No. 26-1581

United States Court of Appeals for the Federal Circuit

ARBUTUS BIOPHARMA CORPORATION, GENEVANT SCIENCES, GMBH

Plaintiffs-Appellees,

v.

MODERNA, INC., MODERNATX, INC.,

Defendants-Appellants.

On Appeal from the United States District Court for the District of Delaware, No. 1:22-cv-000252, Hon. Joshua D. Wolson

BRIEF FOR AMICI CURIAE BIOPHARMACEUTICAL INNOVATORS IN SUPPORT OF APPELLEES AND AFFIRMANCE

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UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF INTEREST

Case Number 26-1581

Short Case Caption Arbutus Biopharma Corp. v. Moderna, Inc.

Filing Party/Entity Pharmaceutical and Biotechnology Companies (listed below)

Instructions:

1. Complete each section of the form and select none or N/A if appropriate.
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Date: 07/15/2026

Signature: /s/ Chase A. Cobern

Name: Chase A. Cobern

1. Represented Entities. Fed. Cir. R. 47.4(a)(1).	**2. Real Party in Interest.** Fed. Cir. R. 47.4(a)(2).	**3. Parent Corporations and Stockholders.** 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. ☑ 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. ☐ None/Not Applicable
Novartis Pharmaceuticals Corporation		Novartis AG
AbbVie Inc.		None
Bayer Healthcare Pharmaceuticals Inc.		Bayer AG
A28 Therapeutics, Inc.		Esperance Pharmaceuticals, Inc.
JURA Bio, Inc.		None
Elutia, Inc.		None
Eloxx Pharmaceuticals, Inc.		None
Archetype Therapeutics, Inc.		None
Yokina Biome, Inc.		None

☐ Additional pages attached

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

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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Note

All quoted emphasis is added unless otherwise indicated.

STATEMENT OF INTEREST OF AMICI CURIAE[1]

Amici Novartis Pharmaceuticals Corporation, AbbVie Inc., Bayer Healthcare Pharmaceuticals Inc., A28 Therapeutics, Inc., JURA Bio, Inc., Elutia, Inc., Eloxx Pharmaceuticals, Inc., Arche-type Therapeutics, Inc., and Yokina Biome, Inc. are patent-owning innovators and developers of new pharmaceutical and biological drug products whose businesses depend on robust and enforceable U.S. patent rights. Amici invest heavily in research and develop-ment necessary to invent and develop breakthrough medicines and to obtain FDA approval to bring them to market—investments that would not be possible without the ability to recoup investments and fund future innovation facilitated by reliable patent protection.

As new drug developers, Amici are subject to both the Hatch-Waxman Act (Drug Price Competition and Patent Term Restoration Act of 1984) and the BPCIA (Biologics Price Competition and Inno-vation Act of 2009). These comprehensive statutory schemes re-flect Congress' considered judgment about how to preserve proper

[1] No counsel for any party authored this brief in whole or in part, and no person or entity other than amici and their counsel contributed money that was intended to fund the preparation or submission of this brief. Pursuant to Federal Rule of Appellate Procedure 29(a)(2), all Parties have consented to the filing of this brief.

incentives for innovation while promoting public access to healthcare. Amici have a direct interest in ensuring that §1498 is properly construed to reflect its intended purpose and not misconstrued to circumvent these carefully calibrated schemes.

Some Amici are at times government contractors and thus have a stake in the proper scope of §1498 immunity. Amici do not ask this Court to narrow the genuine protection §1498 affords contractors who manufacture goods for the Government's own benefit. They ask only that the Court decline to construe §1498 beyond its plain meaning, history, and purpose—so broadly that it could undermine Congress' healthcare-specific statutory schemes, and convert a procurement statute into a vehicle for unlimited price control.

The Court's construction of §1498—including whether it can immunize infringing products made for the benefit of private citizens—may also bear directly on the enforcement rights of affiliates of Amicus Bayer Healthcare Pharmaceuticals Inc. (including Bayer CropScience LLC, Monsanto Company, and Monsanto Technology, LLC), which are parties to ongoing patent infringement litigation in other cases involving sales made pursuant to the same Moderna C-100 contract at issue in this appeal.

INTRODUCTION AND SUMMARY OF ARGUMENT

Amici do not question the Government's laudable efforts to encourage vaccine development during a once-in-a-century pandemic, nor Moderna's commendable work to produce one. But the interpretation of 28 U.S.C. §1498 that Moderna and the Government ask this Court to adopt is inconsistent with the statute's text and purpose, and not limited to vaccines, pandemics, or emergencies. It is not limited to anything at all.

On their reading, the word "for" in the phrase "for the Government" confers unbounded executive authority to strip patent holders of their exclusionary rights by routing infringing products to private citizens through procurement contracts. The circumstances of this case—pandemics, emergencies, public health crises—are legally irrelevant to that interpretation. Moderna and the Government's reading requires no extraordinary circumstances; just a boilerplate authorization-and-consent clause and a willing contractor.

That is not what §1498 says or means. Congress enacted §1498 to protect contractors who supply patented goods for the Government's own benefit—not to empower agencies to subsidize infringing products for private citizens. For over a century, courts have

applied the statute to that limited end. No court has ever construed §1498 to immunize the Government's funding of infringing products for the general public. The Government itself has never previously claimed such power—and has successfully opposed its assertion by others.

The district court correctly rejected Moderna and the Government's interpretation. This Court should affirm.

First, only the district court's interpretation gives meaning to the "for the Government" requirement consistent with the statutory text and this Court's precedent. Beyond the Government's authorization and consent, infringing products must be made "for the Government"—meaning the Government's own benefit. Courts have thus repeatedly held §1498 inapplicable when the Government merely pays for products for the benefit of private parties. Because Moderna manufactured vaccines with Appellees' patented lipid technology for the benefit and use of private citizens—not the Government—§1498 does not apply.

Second, Moderna and the Government's contrary interpretation violates the major questions doctrine as articulated by the Supreme Court. They argue a WWI-era procurement statute delegates blank-

check agency authority to subsidize infringing products for the public at unlimited cost to taxpayers—while simultaneously nullifying patent holders' constitutionally protected rights of exclusion. That is precisely the kind of "unheralded" and "transformative" assertion of executive authority that the major questions doctrine forbids absent clear congressional authorization, which is lacking here.

Third, Moderna and the Government's interpretation is incompatible with Congress' later-enacted healthcare-specific patent legislation. The Hatch-Waxman Act and the BPCIA establish carefully calibrated schemes for balancing pharmaceutical patent protection with public access to medication. A core premise of both statutes is that new-drug manufacturers will have the opportunity to enforce exclusionary patent rights *before* generic or biosimilar competitors flood the market. If adopted, Moderna and the Government's interpretation of §1498 is so broad that it could be read to allow agencies to bypass those schemes entirely—routing injunction-proof infringing drugs to the public through procurement contracts while leaving new-drug manufacturers with only post-market money damages against the Government.

Section 1498 is a government procurement statute, not a general-purpose conduit for public access to infringing products. The Court should reject Moderna and the Government's expansive interpretation and affirm.

ARGUMENT

I. The district court correctly held §1498 only immunizes infringing products for the Government's own benefit.

Section 1498(a) immunizes anyone who "use[s] or manufacture[s]" patented inventions "for the Government and with the authorization or consent of the Government." 28 U.S.C. §1498(a). When it applies, §1498 "remov[es] the threat of injunction," *Advanced Software Design Corp. v. Fed. Rsrv. Bank of St. Louis*, 583 F.3d 1371, 1375 (Fed. Cir. 2009), and limits the patent holder to suing the Government in the Court of Federal Claims for "only reasonable and entire compensation" without "increased damages." *Leesona Corp. v. United States*, 599 F.2d 958, 969 (Ct. Cl. 1979).

Congress first extended §1498(a) immunity to private contractors "to aid the government's procurement efforts during World War I." *Advanced Software*, 583 F.3d at 1375. The Supreme Court has explained that the statute's "special legislative intent" was "to

stimulate contractors to furnish what was needed for the war." *Richmond Screw Anchor Co. v. United States*, 275 U.S. 331, 345-46 (1928). "[T]o give effect to that special intent," *id.* at 346, courts have long applied §1498 to immunize contractors who manufacture patented products for the benefit and use of military and government personnel. *See, e.g.*, *Nasatka v. Delta Sci. Corp.*, 58 F.3d 1578, 1579 (Fed. Cir. 1995) ("vehicle security barricades … sold only to the United States government for use at the Pentagon"); *Ball Corp. v. United States*, 729 F.2d 1429, 1431 (Fed. Cir. 1984) ("dual slot antenna assembly … intended for use on missiles"); *Hughes Aircraft Co. v. United States*, 534 F.2d 889, 898 (Ct. Cl. 1976) ("interoperability and shared use of U.S. and U.K. satellites so that each country could effectively augment its own defense communications capacity"). These products were "for the Government" because they were made "for the benefit of the government" and their use "require[d] the [Government]'s participation"—not its mere "pay[ment of] money" for others' benefit. *Advanced Software*, 583 F.3d at 1378-79.

The Government's authorization and consent does not make infringing products "for the Government." The statute expressly

requires the products to be made both "for the Government ***and*** with the authorization or consent of the Government." 28 U.S.C. §1498(a). This Court thus treats "authorization and consent" and "for the Government" as "two requirements" for §1498 immunity. *IRIS Corp. v. Japan Airlines Corp.*, 769 F.3d 1359, 1362 (Fed. Cir. 2014). Government employees can satisfy the "authorization and consent" prong by including a boilerplate FAR clause in a contract. *See* 48 C.F.R. §52.227-1. But "standing alone, a governmental grant of authorization or consent does not mean that the alleged use or manufacture is done 'for the United States' under §1498(a)." *IRIS*, 769 F.3d at 1362.

As relevant here, §1498's distinct "for the Government" requirement means the statute does not immunize government-funded healthcare for private citizens. In *Larson v. United States*, §1498 did not apply to HHS's agreement to "fund[] or reimburse[] all or part of [the] costs" of a "procedure rendered to [a] patient" using infringing medical devices. 26 Cl. Ct. 365, 367, 369 (1992). The government-funded "[m]edical care [was] provided *for the benefit of the patient*, not the [G]overnment," so it was not "for the Government" under §1498. *Id.* The Government's "general interest in

funding medical treatment for certain citizens" was "too remote to make the [G]overnment the program's beneficiary." *Id.* at 369. Applying *Larson*, this Court later held that procurement is not "for the Government" when "the government's participation [is] to receive or pay money but with no relation to the benefits of the technology." *Advanced Software*, 583 F.3d at 1379. An "[i]ncidental benefit to the [G]overnment" is not enough. *IRIS*, 769 F.3d at 1362.

The district court's decision follows directly from these precedents. The court held that §1498's "for the Government" requirement was not satisfied because "the patients receiving Moderna's mRNA vaccines were the beneficiaries," not the Government—which served as little more than a payment conduit. Appx15. That ruling applies the straightforward inquiry this Court's precedents require: who is the intended beneficiary of the infringing product? Here, the answer is unambiguous. Unlike the "seal encoding technology" in *Advanced Software* that "require[d] the [Government]'s participation in every encoded Treasury check," 583 F.3d at 1379, Moderna's use of Appellees' patented lipid technology required no Government participation at all. Private parties—not the Government—manufactured, possessed, distributed, and used the

vaccines, and continued doing so after the procurement contract was fulfilled.[2] Even if the Government "pa[id] money" for vaccine doses, *Advanced Software*, 583 F.3d at 1379, and had a "general interest in funding medical treatment for certain citizens," that is insufficient for §1498 immunity as a matter of law. *Larson*, 26 Cl. Ct. at 369. The judgment should be affirmed.

II. This Court should not expand §1498 to immunize infringing products for the benefit of private citizens.

Moderna and the Government ask this Court to transform a WWI-era procurement statute into a delegation of sweeping

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[2] Amicus TCCRI's argument that mere "possession of the contracted for goods satisfies the requirement" incorrectly assumes the Government "took possession" of Moderna's infringing vaccines. Dkt. 15 at 14-15. The Government admitted it "did *not* take physical possession" of the vaccines because "[t]hey would go from Moderna to McKesson." Appx7391; *see also* Appx7455 (HHS: "When the government accepted [a] vaccine, it did not go to … a government warehouse."). The Government and Moderna do not claim otherwise on appeal. Moreover, technical "possession" by the Government—even if it had existed—would not be dispositive. What matters is whether the Government is the intended beneficiary, not whether it serves as a pass-through. If fleeting governmental possession were enough, any product routed through a federal warehouse on its way to private citizens would qualify for §1498 immunity. Congress could easily have written "possessed by the Government"; it wrote "for the Government" instead.

executive power—one that would let federal agencies underwrite injunction-proof infringing products for the general public. They read §1498's "for the Government" limitation as functionally meaningless: it "does not limit *what* the Government may procure using §1498," but "simply ensures *the Government* is doing the procuring"—meaning the Government need only "employ somebody to do the business *for* them." Moderna.Br.23, 38 (Moderna's emphasis). On this reading, it does not matter whether the Government ever possesses, uses, or benefits from what it "procures": "[b]oth" prongs of §1498 would be satisfied whenever it merely "includes in a procurement contract an express authorization-and-consent provision." DOJ.13; *accord* Moderna.Br.28 ("Where, as here, the Government directly contracts for the manufacture of a product, that manufacture is on the Government's behalf—and therefore 'for the Government.'").

Beyond the district court's reasons for rejecting this interpretation, this Court should reject it because it violates the major questions doctrine and is incompatible with later-enacted statutory schemes governing patent rights and public access to healthcare.

A. Moderna and the Government's reading asserts unlimited and unheralded executive power without clear congressional authorization.

The major questions doctrine rests on a "presum[ption]" that "'Congress intends to make major policy decisions itself, not leave those decisions to agencies.'" *West Virginia v. EPA*, 142 S.Ct. 2587, 2609 (2022). It "applies in cases in which the history and the breadth of the authority asserted by the Government entails vast economic and political significance." *V.O.S. Selections, Inc. v. Trump*, 149 F.4th 1312, 1334 (Fed. Cir. 2025) (en banc) (cleaned up), *aff'd sub nom. on other grounds*, *Learning Res., Inc. v. Trump*, 146 S.Ct. 628 (2026). When agencies "claim to discover in a long-extant statute an unheralded power" representing a "transformative expansion in its regulatory authority," "both separation of powers principles and a practical understanding of legislative intent make [courts] reluctant to read into ambiguous statutory text the delegation claimed to be lurking there." *West Virginia*, 142 S.Ct. at 2609-10 (cleaned up). To overcome that reluctance, "something more than a merely plausible textual basis" is required; the proponent "must point to 'clear congressional authorization' for the power it claims." *Id.* at 2609.

Based on one word—"for" in "for the Government"—Moderna and the Government contend that executive agencies have blank-check authority to underwrite and immunize the distribution of any infringing product, from any private company, for any private citizen, at any cost to taxpayers, in violation of any inventors' patent and jury rights. In their view, §1498 simply "does not limit" the Government's authority to bankroll public access to patented technology and divest patent holders of constitutionally protected rights. Moderna.Br.23. As explained below, this reading "implicate[s] the concerns animating the major questions doctrine." *V.O.S.*, 149 F.4th at 1334; *see also id.* at 1346 (rejecting statutory construction with "no limit"). And because no "clear congressional authorization" exists for the executive power Moderna and the Government assert, their interpretation must fail. *Id.*[3]

[3] Amicus AIPLA agrees that "[a]ccepting the position advanced by the Government" would "raise significant separation-of-powers concerns." Dkt. 18 at 13. But AIPLA focuses on the wrong concern. It frames the issue as whether *courts*, rather than executive agencies, should decide whether an agency's "administration to the 'public'" of infringing products is "a direct governmental necessity." *Id.* at 21. That skips the antecedent question of "whether *Congress* in fact meant to confer the power" to provide infringing products to the public in the first place. *West Virginia*, 142 S.Ct. at 2608.

1. The asserted power is "unheralded" and "transformative." In the century since §1498 was amended to immunize contractors who make patented products "for the Government," the statute has been uniformly applied to infringing products procured *for the Government's own benefit*—especially "what [the Government] needed for [] war." *Richmond*, 275 U.S. at 345. No court has ever construed §1498 to immunize infringing products for *private citizens*. The Government itself "has never relied on or argued that §1498 applies outside of the federal government procuring patented goods and services for its own use by its own agencies or officials."[4] On the contrary, it has successfully *opposed* §1498's application to goods and services it merely funds for the public, including "funding medical treatment for certain citizens." *Larson*, 26 Cl. Ct. at 369.

This "lack of historical precedent" is a "telling indication" that Moderna and the Government's reading of §1498 is "incorrect." *V.O.S.*, 149 F.4th at 1335. That the Government "has 'never previously claimed powers of this magnitude,'" *id.* at 1334-35, is

[4] Adam Mossoff et al., *Proposal for Drug Price Controls is Legally Unprecedented and Threatens Medical Innovation*, GEO. MASON UNIV. CTR. FOR INTELL. PROP. X INNOVATION POL'Y (Nov. 5, 2018), perma.cc/TPE5-G8DU.

unsurprising given §1498's "special legislative intent" to ensure the Government's own access to patented technology in wartime—not to transform agencies into general-purpose conduits for subsidizing public access to infringing products. "[T]he want of assertion of power by those who presumably would be alert to exercise it, is [] significant in determining whether such power was actually conferred." *West Virginia*, 142 S.Ct. at 2610.

2. The asserted power also "entails vast 'economic and political significance.'" *V.O.S.*, 149 F.4th at 1334. Start with economic significance. Under Moderna and the Government's reading, an executive officer's inclusion of standard authorization-and-consent language in a procurement contract unlocks unlimited power to subsidize the infringement of any patent for any purpose—while nullifying the patent holder's exclusionary rights. Agencies could saddle U.S. taxpayers with all "reasonable and entire compensation" arising from any desired infringement, 28 U.S.C. §1498(a), courtesy of Congress' "permanent, indefinite appropriation" to the Judgment Fund. 31 C.F.R. §256.1(a); 31 U.S.C. §1304(a). Taxpayers would bear responsibility for infringement liability *plus* whatever the Government agrees to pay for the infringing product. In this case alone,

HHS's decision to fund 500 million vaccines would cost taxpayers not only the $8.2 billion it paid Moderna to make them, but all "reasonable and entire compensation" for every patent Moderna infringed along the way. *See Biden v. Nebraska*, 143 S.Ct. 2355, 2373 (2023) (considering what asserted power "will cost taxpayers" as relevant "economic impact" under major questions doctrine).

The economic consequences of that single transaction pale beside the potential aggregate impact. Consider healthcare alone, where the Government is "the largest purchaser of prescription drugs in the United States." CONG. BUDGET OFFICE, PRESCRIPTION DRUGS, perma.cc/4VMK-TG4P. If §1498 were construed so broadly as to allow the Government to channel injunction-proof generics or biosimilars to the public through procurement contracts, it would fundamentally reshape the industry, diverting enormous taxpayer funds to compensating infringement while nullifying the constitutionally protected exclusionary rights manufacturers rely on to fund innovation. *See infra* §II.B. If Congress had intended to delegate such discretion over the public purse and private patent rights, a reasonable interpreter would "expect Congress to speak clearly." *West Virginia*, 142 S.Ct. at 2605; *see also Nebraska*, 143 S.Ct. at 2375

("Among Congress's most important authorities is its control of the purse."); *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 168 (1989) ("It is for Congress to determine if the present system of design and utility patents is ineffectual in promoting the useful arts[.]").

Moderna and the Government do not dispute the lack of limiting principle their reading assumes; they defend it. They argue that private patent rights must not "impede the Government's ability to leverage private industry to protect the Nation from the next pandemic," which they analogize to "war, or other national emergenc[ies]." Moderna.Br.4. But "it simply does not follow from the fact that a statute deals with major problems that it should be read to delegate all major powers for which there may be a 'colorable textual basis.'" *Learning Res.*, 146 S.Ct. at 642 (plurality op.). Because "emergencies can 'afford a ready pretext for usurpation' of congressional power," it is in "precisely such cases that [courts] should be alert to claims that sweeping delegations … 'lurk' in 'ambiguous statutory text.'" *Id.* (cleaned up). "There is no major questions exception to the major questions doctrine." *Id.*

In any case, the existence of a pandemic, war, or other emergency is legally irrelevant to Moderna and the Government's expansive interpretation, which treats the mere "inclusion of an express authorization-and-consent clause" in any "government contract" as "*per se* sufficient" for immunity. DOJ.17. The district court recognized—and Moderna and the Government do not dispute—that this interpretation would empower agencies to confer §1498 immunity for "every government-funded product used to advance any policy articulated by the U.S. Government," including, for example, "IV needles to fight HIV" or "cancer drugs to fight the war on cancer." Appx832-833. It would render courts powerless to "second-guess whether the government properly benefitted from a procurement contract," DOJ.25, even if the Government destroyed a disfavored patent holder's business by procuring its invention from competitors and flooding the market with injunction-proof copies. Virtually any government funding of any patented product—pharmaceuticals, medical devices, software, semiconductors, consumer goods, industrial equipment—could readily be structured to channel infringement liability to taxpayers through a boilerplate FAR clause. The resulting aggregate fiscal exposure would be

staggering—potentially tens or hundreds of billions of dollars in patent-compensation claims that Congress never directly appropriated, much less authorized the executive branch to assume. The major questions doctrine "appl[ies] with particular force where, as here, the purported delegation involves the core congressional power of the purse." *Learning Res.*, 146 S.Ct. at 639 (plurality op.).

The "political" stakes are no less significant. A claimed delegation is "all the more suspect" when it involves "the subject of an earnest and profound debate across the country." *West Virginia*, 142 S.Ct. at 2614. Politicians, academics, and journalists have repeatedly advanced Moderna and the Government's interpretation of §1498 for the explicit purpose of circumventing pharmaceutical patents and controlling healthcare prices.[5] Despite these efforts,

[5] *See, e.g.*, Amy Kapczynski & Aaron S. Kesselheim, *'Government Patent Use': A Legal Approach to Reducing Drug Spending*, 35 HEALTH AFFS. 791, 791-92 (2016), perma.cc/DF2T-MQGB (arguing §1498 "could allow the federal government to substantially lower prices for high-cost drugs" by "allowing … generic manufacturers[] to produce or import the medicine"); Hannah Brennan et al., *A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health*, 18 YALE J.L. & TECH. 275, 275 (2016), perma.cc/E79S-4M3D (arguing §1498 allows the Government to "buy generic versions of [patented] medicines at less than 1% of their list price plus a reasonable royalty"); Editorial, *How the*

Congress has "considered and rejected" legislative action that would delegate such powers.[6] *Id.* at 2614. The "basic and consequential tradeoffs" in balancing patent rights with public access to healthcare "are ones that Congress would likely have intended for

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Government Can Lower Drug Prices, N.Y. TIMES (June 20, 2021), perma.cc/WUN4-P9F2 (endorsing §1498 interpretation proposed in Yale article); Letter from Sen. Warren, et al. to HHS Secretary (July 28, 2021), perma.cc/GJ9H-BYK2 (urging HHS to "utilize administrative authorities—such as government patent use compulsory licensing under 28 U.S.C. §1498 … —to lower prescription drug prices"); Letter from Sen. Warren, et al. to HHS Secretary (June 23, 2022), perma.cc/PP8D-8ZE5 (urging HHS to "break[] patent monopolies to reduce drug prices"); Letter from Sen. Sanders to HHS Secretary (June 7, 2023), perma.cc/NT6E-49DC (urging HHS to exercise "authority (under 28 U.S.C. [§]1498) to break the patent monopoly on Leqembi").

[6] *See, e.g.*, H.R. 6505, 115th Cong. §2 (2018) (aiming to permit HHS to "authorize the use of any patent" for Medicare drugs if price negotiation fails and permitting patentee to "seek recovery against the United States in the United States Court of Federal Claims"), reintroduced as H.R. 1046 & S. 377, 116th Cong. (2019); H.R. 465, 116th Cong. §§3(a)(1)-(2) (2019) (aiming to require HHS, upon "excessive price" determination, to "waive or void any government-granted exclusivities" and "grant open, non-exclusive licenses" for drugs), reintroduced as H.R. 2148, 117th Cong. (2021), and H.R. 3546, 119th Cong. (2025); H.R. 2927, 106th Cong. §2 (1999) (aiming to authorize compulsory licensing of medical inventions); H.R. 4131, 109th Cong. §2 (2005) (aiming to authorize compulsory licensing of "any invention relating to health care").

itself." *Id.* at 2613. Indeed, Congress has directly addressed such tradeoffs through distinct healthcare-specific statutory schemes enacted long after §1498. *See infra* §II.B.

3. Moderna and the Government cannot "point to clear congressional authorization" for the power they assert. *Nebraska*, 143 S.Ct. at 2375 (cleaned up). They contend that the preposition "for" in "for the Government" empowers agencies to underwrite any infringing product for private citizens. But "[e]xtraordinary grants of regulatory authority are rarely accomplished through 'modest words,' 'vague terms,' or 'subtle device[s].'" *West Virginia*, 142 S.Ct. at 2609 (original alteration). Congress "does not, one might say, hide elephants in mouseholes." *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468 (2001). Far from conferring power, "for the Government" *limits* what acts of infringement agencies may immunize—the statute enumerates both "for the Government" and "authorization or consent" as "two requirements" that must be independently satisfied. *IRIS*, 769 F.3d at 1362. And until now, the Government itself has argued that "for the Government" excludes infringement performed for "a public purpose." *Power Density Sols.*

LLC v. United States, 159 Fed. Cl. 208, 215 (2022). The Court should not read "for" to eliminate the very limitation it imposes.

* * *

Neither Moderna nor the Government can identify clear congressional authorization for the sweeping executive power they assert under §1498. The judgment should be affirmed.

B. Reading §1498 to immunize government-funded healthcare would undermine the Hatch-Waxman Act and BPCIA.

As discussed above, there is no indication that Congress intended §1498 to immunize infringing goods for the general public's benefit. But even if there was, Moderna and the Government's reading of §1498 would fail because it also contradicts Congress' clear intent in later-enacted, healthcare-specific patent legislation. "The classic judicial task of reconciling many laws enacted over time, and getting them to 'make sense' in combination, necessarily assumes that the implications of a statute may be altered by the implications of a later statute." *United States v. Fausto*, 484 U.S. 439, 453 (1988) (Scalia, J.). Notwithstanding the "range of plausible meanings" a statute may have "[a]t the time [it] is enacted," "subsequent acts can shape or focus those meanings"—"particularly where Congress

has spoken subsequently and more specifically to the topic at hand." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133, 143 (2000). When Congress has done so, the "specific policy embodied in a later federal statute should control [the] construction of the earlier statute, even though it has not been expressly amended." *Id.* at 143 (cleaned up).

After enacting §1498 to aid wartime procurement, Congress enacted specific, comprehensive statutory schemes to balance patent rights with public access to healthcare: the Hatch-Waxman Act and the BPCIA. Because Moderna and the Government's interpretation of §1498 is incompatible with these later-enacted schemes (in addition to the text and purpose of §1498 itself) it should be rejected.

1. Notwithstanding the Government's procurement power under §1498, Congress "creat[ed] a distinct regulatory scheme" for public access to patented healthcare products. *Brown & Williamson*, 529 U.S. at 155. The need for reliable patent incentives in healthcare is particularly acute, because before "market[ing] a new prescription drug," branded manufacturers "must … undergo a long, comprehensive, and costly testing process, after which, if successful, the manufacturer will receive marketing approval from the

FDA." *FTC v. Actavis, Inc.*, 133 S.Ct. 2223, 2228 (2013). What motivates branded manufacturers to shoulder those scientific and regulatory burdens—typically exceeding billions of dollars with less than a 15% chance of FDA approval[7]—is the financial incentive of temporary market exclusivity afforded by the patent system. *See Patlex Corp. v. Mossinghoff*, 758 F.2d 594, 599 (Fed. Cir. 1985) ("The encouragement of investment-based risk is the fundamental purpose of the patent grant, and is based directly on the right to exclude.").

Against this backdrop, Congress passed comprehensive healthcare-specific patent legislation to "determin[e] [] the proper balance between innovators' profit and consumer access to medication." *Biotech. Indus. Org. v. Dist. of Columbia*, 496 F.3d 1362, 1374 (Fed. Cir. 2007); *see also Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 669 (1990); *Sandoz Inc. v. Amgen Inc.*, 582 U.S. 1, 7 (2017). These "carefully calibrated scheme[s]" let generic and biosimilar competitors seek premarket approval by "piggyback[ing] on the

[7] Joseph A. DiMasi et al., *Innovation in the pharmaceutical industry: New estimates of R&D costs*, 47 J. HEALTH ECON. 20 (2016), perma.cc/R3AP-GPBY.

showing made by the manufacturer," while "facilitat[ing] litigation during the period preceding [such] approval so that the parties do not have to wait until commercial marketing to resolve their patent disputes." *Sandoz*, 582 U.S. at 7-8.

Premarket enforcement is "the collective premise of these statutes." *Brown & Williamson*, 529 U.S. at 139. Both "scheme[s] will not work … if the holder of the patent pertaining to the pioneer drug is disabled from establishing in court that there has been an act of infringement." *Eli Lilly*, 496 U.S. at 678. So while Congress immunized competitors' "use of [the] patented invention only for the purpose of obtaining premarketing approval," 35 U.S.C. §271(e)(1), it also made their applications for such approval actionable "artificial" acts of infringement, *Eli Lilly*, 496 U.S. at 678; *Sandoz*, 582 U.S. at 10, giving the branded manufacturer "the opportunity to litigate the relevant patents *before the biosimilar* [*or generic*] *is marketed*." *Sandoz*, 582 U.S. at 11. That opportunity matters because premarket injunctive relief can "prevent[] effective FDA approval of the generic drug until the original patent expires," *Mylan Inc. v. Comm'r of Internal Revenue*, 76 F.4th 230, 237 (3d Cir. 2023), whereas post-market money damages cannot undo the brand's

"irreversible price erosion," "loss of good will," and "lay-offs of [] employees" caused by generic competition. *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1381-83 (Fed. Cir. 2006).

2. These acts of Congress preclude any interpretation of §1498 that would allow the Government to circumvent exclusionary patent rights in healthcare markets. Under Moderna and the Government's sweeping interpretation, executive agencies could bypass the premarket enforcement mechanisms of both statutes by routing infringing generic and biosimilar drugs to the public through government contracts. Because §1498, if construed to apply, would immunize the competitor and "ha[ve] the effect of removing the threat of injunction," *Advanced Software*, 583 F.3d at 1375, generic and biosimilar manufacturers could flood the market with government-funded infringing copies with impunity, leaving branded manufacturers with only post-market redress against the Government in the Court of Federal Claims—which cannot award the exclusionary remedies necessary to prevent market-destroying infringement.

How this might play out is easy to imagine, as it has been proposed by those seeking to employ §1498 to suppress drug prices. *See, e.g.*, Kapczynski, *supra* note 5 at 793-95. If §1498's application

is not limited to infringing products made "for the Government," any agency seeking to control drug prices could presumably contract with generic or biosimilar applicants to make lower-cost infringing copies of brand-name drugs for public distribution. As soon as a branded manufacturer exercises its premarket right to sue for artificial infringement under the Hatch-Waxman Act or BPCIA, the applicants would move to dismiss under the "affirmative defense" of §1498, *Advanced Software*, 583 F.3d at 1375, arguing that their public distribution of generics or biosimilars "for the Government" makes them "immune from suit" in district court. *Sevenson Env't Servs., Inc. v. Shaw Env't, Inc.*, 477 F.3d 1361, 1365 (Fed. Cir. 2007); *see, e.g.*, *IRIS*, 769 F.3d at 1361-63 (affirming 12(b)(6) dismissal of infringement claims against contractor under §1498); *Astornet Techs. Inc. v. BAE Sys., Inc.*, 802 F.3d 1271, 1273-77 (Fed. Cir. 2015) (same). As soon as the "court[] decide[s] the matter" and dismisses the infringement suit, "the FDA follows that determination" and could immediately approve the generic or biosimilar's market entry. *Actavis*, 133 S.Ct. at 2228.

Accordingly, both "scheme[s] ***will not work***" if §1498 were construed to mean that the Government can "disable[]" the "holder of

the patent pertaining to the pioneer drug … from establishing in court that there has been an act of infringement" by generic competitors. *Eli Lilly*, 496 U.S. at 678. Far from "hav[ing] the opportunity to litigate the relevant patents ***before*** the [generic or] biosimilar is marketed," *Sandoz*, 582 U.S. at 11, branded manufacturers would be relegated to seeking money damages from the Government *after* the generic or biosimilar has flooded the market in violation of the patent holder's exclusionary rights. Congress did not build these "carefully calibrated scheme[s] for preparing to adjudicate, and then adjudicating claims of infringement," *id.* at 8, only to have them bypassed by a boilerplate procurement clause based on a strained (and erroneous) reading of §1498.

Moderna did not reconcile its interpretation of §1498 with either statutory scheme. It argued below that §1498 "has existed in its current form for over 75 years without leading to [such] abuses of power." D.I. 605 at 14. But that's because courts have rejected Moderna's expansive reading. *See, e.g.*, *Larson*, 26 Cl. Ct. at 367, 369. That remains true today, even though the Government is "the largest purchaser of prescription drugs in the United States," CONG. BUDGET OFFICE, PRESCRIPTION DRUGS, perma.cc/4VMK-TG4P, and

proponents of subsidized healthcare have persistently advanced the same interpretation Moderna and the Government advance here. *See, e.g.*, *supra* note 5.

Public access to healthcare is important. But "no matter how 'important, conspicuous, and controversial' the issue, … an administrative agency's power to regulate in the public interest must always be grounded in a valid grant of authority from Congress." *Brown & Williamson*, 529 U.S. at 161. Congress did not grant such authority to agencies contracting "for the Government" under §1498. Instead, Congress created subsequent, comprehensive, and distinct statutory schemes that specifically address the balance between public access and patent rights in healthcare. Because Moderna and the Government's interpretation of §1498 "would contradict Congress' clear intent as expressed in its more recent, [healthcare]-specific legislation," it should be rejected. *Id.* at 143.

CONCLUSION

Section 1498 was enacted to protect contractors who supply patented goods for the Government's own benefit—not to give executive agencies blank-check authority to subsidize infringing products for the general public. Moderna and the Government's contrary

interpretation finds no support in the statute's text, history, or purpose. It would vest agencies with unheralded authority of vast economic and political significance without clear congressional authorization. And it would risk circumventing the more specific, carefully calibrated statutory frameworks Congress *has* enacted to balance pharmaceutical patent protection with public access to healthcare. The Court should reject that interpretation and affirm.

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Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitations and typeface requirements of the Federal Rules of Appellate Procedure and Federal Circuit Rules because it has been prepared using a proportionally-spaced typeface and contains 5,608 words.

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