

No. 26-1581

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**In the United States Court of Appeals  
for the Federal Circuit**

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ARBUTUS BIOPHARMA CORPORATION, GENEVANT SCIENCES, GMBH,

*Plaintiffs-Appellees,*

*v.*

MODERNA, INC., MODERNATX, INC.,

*Defendants-Appellants.*

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On Appeal from the United States District Court for the District of  
Delaware, The Honorable Joshua D. Wolson (No. 1:22-CV-00252-JDW)

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**RESPONSIVE BRIEF OF PLAINTIFFS-APPELLEES  
ARBUTUS BIOPHARMA CORPORATION &  
GENEVANT SCIENCES GMBH**

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JULY 8, 2026

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## **REPRESENTATIVE PATENT CLAIMS**

### **U.S. Patent No. 9,504,651**

1. A lipid vesicle formulation comprising:

- (a) a plurality of lipid vesicles, wherein each lipid vesicle comprises:
  - a cationic lipid;
  - an amphipathic lipid; and
  - a polyethyleneglycol (PEG)-lipid; and
- (b) messenger RNA (mRNA), wherein at least 70% of the mRNA in the formulation is fully encapsulated in the lipid vesicles.

14. The lipid vesicle formulation of claim 1, wherein about 90% of the mRNA in the formulation is fully encapsulated in the lipid vesicles.

### **U.S. Patent No. 9,364,435**

1. A nucleic acid-lipid particle comprising:

- (a) a nucleic acid;
- (b) a cationic lipid comprising from 50 mol % to 85 mol % of the total lipid present in the particle;
- (c) a non-cationic lipid comprising from 13 mol % to 49.5 mol % of the total lipid present in the particle; and
- (d) a conjugated lipid that inhibits aggregation of particles comprising from 0.5 mol % to 2 mol % of the total lipid present in the particle.

16. A method for the in vitro delivery of a nucleic acid, the method comprising:

administering to a mammalian subject a nucleic acid-lipid particle of claim 1.

**U.S. Patent No. 11,141,378**

1. A nucleic acid-lipid particle consisting essentially of:

- (a) an RNA;
- (b) a cationic lipid having a protonatable tertiary amine;
- (c) a mixture of a phospholipid and cholesterol of from 30 mol % to 55 mol % of the total lipid present in the particle, wherein the phospholipid consists of from 3 mol % to 15 mol % of the total lipid present in the particle; and
- (d) a polyethyleneglycol (PEG)-lipid conjugate consisting of from 0.1 mol % to 2 mol % of the total lipid present in the particle.

FORM 9. Certificate of Interest

Form 9 (p. 1)  
March 2023

**UNITED STATES COURT OF APPEALS  
FOR THE FEDERAL CIRCUIT**

**CERTIFICATE OF INTEREST**

**Case Number** 26-1581

**Short Case Caption** Arbutus Biopharma Corporation v. Moderna, Inc.

**Filing Party/Entity** Arbutus Biopharma Corporation and Genevant Sciences GmbH

**Instructions:**

1. Complete each section of the form and select none or N/A if appropriate.
2. Please enter only one item per box; attach additional pages as needed, and check the box to indicate such pages are attached.
3. In answering Sections 2 and 3, be specific as to which represented entities the answers apply; lack of specificity may result in non-compliance.
4. Please do not duplicate entries within Section 5.
5. Counsel must file an amended Certificate of Interest within seven days after any information on this form changes. Fed. Cir. R. 47.4(c).

I certify the following information and any attached sheets are accurate and complete to the best of my knowledge.

Date: 07/08/2026

Signature: /s David I. Berl

Name: David I. Berl



## FORM 9. Certificate of Interest

Form 9 (p. 2)  
March 2023

| <b>1. Represented Entities.</b><br>Fed. Cir. R. 47.4(a)(1).                             | <b>2. Real Party in Interest.</b><br>Fed. Cir. R. 47.4(a)(2).                                                                                                                                              | <b>3. Parent Corporations and Stockholders.</b><br>Fed. Cir. R. 47.4(a)(3).                                                                                                                        |
|-----------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Provide the full names of all entities represented by undersigned counsel in this case. | 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.<br><br><input checked="" type="checkbox"/> None/Not Applicable | 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.<br><br><input type="checkbox"/> None/Not Applicable |
| Arbutus Biopharma Corporation                                                           |                                                                                                                                                                                                            | Roivant Sciences Ltd.                                                                                                                                                                              |
|                                                                                         |                                                                                                                                                                                                            | Morgan Stanley Investment Management Inc.                                                                                                                                                          |
| Genevant Sciences GmbH                                                                  |                                                                                                                                                                                                            | Roivant Sciences Ltd.                                                                                                                                                                              |
|                                                                                         |                                                                                                                                                                                                            | Arbutus Biopharma Corporation                                                                                                                                                                      |
|                                                                                         |                                                                                                                                                                                                            | Genevant Sciences Holdings Limited                                                                                                                                                                 |
|                                                                                         |                                                                                                                                                                                                            | Genevant Sciences Ltd.                                                                                                                                                                             |
|                                                                                         |                                                                                                                                                                                                            |                                                                                                                                                                                                    |
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|                                                                                         |                                                                                                                                                                                                            |                                                                                                                                                                                                    |

☐ Additional pages attached

## FORM 9. Certificate of Interest

Form 9 (p. 3)  
March 2023

**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 ☒ Additional pages attached

|                   |                  |                 |
|-------------------|------------------|-----------------|
| Arthur Argall     | Falicia Elenberg | Thomas Fletcher |
| Philip Haunschild | Denis Hurley     | Kathryn Larkin  |
| Ricardo Leyva     | Jessica Ryen     | Anthony Sheh    |

**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)?

☒ Yes (file separate notice; see below) ☐ No ☐ N/A (amicus/movant)

If yes, concurrently file a separate Notice of Related Case Information that complies with Fed. Cir. R. 47.5(b). **Please do not duplicate information.** This separate Notice must only be filed with the first Certificate of Interest or, subsequently, if information changes during the pendency of the appeal. Fed. Cir. R. 47.5(b).

**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 ☐ Additional pages attached

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**Certificate of Interest – Addendum**

*Arbutus Biopharma Inc. v. Moderna, Inc. (26-1581)*

**4. Legal Representatives.** In addition to those listed above, Appellees Arbutus Biopharma Corporation and Genevant Sciences, GmbH identify the following additional 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.

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## STATEMENT OF RELATED CASES

The following pending cases are related to this one:

*Arbutus Biopharma Corp. v. United States*, Case No. 26-cv-00446

(Fed. Cl.)

*GlaxoSmithKline Biologicals SA v. Moderna, Inc.*, No. 24-cv-1135 (D. Del.)

*mNG Bio, LLC v. Moderna Inc.*, No. 26-cv-10074 (D. Mass.)

*Bayer CropScience LLC v. Moderna, Inc.*, No. 26-cv-0012 (D. Del.)

*Northwestern Univ. v. Moderna, Inc.*, No. 24-cv-1151 (D. Del.)

/s/ David I. Berl  
David I. Berl

## INTRODUCTION

Moderna’s infringing vaccine was designed and developed by a private party, shipped to private warehouses, and distributed to private companies and states to administer to private citizens. As two district judges independently held, nothing in the text, history, or purpose of 28 U.S.C. §1498(a) supports labeling these doses “for the Government.” To hold otherwise would sweep in a wide swath of private conduct the statute was never intended to—and does not—cover.

The statute’s clear language and decades of settled precedent dictate that what matters when applying §1498 is whether the purchased goods are “for the Government” in the most straightforward and obvious sense—is the United States government the direct beneficiary or not? Moderna’s glib juxtaposition (at 2) of vaccines with staples from the IRS supply closet captures the fundamental flaw in its position. Section 1498’s “for the Government” requirement does not turn on the invention’s importance or the particular policy goal it promotes. Staples may not be important, but their use by IRS employees directly benefits the government. Moderna’s vaccine directly benefited the millions of private citizens who received it.

Because it cannot meet the long-established direct-benefit test, Moderna attempts to supplant it with two alternative rules that no court ever has articulated, much less endorsed. First, Moderna (at 33) urges that all

manufactures or uses agreed to in procurement contracts are *per se* “for the Government,” irrespective of the beneficiary of the procured good or service. Per Moderna (at 46) and the Executive in amicus, infringement is “for the Government” whenever any of the tens of thousands of government employees with contracting authority chooses to execute a procurement contract—a choice that courts (including this one) are powerless to review or “second guess,” DOJ 1, 12, 25.

This unprecedented expansion of the Executive’s power to expropriate constitutionally protected patent rights defies text and precedent, and it would reduce a key statutory requirement to a rubberstamp.

Alternatively, Moderna conjures a fact-intensive, precedentially foreclosed “for the Government” standard that requires only conduct in furtherance of a government policy with incidental effects on the government, which Moderna (at 28) acknowledges would sweep in every private transaction. The direct-benefit test—not the tests Moderna concocts to avert it—governs and precludes application of §1498 to the vaccine Moderna represented was “for the American people,” “for purposes other than Governmental purposes.” Appx4504.

Moderna also parades various harms it warns will follow if §1498 does not cover private vaccine doses. They do not withstand scrutiny. Moderna claims §1498 is necessary for the government to obtain critical items like



COVID-19 vaccines. But Pfizer developed COVID-19 vaccines and provided more doses than Moderna without the §1498 protection Moderna claims is indispensable. Moderna also raises the specter of injunctions barring vaccine distribution—an implausible result under controlling precedent permitting only injunctions in the public interest.

The real harm is the risk to innovation from Moderna's novel construction that permits any government purchase or program to override patent rights to jury trials and enhanced damages. Moderna (at 50-51) observes, without irony, that American companies developed effective COVID-19 vaccines where other countries failed. True enough, but Moderna misses the plot: American innovation succeeds because private patent rights are protected and honored, not (as Moderna urges, and as in nations that failed) trampled when inconvenient and subjected to a compulsory licensing scheme according to the whims of an unconstrained bureaucrat. Congress did not cede such authority in §1498, and no court in the century since its enactment has applied Moderna's interpretation. If the government wishes to pay for Moderna's infringing vaccine for the American public's benefit, it can do so without stretching §1498 beyond its text and purpose and harming patentholders and the American patent system. This Court should affirm.

## **JURISDICTIONAL STATEMENT**

The district court had jurisdiction under 28 U.S.C. §§1331 and 1338.

This Court has jurisdiction under 28 U.S.C. §1295.

## **STATEMENT OF THE ISSUES**

Whether the district court correctly held that 28 U.S.C. §1498(a) does not bar Plaintiffs’ patent infringement claims against Moderna for doses sold under the C-100 Contract that were provided for the benefit of the public, and not the federal government.

## **STATEMENT OF THE CASE**

### **I. Congress’s Regime To Protect Patentees’ Rights and the Government’s Ability To Procure Wartime Materiel.**

In 1894, the Supreme Court held that sovereign immunity generally barred patent infringement actions against the United States. *Schillinger v. United States*, 155 U.S. 163, 169-71 (1894). Congress recognized the “injustice” of denying patentees relief. *Crozier v. Fried. Krupp Aktiengesellschaft*, 224 U.S. 290, 304 (1912). So it passed an act “to provide additional protection for owners of patents,” waiving sovereign immunity for the unauthorized use of patented inventions “by the United States.” Act of June 25, 1910, Pub. L. No. 61-305, ch. 423, 36 Stat. 851, 851.

World War I revealed a flaw: the Act did not cover a government contractor manufacturing vessels under the Navy’s “comprehensively detailed” specifications. *William Cramp & Sons Ship & Engine Bldg. Co. v.*

*Int'l Curtis Marine Turbine Co.*, 246 U.S. 28, 35, 42-43 (1918). Congress responded by extending the statute to inventions “used or manufactured...for the United States.” Act of July 1, 1918, Pub. L. No. 65-182, 40 Stat. 704, 705. This amendment narrowed patent owners’ rights as to contractors, for the limited purpose of helping the government procure goods for its own operations. *Richmond Screw Anchor Co. v. United States*, 275 U.S. 331, 345 (1928). Congress later amended the Act, clarifying its application to subcontractors, Act of Oct. 31, 1942, Pub. L. No. 77-768, §6, 56 Stat. 1013, 1014, and emphasizing its narrow purpose to compensate when an “invention is used” “in connection with *war procurement*,” S. Rep. No. 77-1640 at 2.<sup>1</sup> Nothing in the legislative history indicates that §1498’s extension to contractors and subcontractors intended to encompass goods supplied to the public. *Contra* Moderna’s Brief (“Br.”) 30-32.

This Act, codified at 28 U.S.C. §1498, provides that, with respect to infringement by “a contractor” done (1) “for the Government” and (2) with the government’s “authorization or consent,” the owner’s remedy “shall be by action against the United States in the United States Court of Federal Claims.” *Id.*

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<sup>1</sup> Except where noted, all emphasis is added and all citations omitted throughout this brief.

## **II. Moderna Uses Plaintiffs’ Patented Technology To Make a COVID-19 Vaccine For the Public.**

### **A. Plaintiffs’ Patented Technology.**

mRNA has long had promise to transform vaccines—enabling faster development and more effective inoculation. But mRNA is fragile and, without protection, quickly degrades in the bloodstream. Appx1469. For an mRNA vaccine like Moderna’s to work, it needs a mechanism that protects the mRNA in the bloodstream and then releases it inside cells. For decades, finding this protective mechanism was the greatest barrier to mRNA medicines. Appx1470; Appx5291-5293. Or, in the words of one Nobel Laureate, the secret to success for RNA-based medicines was “delivery, delivery, delivery.” Appx5292.

Plaintiffs<sup>2</sup> solved this vexing delivery problem. They developed novel Lipid Nanoparticles (“LNPs”) that protect and deliver mRNA. Appx40-294. Their inventions resulted in the patents asserted against Moderna. Appx40-294.

The USPTO was not alone in recognizing the value of Plaintiffs’ technology. Many companies partnered with Plaintiffs, with one partnership resulting in the first-ever RNA medicine. Appx1477-1478. This success fostered growing interest in mRNA medicines. Appx4874-4875.

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<sup>2</sup> Arbutus Biopharma Corporation is the patents’ owner and assignee, and Genevant Sciences GmbH holds exclusive rights. Appx1478-1479.

## **B. Moderna Uses Plaintiffs’ Technology Without a License.**

Moderna was founded in 2010 amid this growing interest. Appx3906; Appx4874-4875. It sought to develop an mRNA “platform” to create varied medicines. Appx3559; Appx6362-6363. But Moderna needed a way to deliver its mRNA, so it turned to the “gold standard” LNP: Plaintiffs’ “[v]alidated LNP formulation.” Appx6583; Appx6819-6821; Appx6826. For years Moderna used Plaintiffs’ technology as its “standard LNP,” incorporating it into Moderna’s “mRNA-based vaccine platform.” Appx7054; Appx7187.

Plaintiffs repeatedly offered Moderna licenses, Appx6583, but Moderna repeatedly declined. Appx7189. Moderna instead pursued a “useful alternative” to licensing from Plaintiffs— sublicenses to Plaintiffs’ technology for certain diseases (not including COVID-19). Appx6833; Appx2083-2084. But a court in 2017 held Moderna’s sublicensor had no right to sublicense and enjoined further sublicenses. Appx6833.

Moderna was left with a choice: license Plaintiffs’ patents or use different delivery technology. It chose neither. Instead, Moderna continued to use the technology and “fib a bit” to conceal its unlicensed use. Appx6851. Moderna also challenged two asserted patents through *inter partes* review, unsuccessfully. This Court rejected Moderna’s ensuing appeals.

*ModernaTx, Inc. v. Arbutus Biopharma Corp.*, 18 F.4th 1352 (Fed. Cir. 2021); *ModernaTx, Inc. v. Arbutus Biopharma Corp.*, 18 F.4th 1364 (Fed. Cir. 2021).

### **C. Moderna Uses Plaintiffs' Invention for COVID-19.**

In January 2020, scientists publicized the genetic sequence of the virus that caused COVID-19. Appx2035. Many companies then began designing vaccines to combat the virus.

Moderna was one of them. Within two days, Moderna selected the sequence for its COVID-19 vaccine. But it needed a way to deliver that mRNA, so it turned to the only clinically validated LNPs it had: Plaintiffs'. Appx6369. As Moderna's lead scientist acknowledged, "there was zero option for Moderna" except to use its existing "platform to be able to respond to the pandemic." Appx6370. Built on Plaintiffs' technology, Moderna's platform produced a vaccine that entered clinical trials in just 42 days. Appx2066-2067.

Moderna's head start from using Plaintiffs' technology as its platform resulted in substantial funding to develop a COVID-19 vaccine. HHS's "BARDA" granted Moderna \$430 million, Appx3242, explicitly due to its "mRNA-based vaccine platform" and vaccine candidates it had developed for other diseases—all of which used Plaintiffs' technology, Appx3250; Appx7053-7054.

The BARDA grants did not dictate how Moderna designed the vaccine, stating that Moderna independently developed the "[m]anufacturing processes for and the formulation of vaccines using Moderna's mRNA platform." Appx3249-3250.

While Moderna (at 8 (citing Appx3385)) now points to the Government’s press-release assertion that it co-developed the vaccine, Moderna consistently has disputed that proposition. Testifying under oath before Congress, Moderna’s CEO outright rejected suggestions that the government was a “co-author[] of the vaccine,” responding that “the design of the mRNA vaccine was done by our team. This is our technology.” Hearing Before S. HELP Comm., 118th Cong. 14 (2023);<sup>3</sup> *see also* Appx8696.

**D. Moderna Enters into the C-100 Contract To Supply 500 Million Doses for Distribution to the Public.**

On May 30, 2020, the head of Operation Warp Speed (“OWS”), Dr. Moncef Slaoui—a member of Moderna’s Board of Directors until he joined the government that month, Appx3381; Appx8645—privately emailed Moderna’s CEO, asking him to submit a proposal to supply 100 million vaccine doses. Appx4453. Moderna submitted its proposal the following day. Appx8681.

Moderna and the government then negotiated a purchase agreement, which both sides acknowledged was for the general public. For example, Moderna offered to negotiate “supply arrangements with the US Government” *“for the benefit of people in the US and across the world.”*

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<sup>3</sup> <https://www.govinfo.gov/content/pkg/CHRG-118shrg54463/pdf/CHRG-118shrg54463.pdf>.

Appx8681. To avoid disclosing cost data, Moderna represented that its vaccine “meets the definition of a commercial item, as defined by FAR Part 2.2101,” because it was “customarily used by the general public or by nongovernmental entities *for purposes other than Governmental purposes.*” Appx4504; Appx8031. Moderna’s lead negotiator confirmed its vaccine is “intended to be administered to the general public, so that’s beyond the internal use by the US Government only.” Appx4504. Government personnel likewise confirmed they were purchasing vaccines to “facilitat[e] the goal of making” vaccine doses “*available to the American population.*” Appx4505.

“The first draft of the agreement that became the C-100 Contract” incorporated FAR 52.227-1, which states that the “Government authorizes and consents to all use and manufacture” resulting in patent infringement. Appx5892; Appx5896-5897. Moderna already had produced and begun clinical trials of its vaccine when it received that draft. Appx2066-2067. No record evidence indicates that Moderna sought this provision as a condition of developing or selling the vaccine; in fact, there were no negotiations whatsoever over this clause. Appx2705; Appx3401-3402 (267:16-268:7); Appx7180. Rather, OWS, helmed by Moderna’s former Board member, Appx8645, (who held valuable Moderna stock options), simply included the provision in Moderna’s (but not Pfizer’s) contract.



In August 2020, the government and Moderna executed the C-100 Contract to supply up to 500 million doses. Appx2778-2830. The contract identified an intended recipient of Moderna’s vaccines as the *American people*, stating that the vaccine was developed to “improve patient care,” Appx2796. It recited that the “manufacturing of vaccine doses” was done for two groups—“the United States Government (USG) and *the US population*.” Appx2796. The vaccine was expected to be available for “nationwide access” and “widespread use.” Appx2796.

The contract outlined how Moderna would distribute the vaccine to the public. Moderna was responsible for storage and delivery “to the designated delivery site,” a private warehouse, Appx2797, and contracted to “secure, manage and maintain storage.” Appx2795. While the contract specified that Moderna would deliver the vaccine in multi-dose vials, Appx2779, it left it to Moderna, without government direction, to develop a commercially approved vaccine. Although Moderna had to provide the Government with certain updates—monthly inventory reports, shipping documentation, and completed dose trackers, for example, Appx2801-2802—Moderna was “responsible for shipment of all vaccine product,” to be “shipped and tracked by the distribution vendor’s shipping tracking number,” for nationwide distribution. Appx2804.

Moderna and the government confirmed repeatedly that the public—not the government—was the contract’s beneficiary. Moderna explained the contract was executed to “secur[e] early access to safe and effective COVID-19 vaccines *for the American people*.” Appx4505. And the Government announced that Moderna’s “vaccine would be available to the American people” through this agreement. Appx3385.

**E. As Anticipated, Moderna’s Doses Are Distributed Almost Entirely to Non-Federal Entities, for Use by the Public.**

“Moderna, as a manufacturer, [was] responsible for producing the product and releasing the product.” Appx7384 (85:6-11). When Moderna released its product, it put “routine” industry-standard certificates of analysis into an “electronic box” shared with the government. Appx7384-7385 (85:5-86:16). After receiving these electronic files, the government would formally “accept[]” the doses. Appx7384 (85:1-4); Appx7456 (168:3-10). The government did not test Moderna’s doses, Appx7385 (86:3-6), or physically inspect them, Appx7391 (92:13-18). Instead, after reviewing the electronic certificates, title would pass to the government as a formality by operation of FAR 52.246-16, which provides that “[t]itle to supplies furnished under this contract shall pass to the Government upon formal acceptance, regardless of when or where the Government takes physical possession....”

The government here “did not take physical possession” of the doses. Appx7391 (92:13-18). Rather, they went from Moderna to McKesson, a

“private company under government contract.” Appx7390-7391 (91:9-17, 92:2-12); Appx3491. McKesson then distributed them into four “channels”: state and local jurisdictions, pharmacies, federal entities, and dialysis clinics. Appx7391 (92:2-8); Appx7398 (99:3-7). Once the doses were distributed into a channel, the federal government did not decide who received them. Appx7457 (169:3-6). Rather, the entities in each channel “decided how to further distribute their allocated vaccine doses to authorized health care providers within their boundaries, including to pharmacies, health centers, local health departments, mass vaccination sites, hospitals, physician offices, and others.” Appx4513.

Dr. Robert Johnson, a top HHS official, testified on HHS’s behalf—in language that maps directly onto the disputed issue here—that the “doses, once they went to the jurisdictions, *weren’t used for the federal government.*” Appx7400-7401 (101:22-102:3). He also agreed that doses that went to pharmacies and dialysis clinics “weren’t for use by the federal government,” Appx7403 (104:7-10), and “are not doses for the federal government,” Appx7406 (107:15-18).

As contemplated by the contract, just 19% of the 500,001,540 doses sold were allocated to the “Federal” channel. Appx5855. In the “Federal” channel, 81% were donated to foreign governments and 6% were distributed to the public. Appx5857. Only approximately 1.25% of C-100 doses—

6,244,340—“went directly to United States Government Employees.”

Appx38; Appx5857-5858.

### **III. Plaintiffs Seek Redress for Infringement.**

Plaintiffs’ February 2022 Complaint asserted infringement, but did “not seek an injunction or any relief...that would impede the sale or manufacture of Moderna’s life-saving vaccine.” Appx381; Appx429.

Plaintiffs sought only “fair compensation for the use of patented technology they developed with great effort and at great expense, without which Moderna’s COVID-19 vaccine would not have been successful.” Appx381.

Moderna moved to dismiss pursuant to §1498. Appx677-678. Judge Goldberg denied the motion. Appx836; 638 F. Supp. 3d 397 (D. Del. 2022). He acknowledged evidence of the government’s authorization and consent. Appx834-835. But “a governmental grant of authorization or consent, standing alone, does not mean that the alleged use or manufacture is done ‘for the United States’ under §1498(a).” Appx829. The court reasoned that “[m]edical care is provided for the benefit of the patient, not the government,” so “the development and sale of the vaccines was for the benefit of the vaccine’s recipients.” Appx832 (quoting *Larson v. United States*, 26 Cl. Ct. 365, 369 (1992)).

The Executive then filed a Statement of Interest asserting that §1498 applied to the C-100 sales. Appx946-962. Like Moderna, the Executive

urged a “truncated inquiry” under which an authorization-and-consent provision satisfies both the “authorization or consent” and “for the Government” prongs. Appx958. The court rejected this novel and atextual reading and reaffirmed its prior ruling. Appx1152.

After discovery, the parties cross-moved for summary judgment on §1498’s applicability, Appx2641; Appx5803, agreeing it was a question of law with no material disputed fact, Appx2665; Appx5815.

Judge Wolson—now assigned to the case—reached the same conclusion: Moderna must satisfy both prongs of §1498(a) and had not established that its infringement was “for the Government.” Appx1-17. Determining the statutory meaning of “for the Government” through text, context, and precedent, Appx13-14, the court concluded that “[e]ven if the Government authorizes the manufacture or use of a patented product, it must do so for its own benefit,” Appx14. The key requirement is “that the Government must receive the benefit itself.” Appx14.

Accordingly, the court held that “[m]ost of Moderna’s vaccine doses were not for the Government, so...Section 1498 does not apply to them.” Appx32. However, §1498 “does apply to the claims of direct infringement for the vaccine doses that the Government acquired and distributed to its own employees.” Appx15. “For those doses, the Government was a direct beneficiary.” Appx15.

The court also held that §1498 “does ‘not waive the Government’s sovereign immunity for indirect infringement.’” Appx16 (quoting *Zoltek Corp. v. United States*, 672 F.3d 1309, 1320 (Fed. Cir. 2012) (en banc)). Thus, such claims, predicated on direct infringement by third parties, are not subject to §1498. Appx16-17.

The court entered a consent judgment that Plaintiffs’ patents were infringed and not invalid. Appx36-39. The court also entered judgment in Plaintiffs’ favor regarding the applicability of §1498 to the doses not administered to Government Employees, and judgment in Moderna’s favor “with respect to the 6,244,340 doses that were directly administered to United States Government employees.” Appx38.

Plaintiffs then sought relief for the latter doses in the Court of Federal Claims and preserved their rights regarding any other doses ultimately (but improperly) deemed subject to §1498(a). *Arbutus Biopharma Corp. v. United States*, No. 1:26-cv-446 (Fed. Cl. Mar. 19, 2026).

## SUMMARY OF THE ARGUMENT

**I.** Moderna’s vaccines were manufactured for the inoculation of private citizens, so §1498 does not apply.

**A.** Section 1498(a) imposes two distinct requirements. Relevant here, the infringing use or manufacture must be “for the Government.” The plain

meaning of “use or manufacture...for the Government” is that the government itself directly benefits from that use or manufacture.

Through a long line of precedent, this Court and others have applied the direct-benefit test to effectuate this statutory command. Cases finding direct government benefit involve fraud-protection technology for Treasury checks, waste-removal services for federal facilities, and passport checks enhancing border security. In contrast, courts reject §1498 defenses where benefits to the government were incidental, not direct. For example, benefits from infringing medical devices for Medicare patients were too remote, the Olympic team’s use of infringing sailboards benefited the government only indirectly, despite its general interest in the Olympics, and a royalty paid to the government from infringing oil drilling was only a byproduct of the infringement.

Moderna’s attempt to cabin the direct-benefit analysis to private conduct the government never asked for cannot be squared with controlling precedent. *Advanced Software Design Corp. v. Fed. Rsrv. Bank*, 583 F.3d 1371, 1376-78 (Fed. Cir. 2009). Moderna (at 37) is also wrong that the district court’s application of the direct-benefit test imposes an “end-user” requirement. The essential question is whether the government directly benefits, not whether it uses an invention.

**B.** Unable to meet the correct test, Moderna rewrites it. Moderna (at 34) claims that the analysis turns not on who receives a benefit but instead on who procures the goods. No court has adopted that approach. In each of Moderna’s cited cases, the government benefited directly from the procured goods.

Nor is Moderna (at 46) correct that the existence of a procurement contract automatically satisfies the “for the Government” inquiry. Moderna’s own cases show that courts must independently evaluate the “for the Government” prong, whether the Government executed a procurement contract or requested the infringing activity another way. *Broome v. Hardie-Tynes Mfg.*, 92 F.2d 886, 888 (5th Cir. 1937); *Advanced Software*, 583 F.3d at 1376-78. And even Moderna (below, but not here) acknowledged binding precedent finding instances of infringement pursuant to a procurement contract not “for the Government.” Appx6933. Moderna’s interpretation of §1498 is literally unprecedented.

Moderna’s interpretation also would render the “for the Government” prong superfluous. Were every contract “for the Government,” Congress would not have separately applied this requirement to “contractor[s].” And Moderna’s insistence that the government’s agreement makes infringement “for the Government” would collapse §1498’s two distinct prongs.



Even if “for the Government” were ambiguous, §1498’s waiver of sovereign immunity must be construed narrowly, in Plaintiffs’ favor. That the Executive seeks liability here is irrelevant; executive officers lack the power to waive sovereign immunity.

C. Section 1498 thus does not apply to vaccine purchases for the general public. The C-100 Contract recited two beneficiaries: “the United States Government” and “the US population.” Appx2796. Moderna understood this distinction—its “express position” was that “a vaccine [is] intended to be administered to the general public,” “for purposes other than Governmental purposes.” Appx4504; Appx8031. The government agreed that the doses “weren’t for use by the federal government.” Appx7403; Appx7406; Appx4504. “Medical care is provided for the benefit of the patient, not the government,” even where the government “funds or reimburses” its costs. *Larson*, 26 Cl. Ct. at 369.

Moderna and its amici respond by citing a string of indirect government benefits, like economic growth and reduced hospitalization. But these byproducts of direct benefits to private individuals cannot meet §1498’s “for the Government” requirement.

Nor can Moderna (at 36-37) satisfy the direct-benefit test based on legal technicalities like acceptance, control, and ownership. Courts look past formalisms to ask the commonsense question of whether the government was

expected to directly benefit from the infringement. *Hughes Aircraft Co. v. United States*, 534 F.2d 889, 895, 897-98 (Ct. Cl. 1976). That is particularly important here, where the government never physically possessed or used the vaccine doses but instead held title only pursuant to a contract provision.

The controlling direct-benefit test is predictable and applied readily based on facts known *ex ante*. Because in most procurement contracts the government purchases goods for its own benefit to perform its functions, the “for the Government” requirement is satisfied without controversy. In the atypical case where the government makes purchases for others’ benefit and is not the direct beneficiary, the infringer remains liable for its infringement. Serious as it was, the pandemic does not justify an unlawful, unprecedented expansion of Executive power to expropriate private patent rights. If it desires, the government can pay for Moderna’s infringement without rewriting §1498.

**D.** Moderna’s interpretation of §1498 endangers rights beyond this case. Moderna would strip patent owners of their rights to a jury trial and enhanced damages for every government-funded product advancing a government policy at the unfettered discretion of any unaccountable government contracting officer. Moderna’s interpretation also strains the separation of powers. If a procurement contract providing authorization and consent automatically satisfies both prongs of §1498, it would arrogate

complete power to contracting officers, impinging on Congress' exclusive powers and averting judicial review.

**II.** Plaintiffs' indirect infringement claims provide an independent basis to affirm. Section 1498 does not waive the Government's sovereign immunity for indirect infringement. Government contractors remain liable for such claims, so long as the government did not commit the predicate direct infringement. Moderna's argument—that §1498 immunizes government contractors *without* waiving sovereign immunity—flouts controlling precedent that §1498's waiver of sovereign immunity and assumption of liability are coterminous.

## **STANDARD OF REVIEW**

This Court reviews grants of summary judgment *de novo*, *Sevenson Env't Servs. v. Shaw Env't, Inc.*, 477 F.3d 1361, 1364 (Fed. Cir. 2007), and exclusion of expert testimony for abuse of discretion, *Carnegie Mellon Univ. v. Marvell Tech. Grp.*, 807 F.3d 1283, 1302 (Fed. Cir. 2015).

## **ARGUMENT**

### **I. Section 1498 Does Not Apply to Vaccines Manufactured for the General Public.**

Section 1498 precludes government contractor liability only where the infringement directly, rather than incidentally, benefits the government. Moderna fails that test.

**A. Under §1498, a Use or Manufacture Is “for the Government” Only When It Directly Benefits *the Government*.**

The §1498 affirmative defense imposes two independent requirements. *Sevenson*, 477 F.3d at 1365. First, an infringing use or manufacture must be “for the Government.” 28 U.S.C. §1498. Second, it must occur with the government’s “authorization or consent.” *Id. Contra Moderna* (at 35-40), text and precedent both confirm that the “for the Government” requirement is distinct from whether the government contracted for or authorized infringement: If the use or manufacture is not done for the government’s direct benefit, then the government’s “grant of authorization or consent does not mean that the alleged use or manufacture is done ‘for the United States’ under §1498(a).” *IRIS Corp. v. Japan Airlines Corp.*, 769 F.3d 1359, 1362 (Fed. Cir. 2014).

**1. Text and Precedent Confirm the Government Must Benefit Directly.**

Section 1498’s plain text establishes that the Government must benefit directly from the infringing use or manufacture. Moderna does not dispute that “Government” means the federal government, and “refer[s] to ‘the system of polity in a state,’ ‘authority,’ ‘the administration,’ ‘a commonwealth,’ and ‘a state.’” Appx13. The question is thus whether vaccine doses distributed to states, foreign governments, and private

healthcare providers, for administration to private individuals, were “for” the federal “administration.” They were not.

When the statute says an invention is “use[d] or manufacture[d]...for the Government,” the ordinary meaning is that the government itself directly benefits from that use or manufacture. Contemporaneous dictionaries confirm as much. The dictionary this Court and the district court used to interpret §1498, *FastShip, LLC v. United States*, 892 F.3d 1298, 1303 (Fed. Cir. 2018); Appx13, explains that “for” was used to “[i]ntroduc[e] the intended recipient.” *For, A New Dictionary on Historical Principles* 409 (1908). More generally, “for” introduced an activity’s ultimate direction. “In the most general sense,” “for” introduced “that in consideration of which, in view of which, or with reference to which anything...is done.” *For, Webster’s New International Dictionary* 846 (1930); 4 *Oxford English Dictionary* 410 (1901) (“[w]ith a view to; with the object or purpose of”).

Consistent with this plain meaning, controlling precedent has long held that “for the Government” means “for the Government’s benefit.” *Hughes*, 534 F.2d at 897 (“for the government, *i.e.*, for the Government’s benefit”). And precedent has required that the benefit the government receives from a contractor’s infringement be “direct,” *id.* at 902, and not merely “incidental,” *IRIS*, 769 F.3d at 1362. Thus, in *Advanced Software*, fraud-prevention technology for U.S. Treasury checks was deemed “for the Government”

because it directly averted fraud in the Treasury's own checks. 583 F.3d at 1378. In *Sevenson*, waste removal for federal facilities was “for the Government” because the government itself directly enjoyed the waste removal benefit. 477 F.3d at 1365-66. And in *IRIS*, statutorily mandated passport examination for travelers to the United States, a “quasi-governmental function[],” was infringement “for the Government” because it “**directly** enhance[d] border security and improve[d] the government’s ability to monitor the flow of people into and out of the country.” 769 F.3d at 1362.

By contrast, §1498 does not apply when an infringer produces goods or provides services for private parties, even if the government pays for and benefits indirectly from that infringement. In *Larson*, the use of medical devices for Medicare recipients was not for the government’s benefit because “medical care is provided for the benefit of the patient, not the government,” even if the government “funds or reimburses all or part of its costs.” 26 Cl. Ct. at 369. The resulting benefit to the government of furthering its interest in funding medical treatment was “**too remote.**” *Id.* In *Windsurfing International, Inc. v. Ostermann*, 534 F. Supp. 581, 588 (S.D.N.Y. 1982), the use of a patented sailboard by the U.S. Olympic team was not “for the Government,” even though “the United States has great interest in the running of the Olympics generally,” because the benefits were “**indirect.**”

And in *Riles v. Amerada Hess Corp.*, 999 F. Supp. 938, 940 (S.D. Tex. 1998), the government’s receipt of royalties from the defendant’s infringing drilling did not make infringement “for the Government” because the royalty was merely a “**byproduct**” of infringement.

Section 1498 did not apply in those instances because the benefits the government derived from infringement were “incidental effects of private interests.” *Advanced Software*, 583 F.3d at 1379 (citing *Larson* and *Riles* with approval). Thus, the “fact that the government has an interest in [a] program generally, or funds or reimburses all or part of its costs” does not “make the government the program’s beneficiary for the purposes underlying §1498.” *Larson*, 26 Cl. Ct. at 369. And critically, *contra* Moderna (at 30), §1498 cannot be invoked merely to allow the government to “achieve its objectives.” This Court’s rule is clear (even if Moderna (at 30) blatantly expurgates it): to invoke §1498, infringement “in furtherance and fulfillment of a stated Government policy” “**must also be done for the benefit of the government.**” *IRIS*, 769 F.3d at 1362; *Advanced Software*, 583 F.3d at 1379.

Moderna points to **no case** where §1498 applied simply because the government paid a private party to provide goods used by the general public—even where that use furthered a government policy.

**2. *The Direct-Benefit Test Applies Even with Government-Requested Conduct.***

Faced with myriad cases assessing whether the government is the direct or incidental beneficiary, Moderna (at 44-45) attempts to evade that test as a mere “safeguard against accidental” liability applying only to “private activity that [the government] never asked for.” That is wrong.

In *Advanced Software*, the U.S. Treasury “instruct[ed]” a Federal Reserve bank to enter a “procurement” contract for antifraud technology for Treasury checks, and advised by letter that it would “implement this technology.” 583 F.3d at 1374. Despite the government clearly “ask[ing] for” the procurement, this Court adjudicated the “for the Government” prong by assessing whether the government’s benefit was direct or “incidental.” *Id.* at 1378-79.

Likewise, in *IRIS*, this Court found that the government expressly authorized and consented (and mandated) an airline’s use of patented passport scanning technology, but that “does not mean that the alleged use or manufacture is done for the United States.” 769 F.3d at 1362-63. For that independent prong, this Court analyzed whether the benefit to the government was incidental or direct. *Id.*; *see also Hughes*, 534 F.2d at 898 (applying “direct benefit” test to U.S. government-facilitated purchase of military satellite by the U.K.).



So too in *Riles*, 999 F. Supp. at 940, *cited in* *Sevenson*, 477 F.3d at 1365-66, which the Executive (at 15 n.3) discusses. *Riles* rejected a §1498 defense where the government approved the defendant’s infringing drilling but benefited only as a “byproduct” of that infringement. *Id.* The government’s approval did not establish, *per se*, that infringement was “for the Government”; a direct-benefit inquiry was necessary. *Id.*

These cases foreclose resoundingly Moderna’s notion (at 45) that “for the Government” requires assessing direct versus incidental benefit only where the infringement is “private activity that [the government] never asked for.”

### **3. *The Direct-Benefit Test Is Not an End-User Requirement.***

Moderna (at 37) mischaracterizes the district court’s application of the direct-benefit test, arguing that it required that an invention is “used...by” the government, negating the statute’s other scenarios (like used or manufactured for). Not so.

In most cases, the same party is the intended recipient of both the infringing goods or services and the direct benefits thereof. *E.g.*, *Gargoyles, Inc. v. United States*, 113 F.3d 1572, 1573 (Fed. Cir. 1997) (eyewear for soldiers). That is certainly the case here, where the Americans who received the vaccine—making them “less likely to develop” “severe infection,”

Appx3658—were the intended recipients of both the disputed doses and the doses’ direct benefits.

But the direct-benefit test does not require that the government be the “end-user.” In atypical cases, like *Hughes*, the intended recipient of the direct benefits is not the intended recipient of the invention itself. The U.K. received and used the infringing satellite. But the U.S. government was a direct beneficiary, because the satellite was to be used cooperatively for “the military defense...of both countries,” so the infringement was “for the Government.” 534 F.2d at 898; *see also IRIS*, 769 F.3d at 1362 (airline’s use of electronic passports directly benefited government by “improv[ing] the government’s ability to monitor the flow of people into and out of the country”). Although the government need not be the “primary” recipient of the benefit, *Sevenson*, 477 F.3d at 1365, the benefit must be “direct,” *Hughes*, 534 F.2d at 902.

For vaccines, the direct beneficiary and the intended recipient of the dose are the same. Appx15. So the district court reasoned that §1498 applies where the government is “the intended recipient of the infringing product, as opposed to the public that the Government represents.” Appx13. The court was not redefining the test to apply §1498, but explicitly applying this Court’s long-established test, requiring not that the government receive the doses, but that “the Government must receive the benefit itself,” and such

benefit must be “direct; it cannot be merely incidental or ‘too remote.’”

Appx13-14.

**B. Moderna Improperly Reads the “for the Government” Requirement out of §1498.**

Unable to meet the rule consistently applied by the courts, Moderna (at 28, 34, 46) proposes a new, purpose-built rule. Having signed a procurement contract, Moderna (at 24, 44) conveniently suggests that a contractor’s “use or manufacture” in fulfillment of a procurement contract is necessarily “for the Government” because the government has agreed to the infringement and receives the “benefit of the bargain.” *See also* DOJ 13. In so doing, Moderna flouts controlling precedent analyzing the government’s benefit despite the existence of a procurement contract, *e.g.*, *Advanced Software*, 583 F.3d at 1378-79, and would collapse §1498’s two prongs.

**1. The “for the Government” Inquiry Does Not Turn on the Identity of the Contracting Party.**

Contrary to Moderna’s assertion (at 34) that “[w]hat matters [for §1498] is who is procuring the goods,” this Court has never required that the government be the contracting party to establish authorization and consent, much less the distinct “for the Government” prong. *E.g.*, *Advanced Software*, 583 F.3d at 1378; *Hughes*, 534 F.2d at 898, 901. Rather, the proper inquiry for the latter is whether the government directly benefits. *See IRIS*,

769 F.3d at 1362 (no government procurement contract, infringing use was “for the Government”).

Moderna’s cases do not hold differently. Moderna (at 33) first cites examples of the U.S. government sending goods to military allies, claiming that because the goods ultimately were provided to allies, §1498 must apply whenever the U.S. government acts as a procurement conduit.

*Yassin v. United States*, 76 F. Supp. 509, 511 (Ct. Cl. 1948), addressed bridges used on D-Day “by the allied forces of the United States and Great Britain.” While British soldiers crossed the bridges, so too did U.S. soldiers. Thus, the infringement directly benefited the U.S. government. Likewise, in *Kaplan v. United States*, 153 F. Supp. 787, 789 (Ct. Cl. 1957), the government contracted for patented sleeping bags for U.S. military use. The contracts did not acquire the sleeping bags “on behalf of any foreign country,” but they “eventually f[ound] their way into the hands of a friendly nation.” *Id.* Both *Yassin* and *Kaplan* thus involve U.S. military acquisitions ***intended for its own use***, a situation where, indisputably, the government directly benefits. *See Richmond Screw*, 275 U.S. at 346; *Hughes*, 534 F.2d at 898 (British-owned satellite was for “***direct benefit*** of the U.S.” because it “expand[ed] the US defense satellite communications system”).

None of Moderna’s cases holds that goods acquired for the purpose of benefiting U.S. allies are covered by §1498. Because §1498 does ***not*** cover

such infringement, Congress passed a separate statute in 1951 addressing military aid to foreign allies: §517 of the Mutual Security Act, now 22 U.S.C. §2356. *See* Pub. L. No. 82-165, §517, 65 Stat. 373, 382-83 (1951). That Act’s purpose was “to provide the same remedy as 28 U.S.C. §1498” when infringement is committed to aid “foreign government[s].” *Advanced Tech. Sys. Co. v. United States*, 174 Fed. Cl. 144, 164 (2024). Were Moderna correct that §1498 already covers the U.S. government’s procurement of goods and subsequent transmission to third parties, including foreign allies, Congress had no need to enact §2356.

Moderna’s domestic cases do not support its position either. In *Broome*, 92 F.2d at 888, §1498’s predecessor applied to sluice gates designed by the Army for use in dams it was building. Moderna (at 34) misleadingly suggests that the court deemed infringement “for the United States” despite finding that the “gates were primarily ‘for the benefit of’” and “furnished to” a non-U.S. government entity. That is wrong. The plaintiff asserted the contract was “for the benefit” of the local district rather than the United States, but the court disagreed. *Id.* at 887. *Broome* therefore does not reject the direct-benefit test, but rather, *contra* Moderna’s improper rule, applies that test despite the existence of a contract “between [the] Defendant and the United States government.” *Id.* The court found that, although the dams were located within a state conservancy district, they were “public

works” of the United States; the federal government was responsible for their construction, and the dams (unlike the vaccine doses here) were not conveyed to the district. *Id.* at 888. The government directly benefited from parts procured for use in its construction of a dam that it never conveyed to others—so the use was “for the Government.”<sup>4</sup>

**2. *The Same Test Applies Regardless of the Form of the Government’s Request.***

Despite Moderna’s singular focus, there is no magic to a “procurement contract” under §1498. The statute does not “require that the government be party to any contract” at all. *Advanced Software*, 583 F.3d at 1378. A contract is just one of many ways the government could ask another party to use or manufacture an invention. The government could send an email, *id.* at 1374, a letter, *Hughes*, 534 F.2d at 899, or require the use by statute, *IRIS*, 769 F.3d at 1361. Moderna’s argument (at 46) that performance of a procurement contract *per se* satisfies the “for the Government” prong, precluding an inquiry into whether the procured good directly benefits the government, is demonstrably wrong.

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<sup>4</sup> Moderna (at 34) also cites *In re Mahurkar*, 831 F. Supp. 1354 (N.D. Ill. 1993), which provided no analysis whatsoever of either prong of §1498, or any indication that its application was disputed, in connection with catheter sales to government agencies (including the VA) that marginally affected damages, *id.* at 1397. In any event, Moderna failed to raise any argument below regarding the VA, which received less than 1% of the C-100 doses. Appx8179-8181.

Moderna's own cases show courts must (and do) independently evaluate whether the manufacture or use is "for the Government" both when the government executes a procurement contract and when it requests infringing conduct another way. In *Broome*, despite the contract "between defendant and the United States government," the court proceeded to analyze whether the infringement was for the benefit of the United States. 92 F.2d at 887-88. Under Moderna's improper view, the analysis should have stopped with the existence of the contract.

*Advanced Software* is similarly instructive. The U.S. Treasury Department "instruct[ed] the Federal Reserve" bank to execute a "procurement" contract explicitly reciting that the bank was acting "in conjunction with" Treasury to use fraud-protection technology. 583 F.3d at 1376. Treasury later wrote a letter "establish[ing] a Check Fraud project to implement this technology in the production of checks that we issue," which satisfied the authorization-or-consent prong. *Id.* at 1377. Under Moderna's *per se* procurement contract rule, if Treasury itself had signed the procurement contract, no analysis of the "for the Government" prong would be proper. But since Treasury instead "instruct[ed] the Federal Reserve" to execute a contract acting "in conjunction with" Treasury and authorized use of the technology by letter, a "for the Government" inquiry is proper. No logic or authority supports that distinction. On the contrary, the question of

“who is procuring” the service, Br. 34, was so irrelevant that this Court declined to decide whether the Federal Reserve “acted in an agency capacity [for Treasury] when they entered into the contracts,” *Advanced Software*, 583 F.3d at 1379.

This precedent requires consideration of direct benefits whether or not the contractor acts pursuant to a procurement contract. Certainly, most government procurement contracts acquire goods or services that the government requires for its own uses. But Moderna (at 46-47) errs in concluding that, because *most* procurement contracts are “for the Government,” *all* procurement contracts are. *See also* DOJ 13-14 (equating procurements’ general support of “governmental objectives” with benefit “for the Government”).

Consider the implication of Moderna’s argument. Were Moderna correct, sailboards used the same way as in *Windsurfing*—except acquired through a procurement contract—would become “for the Government.” Likewise for the splints in *Larson* or the oil-drilling services in *Riles*. And this concept is not merely hypothetical. The Executive’s FY2025 budget proposed a direct provision program “whereby the Federal Government purchases and distributes [Hepatitis C] drugs to eligible individuals—including, but not limited to, Medicaid enrollees.” Appx6159. The notion that the same good or service, used the same way, could be “for the



Government” or not depending on how it was obtained is as illogical as it is unprecedented.

The law is clear: even with procurement contracts, §1498 applies only “where infringing activity has been performed by a government contractor pursuant to a government contract ***and for the benefit of the government.***” *Sevenson*, 477 F.3d at 1366. Moderna (at 46) brazenly ignores this language and claims that *Sevenson* makes fulfilling a contract “sufficient to show the contractor was acting ‘for the Government.’” The parties there did not dispute that performing waste remediation for a government-owned facility directly benefited the government. *Id.* at 1363. The Court’s “for the Government” analysis was thus limited to rejecting a “primary purpose” test unsupported by precedent. *Id.* at 1365-66.

That cases (including *Sevenson*) often address authorization-and-consent disputes does not support ignoring the other prong where, as here, direct government benefit ***is*** disputed. Moderna also cites *Piecznik v. United States*, 2023 WL 5031507, at \*2 (Fed. Cir. Aug. 8, 2023), which (unhelpfully for Moderna) relied on the absence of “factual allegations linking the accused use to any ***authorization and consent*** by the government,” not the “for the Government” prong.

Because the question of how the government obtains goods or services is distinct from whether they directly benefit the government, a defendant

selling pursuant to a procurement contract still “must establish that its use or manufacture of the allegedly infringing products is ‘for the Government.’”

*Racing Optics, Inc. v. Clear Def., LLC*, 2017 WL 3242258, at \*1, \*4

(M.D.N.C. July 28, 2017); *see also Advanced Software*, 583 F.3d at 1378.

Indeed, this Court’s predecessor held that infringement was not “for the Government” in circumstances involving a procurement contract. *See Carrier Corp. v. United States*, 534 F.2d 244, 247 (Ct. Cl. 1976). Moderna (at 47) claims that *Carrier* “**bypassed** the ‘for the Government’ inquiry.” Not so. In *Carrier*, a contractor operating under a procurement contract with express authorization and consent supplied trash removal services. *Id.* Nonetheless, the court found the infringement was not “for the Government” because it did not benefit the government; instead, the infringement—which “was used to service both public and private clients”—“had a usefulness only with respect to” the contractor. *Id.* at 247, 249.

Directly contradicting the *per se* rule it advances here, Moderna acknowledged below that—notwithstanding a procurement contract providing authorization and consent—“the contract [in *Carrier*] **was not ‘for the Government’** because” the infringement “had no ‘relation to the function performed by the Government.’” Appx6933. Courts likewise have concluded that *Carrier* addressed both prongs and found the “contractor’s infringing use of the plaintiff’s patent was **not use ‘for’ the Government.**” *Riles*, 999 F.

Supp. at 941. Thus, not even Moderna (at 46-47) believes its argument that no authority “hold[s] that government-authorized patent use in manufacturing directed by a government procurement contract was **not** ‘for the United States.’”

In aid of its procurement-contract rule, Moderna (at 30) also claims that §1498 should apply to Moderna’s contract work because the statute would apply if the government manufactured the vaccine itself. But Moderna conflates Congress’s distinct treatment of infringement by a contractor with infringement directly by the government, which could not otherwise be sued for infringement. While “use or manufacture...by a contractor must be done “for the Government,” there is no such limit for the government’s own infringement. Moreover, contrary to Moderna’s counterfactual scenario, Moderna was not manufacturing the government’s vaccine; Moderna developed and manufactured its vaccine independent of the government. Appx3249-3250; Appx8696. The statute sensibly treats those scenarios differently.

That the “for the Government” prong is often an “easy lift” in cases involving a procurement contract does not support Moderna’s effort (at 33) to pretermitt the inquiry altogether. The reason more cases do not address and reject Moderna’s contention is that contractors rarely, if ever, invoke §1498

to cover purchases of goods for the general public. The unprecedented nature of Moderna's request is hardly a fact in its favor.

### 3. *Moderna's Rule Collapses the Structure of §1498.*

Moderna's interpretation is also wrong because it would render the "for the Government" prong superfluous. "[E]very word and every provision is to be given effect...." *Nielsen v. Preap*, 586 U.S. 392, 414 (2019). Courts thus "generally do not read a statute in a way that makes part of it redundant," *Chevron USA Inc. v. Plaquemines Par.*, 146 S. Ct. 1052, 1063 (2026), except when clashing interpretations both involve superfluity, *Kendall v. Collins*, 171 F.4th 1294, 1302 n.2 (Fed. Cir. 2026).

Moderna's rule would create two redundancies. **First**, §1498 applies to "the use or manufacture of an invention...**by a contractor**...for the Government and with the authorization or consent of the Government." §1498(a). Were Moderna correct that a procurement contract itself establishes that use or manufacture is for the government, then applying the "for the Government" prong to uses or manufactures "by a contractor" would be superfluous.

**Second**, Moderna (at 28, 33-34) argues that infringement that fulfills a procurement contract is "for the Government" not because of any benefit, but because the government **agreed** to that use or manufacture. This approach collapses §1498's two prongs. Under Moderna's interpretation,

government conduct conveying authorization or consent—*i.e.*, its approval of infringement, *see IRIS*, 769 F.3d at 1362; *TVI Energy Corp. v. Blane*, 806 F.2d 1057, 1060 (Fed. Cir. 1986)—would likewise always satisfy the “for the Government” prong, which per Moderna (at 44) encompasses any “intended effect of government conduct.” Put another way, when the government authorizes a contractor’s patent infringement, such infringement is necessarily the “intended effect of government conduct.” So Moderna would render “for the Government” superfluous to “authorization or consent.”

Moderna (at 39-40) responds by arguing that not all procurement contracts include “[s]eparate FAR clauses” authorizing infringement. Moderna’s truism reflects only that the authorization-or-consent prong is not superfluous to “for the Government,” not the other way around. Authorization or consent is not limited to FAR clauses; it can be broadly implied from the government’s decision to procure something. *TVI Energy*, 806 F.2d at 1060. Moderna’s “for the Government” test (at 44) hinges on whether the government has provided its agreement or authorization for infringement (whether by FAR clause or otherwise). If Congress so intended, it would not have included the separate “for the Government” prong. *Kendall*, 171 F.4th at 1302 n.2. Even Moderna’s amicus recognizes that Moderna’s test improperly renders §1498’s two prongs superfluous. AIPLA 10-11.

#### 4. *Moderna Cannot Disregard the Text of §1498.*

Moderna (at 38) offers little support for its test in §1498’s text, instead critiquing the district court’s definition of “for,” and only perfunctorily offering an alternative. The district court’s definition comports with ordinary meaning, while Moderna’s definition comes from the inapposite context of agency relationships.

a. Moderna (at 35-36) criticizes the district court’s “intended recipient” definition as definition 12(c) among 31 definitions. But that selection was hardly arbitrary, since most of the 31—including the first 11—are either clearly inapplicable or variations of the district court’s choice. For example, “in front of” (definition one); “[o]f time;...before” (definition two); “in preference to” (definition three); “[o]f payment...in exchange for” (definition six); “[i]n defence or support of” (definition seven); “[i]n order to obtain...[a]lso after verbs like *ask*, *search*, etc.” (definition nine); “[i]ndicating the object to which the activity of the faculties or feelings is directed” (definition ten); “[b]efore an [infinitive],...indicating the object of an action” (definition eleven), have no relevance to §1498. *For, A New Dictionary on Historical Principles* 409 (1908).

Moderna (at 38) cites other dictionaries that “omit[] any reference to the ‘intended recipient.’” But Moderna’s dictionaries use slightly different words to reflect that concept. For example, the second definition in Moderna’s preferred dictionary (at 38) is “[i]n the direction of; toward; with

the view of reaching.” *For*, 4 *Century Dictionary* 2314 (1914); *The Concise Standard Dictionary of the English Language* 214 (1918) (“with a view to”) (cited at Br. 38).

A variation on Moderna’s pizza-delivery example (at 36-37) illustrates how the district court’s definition tracks ordinary usage. If John orders a pizza to be delivered to a party at his home, the pizza is for him and his guests, just as certain (but not all) vaccine doses were for government employees. But consider facts more analogous to this case: John calls a pizzeria, orders a pizza on his tab, and pays to have it delivered to *Jane’s* home. In common parlance that pizza is not “for” John; it is “for” Jane. It is irrelevant that John placed the order, purchased the pizza, paid for delivery, and even technically took “title” to the pizza before Jane received it.

The Executive (at 19) also objects to the district court’s definition. It urges that “for” cannot introduce an intended recipient because “for the Government” also applies to the “use” of an invention, but only “tangible product[s]” can have an intended recipient. The Executive is doubly wrong. First, the Executive (at 15) disproves its own grammatical rule by quoting *Sevenson’s* statement that the “government sought and *received* hazardous waste remediation *services*” in that case. 477 F.3d at 1366. Second, it attacks a strawman—the direct beneficiary is usually, but not always, the “intended recipient” of the infringing product, and “for the Government”

turns on the former, not the latter. Even if uses could not have recipients (they can), they certainly have beneficiaries.

b. In place of the district court's definition, Moderna (at 38) argues that "for" means "[i]n place of, instead of," or "in [sic] behalf of." This definition pertains to representative relationships, such as when someone "act[s] as attorney **for** another." *For*, 4 *Century Dictionary* 2314 (1914) (cited at Br. 38). Procurement contracts are not akin to an attorney-client relationship. The C-100 Contract explains that "[i]ndependently, and **not as an agent of the USG**...the Contractor shall provide all necessary services...." Appx2796. Section 1498 does not assess whether a contractor's use or manufacture was "in place of" the government. Nor does the Executive's use of the phrase "on behalf of" in FAR 27.201-1(a) support Moderna's position (at 28, 39). In promulgating that regulation, the Executive explained "'on behalf of'...depends on whether the Government has provided its '**authorization or consent**,'" 72 Fed. Reg. 63045, 63046 (Nov. 7, 2007); it was not talking about the "for the Government" prong.

Moderna (at 39) also is wrong that courts endorse its definition. Moderna cites *Sheridan*, which equated "acting on behalf of" to "authorization from" the government; it was not addressing the separate "for the Government" prong. 629 F. App'x 948, 951 (Fed. Cir. 2015). Nor did *Larson* use Moderna's definition, as Moderna (at 42-43) implies. It used "on



behalf of” only when directly quoting a license agreement in a different case.  
26 Cl. Ct. at 369.

**5. *Any Ambiguity Concerning §1498 Must Be Construed Against Moderna.***

Even if Moderna’s rule were one possible interpretation of §1498, the principle that ambiguity “must be resolved in favor of [sovereign] immunity,” *Zoltek*, 672 F.3d at 1318, compels Plaintiffs’ interpretation. “[A]mbiguity exists if there is a plausible interpretation of the statute that would not authorize money damages against the Government.” *FAA v. Cooper*, 566 U.S. 284, 290-91 (2012).

The statute’s text and the precedent applying it require that the contractor’s infringing action directly benefit the government. It is, at minimum, undeniably “plausible,” *id.*, that Moderna and the government’s representations (Appx4504, Appx7403, Appx7406) were correct: vaccines Moderna delivered to states, foreign governments, and private healthcare entities for inoculating private citizens were not “for” the federal government. Therefore, any “ambiguity in the statute must be resolved in favor of immunity.” *Zoltek*, 672 F.3d at 1318. This presumption is particularly important here, as §1498 both waives sovereign immunity and extinguishes private patent rights. *See Madey v. Duke Univ.*, 307 F.3d 1351, 1359 (Fed. Cir. 2002).

In considering waiver, it does not matter that the Executive wishes to assume Moderna's liability (and massively expand its own authority), Appx946, since, unlike Congress, "executive officers lack the power to waive the federal government's sovereign immunity." *United States v. Horn*, 29 F.3d 754, 762 (1st Cir. 1994); *Pacrim Pizza Co. v. Pirie*, 304 F.3d 1291, 1294 (Fed. Cir. 2002). While the Executive (at 4) would arrogate unilateral, unreviewable authority to choose when §1498 applies, its cited authority, *TVI Energy*, 806 F.2d at 1060, provides no support. *TVI Energy's* statements about §1498's coverage concerned the government's grant of authorization and consent (which it controls), not any Executive authority to declare its actions "for the Government." 806 F.2d at 1060.

**C. Moderna's Infringement Was Not "for the Government."**

Under the established legal standard, the C-100 doses the government purchased for private citizens were not "for the Government." Whether §1498 applies depends on the facts known *ex ante*. See *Kaplan*, 153 F. Supp. at 789-90 (determining §1498's coverage *ex ante*, rather than on what "eventually" happens). Here, the contracting parties recognized, and the C-100 Contract reflected, separate provision of doses for the government and doses for the benefit of the American populace. Appx2796; Appx4504; Appx7403; Appx7406. That is sufficient to find that Moderna, and not the

taxpayer, is responsible for its admitted infringement, without any irrelevant fact-bound analysis of the vaccine’s eventual incidental effects.

**1. *From the Outset, the Vaccines Were for the American People.***

The C-100 Contract expressly recites two categories of doses: doses for “the United States Government” and doses for “the US population.” Appx2796. The very size of the contract—500 million doses—makes self-evident that a large majority were not for the government. Appx2796. That was Moderna’s understanding from the start. Moderna’s “express position when negotiating the C[-]100 contract” was that it was “developing a vaccine that’s intended to be administered to the general public,...beyond the internal use by the US Government only.” Appx4504; Appx8031. Moderna explained the contract’s intent was to provide “vaccines ***for the American people,***” “for purposes other than Governmental purposes.” Appx4504-4505; Appx8032. The government similarly entered the contract with “the goal of making [the vaccine]...***available to the American population.***” Appx4505.

The actual distribution reflected these expectations, with the overwhelming majority of doses going to non-federal entities that the government’s designee testified repeatedly, in language that mirrors the statute precisely, “***weren’t used for the federal government.***” Appx7400-7406; *supra* 12-14. The Executive’s brief (at 13-18) urges precisely the opposite, but it is not under oath or subject to the “greatest legal engine ever

invented for the discovery of truth,” *California v. Green*, 399 U.S. 149, 158 (1970).

The benefits followed that distribution. “[M]edical care is provided for the benefit of the patient, not the government” even if the Government “funds or reimburses all or part of its costs.” *Larson*, 26 Cl. Ct. at 369. In *Larson*, the patented splints and casts, paid for by the federal government through Medicare and Medicaid, were not “for the Government.” *Id.* at 367, 369. Although *Larson* acknowledged the government’s interest in paying for that care, the government’s benefit was “too remote.” *Id.* at 369.

That *Larson* involved “splints and casts to treat...broken bones, strains, arthritis, and burn injuries,” Br. 42, rather than vaccines, does not change the beneficiary. The direct benefits identically accrued to recipients of that care—those “who received the vaccine were less likely to develop...severe infection.” Appx3658.

Moderna (at 44) argues *Larson* stands only for the meager proposition that “[p]rivate parties cannot foist §1498 liability on the Government for conduct the Government never sought, required, or bargained for.” But Moderna’s argument ignores controlling authority assiduously applying the direct-benefit test even to conduct the government specifically desires and requests. *Supra* 26-27. And *Larson* (as precedent dictates, *supra* 22-25) explicitly evaluated whether the infringement benefited the government

independently of its authorization-or-consent inquiry. 26 Cl. Ct. at 369 (“Even assuming that Medicare providers’ activities were ‘for’ the government, liability would not attach” without “the government’s authorization or consent.”); *see also IRIS*, 769 F.3d at 1362; *Advanced Software*, 583 F.3d at 1378; *Hughes*, 534 F.2d at 902. Moderna cannot avoid the holding on the former by conflating it with the latter. The splints would have been no more for the government, and no less for patients, had the parties used a procurement contract rather than reimbursement. The inquiries are orthogonal.

As in *Larson*, the broader benefits Moderna and its amici cite—like reduced transmission and hospitalization, increased economic growth and income-tax receipts, *see* Br. 50, Hepburn 16-17,<sup>5</sup> and less pandemic-related spending, DOJ 22—are all byproducts of the direct benefit to vaccine

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<sup>5</sup> The Amicus Brief of Dr. Hepburn (Director of the government’s COVID-19 Vaccine Development, who reported to Moderna’s Dr. Slaoui) fails to disclose that it was authored by Moderna’s counsel in a related matter, *Northwestern University v. Moderna, Inc.*, No. 24-1151 (D. Del.). Instead, it (at 1 n.1) misleadingly conveys the opposite—that attorneys “other than the undersigned” represent Moderna. Not true. An “undersigned” lawyer, days before filing the “Hepburn” brief, argued in representing Moderna in *Northwestern* that the court “Should Defer Application Of Any Issue Preclusion [about §1498] Until Moderna’s” appeal in this case “Is Decided.” *Id.*, D.I. 82 at 11 (May 29, 2026). The notion that the improper (Fed. R. App. P. 29(a)(4)) Hepburn “amicus” brief is something other than a thinly-veiled, unauthorized Moderna brief written by Moderna’s lawyers strains credulity.

recipients. They do not establish that the vaccinations were “for the Government.” *See Riles*, 999 F. Supp. at 940-41.

The indirect nature of these benefits is demonstrated by their attenuated connection to Moderna’s vaccine—*e.g.*, tax receipts resulting from economic growth, resulting from businesses reopening, resulting from fewer infections, only partially caused by vaccinations using Moderna’s (rather than other companies’) vaccines. Appx4464-4466. The same indirect benefits would accrue to the government from ameliorating any substantial health problem, from opioid misuse to cancer to (in *Larson*) arthritis to obesity. The line-drawing exercise Moderna and its amici propose is dangerously expansive and antithetical to §1498’s purpose and precedent applying it.

The Executive (at 18) acknowledges, *sotto voce*, the lack of a sufficient government benefit here. Though it sets forth the controlling three-part test from *IRIS* that Moderna ignores—(i) furthers a government policy, (ii) “serves government interest,” and (iii) “for the Government’s benefit”—the Executive argues only that the “manufacture of vaccine doses” was “in furtherance of federal policy” and “served the government’s interests.” Its pregnant silence as to “for the government’s benefit” is telling.

## **2. *The Government Did Not Directly Benefit by Taking Formal Title to the Vaccines.***

Unable to satisfy the direct-benefit test precedent requires, Moderna (at 36-37) ignores the reality of whom the doses were for and asserts that the

government was “the intended recipient of *all* vaccine stock that Moderna produced” under the contract, based on legally irrelevant formalisms about “accept[ance],” “control[[]],” and “own[ership].” But as *Hughes* illustrates, receiving direct benefits, not contractual formalities, governs the “for the Government” inquiry. In *Hughes*, the procurement contract provided that title to the satellite “would vest in and become the absolute property of the [UK] Ministry of Defence.” 534 F.2d at 895. The court did not rely on formalistic title to examine whether the infringement was “for the Government’s benefit.” *Id.* at 897-98. Because the UK-owned satellite was a “segment of the U.S.” satellite communications systems, and thus “undertaken for the direct benefit of the U.S.,” the satellites were “for the government, i.e., for the Government’s benefit.” *Id.* Formal title was inapposite. *Id.*; *IRIS*, 769 F.3d at 1361-62 (Defendant airline’s “passenger check-in facilities” system—not government’s system—used patented technology “for the government” because it was “done for the benefit of the government.”).

Other courts likewise look past formal title to decide whether §1498 applies. *E.g.*, *Bath Iron Works Corp. v. Parmatic Filter Corp.*, 736 F. Supp. 1175, 1177 (D. Me. 1990) (applying §1498 to Naval vessel components even though “the Navy ha[d] not yet accepted the vessel”); *Systron-Donner Corp. v. Palomar Sci. Corp.*, 239 F. Supp. 148, 151 (N.D. Cal. 1965) (declining to

apply §1498 for products that “bec[a]me the property of the United States”). Even where courts reference title, it has not controlled the “for the Government” inquiry. Moderna unsurprisingly chose not to cite *Bereslavsky v. Standard Oil Co.*, 82 F. Supp. 939, 942 (D. Md. 1949), which discusses title in connection with §1498. In concluding §1498 applied to the wartime acquisition of patented fuel—notwithstanding the government’s subsequent decision to sell a small amount of it—*Bereslavsky* relied on title only as evidence of the government’s *ex ante* expectation that it would use the fuel. *Id.* Moderna’s vaccine was always intended for the public. Appx2796.

The immateriality of the formal title on which Moderna relies heavily is even more striking here, where the government’s title was ethereal. The government “did not take physical possession” of the doses, Appx7391 (92:13-18), or test or physically inspect them, Appx7385 (86:3-6). The doses were distributed by private contractors, mostly to private pharmacies and state governments. Appx7390-7391 (91:992:18); Appx3491; Appx7398 (99:3-7). These entities ultimately decided who would receive the vaccines. Appx7457 (169:3-6); Appx7058. The government’s transitory title resulted from mere operation of a boilerplate contractual provision. Appx2806 (incorporating FAR 52.246-16).

The idea that Moderna’s position would be any different in the absence of an incorporated contract clause about transitory title is risible. And if



§1498’s application turned on such formalities, the “for the Government” prong would no longer effectively limit the Executive, which could arrange transaction formalities to invoke (or not invoke, for less favored and connected infringers) §1498 for *any* good or service it procures.

### **3. *Section 1498 Is Easily Administrable in this Case and Others.***

Because whether a “manufacture or use” is for the government’s benefit is assessed at the outset, §1498 applies predictably without Moderna’s atextual procurement-contract rule. Moderna’s (at 48) and some amici’s, TCRI 9; NAM 17; DOJ 24-28, concerns about unpredictable litigation risk hindering procurements or deterring contractors are misplaced. The outcome under either this Court’s direct-benefit test or Moderna’s conjured test would be the same for typical procurement contracts, which involve the government acquiring goods or services for its own functions. But in unusual circumstances where the purchase is not intended for the government’s benefit, the infringer remains liable.<sup>6</sup>

Moderna’s amici argue that the pandemic’s exigency justifies reading §1498 broadly. NAM 16; AIPLA 21; *see generally* Hepburn. But the

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<sup>6</sup> The actual distribution of doses is a proxy for the parties’ expectations, as the data reflect the *ex ante* intent to make the doses available to the public. Appx4504. Moderna, who bore the burden of proof, *Toxgon Corp. v. BNFL, Inc.*, 312 F.3d 1379, 1383 (Fed. Cir. 2002), did not dispute those data or offer an alternative. Appx8180.

pandemic did not transform *ultra vires* actions into permissible conduct. “It is indisputable that the public has a strong interest in combating the spread of [COVID-19]...[b]ut our system does not permit agencies to act unlawfully even in pursuit of desirable ends.” *Ala. Ass’n of Realtors v. HHS*, 594 U.S. 758, 766 (2021) (per curiam). Rights—especially those ensconced in the Bill of Rights, like the right to a jury trial—are not blithely jettisoned simply because the government perceives an emergency. *Roman Cath. Diocese v. Cuomo*, 592 U.S. 14, 19 (2020) (per curiam). Nor has Moderna offered evidence that §1498 was needed to create a vaccine; Moderna developed its vaccine months before contract discussions began, Appx2067; Appx5892, and the government purchased a majority of vaccine doses from other manufacturers without §1498.

Regardless, had patent liability posed a barrier to developing vaccines, Congress could have addressed it. Congress legislated extensively on the pandemic, *e.g.*, FFCRA, Pub. L. No. 116-127, 134 Stat. 178 (Mar. 18, 2020); CARES Act, Pub. L. No. 116-136, 134 Stat. 281 (Mar. 26, 2020), enacting (for example) liability shields for respiratory mask manufacturers (FFCRA §6005, CARES Act §3103) and volunteer healthcare professionals (CARES Act §3215). Had Congress thought it necessary to extinguish third-party patent liability in addressing the pandemic, it could have done so. It did not.

Concerns about injunctive relief, Br. 62; DOJ 26, are also misplaced. Without expanding §1498, courts “refuse[]” to “enjoin activities [where it] would injure the public health.” *Cordis Corp. v. Bos. Sci. Corp.*, 99 F. App’x 928, 935 (Fed. Cir. 2004); *Bianco v. Globus Med., Inc.*, 2014 WL 1049067, at \*11 (E.D. Tex. Mar. 17, 2014) (collecting cases). Courts refused injunctions related to COVID-19 for that reason. *E.g., Intrivo Diagnostics, Inc. v. Access Bio, Inc.*, 2022 WL 204618, at \*2 (C.D. Cal. Jan. 24, 2022) (denying injunction against COVID-19 tests).

Nor will the precedentially compelled interpretation of §1498 deter government contracting. Determining *ex ante* whether the purchase is for the government’s benefit provides the government, contractors, and patent owners with certainty, even with respect to goods that have both governmental and non-governmental uses. *See* NAM 21. Moderna and the government had no uncertainty regarding the direct beneficiary—they both recognized that the vaccine was for the public, not the government. *Supra* 9-12. And the C-100 Contract likewise reflected that the government procured doses both “for the United States Government (USG) *and the US population*,” Appx2796, establishing a clear dividing line as to what was—and was not—for the government.

The clear evidence that the C-100 Contract included large numbers of doses so they would be “immediately available for nationwide access” for

“the US population,” Appx2796, “as quickly as possible,” Appx3357, also separates it from Moderna’s irrelevant hypotheticals (at 37-38) about stockpiling and circumstances where the “disposition may be uncertain for years.” *See Olsson v. United States*, 25 F. Supp. 495, 497-98 (Ct. Cl. 1938) (stockpiling weapons in peacetime is government use). Section 1498 does not require predicting how a product “eventually” will be used, only the intended beneficiary. *Kaplan*, 153 F. Supp. at 789-90.

Ultimately, it is Moderna (at 49-52) that relies on unpredictable, hard-to-administer, *post-hoc* evaluations, claiming (at 49) to have “put forward abundant evidence of how vaccine procurement ‘benefited’ the government.” Its amici follow suit, proposing that “for the Government” turns on a fact-intensive, unpredictable inquiry that assesses the quantum of indirect government benefits. NAM 16; AIPLA 21; *see generally* Hepburn. As the district court rightly noted, a *post-hoc* analysis of the benefits that accrued is legally irrelevant. Appx17.

But even were it relevant, Moderna’s “evidence” of government benefits advanced only generalized facts, like the changes in economic growth, government revenue and spending, and COVID-19 hospitalizations and deaths. Not only was any connection between COVID-19 vaccination and these changes attenuated, but Moderna (and its amici) failed to link the changes to the C-100 Contract doses (instead of Pfizer’s or others’ doses).

Appx4465-4466. And despite asserting that “[e]ven a basic cost-benefit analysis proves [its] point,” Moderna’s analysis (at 50) below considered only benefits, not costs.<sup>7</sup> Moderna thus failed to offer sufficient evidence to discharge its burden of proof.<sup>8</sup> *Toxgon*, 312 F.3d at 1383.

More fundamentally, the asserted benefits, like economic growth and reduced hospitalizations, cannot satisfy §1498 even if proven because they are simply downstream effects of the direct benefit received by the American public. *Supra* 47-48. These “indirect” benefits, however important, *Windsurfing*, 534 F. Supp. at 588, are “too remote” to meet the statutory test, *Larson*, 26 Cl. Ct. at 369.

Ironically, the flaw in Moderna’s government-benefit theory is best described by Moderna itself (at 40-41) in discussing *Sheridan*, where the

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<sup>7</sup> Moderna (at 50 n.6) calumnies Plaintiffs’ criticisms below as “bleakly actuarial.” But **Moderna**—not Plaintiffs—proposed an actuarial analysis of the vaccine’s benefits, submitting expert reports purporting to conduct a cost-benefit analysis. Appx7096-97. Plaintiffs’ rebuttal expert simply criticized the one-sided nature of that analysis and cited more rigorous analyses from organizations like the CBO. Appx7097.

<sup>8</sup> Moderna (at 52 n.7) requests vacatur so the district court may consider expert testimony on §1498. But below, **Moderna** moved to exclude other expert testimony on that topic. Appx2757 (“The ‘For the Government’ Prong of §1498 Involves a Legal Question—Not a Fact Question Requiring Expert Testimony.”). Moderna cannot now challenge a ruling it invited, *Lesende v. Borrero*, 752 F.3d 324, 337 (3d Cir. 2014), much less demonstrate abuse of discretion, Appx17.

plaintiff argued “that the government was liable” for private infringement “because it received downstream incidental benefits in ‘stimulus, jobs, and revenue.’” As Moderna (at 41) explains, “[o]n that theory, *every* private transaction is actually ‘for the Government.’” Just so.

#### **D. Moderna’s Rule Upsets Private Rights and the Constitutional Structure.**

Moderna’s *per se* rule for procurement contracts would eviscerate §1498’s guardrails at significant cost to patent holders and the rule of law.

##### ***1. Moderna’s Theory Violates Patent Rights.***

**a.** Finding for Moderna on its §1498 defense is not just a question of venue, *see* TCRI 12 n.1, or of “*who* (Moderna or the Government) should pay,” NAM 20. It has real consequences for Plaintiffs and all patent holders.

To begin, it would strip Plaintiffs (and others) of their jury-trial right. *Return Mail, Inc. v. USPS*, 587 U.S. 618, 634 (2019). Moderna ignores the Seventh Amendment entirely. But “[t]he right to trial by jury is ‘of such importance and occupies so firm a place in our history and jurisprudence that any seeming curtailment of the right’ has always been and ‘should be scrutinized with the utmost care.’” *Perttu v. Richards*, 605 U.S. 460, 467 (2025). Yet Moderna and the Executive would grant each of tens of thousands of government contracting officers unlimited, unreviewable power to nullify patentees’ jury-trial rights simply by acting through a procurement contract incorporating FAR 52.227-1. *See* FAR 1.602-1; *Workforce Size &*

*Composition*, OPM, (May 2026) (37,520 employees in 1102-Contracting Occupational Series).<sup>9</sup>

Moderna would also extirpate the right to enhanced damages under 35 U.S.C. §284. *Return Mail*, 587 U.S. at 622. Overwhelming evidence establishes that Moderna willfully infringed. Appx5828-5830. Moderna knew it was infringing; every test it conducted showed infringement. Appx6587. Moderna then instructed its scientist to stop further testing because the results could “pose uncomfortable questions.” Appx6844. Moderna also covered up evidence of infringement, ordering its scientist to remove references to Plaintiffs’ technology from scientific presentations: “I know it is hard as a chemist but we have to *fib a bit*.” Appx6851.

**b.** Moderna’s interpretation would permit the government to eviscerate private patent rights virtually without limit. As the district court recognized, “every government-funded product used to advance any policy goal articulated by the U.S. Government—such as IV needles to fight HIV to cancer drugs to fight the war on cancer—would be subject to a §1498(a) defense.” Appx832-833.

This scenario is not merely hypothetical. Following the lead of a law review article outlining a scheme to reduce drug prices by curtailing

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<sup>9</sup> <https://data.opm.gov/explore-data/analytics/workforce-size-and-composition>.

pharmaceutical patent rights, Appx6068, certain members of Congress proposed that the Executive apply Moderna’s interpretation of §1498 to create “a compulsory licensing” system for pharmaceuticals, given Congress’s inability to “pass drug pricing legislation,” Appx6150-6151. The federal government is “the largest purchaser of prescription drugs in the United States,” Appx8183, making the potential consequences to private patent rights staggering.

No court has endorsed this scheme, but the Executive signs on to expand its own authority enormously. DOJ 14. Such authority would destroy the careful balance Congress struck in the Hatch-Waxman Act and BPCIA, in which generic and biosimilar manufacturers face injunctive relief and enhanced damages if they commercialize infringing products. *E.g.*, *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1385 (Fed. Cir. 2006) (affirming post-launch Hatch-Waxman preliminary injunction). Under Moderna’s test, biosimilar and generic manufacturers may (like Moderna) willfully infringe with impunity by selling their infringing products in a procurement contract, leaving patentees with no redress other than “compulsory licensing” from the government. Appx6150.

Moderna (at 42) seeks to obscure the transformative consequences of its position by suggesting that “government reimbursement” (how the government now often pays through Medicare) is different than “government



procurement.” But Moderna offers no legal basis to conclude that whether infringement is “for the Government” turns on the particular method of funding the purchase. Rather, the transactional form is irrelevant to the “for the Government” prong. *Supra* 32-38. Moderna’s expert (whom Moderna (at 5-6, 16, 50) cites repeatedly) testified that Moderna’s argument is not so limited: “benefits received under Medicare and Medicaid” are “benefits to the United States government.” Appx6692 (135:9-13).

Regardless, requiring a purchase contract rather than reimbursement is no real barrier, as the government could simply convert reimbursements into direct purchases, as certain law professors, Congressional members, and the Executive’s proposed budget urged. Appx6068; Appx6150-6157. Under Moderna’s interpretation of §1498, patents protecting every substantial pharmaceutical product (and other products the government wishes were less expensive) are all targets.

## **2. *Moderna’s Theory Violates the Separation of Powers.***

Moderna’s transmogrification of §1498 also threatens the separation of powers. A procurement-contract exception would allow any Executive contracting officer to invoke §1498 for any product by mere *diktat* and Moderna and the Executive urge here that such decisions should not be subject to judicial review.

But unfettered Executive discretion to intrude on private patent rights contravenes our constitutional structure. Congress alone—not the “Attorney General” or any other “government official[]”—is empowered to waive sovereign immunity. *Admiral Fin. Corp. v. United States*, 51 Fed. Cl. 366, 368-69 (2002); *Pacrim*, 304 F.3d at 1294. Congress accordingly limited the Executive’s discretion to assume private liability—by requiring that infringement be “for the Government.” Yet Moderna and the Executive assert that Congress provided every functionary with contracting authority power to waive sovereign immunity and strip rights at will.

Similarly, neither Moderna nor the Executive can nullify the role of the courts. Section 1498 codifies an affirmative defense with textual limitations requiring meaningful adjudication, *Toxgon*, 312 F.3d at 1382-83—the Executive cannot circumvent those limitations by fiat. Predictably, the Executive (at 12) joins Moderna, embracing a rule that would vest itself with unfettered discretion to decide whether §1498 applies, *see* FAR 1.602-2 (providing “wide latitude” for contracting officers’ discretion), and even demeaning judicial oversight as impermissible “second-guess[ing].” But courts are tasked with preventing “arbitrary governmental acts” by the Executive. *INS v. Chadha*, 462 U.S. 919, 959 (1983). As another Moderna amicus explains, this interpretation “would effectively allow agency action to preempt judicial review...a result inconsistent with...[the] separation of

powers.” AIPLA 13. This Court should reject the Executive’s arrogation of unchecked power to pick-and-choose which well-connected contractors like Moderna to release from infringement liability.

Moderna (at 28-29) and its amici, AIPLA 17-23; NAM 15-17, including the Executive (at 1, 25-26), would have pandemic exigencies supersede the separation of powers. That is wrong. This Court’s responsibility to scrutinize sweeping assertions of Executive power is not at its nadir in exigency; it is at its zenith. *See V.O.S. Selections, Inc. v. Trump*, 149 F.4th 1312, 1333, 1335-36 (Fed. Cir. 2025) (en banc), *aff’d sub nom. Learning Res., Inc. v. Trump*, 607 U.S. 229 (2026). “[E]mergency powers...tend to kindle emergencies.” *Youngstown Sheet & Tube Co. v. Sawyer*, 343 U.S. 579, 650 (1952) (Jackson, J., concurring). The Executive has declared more than 160 public-health “emergencies” since 2005. Appx5883-5885. If the Executive could unlock the “extraordinary power [it seeks here]” simply through “a Presidential declaration of emergency,” Congress’s limitations would be meaningless. *Learning Res.*, 607 U.S. at 244. That the President launched OWS “[f]lanked by military leaders,” Br. 44, neither makes this case unique<sup>10</sup> nor justifies disturbing settled property rights and the constitutional order.

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<sup>10</sup> Examples abound. *E.g.*, *Biden: ‘Let’s End Cancer As We Know It,’* (YouTube, March 2, 2022), <https://www.youtube.com/watch?v=iiTC6r8yYg4> (President re-launching 51-year war on cancer, codified at 42 U.S.C. §285, flanked by nearly every high-ranking federal official); Appx4508.

## II. Section 1498 Does Not Apply to Indirect Infringement Claims.

This Court should affirm for a second, independent reason: Plaintiffs’ indirect infringement claims are not subject to §1498.

Congress only waived sovereign immunity for **direct** infringement claims, not **indirect** infringement. “[T]he Government is not liable for its inducing infringement by others,” “or for what, but for section 1498, would be contributory (rather than direct) infringement of its suppliers.” *Decca Ltd. v. United States*, 640 F.2d 1156, 1167 (Ct. Cl. 1980). Moderna dustbins this blackletter law—arguing, contrary to text and precedent, that §1498 bars indirect infringement claims against government contractors based on the directly infringing conduct of private parties.

### A. Precedent Forecloses §1498’s Application Here.

Unlike §271, §1498 does not demarcate between direct, indirect, contributory, or induced infringement. *Zoltek*, 672 F.3d at 1319-20. Instead, §1498 provides a distinct cause of action for the “use or manufacture” by or for the government. *Id.*; see also *Leesona Corp. v. United States*, 599 F.2d 958, 968-69 (Ct. Cl. 1979). So, where an indirect-infringement claim rests on a predicate act of direct infringement **by the government**, there is no claim for indirect infringement, only a claim against the government under §1498. But where the predicate direct infringement is by a private party, §1498 does not apply. *Decca*, 640 F.2d at 1167.

These limits do not “eviscerate the protections of §1498.” Br. 61. They give effect to Congress’s commonsense judgment that sovereign immunity should not be waived for infringing conduct that does not involve use or manufacture by or for the government. *En banc* precedent confirms that “inducement and contributory infringement are outside §1498(a) because they ‘do not involve *the Government’s* making or using a patented invention.’” *Zoltek*, 672 F.3d at 1320 (emphasis in original) (quoting *Decca*, 640 F.2d at 1170 & n.31).

Here, the government did not commit the predicate acts of direct infringement for Plaintiffs’ indirect infringement claims. *E.g.*, Appx1500-1501. Plaintiffs’ claims—on which Moderna consented to judgment, Appx37, Appx1508—alleged that Moderna indirectly infringed by “intentionally encourag[ing] doctors and other healthcare professionals to administer the COVID-19 vaccine” and individuals to receive it. Appx6572-6576. As the district court explained, Plaintiffs “assert[] that non-governmental third parties infringed and that Moderna contributed to or induced that infringement.” Appx16. Section 1498 does not bar these claims because they concern only private parties’ actions. *Zoltek*, 672 F.3d at 1320.

Moderna’s cited cases (at 54-57) prove the point. In each, the government was liable for the underlying act of “*direct infringement*” alleged as a prerequisite for the alleged indirect infringement—“a use of the

patented invention ‘**by...the United States.**’” *Astornet Techs. Inc. v. BAE Sys., Inc.*, 802 F.3d 1271, 1277 (Fed. Cir. 2015) (use by TSA agents); *Morpho Detection, Inc. v. Smiths Detection Inc.*, 2013 WL 5701522, at \*4-5 (E.D. Va. Oct. 17, 2013) (same); *Messerschmidt v. United States*, 29 Fed. Cl. 1, 10, 43 (1993) (use by government pilot); *Marconi Wireless Tel. Co. of Am. v. Simon*, 246 U.S. 46, 56-57 (1918) (contributory infringement based on “acts of the United States”); *Leading Tech. Composites, Inc. v. MV2, LLC*, 2020 WL 13891409, at \*10, \*13 (D. Md. Nov. 20, 2020) (no indirect infringement for government’s “approval and qualification” of items). Rather than holding that government contractors can **never** be liable for indirect infringement, these cases confirm that “section 1498 is a waiver of sovereign immunity **only with respect to a direct governmental infringement** of a patent.” *Decca*, 640 F.2d at 1167.

With no cases applying §1498 to indirect infringement claims predicated on a third party’s directly infringing acts, the Court should not contravene precedent and expand §1498 here.

**B. Section 1498’s Sovereign Immunity Waiver Is Coterminous with Its Relief to Contractors.**

In response, Moderna (at 58) argues that §1498 immunizes government contractors even without waiving sovereign immunity for indirect infringement. Section 1498 both “waive[s]...sovereign immunity” and “relieves a third party from patent infringement liability.” *Madey*, 307 F.3d

at 1359. Text and precedent confirm that these two functions are coterminous. Section 1498 “secure[s] to the owner of the patent the exact equivalent of what it was taking away from him.” *Richmond Screw*, 275 U.S. at 344-45.

The text is clear: §1498’s sovereign immunity waiver is for “use[] or manufacture[] by or for the United States,” while providing that “the owners’ remedy” is “his reasonable and entire compensation ***for such use and manufacture.***” The scope of the waiver (“use[] or manufacture[]”) and the scope of the actions for which a remedy is available (“such use and manufacture”) are necessarily identical. *See Littlefield v. Mashpee Wampanoag Indian Tribe*, 951 F.3d 30, 37 (1st Cir. 2020) (“such’...refer[s] to the entire antecedent phrase”).

Thus, Moderna (at 53-54) misapprehends §1498’s reference to the patentee’s “entire compensation,” and *Richmond Screw*’s characterization of this remedy as “exclusive and comprehensive,” 275 U.S. at 343. Section 1498 indeed provides the entire compensation, and is the exclusive and comprehensive remedy, but only for “such use or manufacture” by or for the government; it simply does not apply to indirect infringement claims based on private parties’ direct infringement, where sovereign immunity was not waived.

Nor does the Federal Tort Claims Act save Moderna. Br. 58-59. As Moderna’s cited cases explain, the FTCA (unlike §1498) recites exceptions that restrict remedies even without waiving sovereign immunity. *See United States v. Smith*, 499 U.S. 160, 166-67 (1991) (“Congress’s express creation of...two exceptions” to relief made it error to “infer[] a third exception.”); *De Martinez v. Lamagno*, 515 U.S. 417, 427 n.5 (1995) (listing FTCA’s exceptions); 28 U.S.C. §2680. Congress explicitly excepted certain FTCA remedies, with no associated sovereign immunity waiver. Moderna cannot engraft such exceptions onto §1498, which has none.

Realizing §1498 does not bar Plaintiffs’ indirect infringement claims, Moderna makes two last-ditch arguments for remand. First, it suggests (at 60-61) that the record does not show which doses were “administered by government healthcare workers.” But Moderna bears the burden to establish its §1498 defense. *Toxgon*, 312 F.3d at 1383. Moderna adduced no evidence on this issue, even after it was on notice of Plaintiffs’ argument, Appx770-771, thereby forfeiting its argument, *Barna v. Bd. of Sch. Dirs.*, 877 F.3d 136, 147 (3d Cir. 2017).

Moderna (at 60) also claims there might be doses for which there was “no direct infringement at all.” But Moderna consented to judgment of indirect infringement as to Plaintiffs’ asserted claims for ***all*** doses at issue here, Appx37; Appx1508, including Plaintiffs’ method claims, Appx187;



Appx8540. Having done so, Moderna cannot now denigrate the sufficiency of infringement proof.

### **CONCLUSION**

The judgment of the district court should be affirmed.

July 8, 2026

Respectfully submitted,

/s/ *David I. Berl*

DAVID I. BERL

**CERTIFICATE OF COMPLIANCE WITH  
TYPEFACE LIMITATION AND WORD COUNT**

I, David I. Berl, counsel for Plaintiffs-Appellees and a member of the Bar of this Court, certify, pursuant to Federal Rule of Appellate Procedure 32(a)(7)(B) and Federal Circuit Rule 32(b), that the attached Responsive Brief of Plaintiffs-Appellees is proportionately spaced, has a typeface of 14 points or more, and contains 13,987 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f) and Federal Circuit Rule 32(b)(2).

July 8, 2026

/s/ David I. Berl

DAVID I. BERL