

EXHIBIT A



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March 2, 2023

VIA CM/ECF (FILED UNDER SEAL)

The Honorable Mitchell S. Goldberg
United States District Court
Eastern District of Pennsylvania
United States Courthouse, Room 7614
601 Market Street
Philadelphia, PA 19106

RE: *Arbutus Biopharma Corp., et al. v. Moderna, Inc., et al.*
C.A. No. 22-252-MSG

Dear Judge Goldberg:

Below is a letter brief from *Amici curiae* Law Professors, Scholars, and Former Government Officials in response to the Statement of Interest filed by the United States of America (the "Government") (D.I. 49) and the Court's February 16, 2023 Order requesting briefing on the impact of the Government's Statement of Interest (D.I. 51).

Interest of *Amicus Curiae*

Amici curiae are law professors, scholars, and former government officials who have researched and published in patent law, takings law, or both. They have an interest in ensuring the integrity of the patent system and the proper application of the federal government's eminent domain power to patented inventions. *Amici* have no stake in the parties or in the outcome of this case. A full list of signatories to this brief is set forth in Addendum A.¹

Summary of Argument

This Court correctly decided that 28 U.S.C. § 1498(a) is inapplicable to a private company that enters into a purchase contract with the federal government for vaccine doses distributed in the healthcare market by other private companies for use by private individuals.

¹ Pursuant to Fed. R. App. P. 29(a)(4)(E), *amici* state that no counsel for a party authored this brief in whole or in part, and that no person other than *amici*, their members, or their counsel contributed money that was intended to fund preparing or submitting the brief.



See Arbutus Biopharma Corp. v. Moderna, Inc., No. CV 22-252, 2022 WL 16635341 (D. Del. Nov. 2, 2022). *Amici* offer supporting legal analysis beyond that provided by the parties that is necessary for this Court to reissue its prior decision, if it decides that some action is necessary given the Statement of Interest by the U.S. Government: The express text, legislative history, and judicial interpretation of § 1498(a) establish that this is an eminent domain statute that has no applicability to the purchase contract between Moderna and the federal government.

The purchase contract between Moderna and the federal government does not meet the express statutory requirement that the patented invention is made or used “by or for the United States,” 28 U.S.C. § 1498(a), or that a contractor uses a patented invention “for the Government.” *Id.* Section 1498(a) is an eminent domain statute, authorizing the U.S. Court of Federal Claims to adjudicate a claim by a patent owner for “reasonable and entire compensation” when its patented invention is “used or manufactured *by or for the United States* without license of the owner.” *Id.* (emphasis added). This is confirmed by the express text and legislative history of § 1498(a) and the consistent interpretation of this statutory provision by courts. Thus, if this Court deems some action is necessary in response to the Statement of Interest of the United States, it should reissue its earlier decision that § 1498(a) is inapposite to the patent infringement claim by Arbutus Biopharma Corporation against Moderna, Inc.

Argument

I. Section 1498(a) is an Eminent Domain Statute

A. The Provenance of § 1498(a)

The provenance of § 1498(a) is found in nineteenth-century court decisions that patents are private property rights secured under the Takings Clause of the U.S. Constitution. In these decisions, the Supreme Court and lower federal courts consistently held that patents are private property secured under the Constitution. They include, for example:

- “[T]he government cannot, after the patent is issued, make use of the improvement any more than a private individual, without license of the inventor or making compensation to him.” *United States v. Burns*, 79 U.S. 246, 252 (1870).
- A patent owner can seek compensation for the unauthorized use of his patented invention by federal officials because “[p]rivate property . . . shall not be taken for public use without just compensation.” *Cammeyer v. Newton*, 94 U.S. 225, 234 (1876).
- “Inventions secured by letters-patent are property in the holder of the patent, and as such are as much entitled to protection as any other property. . . . Private property, the constitution provides, shall not be taken for public use without just compensation” *Brady v. Atlantic Works*, 3 F. Cas. 1190, 1192 (C.C.D. Mass. 1876) (Clifford, Circuit Justice), *rev’d on other grounds*, 107 U.S. 192 (1883).



- A patent is not a “grant” of special privilege; the text and structure of the Constitution, as well as court decisions, establish that patents are property rights secured under the Takings Clause). *McKeever v. United States*, 14 Ct. Cl. 396, 421 (1878).

Due to some unfortunate confusion at the turn of the twentieth century concerning the jurisdiction of a court to adjudicate a takings claim by a patent owner, Congress enacted in 1910 the predecessor statute to § 1498(a) to resolve this constitutional confusion. *See* Act of June 26, 1910, ch. 423, 36 Stat. 851, 851-52 (1910) (codified as amended in 28 U.S.C. § 1498(a)). The text and legislative history confirm that this is an eminent domain statute.

The modern Supreme Court has confirmed the long-standing rule that patents are property rights secured under the Takings Clause and Due Process Clauses. Roughly twenty years ago, the Supreme Court held that patents are “property” under the Due Process Clause of the Fourteenth Amendment. *See* *Florida Prepaid Postsecondary Educ. Expense Bd. v. Coll. Sav. Bank*, 527 U.S. 627, 642-43 (1999). In 2015, the Court approvingly quoted an 1882 decision stating that “[a patent] confers upon the patentee an exclusive property in the patented invention which cannot be appropriated or used by the government itself, without just compensation, any more than it can appropriate or use without compensation land which has been patented to a private purchaser.” *Horne v. U.S. Dept. of Agriculture*, 135 S. Ct. 2419, 2427 (2015) (quoting *James v. Campbell*, 104 U.S. 356, 358 (1882)).

B. The Legislative History of § 1498(a) Confirms it is an Eminent Domain Statute

The House committee report for the bill that became § 1498(a) expressly stated that the federal government was using patents without authorization “in flat violation of [the Takings Clause] and the decisions of the Supreme Court.” H.R. Rep. No. 61-1288, at 3 (1910). During the congressional debates leading up to the enactment of § 1498(a), the bill’s sponsor, Representative Currier, emphasized that the legislation “does not create any liability; it simply gives a remedy upon an existing liability.” 45 Cong. Rec. 8755, 8756 (1910). Throughout the congressional debates, legislators repeatedly referenced the earlier-cited court decisions that had already secured to patent owners their constitutional remedy under the Takings Clause. *See* H.R. Rep. No. 61-1288, at 1-4.

C. The Text of § 1498(a) Confirms it is an Eminent Domain Statute

The court precedents and legislative history explain the text of § 1498(a), which provides for claims of compensation arising from exercises of the government’s eminent domain power. Section 1498(a) states that a patent owner can sue the federal government in the Court of Federal Claims (originally the Court of Claims) for “recovery of his reasonable and entire compensation” when a patented invention is “used or manufactured by or for the United States without license of the owner.”



In 1918, after extensive federal procurement efforts with contractors during World War One, Congress amended § 1498(a) for patent owners to sue the government for reasonable compensation when federal contractors infringe their patents. *See* Act of July 1, 1918, ch. 114, 40 Stat. 704, 705 (1918) (codified as amended in 28 U.S.C. § 1498(a)). This amendment added the “used or manufactured by or for the United States” that currently exists in § 1498(a). *Id.* Consistent with its function as an eminent domain statute, the statute was amended again shortly after the U.S. entered World War Two, requiring suits against the government for compensation for patent infringement by federal contractors, but again this amendment is limited to only when contractors make or use a patented invention “for the Government.” Act of October 31, 1942, Pub. L. 768, § 6, 77th Cong. 2d Sess., 56 Stat. 1013, 1014 (1942) (codified as amended in 28 U.S.C. § 1498(a)).

As this Court recognized, Moderna’s contract is not an example of a contractor making and using a patented invention “for the United States,” as Moderna vaccine doses were distributed by private companies for use by private healthcare patients. The “by and for the United States” text in § 1498(a) limits its applicability to manufacture or use of patent inventions by the federal government, or by federal contractors acting “for the Government,” such as the unauthorized use of patented inventions for the U.S. military in the nineteenth century. *See Burns*, 79 U.S. at 251-54 (1870) (unauthorized use of patented tent by U.S. military); *McKeever*, 14 Ct. Cl. At 417 (unauthorized use of a patented cartridge by U.S. military).

The twentieth-century lawsuits brought by patent owners under § 1498(a) are no different. *See, e.g.,* *Hughes Aircraft Co. v. Messerschmitt-Boelkow-Blohm*, 625 F.2d 580 (5th Cir. 1980); *Hughes Aircraft Co. v. United States*, 534 F.2d 889 (Ct. Cl. 1976); *Croll-Reynolds Co. v. Perini-Leavell-Jones-Vinell*, 399 F.2d 913 (5th Cir. 1968), *cert. denied*, 393 U.S. 1050 (1969). One famous § 1498(a) case arose from the U.S. military’s unauthorized use of a patented battery during World War Two. *See United States v. Adams*, 383 U.S. 39 (1966).

In sum, the plain text of § 1498(a) and its legislative history makes clear that it does not apply to products and services, which may be paid for by the public fisc, but are ultimately made for private companies to distribute for use by private parties. Although the government emphasizes in its Statement of Interest its “authorization or consent of the Government,” 23 U.S.C. § 1498(a), in its purchase agreement with Moderna to manufacture its vaccine doses, such consent triggers this statute only when such manufacture or use is “for the Government.” *Id.* For example, this authorization and consent clearly applies to the use of the vaccine doses for U.S. military personnel and federal employees. Beyond this, § 1498(a) is inapplicable to Moderna’s manufacture of its vaccine doses pursuant to its purchase agreement with the federal government *for use by private patients* in the U.S. healthcare market.

This Court correctly denied Moderna’s motion to dismiss by recognizing that § 1498(a) applies only when a contractor makes or uses a patented invention “for the Government.” *Arbutus Biopharma Corp.*, 2022 WL 16635341, at *7. The federal government may have derived an incidental benefit from resolution of the COVID-19 public health emergency through the



private distribution and use of vaccines by private patients, but this Court rightly recognized, “[i]ncidental benefit to the government is insufficient” to trigger § 1498(a) as an affirmative defense in a patent infringement lawsuit. *Id.* at *5 (quoting *IRIS Corp. v. Japan Airlines Corp.*, 769 F.3d 1359, 1361 (Fed. Cir. 2014)).

II. Judicial Interpretation of § 1498(a) Confirms it is an Eminent Domain Statute Inapposite to Private Transactions in the Marketplace

This Court correctly recognized and applied the precedents that have construed § 1498(a) as an eminent domain statute. This explains why the federal government must use a patented invention, or at least be a direct beneficiary of a contractor making or using a patented invention for the government, to trigger its requirement of payment of “reasonable and entire compensation” by the government. 28 U.S.C. § 1498(a). In addition to the cases discussed by this Court in its earlier order, see *Arbutus Biopharma Corp.*, 2022 WL 16635341, at *4-*7, courts have consistently recognized for well over half a century that § 1498 is an eminent domain statute. See *Decca Ltd. v. United States*, 544 F.2d 1070, 1082 (Ct. Cl. 1976) (“It is [the government’s] taking of a license, without compensation, that is, under an eminent domain theory, the basis for a suit under § 1498.”); *Carter-Wallace, Inc. v. United States*, 449 F.2d 1374, 1390 (Ct. Cl. 1971) (Nichols, J., concurring) (stating that § 1498(a) authorizes a claim in court “to recover just compensation for a taking under the power of Eminent Domain”); *Irving Air Chute Co. v. United States*, 93 F. Supp. 633, 635 (Ct. Cl. 1950) (stating that § 1498(a) is “an eminent domain statute”).

This Court acknowledged in its earlier decision that courts have recognized that the federal government need not be a primary or sole beneficiary, as first stated in *Advanced Software Design Corp. v. Federal Reserve Bank of St. Louis*, 583 F.3d 1371, 1373-74 (Fed. Cir. 2009). In *Advanced Software*, the Federal Circuit held that a regional Federal Reserve bank acted “for the government” when it used a process for detecting fraudulent Treasury checks that infringed a patent on this process. The court concluded that “the benefits to the government of using the [infringing fraud-detection] technology on Treasury checks are not incidental effects of private interests.” *Id.* at 1379. Thus, the *Advanced Software* court concluded that the patent owner had to proceed in a lawsuit against the federal government under § 1498(a), and not in a lawsuit against the specific Federal Reserve bank that infringed its patent. Given the formal relationship between the federal government and the Federal Reserve System in managing the official currency printed by the U.S. Bureau of Engraving and Printing in the U.S. Department of Treasury, this decision makes sense, both legally and commonsensically.

The Federal Reserve System is not the same legal or commercial entity as a private company that manufactures and sells a drug to other companies or distributes a drug for use by private patients in the marketplace. The *Advanced Software* court expressly distinguished the Federal Reserve System as a patent infringer acting “for the Government” from patent infringement by a private company that was paid by Medicare in providing a medical device to a private patient in *Larson v. United States*, 26 Cl. Ct. 365, 369 (1992). *Larson* is more similar in its facts to the purchase contract between Moderna and the federal government than the facts of



Advanced Software, as recognized by this Court. *Arbutus Biopharma Corp.*, 2022 WL 16635341, at *7 (“I find this case more akin to *Larson* than *Advanced Software Design*”).

In *Larson*, a patent owner sued a private medical company for infringing its patent on a medical device (a splint); the splints were paid through government programs such as Medicaid or Medicare, or at least the purchase price was reimbursed. *Id.* at 367-68. Given that “the government reimbursed the cost [of the infringing splint] through Medicare and other federal programs,” *id.*, the defendant argued that the patent owner’s lawsuit must proceed against the government under § 1498(a). The *Larson* court rejected this argument, stating that “government reimbursement of medical care expenses did not constitute a use of a medical patent for government purposes,” as required by the text of § 1498(a) in authorizing lawsuits against the federal government for compensation. *Id.* at 369. Similarly in this case, the federal government’s payment to Moderna for its vaccine doses to be distributed in the healthcare market for use by private individuals is not a use of a patent “for the Government.” 23 U.S.C. § 1498(a).

In fact, the *Advanced Software* court reaffirmed the precedential import of *Larson*, stating that “[t]he fact that the government has an interest in the [healthcare] program generally, or funds or reimburses all or part of its costs, is too remote to make the government the program’s beneficiary for the purposes underlying § 1498.” *Advanced Software*, 583 F.3d at 1379 (quoting *Larson*, 26 Ct. Cl. at 369). This has long been recognized by scholars as well. One prominent monograph acknowledges that § 1498(a) must be “modified” if it is “to apply to governmental payment for drugs prescribed for beneficiaries of such federal health programs as Medicare and Medicaid.” Milton Silverman & Philip R. Lee, *Pills, Profits, and Politics* 187 (1974).² A federal health program funding the manufacture of vaccine doses for use by private patients is no different from the federal health programs of Medicare or Medicaid funding drugs for use by private patients. In either case, there is no basis to conclude that this is “use or manufacture . . . for the Government” under § 1498(a).

Applying both *Advanced Software* and *Larson*, this Court rightly recognized that “Moderna’s argument . . . could mean that 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.” *Arbutus Biopharma Corp.*, 2022 WL 16635341, at *7. Given the widespread activities of the federal government in funding healthcare products and services today, Moderna’s argument would convert every patent infringement lawsuit arising from patents covering drugs or other healthcare treatments into a suit for compensation against the federal government for the exercise of its eminent domain power. The absence of any limiting principle in Moderna’s argument that § 1498(a) applies in this case reveals how divorced its argument is from the text, function, and policy of § 1498(a) as

² For more recent scholarship analyzing the text and judicial construction of § 1498(a) and reaching the same conclusion, see Susan G. Braden & Joshua A. Kresh, *Section 1498(a) is Not a Rx to Reduce Drug Prices*, 77 FOOD & DRUG L.J. 274 (2022); Adam Mossoff, *The False Promise of Breaking Patents to Lower Drug Prices* (Feb. 8, 2023), <https://papers.ssrn.com/abstract=4348499>.



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an eminent domain statute. Section 1498(a) does not apply to a situation in which a drug is produced by a private company for use by private citizens in the healthcare market, even if the federal government has an incidental interest in the results of this transaction and contributes public funds.

Conclusion

If this Court concludes that a response to the Statement of Interest of the United States is necessary, it should reissue its earlier decision that the purchase agreement between Moderna and the federal government does not qualify for use of a patented invention “for the Government.” This Court rightly recognized that the text, function, and judicial interpretation of § 1498(a) necessitates the conclusion that it is inapplicable to private transactions between private parties in the marketplace, even if the federal government has an incidental interest in these transactions through payments from the public fisc in a public health emergency. As an eminent domain statute, § 1498(a) applies only to unauthorized uses of patented inventions by or for the federal government, such as use of patented inventions by the military or by federal agencies, or by contractors providing products and services for use by these agencies and departments in the federal government.

Respectfully submitted,

/s/ Stephen B. Brauerman

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cc: All Counsel



APPENDIX OF AMICI

Full List of Amici Curiae*

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