentee's patented boarding pass scanning system. 802 F.3d at 1275–76. Thus, the patentee's indirect infringement theory was predicated on acts of direct infringement by TSA itself. *Id.* at 1277–78. The Federal Circuit held that § 1498(a) applied because the underlying direct infringement was "use of the patented invention by the United States," which "is squarely within the statutory terms." *Id.* at 1277 (citation modified). In *Decca*, the court held that "the Government has agreed under section 1498 merely to assume liability for its direct infringement of a patent; it has not

agreed thereunder to assume liability for its active inducement of infringement or for its contributory infringement." 640 F.2d at 1170.

At most, *Astornet* and *Decca* would bar indirect infringement claims against Moderna for the doses that went to U.S. government employees if a patentee proceeded on a theory that government employees directly infringed the asserted patents when they were vaccinated and Moderna induced that infringement. But theories of indirect infringement not predicated upon any "use or manufacture" by the United States, such as where doctors or civilians are the direct infringers, are not within the scope of § 1498(a).

The district court was thus correct in holding that § 1498(a) does not bar indirect infringement theories based on allegations that "non-governmental third parties infringed and that Moderna contributed to or induced that infringement." Appx16. The statute says nothing about actively inducing infringement (§ 271(b)), contributory infringement (§ 271(c)), or supplying components for combination outside the United States (§ 271(f)). Because waivers of sovereign immunity must be strictly construed "and exceptions thereto are not to be implied," *Lehman*, 453 U.S. at 161 (quoting *Soriano*, 352 U.S. at 276), Congress's silence is dispositive.

CONCLUSION

The Court should affirm the district court's judgment.

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Respectfully submitted,

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