No. 26-1581

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

ARBUTUS BIOPHARMA CORPORATION, GENEVANT SCIENCES, GMBH,

Plaintiffs-Appellees,

v.

MODERNA, INC., MODERNATX, INC.,

Defendants-Appellants.

Appeal from the United States District Court for the District of Delaware, Case No. 1:22-cv-00252-JDW.

BRIEF OF THE NATIONAL ASSOCIATION OF MANUFACTURERS AS *AMICUS CURIAE* IN SUPPORT OF APPELLANTS

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CERTIFICATE OF INTEREST

Counsel for the National Association of Manufacturers certifies under Federal Circuit Rule 47.4 that the following information is accurate and complete to the best of their knowledge:

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

National Association of Manufacturers (the "NAM").

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

None.

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

None. Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure, the undersigned counsel certifies that NAM is a not for profit organization. The NAM has no parent corporation, and no publicly held company has 10% or greater ownership in the NAM.

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.

Duane Morris LLP: Brian Pandya, Seth Rokosky, Brianna Vinci

5. **Authorship and Funding.**

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

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

Not applicable.

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

Not applicable.

Dated: June 5, 2026

/s/ Brian Pandya
Brian Pandya

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STATEMENT OF INTEREST OF AMICI

The National Association of Manufacturers (NAM) is the largest manufacturing association in the United States, representing small and large manufacturers in all fifty states and in every industrial sector. Manufacturing employs nearly 13 million people, contributes $2.9 trillion to the economy annually, has the largest economic impact of any major sector, and accounts for over half of all private-sector research and development in the nation, fostering the innovation that is vital for this economic ecosystem to thrive. The NAM is the voice of the manufacturing community and the leading advocate for a policy agenda that helps manufacturers compete in the global economy and create jobs across the United States.

Many NAM members sell products to the U.S. government, both as prime contractors and subcontractors. The members span traditional government contractors in the aerospace, defense, and IT sectors to healthcare, life sciences, and consumer products companies that derive significant revenue from direct and indirect sales to the U.S. government. Regardless of where they fit into the government contracting supply chain, these companies carry an expectation that if the government promises to assume liability for patent infringement lawsuits, that promise will be enforceable. The decision of the District of Delaware undermines

those expectations, and if not corrected, will create consequences for manufacturers and the government.

Manufacturing is, by nature, a capital-intensive endeavor that requires significant investments at all phases, from initial research and development to building and maintaining production facilities and distribution channels, in the face of litigation risk over such efforts. Manufacturers that sell to the government face exceptional capital requirements, because government contractors must often build out capacity before a contract is awarded. The initial delivery on the contract is often the largest delivery and only opportunity to recover those ex-ante investments.

If a manufacturer expects to be shielded by the government for private patent infringement lawsuits based on its sales to the government but then faces liability for such claims after the contract has been bid and awarded, after contracted goods have been made and sold, and after the manufacturer has been paid, manufacturers may either decline to sell to the government in the future or significantly increase prices to account for these ex-post risks. Both outcomes would undermine the government's ability to procure manufactured goods that are vitally important for responding to national crises and to keeping the daily operations of government running.

At the same time, the NAM strongly supports robust protection of manufacturers' intellectual property rights. Most NAM members rely on patents to

safeguard their innovations and oppose efforts to weaken patent rights. Thus, just as manufacturers who sell to the government must be protected to promote stability in government contracting, the intellectual property rights of manufacturers must also be protected. This case should be adjudicated on its specific facts—a manufacturer stepping up to make a life-saving product during a global public health crisis. It is not a broader vehicle to expand the government's ability to undermine private patent rights or to upend longstanding notions of government authorization-and-consent to patent infringement in government contracts.

STATEMENT OF COMPLIANCE WITH RULE 29(a)

This brief is submitted in accordance with Rule 29(a) of the Federal Rules of Appellate Procedure. All parties have consented to the filing of this brief.

No party or party's counsel authored this brief in whole or in part; no party or party's counsel contributed money to fund the preparation or submission of this brief; and no other person except *amici curiae*, its members, or its counsel contributed money intended to fund the preparation or submission of this brief.

ARGUMENT

The District of Delaware's summary judgment order should be reversed. When Moderna manufactured and sold approximately 500 million doses of Covid vaccines under a contract with the U.S. Army, it did so with the U.S. Department of Defense's promise that it would shield Moderna from claims of patent infringement by instead subjecting the Government to suit in the Court of Federal Claims under 28 U.S.C. § 1498(a).

To invoke Section 1498(a), the Army included in the contract Federal Acquisition Regulation ("FAR") Clauses 52.227-1 and 52.227-1, Alternate I, which respectively state that "[t]he Government authorizes and consents to all use and manufacture . . . of any invention described in and covered by a United States patent – (1) [e]mbodied in the structure or composition of any article the delivery of which is accepted by the Government under this contract . . ." and that "[t]he Government authorizes and consents to all use and manufacture of any invention described in and covered by a United States patent in the performance of this contract or any subcontract at any tier." 48 C.F.R. § 52.227-1 (Appx2823). The Department of Justice affirmed this promise, filing a statement of interest in the district court that making and selling these vaccines was immunized under 28 U.S.C. § 1498(a). *See* Appx946-963.

Although Moderna agreed to manufacture and sell vaccine doses to the Army in service of a national pandemic response that the Department of Defense was undertaking for the United States, the District of Delaware concluded that Section 1498 applies only to the subset of vaccine doses that "the Government acquired and distributed to its *own* employees" because the Government "distributed the vaccines itself to its employees to ensure that it could continue to function." Appx15 (emphasis added). For all other doses, the district court concluded that the Army contract "did not authorize the manufacture or use of vaccines for the Government" but instead "authorized their manufacture and use for residents of the United States" generally. *Id*. at 14-15.

The district court's decision is unsupported by the text and history of Section 1498(a), is inconsistent with the experiences of manufacturers that regularly sell to the government, and threatens to chill government contracting. When manufacturers sign a government contract with authorization-and-consent clauses, they expect to be shielded by the Government.[1] This decision, if allowed to stand, undermines those expectations.

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[1] Section 1498 serves dual purposes: "It relieves a third party from patent infringement liability, and it acts as a waiver of sovereign immunity and consent to liability by the United States." *Madey v. Duke Univ*., 307 F.3d 1351, 1359 (Fed. Cir. 2002); *see also Manville Sales Corp. v. Paramount Sys*., 917 F.2d 544, 555 n.6 (Fed. Cir. 1990) ("we see no inconsistency between" the "two different effects" of Section 1498). If Arbutus had brought suit in the Court of Federal Claims, it presumably would have recovered damages for the entire Army contract, not only for those doses

At minimum, the District of Delaware incorrectly concluded at the summary judgment stage that some of Moderna's sales were not "for the government" and that Moderna was required to demonstrate "that the benefit to the Government must be material and direct." Appx13-14. The district court acknowledged "the language of the [Army] Contract and [Moderna's] proposed expert testimony" that potentially explained why Moderna's actions were for the Government but instead credited language that "arguably supports the holding that the vaccines were not for the Government." Appx15. The district court's approach creates uncertainty for manufacturers over what is required to establish the defense.

Even if the district court still concludes on remand that some sales were not for the government and thus not immunized by Section 1498(a), it would reach that conclusion on a better explained record. Greater clarity alone on the application of Section 1498(a) would benefit the manufacturing community, which must often make capital investments and bid on government contracts without an opportunity to recoup those investments after the contract has been performed.

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that were administered to government employees. The fact that Arbutus chose to file in district court should not impact Moderna's liability.

I. Section 1498(a) Plays a Vital Role in Facilitating Private Sector Sales to the Government

American manufacturers have a long history of selling products to the U.S. government, from building airplanes and tanks that helped the United States win two World Wars, to building the rockets that fly Americans to outer space, to providing the hardware and software that drives daily government operations, to supplying lifesaving medications administered during public health crises. Section 1498(a) has been a critical aspect of those efforts, ensuring that the government has the flexibility to procure needed goods for the national welfare while protecting the private rights of both manufacturers and patent holders.[2] The district court's overly narrow interpretation and application of the statute cannot be squared with the text or history of Section 1498.

[2] Previously, when manufacturers would more routinely indemnify the government for third-party infringement claims, they would often license their patents to the government at nominal rates to forgo providing indemnity to the government. *See* Lawrence Glassman, *Patent Indemnity Clauses in Government Contracts*, 25 Geo. Wash. L. Rev. 256, 280 (1957) ("During World War II, the Army and Navy were successful in persuading approximately 165 manufacturers, both large and small, to give the Government licenses at the nominal rate of one dollar each, covering use of their patents. . . . In return, the Government agreed to waive use of indemnity clauses."). Section 1498(a) thus provides both protections to manufacturers that supply products to the government and a pathway for manufacturers to recover for the infringement of their patents by other manufacturers.

A. Section 1498 Is Intended to be a Waiver of Sovereign Immunity and Assumption of Liability to Induce Manufacturing for the United States

Section 1498(a) provides vital statutory protection for our nation's manufacturers. In its current form, the statute provides that:

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

28 U.S.C. § 1498(a).

This statutory text reflects multiple amendments to the statute and the practical realities that as new innovations are needed to address new challenges, the government must be able to induce manufacturing of certain goods and procure those goods for the government's response to those challenges, and at the same time, contractors must be sufficiently free to supply them. An essential part of the Congressional policy is the United States Government assuming private litigation risk that Congress recognized may otherwise inhibit manufacturers from supplying goods to the government. This tradeoff is important given the large volume of goods that contractors must often supply the government and the attendant upfront costs

and risks that manufacturers bear. As this court explained forty years ago, Section 1498(a) is construed broadly "so as not to limit the Government's freedom in procurement by considerations of private patent infringement." *See TVI Energy Corp. v. Blane*, 806 F.2d 1057, 1060 (Fed. Cir. 1986).

Historically, "the holder of a patent infringed by the government" had limited pathways for recovery from the United States, "but . . . generally the way was hard." *Leesona Corp. v. United States*, 599 F.2d 958, 966 (Ct. Cl. 1979) (en banc); *see Sperry Gyroscope Co. v. Arma Eng'g Co*., 271 U.S. 232, 234 (1926) ("But for the allegation that the inventions were made and sold under such a [government] contract, this would be but the ordinary patent suit."). Things began to change with the Act of June 25, 1910 which provided a limited waiver of sovereign immunity, stating that, "to provide additional protection for owners of patents," "whenever an invention described in and covered by a patent of the United States shall hereafter be used by the United States without license of the owner thereof . . . such owner may recover reasonable compensation for such use by suit in the Court of Claims." Pub. L. 61-305, ch. 423, 36 Stat. 851, 851-52 (1910).

The Act of 1910 provided important remedies to patent owners by permitting infringement claims against the government for the infringement of their patents, but it provided few protections for contractors supplying those goods to the government. *See, e.g.*, *Crozier v. Krupp*, 224 U.S. 290, 297 (1912) ("In times of peace they are

personally liable to an individual whose rights of property they have wrongfully invaded, even by authority of the United States."); *Cramp & Sons Ship & Engine Bldg. Co. v. Int'l Curtis Marine Turbine Co*., 246 U.S. 28, 45 (1918) (finding "no ground for the proposition that the [1910] statute invested every person contracting with the United States . . . the assumed right to violate patent rights").

With the United States entering World War I, however, and facing the vital need to support the global war effort, Congress sought "to stimulate contractors to furnish what was needed . . . without fear of becoming liable themselves for infringements to inventors or the owners or assignees of patents." *Richmond Screw Anchor Co. v. United States*, 275 U.S. 331, 345 (1928).[3] Congress therefore passed the Naval Appropriations Act of July 1, 1918, which amended the statute to provide that "whenever an invention described in and covered by a patent . . . shall hereafter be used or manufactured by or for the United States without license of the owner… such owner's remedy shall be by suit against the United States in the Court of Claims

[3] Patent holders also required remedies. Although the Tucker Act waived sovereign immunity for claims sounding in "contract, implied or expressed," patent infringement claims were considered torts and thus outside the scope of the waiver, leaving patent holders with few remedies and protections. *See* William Brownell Humphrey, A History and Analysis of Section 1498 of Title 28 of the United States Code Dealing with Unlicensed Use of Patents by the United States Government and Its Effect on Procurement, p. 7 (Master's Thesis, Naval Postgraduate School, 1974) (on file with National Technical Information Service).

for the recovery of his reasonable *and entire* compensation for such use and manufacture." Pub. L. 65-182, ch. 114, 40 Stat. 704, 705 (1918) (emphasis added).

So long as an invention was used or manufactured "for the United States," "the effect of the Act of 1918 [was] to take away from the [patentee] not only the cause of action against the government [in district court], but also to deprive it of the cause of action against the infringing contractor for injury by his infringement." *Richmond Screw Anchor Co.*, 275 U.S. at 345. In such cases, Congress facilitated procurement of goods for government use by making "the government indemnitor for its manufacturer or contractor in its infringement." *Id*. at 346.

With the nation again mobilizing its industrial capacity for the war effort against the Axis powers, Congress again affirmed protections for government contractors with the passage of the Royalty Adjustment Act during World War II. Pub. L. 77-768, § 6, 56 Stat. 1013, 1014 (1942). That law expressly protected contractors but further clarified that "the use or manufacture of an invention described in and covered by a patent of the United States by a contractor, a subcontractor, or any person, firm or corporation for the Government and with the authorization or consent of the Government, shall be construed as use or manufacture for the United States." *Id.*

The 1942 Amendment represented a substantial expansion of protections for government contractors. The Judge Advocate General of the Army went so far to

declare that the "sole and only purpose [of this legislation] was to broaden the scope of the act of June 25, 1910, as amended [in 1918], so to remove any further doubt that *subcontractors and other suppliers* of goods and materials to the government were included within the terms of that act to the same extent as prime contractors." *See* 2 Bulletin of the Judge Advocate General of the Army, 75–76 (Feb. 8, 1943) (emphasis added). Courts also recognized that the statute that became today's Section 1498 specifically addressed "use by a contractor, subcontractor or other person for the government." *Bereslavsky v. Esso Stand. Oil Co*., 175 F.2d 148, 150 (4th Cir. 1949).

The current version of Section 1498(a) was enacted in 1949 (with later technical amendments) and tracks the same broad protections for contractors provided by the World War I and World War II amendments. *See* May 24, 1949, ch. 139, § 87, 63 Stat. 102. Specifically, today's Section 1498(a) dictates:

> Whenever an invention described in and covered by a patent of the United States is used . . . for the United States without license of the owner thereof . . . the owner's remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use.

28 U.S.C. § 1498(a). Thus, a private party, such as a manufacturer selling products or providing service to the government, is "immune from suit" in district court if its manufacture or use of a patented invention is "for the Government" and "with the authorization and consent of the Government." *Sevenson Envtl. Servs. v. Shaw*

Envtl., Inc., 477 F.3d 1361, 1365 (Fed. Cir. 2007). In such a case, a patent holder's claim must be brought as an "action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation." 28 U.S.C. § 1498(a).

Because a contractor's use or manufacture of goods for the United States, rather than for private parties, is undertaken through a contract with the Government and relates to performing services for the government, "the 'for the Government' prong of the definition imposes only a requirement that the use or manufacture of a patented method or apparatus occur pursuant to a contract with the government and for the benefit of the government. The statute imposes no additional 'primary purpose' condition." *Sevenson*, 477 F.3d at 1365. Although a government contract is not required to invoke Section 1498(a), when there is a government contract for the delivery of goods, "courts have all but bypassed a separate inquiry into whether infringing activity was performed 'for the Government.'" *Id*. at 1366.

Thus, it should make no difference whether the Government, upon buying and paying for stockpiles of goods (such as bread, iron, or Covid vaccines), provides those goods to their own employees, distributes them to the broader public as part of the government's response to a public health crisis, natural disaster, or national security situation, or does countless other things with those goods, from storing them in strategic stockpiles to sharing them with state and local governments or

international allies. Regardless of whether the contractor's goods are manufactured for ultimate use by Government employees or by persons the Government deems best placed to support core Government efforts, the contractor still acts pursuant to an agreement with the Government to produce goods "for the United States." 28 U.S.C. § 1498(a). The Government may later choose how to best allocate and use the stockpiled supply, but from the perspective of the manufacturer, the government has already waived its sovereign immunity and subjected itself to suit for any alleged patent infringements.

B. The Government Contracting with Moderna for Vaccines Should Have Triggered Section 1498(a) Immunity

Moderna's development, design, manufacturing, and sale of vaccine doses to the government, pursuant to a government contract that included authorization-and-consent clauses, should have been enough to convey immunity under Section 1498. But the district court found that "Section 1498 does not apply to the infringement claims related to the vaccine doses that went to the general public." Appx15. The district court should not have split responsibility based on whether the Government "distributed the vaccines itself to its employees." Appx15. Nor should the district court have attempted to draw a line between whether "the Government perceives a public benefit" or whether its actions were motivated by the desire "to ensure that it could continue to function." Appx14-15.

Unlike cases where companies pay the government for oil drilling leases or where healthcare providers receive some Medicare or Medicaid reimbursements for services rendered to patients, the Government in this case "sought" vaccines in the interest of the Government's Covid response, and Moderna in turn was "required…to carry out" a contract to deliver those vaccines to the government. *Sevenson*, 477 F.3d at 1366 (infringing method practiced "for the Government" where "the government sought and received" services). Having performed a patriotic act at the behest of the Government, Moderna should not be facing liability in district court for the actions it took under a procurement contract to deliver goods to the Government.

The district court's parsing of the phrase "for the government" to exclude products that were ultimately administered to hundreds of millions of non-government employees (Appx15) is inconsistent with the history and intent of Section 1498. The statute was intended to facilitate procurement of goods "for the United States"—not merely for employees of government agencies. *Richmond Screw Anchor*, 275 U.S. at 345. The statute's reference to sales by contractors, subcontractors, and suppliers of good manufactured "for the Government" and "with the authorization and consent of the Government" simply means that persons manufacturing or using goods for the United States as subcontractors and suppliers are entitled to the same protections as contractors or as if the Government itself

manufactured and developed the product. *Bereslavsky*, 175 F.2d at 150–51. It would contravene the statute to read that provision as curtailing vital protections for contractors, subcontractors, and suppliers, rather than aligning such protections.

If uncorrected, the district court's ruling would have profound national security consequences—especially in times of emergency, such as World Wars I and II or the Covid-19 pandemic. Government contractors of all stripes could face liability based on how the government subsequently decides to use products that they were induced to manufacture and then sell to the government, chilling manufacturing and procurement in times of great need. It would be impractical to expect manufacturers to enter into government contracts (often without precisely knowing how the government will use products), make and sell products to the government, and then be told that the government's use of such products was not "for the government" so the government's promises do not apply.[4] Such a result would run counter to the certainty intended by the statute.

[4] The district court's decision also creates more questions than it answers. For example, if the district court were correct that a "direct" benefit to the Government requires that the Government "perceive a public benefit" or that the contractor be motivated by the desire "to ensure that it could continue to function" (Appx14-15), does Moderna need to show that the vaccine worked as intended, or that a worker's role is essential to allowing the government to function? It is not practical to expect manufacturers to answer these questions after the fact.

C. Section 1498(a) Also Ensures That Patent Holders Are Appropriately Compensated.

Although Moderna's sales to the government should be immunized, it is also important that the statute not be distorted to deprive patent holders of meaningful remedies. Thus, if Arbutus proceeds in the Court of Federal Claims, Arbutus, as the patent holder, should receive full and fair compensation for use of its patents.

Section 1498 is not a tool for the government to take compulsory licenses to patents at below-market rates. Although most discussions around Section 1498 focus on the government's waiver of sovereign immunity and the indemnification of government contractors, the statute also provides important protections for patent holders.[5] Despite making no provisions for injunctive relief, Section 1498(a) expressly provides for "reasonable and entire compensation." 28 U.S.C. § 1498(a). "Generally, the preferred manner of reasonably and entirely compensating the patent holder is to require the government to pay a reasonable royalty for its license." *See Hughes Aircraft Co. v. United States*, 86 F.3d 1566, 1572 (Fed. Cir. 1996).

[5] The Federal Circuit's predecessor court underlined the importance of protecting patent holders: "When the government has infringed, it is deemed to have 'taken' the patent license under an eminent domain theory, and compensation is the just compensation required by the Fifth Amendment. . . . § 1498 contains no directions or limitations as to the grant of damages other than its mandate of 'reasonableness' and 'entirety.'" *Leesona*, 599 F.2d at 964.

Reasonable royalty awards can be substantial in the Court of Federal Claims. *See, e.g.,* Ellen Bardash, *Award of More Than $100 Million in Patent Case Could Be Largest-Ever Against Federal Government*, NAT. L. J. (Oct. 25, 2021), available at https://www.law.com/nationallawjournal/2021/10/25/award-of-more-than-100-million-in-patent-case-could-be-largest-ever-against-federal-government/. Section 1498(a) also provides unique protections for patent holders that are small businesses, non-profits, and independent inventors, including the ability to recover attorney's fees and out of pocket costs, which are often substantial in patent cases, when "the position of the United States [is] not substantially justified" in defending the infringement claims. *Hitkansut LLC v. United States*, 958 F.3d 1162, 1169 (Fed. Cir. 2020).

The NAM is concerned about proposals and outcomes that undermine patent rights. Nearly every NAM member holds patents. The NAM's Board-approved policy agenda notes that "Intellectual property rights are the lifeblood of our economy, and the protection of those rights assures manufacturers that their inventions will be secure as they create jobs and build industries around them. Clearly defined IP rights, supported by a stable policy environment also gives inventors and creators the confidence to collaborate and improve manufacturing processes and products." National Association of Manufacturers, *Policy Positions,*

Policy IIHRP-2.04, available at https://nam.org/wp-content/uploads/2024/04/NAM-Policy-Positions_Feb.-2024-FINAL.pdf.

But this is not a case where intellectual property rights are threatened.[6] The issue is *who* (Moderna or the U.S. Government) should pay the reasonable royalty and whether entitlement to that award should be determined in the District of Delaware or Court of Federal Claims. Arbutus understandably may prefer to choose where and how it proceeds, but its patent rights should be upheld and affirmed in either scenario. Moderna, however, faces massive liability after expecting the government to pay for any patent infringement awards. An American company that stepped up during the greatest public health crisis of the past century should not be subject to such liability.

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[6] The NAM vigorously opposes efforts by policymakers and courts to expand march-in rights or otherwise create compulsory licensing regimes. *See, e.g.*, National Association of Manufacturers, IIHRP-2.04b (Government contracts and regulations "should not convey rights to the government to background inventions and technology or to manufacture or use an invention for the purpose of providing services or supplies to the general public in competition with the contractor or the contractor's commercial licensees in the licensed fields").

Importantly, "Section 1498 does not grant the government a new power to authorize infringement of a patent for the sole purpose of a company selling a product at a lower price in the market, effectively imposing de facto government price controls on drugs." Adam Mossoff et al., *Proposal for Drug Price Controls Is Legally Unprecedented and Threatens Medical Innovation*, Center for Intellectual Property x Innovation Policy (Nov. 5, 2018), available at https://cip2.gmu.edu/2018/11/05/proposal-for-drug-price-controls-is-legally-unprecedented-and-threatens-medical-innovation/

Notably, this is not a case where Arbutus contends it is entitled to injunctive relief. If Arbutus's right to injunctive relief was materially undermined, this could be a harder case, even if Congress made the policy judgment that such a result was appropriate in cases where contractors manufacture goods for the Government. But this particular case does not raise those concerns.

II. The District Court's Ruling Runs Counter to the Settled Expectations and Experiences of Manufacturers

Manufacturers make significant investments when undertaking government contracts. Securing a government contract requires tangible proof that the contractor can manufacture the goods and deliver the goods—all before receiving payment for the goods. *E.g.,* 48 CFR § 9.104-1 ("To be determined responsible, a prospective contractor must – (a) Have adequate financial resources to perform the contract . . . (f) Have the necessary production, construction, and technical equipment and facilities. . . ."). Often, the initial delivery is the only or the largest delivery under the contract. Thus, a contractor must invest in research and development, respond to the proposal, invest in manufacturing facilities, make the goods, and deliver the goods, all with the hope that it will eventually be compensated.

Uncertainty over whether the contractor will undertake those efforts and nonetheless face private patent infringement lawsuits, particularly after the government agreed to assume liability, would destabilize manufacturing for the government. Unless corrected, this case will have far-reaching consequences,

including contractors being more circumspect about developing and supplying goods at the behest of the Government or charging higher prices for goods the Government deems important to mitigate the risk of later facing patent infringement liability for its government sales.

The lack of clarity from the district court decision threatens innovation beyond the healthcare sector and potentially impacts national security. Many NAM members make dual-use products—that is, products with civilian and military applications. Today, the Department of War "increasingly relies on neoprimes to rapidly develop dual-use software and autonomous systems." Tony Rowles, *The Pentagon Wants Dual-Use Innovation. Patent Law Might Punish It*, War on the Rocks (Mar. 27, 2026), available at https://warontherocks.com/cogs-of-war/the-pentagon-wants-dual-use-innovation-patent-law-might-punish-it/. "A binding Federal Circuit decision establishing that public benefit does not equal government benefit would give patent holders a new theory to deploy against dual-use contractors across the defense industrial base." *Id*. These additional reasons underscore the problems created by the District of Delaware's decision.[7]

[7] Indeed, Section 1498(a) and its predecessor statues were meant to make IP rights in the context of government contracting predictable. During World War II, the Army encountered that era's dual-use or "hybrid" products, such as a "commercial truck, modified according to Ordnance specifications to convert it to a mobile machine shop." Ralph L. Chappell & W. Houston Kenyon Jr., *Patent Costs of Military Procurement in Wartime*, 12 Law and Contemporary Problems 695, 700 (1947). "It had proved to be impracticable to educate all of the thousands of

A. The District of Delaware Decision Is Contrary to Past Cases Where American Businesses Supported Government Efforts

The District of Delaware concluded that "because [it] can resolve the meaning of the statutory phrase 'for the Government' through traditional tools of statutory construction, [it does] not need expert testimony on what actions were, and were not, for the Government." Appx17. It reached that conclusion even though it based its analysis on whether the Government receives a "benefit" that is sufficiently "direct" from manufacturing. Appx14. The district court overlooked how manufacturing products for the government directly benefits the government *and* the broader American public, particularly in the circumstances of this case.

Precisely because contractors can agree with the Government ex-ante to shift potential liability and its attendant costs under Section 1498(a), manufacturers routinely support programs like the Covid vaccine distribution program here. But not every government contract involves the delivery of a product that is consumed by the government. Many programs involve contractors performing services at the behest of the government, thus providing benefits to the government and the public. The District of Delaware's decision would exclude those efforts, even though the Federal Circuit has typically found those services to be immunized. Two cases are

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contracting officers in the field to observe a wholly consistent pattern in the use or omission of indemnity or hybrid indemnity, or to grasp the differing implications of 'authorization and consent' in the presence and absence of indemnity." *Id*. at 701.

particularly instructive, even though both involved what the district court deemed a public benefit:

In *Advanced Software Design Corp. v. FRB of St. Louis*, Department of Treasury regulations required private parties to adopt "seal encoding technology" to detect fraudulent attempts to withdraw Treasury funds. 583 F.3d 1371, 1373 (Fed. Cir. 2009). "[T]he detection system [could] detect fraudulent checks promptly at the Reserve Bank, notifying the bank of first deposit to freeze the funds before they are withdrawn by the perpetrator." *Id*. This protected private banks, as previously "the perpetrator will have received the funds from the bank of first deposit, and the system is such that the member bank or the Reserve Bank generally bears the loss." *Id*. These private banks were also enhancing public safety by adopting check processing technology mandated by federal regulations. Thus, the Department of Treasury was benefiting but so were private banks and the broader banking public by being safer from fraudulent checks.

Similarly, in *Iris Corp. v. Japan Airlines Corp*., airlines "examine[d] passports according to federal law, including the Enhanced Border Security Act [and] Visa Entry Reform Act of 2002." 769 F.3d 1359, 1361 (Fed. Cir. 2014). The Act directed "the master or commanding officer, or authorized agent, owner, or consignee, of [any] commercial vessel or aircraft" departing or arriving in the United States to "to provide any United States border officer . . . manifest information about each

passenger, crew member, and other occupant to be transported." 8 U.S.C. § 1221(a)-(b), (d). Airlines were assisting "United States border officer[s]" by collecting information then used by "United States official[s]" to secure the border. 8 U.S.C. § 1221(a)-(b). Thus, the airlines that implemented the Enhanced Border Security Act and Visa Reform Act of 2002 were serving the public interest of ensuring "our borders are well-screened." *See* Presidential Statement on the Signing of the Enhanced Border Security Act and Visa Reform Act of 2002, 38 WEEKLY COMP. PRES. DOCS. 20 (May 14, 2002).

In neither case did the court engage in the line drawing exercise that the District of Delaware undertook here.

Admittedly, it is not enough that the government merely reimburses a contractor after the fact to deem its actions "for the Government." *Larson v. United States*, 26 Cl. Ct. 365, 369 (1992) ("The fact that the government has an interest in the program generally, or funds or reimburses all or part of its costs, is too remote to make the government the program's beneficiary."). For example, if the government merely issues block grants that state or local governments then use to purchase products, that alone would probably not be enough to immunize sales under Section 1498(a). Nor would strictly private sector purchases that federal payor programs later reimburse be covered by Section 1498(a).

But the Federal Circuit need not address such cases here. The government issued a procurement contract for the purchase of vaccines, and Moderna manufactured and sold vaccines to the government pursuant to this contract. This case is not an attempt to broaden the scope of Section 1498 or endorse public policy initiatives to bypass patent rights. Section 1498 squarely applies here.

B. The Decision Contains Loopholes

The district court also concluded "Section 1498 does not apply to claims of indirect infringement." Appx16. But black letter law states that where there is no direct infringement, there can be no indirect infringement. *Limelight Networks, Inc. v. Akamai Techs., Inc.*, 572 U.S. 915, 921 (2014). It thus follows that if the direct infringement is immunized, then any actions of indirect infringement should also be immunized. That is particularly true where a plaintiff alleges that a government contractor is inducing the government to use the product described in the patented invention and there is nothing else novel about the use of the patent. The applicability of Section 1498 should turn on bright-line rules amenable to determining ex-ante whether a contractor's manufacture or use of a product is immunized from patent liability. It should not turn on litigation decisions made by a plaintiff bringing a patent claim long after the contractor has performed its contract.

III. Conclusion

The judgment of the District of Delaware should be reversed, and Moderna's actions under its contract should be deemed immunized under Section 1498(a).

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitations of Federal Circuit Rule 29(b) because it contains 5,378 words and 469 lines excluding the parts of the brief excluded by Fed. R. App. P. 32(f) and Federal Circuit Rule 32(b)(2), as determined by the word-counting feature of Microsoft Word, and is therefore not more than one half of the maximum page length authorized for a party's principal brief.

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