IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARBUTUS BIOPHARMA CORPORATION and GENEVANT SCIENCES GMBH,	)	
Plaintiffs,	)	
v.	)	C.A. No. 22-252 (MSG)
MODERNA, INC. and MODERNATX, INC.	)	
Defendants.	)	

DEFENDANTS' OPENING BRIEF IN SUPPORT OF THEIR PARTIAL MOTION TO DISMISS PURSUANT TO FEDERAL RULE OF CIVIL PROCEDURE 12(B)(6)

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I. INTRODUCTION

The COVID-19 pandemic presented an urgent and historic public health challenge that, in Plaintiffs' own words, would have been "immeasurably worse but for the rapid, widespread availability of cutting-edge mRNA-based vaccines like Moderna's." Moderna acted swiftly and worked tirelessly to provide the U.S. Government with vaccine supply—precisely as Congress envisioned when it enacted 28 U.S.C. § 1498(a) many years ago to encourage suppliers "to furnish what [is] needed by the government, without fear of becoming liable themselves for infringements to . . . the owners or assignees of patents." This is an important statutory protection that covers all those who supply the U.S. Government with its authorization and consent, and played a critical role in encouraging companies to step up to help fight the COVID-19 pandemic.

When the pandemic started, Moderna was a comparatively small biotech company in Cambridge, Massachusetts, pioneering a new class of medicines made of messenger RNA ("mRNA") for therapeutic and prophylactic uses, such as vaccines. These medicines have the potential to treat and prevent a wide range of diseases—from infectious diseases like influenza and HIV, to autoimmune and cardiovascular diseases and rare forms of cancer. Over the past twelve years, Moderna has worked diligently in its laboratories to pioneer several fundamental breakthroughs in the field of mRNA technology. These discoveries span all aspects of mRNA medicines—from the characteristics and design of the mRNA itself and the protein it encodes, to the technologies to deliver mRNA to patients safely and effectively. Based on Moderna's experience, and believing its mRNA technology could make a difference in combating the pandemic, Moderna quickly pivoted when the crisis struck, developing the COVID-19 Vaccine in record time, "sav[ing] countless lives."

Plaintiffs now seek royalties for Moderna's COVID-19 Vaccine,[2] also called "Spikevax®." But Moderna supplied COVID-19 Vaccine to the U.S. Government pursuant to a contract, as part "of the national emergency response to . . . COVID-19[], for the United States Government . . . and the US population." In that contract, the Government expressly invoked its sovereign authority to "authorize[] and consent[] to all use and manufacture . . . of any invention described in and covered by a United States patent." Accordingly, Plaintiffs' claims concerning the sale and provision of COVID-19 Vaccine doses to the U.S. Government can only proceed against the Government in the Court of Federal Claims under Section 1498.

Moderna will demonstrate that its COVID-19 Vaccine does not infringe any valid patents, including those held by Plaintiffs Arbutus and Genevant—but that dispute is for later. The only issue is where, against whom, and how the dispute should be decided with respect to U.S. Government sales. Under Section 1498, when an allegedly infringing product is "used or manufactured by or for the United States," the only remedy for the alleged infringement is an "action against the United States in the United States Court of Federal Claims." Thus, because Plaintiffs seek royalties on the sale and provision of COVID-19 Vaccine doses to the U.S. Government, such claims should be dismissed in this Court, and they can only proceed against the Government in the Court of Federal Claims.

[2] As used herein, "COVID-19 Vaccine" refers to the accused "mRNA-1273 COVID-19 mRNA LNP vaccine product . . . or any supplemental or booster COVID mRNA LNP vaccine product." Compl. ¶ 8.

II. NATURE AND STAGE OF THE PROCEEDINGS

On February 28, 2022, Plaintiffs Arbutus Biopharma Corporation ("Arbutus") and Genevant Sciences GmbH ("Genevant") filed this action for patent infringement against Moderna, Inc. and ModernaTX, Inc. (together, "Moderna"). Plaintiffs' Complaint alleges that Moderna's mRNA-1273 COVID-19 Vaccine infringes Plaintiffs' patents. D.I. 1 ("Compl."), ¶¶ 1, 8.

III. SUMMARY OF ARGUMENT

The Court should dismiss Plaintiffs' infringement claims (both direct and indirect) relating to Moderna's sale and provision of COVID-19 Vaccine doses to the U.S. Government because, under 28 U.S.C. § 1498(a), Plaintiffs' only remedy is an action against the U.S. Government in the Court of Federal Claims.[3] Specifically, in accordance with the requirements of Section 1498(a), Moderna acted for the U.S. Government and with its authorization and consent. As a result, Plaintiffs should seek any such alleged damages for those claims from the Government in the Court of Federal Claims, not from Moderna in this Court.

IV. STATEMENT OF FACTS

The facts here come from the Complaint and matters of public record, including Moderna's COVID-19 Vaccine contract with the U.S. government. Among other places, the contract is available on the website for the Department of Health and Human Services.[4] Moderna attaches the contract as Exhibit A to this brief for the Court's convenience.

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[3] Moderna's motion addresses part of the complaint and thus suspends the time to respond to the remaining allegations in the complaint. *See* Fed. R. Civ. P. 12(a)(4)(A); *see also Circuit City Stores, Inc. v. Citgo Petroleum Corp.*, No. CIV. A. 92-CV-7394, 1994 WL 483463, at *4 (E.D. Pa. Sept. 7, 1994) ("A partial 12(b) motion enlarges the time to file an answer."); *Godlewski v. Affiliated Comput. Servs., Inc.*, 210 F.R.D. 571, 572 (E.D. Va. 2002) ("A majority of courts . . . hold that the filing of a motion that only addresses part of a complaint suspends the time to respond to the entire complaint, not just to the claims that are the subject of the motion.").

[4] *See, e.g.*, https://www.hhs.gov/sites/default/files/moderna-covid-19-vaccine-contract.pdf.

A. The Parties

Plaintiffs Arbutus and Genevant allegedly own several patents related to lipid nanoparticles, or "LNPs." Compl. ¶¶ 1, 9, 29–30, 67, 86, 105, 127, 151, 170. LNPs are part of the delivery system for Moderna's mRNA, and Plaintiffs allege that Moderna's COVID-19 Vaccine employs Plaintiffs' LNPs. Compl. ¶¶ 41, 43, 45, 70, 89, 108, 130, 154, 173.

"[I]n the midst of a global pandemic," Defendant Moderna undertook "extensive" and "vitally important" efforts to develop, manufacture and sell its COVID-19 Vaccine doses to the U.S. Government and others around the world—efforts that "have saved countless lives." Compl. ¶¶ 1, 57. Since its founding in 2010, Moderna has worked to build a leading mRNA technology platform to develop and test candidates for its "cutting-edge," "new class" of mRNA-based vaccines and therapies, spanning several therapeutic areas. Compl. ¶¶ 1, 21; Ex. B, Decl. of Shaun Ryan, Mot. to Supplement the Record to Provide Evidence of Standing, D.I. No. 18, 11 ¶ 2, *Moderna TX, Inc. v. Arbutus Biopharma Corp.*, No. 2020-2329 (Fed. Cir.) ("Ryan Decl.") (cited at Compl. ¶ 50 n.16). Moderna created this platform to improve the pharmaceutical properties of its mRNA medicines, investing years of work and resources to develop LNPs that would work with mRNA (*id.*), whereas Plaintiffs' work had a very different focus (Compl. ¶¶ 24, 28). Ultimately, "with the novel SARS-CoV-2 virus quickly spreading around the world," and believing its mRNA technology could make a difference in combating the pandemic, Moderna mobilized its mRNA platform to develop, study, and manufacture its COVID-19 Vaccine in such a short period that "[c]ompared to the timelines of prior vaccine-development efforts, Moderna's accomplishment was unprecedented." Compl. ¶¶ 39, 41.

B. Moderna's Government Contract

As stated in the Complaint, the COVID-19 pandemic has been "one of the greatest public health challenges in modern history"; it would have been "immeasurably worse but for the rapid,

widespread availability of cutting-edge mRNA-based vaccines like Moderna's." Compl. ¶ 1. An important ingredient in accelerating that "widespread availability" was the U.S. Government's use of emergency powers in contracting with Moderna to supply it with doses of the COVID-19 Vaccine. *See* Ex. A.

The contract sets out the background of the pandemic and the Government's response. "In December 2019, a novel coronavirus now known as SARS-CoV-2 was first detected . . . , causing outbreaks of the coronavirus disease COVID-19 that has now spread globally." Ex. A at 19 C. 1.1. As a result, the "Secretary of Health and Human Service declared a public health emergency on January 31, 2020," and "[o]n March 1, 2020, the President of the United States . . . proclaimed that the COVID-19 outbreak in the United States constitute[d] a national emergency." *Id.* Under Operation Warp Speed, "the Department of Defense and HHS [led] a whole of nation effort to ensure development of promising vaccine, diagnostic and therapeutic candidates and ensure that these medical countermeasures" would be "available in the quantities required to reduce SARS-CoV-2 transmission, identify prior and/or current infection, and improve patient care, thereby mitigating the impact of COVID-19 on the nation and its people." *Id.* at C.1.1.1.

Contracting expertise was critical to the effort. "The DoD Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense" provided "expertise and contracting support to HHS[.]" *Id.* As candidate products progressed "to clinical trials to evaluate the safety and efficacy of vaccines and therapeutics," it was "critical that, in parallel," the Government would support "large scale manufacturing so that vaccine doses or therapeutic treatment courses are immediately available for nationwide access as soon as a positive efficacy signal is obtained and the medical countermeasures are authorized for widespread use." *Id.*

Consistent with that mission, the U.S. Army Contracting Command contracted with Moderna in August 2020 (Ex. A at 1-2), even before the FDA had granted Emergency Use Approval to Moderna's COVID-19 Vaccine in December 2020 (Compl. ¶¶ 16, 51). The contract includes a list of "Federal Acquisition Regulations" that were "incorporated by reference." Ex. A at 45–47, 51. Among these is the express "authorization and consent" provision of FAR 52.227-1 (*id.* at 46), by which "[t]he Government authorizes and consents to all use and manufacture, in performing this contract or any subcontract at any tier, of any invention described in and covered by a United States patent. . . " (Federal Acquisition Regulation ("FAR") 48 C.F.R. § 52.227–1(a) (2020)). This authorization and consent is broad, covering among other things patents on "the structure or composition of any article the delivery of which is accepted by the Government under this contract." FAR 52.227-1(a)(1).

C. The Complaint

Plaintiffs' Complaint completely ignores the terms of Moderna's contract with the Government. This was not by mistake—in prior disputes with Plaintiffs, Moderna informed Plaintiffs that sales to the U.S. Government are subject to Section 1498.[5] Nevertheless, the

[5] In a declaration filed in an IPR appeal between Moderna and Arbutus on February 23, 2021, Moderna's Senior Vice President and Deputy General Counsel, Shaun Ryan, explained that Moderna's sales of its COVID-19 vaccine "went to the U.S. government . . . and are subject to 28 U.S.C. § 1498." Ex. B (Ryan Decl.) ¶ 8. Plaintiffs cite this declaration in their Complaint (*see* Compl. ¶ 50 n.16), but ignore the statements showing that their claims are subject to Section 1498 and that they must seek their royalties from the U.S. Government in a separate judicial forum. Other public documents cited in the Complaint similarly flag Moderna's sales to the U.S. Government. *See* Press Release, Moderna, Moderna Reports Fourth Quarter and Fiscal Year 2021 Financial Results and Provides Business Updates (Feb. 24, 2022), https://investors.modernatx.com/news/news-details/2022/Moderna-Reports-Fourth-Quarter-and-Fiscal-Year-2021-Financial-Results-and-Provides-Business-Updates/default.aspx ("The U.S. government has agreed to purchase supply of mRNA-1273 under U.S. Department of Defense contract no. W911QY-20-C-0100.") (cited at Compl. ¶ 52 n.21); Vaccine Exports From U.S. Accelerate as Moderna Ships Abroad, Bloomberg.com (May 20, 2021), https://www.bloomberg.com/news/articles/2021-05-20/moderna-starts-shipping-vaccine-from-u-

Complaint contains no indication that Plaintiffs ever approached the Government to seek compensation. Plaintiffs instead brought this action, which includes and does not carve-out purchases by the U.S. Government. Compl. ¶¶ 51, 70–72, 89–91, 108–110, 130132, 154–156, 173–175.

V. ARGUMENT

A. Legal Standards

Under Rule 12(b)(6), a complaint should be dismissed, in whole or in part, if the allegations fail to give rise to a "plausible" claim for relief. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). As an affirmative defense, Section 1498 immunity provides a basis for dismissal under Rule 12(b)(6) when the elements of the defense appear on the face of the complaint. *D3D Techs., Inc. v. Microsoft Corp.*, No. 6:20-CV-1699-PGB-DCI, 2021 WL 2194601, at *2 (M.D. Fla. Mar. 22, 2021); *ALA, Inc. v. CCAIR, Inc.*, 29 F.3d 855, 859 (3d Cir. 1994).

In considering a 12(b)(6) motion, the Court must take the complaint's plausible allegations as true, and may also consider any "document integral to or explicitly relied upon in the complaint," matters of public record, and items subject to judicial notice. *Angstadt v. Midd-West Sch. Dist.*, 377 F.3d 338, 342 (3d Cir. 2004); *Tellabs, Inc. v. Makor Issues & Rts., Ltd.*, 551 U.S. 308, 322 (2007) (court may consider "matters of which [it] may take judicial notice"); *Twombly*, 550 U.S. at 568 n.13 (court may consider "the full content of the published articles referenced in the complaint . . ."); *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997) (holding that "document[s] integral to or explicitly relied upon in the complaint" may be considered in connection with a motion to dismiss); Fed. R. Evid. 201; *Williams v. Magee*,

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s-boosting-shot-exports ("[Moderna's] early U.S. production had been fully absorbed by a single buyer -- the federal government.") (cited at Compl. ¶ 53 n.24).

No. 1:19-CV-720, 2019 WL 3337085, at *4 (M.D. Pa. July 24, 2019) (court may consider "matters of public record").

Here, Moderna's government contract is a matter of public record subject to judicial notice. The contract is published on the website of the Department of Health and Human Services, one of the agreement's parties. *See* Ex. A, https://www.hhs.gov/sites/default/files/moderna-covid-19-vaccine-contract.pdf. Courts may, and routinely do, take judicial notice of government websites and contracts whose existence and contents are not subject to reasonable dispute. *Williams*, 2019 WL 3337085, at *4 ("The Court may take judicial notice of publicly available documents, including publicly-executed contracts involving governmental entities . . . ."); *Inman v. Technicolor USA, Inc.*, No. CIV.A. 11-666, 2011 WL 5829024, at *4 (W.D. Pa. Nov. 18, 2011) (taking judicial notice of publicly available user agreement when there was no dispute as to authenticity); *London v. Del. Dep't of Corr.*, No. CV 19-1518-MN-SRF, 2021 WL 3422360, at *7 n.15 (D. Del. Aug. 5, 2021), *report and recommendation adopted*, No. CV 19-1518 (MN), 2021 WL 4262458 (D. Del. Sept. 20, 2021) (taking judicial notice of government website as a matter of public record).

In addition to being cited on HHS.gov, the contract is also publicly available on other government websites, like SEC.gov, as part of Moderna, Inc.'s Form 10-Q with the Securities and Exchange Commission ("SEC"). Moderna (Form 10-Q) Quarterly Report (Oct. 30, 2020) at 30 (https://www.sec.gov/ix?doc=/Archives/edgar/data/0001682852/000168285220000023/mrna-20200930.htm); Exhibit 10.3 (Contract No. W911QY20C0100) https://www.sec.gov/Archives/edgar/data/1682852/000168285220000023/exhibit103.htm. Courts may also take judicial notice of public filings, like those with the SEC. *Novartis Pharms. Corp. v. Handa Neuroscience, LLC*, No. CV 21-645-LPS, 2022 WL 610771, at *4 n.1 (D. Del.

Mar. 1, 2022); *cf. Southmark Prime Plus, L.P. v. Falzone*, 776 F. Supp. 888, 892 (D. Del. 1991) (taking judicial notice of SEC filings when considering motion for judgment on the pleadings, applying the same standards as for a motion to dismiss under 12(b)(6)).

In other words, Plaintiffs' calculated avoidance of the terms of the contract in their Complaint cannot deprive this Court of the ability to consider it. *See In re Burlington*, 114 F.3d at 1426 ("Plaintiffs cannot prevent a court from looking at the texts of the documents on which its claim is based by failing to attach or explicitly cite them."). Nor would it make sense to proceed as if the contract does not exist. The whole point of the authorization and consent term in the contract is to ensure that the case proceeds in the correct forum (the Court of Federal Claims) against the correct party (the Government). The Court accordingly should consider the contract here and dismiss the claims that are based on it.

B. The Court Should Dismiss Plaintiffs' Claims Based on U.S. Sales under 28 U.S.C. § 1498(a)

Every patent granted by the U.S. Government comes with an important caveat—the patentee may not inhibit the Government from having its suppliers work on its behalf to make or use an invention, subject to compensation in the Court of Federal Claims. To that end, the "government has graciously consented" in Section 1498 "to be sued in the Claims Court for reasonable and entire compensation, for what would be infringement if by a private person." *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 842 F.2d 1275, 1283 (Fed. Cir. 1988).

Section 1498(a) 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 . . . 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[.]" The statute thus seeks "to stimulate contractors to furnish what [is] needed by the government, without fear of becoming liable

themselves for infringements to inventors or the owners or assignees of patents" (*Astornet Techs. Inc. v. BAE Systems, Inc.*, 802 F.3d 1271, 1277) and to "enabl[e] the Government to purchase goods for the performance of its functions without the threat of having the supplier enjoined from selling patented goods to the Government" (*Coakwell v. United States*, 372 F.2d 508, 511 (Ct. Cl. 1967)). The statute was amended over a century ago specifically "to prevent patent infringement suits from interfering with the supply of war materials during World War I," as "Congressional concern was that if contractors feared an infringement suit, they might decide not to manufacture desperately-needed products for the United States' war effort." *Saint Switch v. Gen. Motors of Can.*, No. 95 C 0250, 1996 U.S. Dist. LEXIS 2762, at *5–6 (N.D. Ill. Mar. 7, 1996) (internal citations omitted).

Short of war, it is difficult to conceive of a situation more within the heart of Section 1498 than the COVID-19 crisis, "one of the greatest public health challenges in modern history." Compl. ¶ 1. The Government declared emergencies twice in the pandemic's wake—a "public health emergency" in January 2020 and a "national emergency" in March 2020. Ex. A at 19 C.1.1. The Government then enlisted the Department of Defense to help the Department of Health and Human Services rally the private sector to develop and distribute a vaccine as quickly as possible. *Id.* at 19 C.1.1.1. Moderna answered the call. Then a relatively small biotech company, Moderna had the right expertise at the right time. Moderna scientists and their collaborators worked to develop and produce a COVID-19 vaccine for distribution on a massive scale while much of the rest of the country quarantined, as government and private industry worked together to respond to the most severe crisis facing the nation. This is exactly when Section 1498 is meant to apply.

By its terms, Section 1498(a) has only two requirements. The allegedly infringing use must be "for the Government," and it must have "the authorization and consent of the

Government." *Sevenson Env't Servs., Inc. v. Shaw Env't, Inc.*, 477 F.3d 1361, 1365 (Fed. Cir. 2007) (citing *Hughes Aircraft Co. v. United States*, 534 F.2d 889, 897–98 (Ct. Cl. 1976)). Moderna's sale and provision of COVID-19 Vaccine doses to the U.S. Government directly satisfy these criteria.

1. Moderna Sold and Provided COVID-19 Vaccine Doses to the U.S. Government "for the Government"

Moderna's supply of its COVID-19 Vaccine is deemed "for the Government" under Section 1498(a) so long as the supply is "for the benefit of the [G]overnment." *Advanced Software Design Corp. v. Fed. Rsrv. Bank of St. Louis*, 583 F.3d 1371, 1378 (Fed. Cir. 2009). In other words, "[a] use is 'for the Government' if it is 'in furtherance and fulfillment of a stated Government policy' which serves the Government's interests and which is 'for the Government's benefit.'" *IRIS Corp. v. Japan Airlines Corp.*, 769 F.3d 1359, 1362 (Fed. Cir. 2014) (quoting *Madey v. Duke Univ.*, 413 F. Supp. 2d 601, 607 (M.D.N.C. 2006)).

Moderna's contract is explicit that it is for the benefit of the Government, describing the agreement as "for the United States Government . . . and the US population." Ex. A at 19 C.1. The contract then goes further and contains provisions explaining how the agreement fits into government policy. The contract's "Scope" section recounts the COVID crisis, the Government's emergency declarations in response, and the commencement of Operation Warp Speed. *Id.* at 19 C.1.1, C.1.1.1. Under the operation, "the Department of Defense and HHS" led "a whole of nation effort to ensure development of promising vaccine, diagnostic and therapeutic candidates and ensure that these medical countermeasures." *Id.* at C.1.1.1. The Department of Defense "Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense" provided "expertise and contracting support to HHS[.]" *Id.* The Government's whole purpose was to support "large scale manufacturing so that vaccine doses . . . are immediately available for

nationwide access as soon as a positive efficacy signal is obtained and the medical countermeasures are authorized for widespread use." *Id.*

In short, Moderna supplied, and continues to supply, COVID-19 Vaccine doses to the U.S. Government for the Government to achieve a specific government objective (i.e., supporting a nationwide vaccination effort). *Cf. Thermalon Indus., Ltd. v. United States*, 34 Fed. Cl. 411, 420 (Fed. Cl. 1995) ("Hence, for example, if the United States purchases vaccines for administration to the public in order to eradicate a particular disease, the government not only would be engaged in the purchase and sale of specific goods, but also would be concurrently exercising its sovereign power for the general public welfare.").

2. Moderna Had "the Authorization and Consent of the Government"

Moderna supplied, and continues to supply, COVID-19 Vaccine under express authorization and consent from the Government, regardless of any issued patents.

Under Section 1498(a), the Government's "authorization or consent" can be express or implied. *TVI Energy Corp. v. Blane*, 806 F.2d 1057, 1060 (Fed. Cir. 1986). An authorization and consent provision in a government contract establishes "authorization and consent" under Section 1498(a). *Crater Corp. v. Lucent Tech., Inc.*, 255 F.3d 1361, 1368 (Fed. Cir. 1976); *see also D3D Techs.*, 2021 WL 2194601, at *2 (satisfying authorization and consent prong when contract "show[ed] the Government expressly authorized the alleged infringing activity").

Here, the Government explicitly authorized and consented to Moderna's manufacture and sale of the COVID-19 Vaccine. The contract incorporates by reference FAR 52.227-1, entitled "Authorization and Consent." Ex. A at 46. That regulation provides that:

> ***The Government authorizes and consents to all use and manufacture, in performing this contract or any subcontract at any tier, of any invention described in and covered by a United States patent- (1) Embodied in the structure or composition of any article the delivery of which is accepted by the Government under this contract***; or (2) Used in machinery, tools, or methods whose use

> necessarily results from compliance by the Contractor or a subcontractor with (i) specifications or written provisions forming a part of this contract or (ii) specific written instructions given by the Contracting Officer directing the manner of performance.

FAR 52.227-1(a) (2020) (emphasis added).[6]

Plaintiffs allege that Moderna's COVID-19 Vaccine includes LNPs covered by Plaintiffs' patents. Compl. ¶¶ 41, 43, 45, 70, 89, 108, 130, 154, 173. Plaintiffs further allege that these particles facilitate delivery of the operative mRNA. *Id*. at ¶¶ 26, 27, 44. As alleged, the LNPs are accordingly part of and embodied in the "structure or composition" of the article covered by the contract—namely, the COVID-19 Vaccine. In these circumstances—when a patented article of manufacture is incorporated into a supply contract—the first clause of FAR 52.227-1 controls. *See Carrier Corp. v. United States*, 534 F.2d 244, 247 n.5 (Ct. Cl. 1976) ("The portion of the authorization and consent clause that provides that the Government authorizes and consents to infringement of any patent 'embodied in the structure or composition of any article the delivery of which is accepted by the Government' is applicable to hardware and other goods procured by and delivered to the Government for its own use, generally through supply contracts."). This clause applies with respect to all patent claims asserted by Plaintiffs—both composition and method claims[7]—because the same "article the delivery of which is accepted by the Government under this contract" is implicated by both sets of claims. *See Saint-Gobain Ceramics & Plastics, Inc. v. II-VI Inc.*, 369 F. Supp. 3d 963, 973–77 (C.D. Cal. 2019) (explaining that including FAR 52.227-

[6] The contract also incorporates by reference FAR 52.227-1 Alternate I (Ex. A at 46), which provides an alternate and broader provision, used in contracts for research and development (*see* FAR 27.201-2(a)(2) (2020)).

[7] According to the Complaint, U.S. Patent Nos. 8,882,668 and 9,364,435 contain both composition and method claims. Compl. ¶¶ 107, 129.

1(a)(1) in a supply contract provides "authorization and consent" to defendants' alleged infringement of apparatus and method claims).

Accordingly, the agreement meets both prongs of Section 1498(a). Insofar as Plaintiffs continue to pursue allegations based on U.S. sales, they must do so in the Court of Federal Claims.

3. Plaintiffs' Indirect Infringement Allegations Are Also Subject to Section 1498(a)

Plaintiffs also allege that Moderna indirectly infringes by supplying COVID-19 vaccine doses to the Government. *See* Compl. ¶¶ 71–72, 78–79, 90–91, 97–98, 109–110, 119–120, 131–132, 143–144, 155–156, 162–163, 174–175, 182–183. These allegations do not circumvent Section 1498(a).

Section 1498(a) bars indirect infringement claims when the underlying act of direct infringement is performed by or for the Government. *Astornet*, 802 F.3d at 1277–78 (indirect infringement claim against government contractor barred where the alleged infringement was performed by the Transportation Security Administration using the contractor's equipment). Put differently, simply appending claims of indirect infringement here is "insufficient to undercut the clear directive in § 1498(a) as to the exclusive nature of the remedy provided therein." *Morpho Detection, Inc. v. Smiths Detection Inc.*, No. 2:11CV498, 2013 WL 5701522, at *4–5 (E.D. Va. Oct. 17, 2013).

VI. CONCLUSION

Moderna respectfully requests that the Court grant its motion pursuant to Rule 12(b)(6) and dismiss with prejudice Plaintiffs' claims based on Moderna's sale and provision of COVID-19 Vaccine doses to the U.S. Government. *D3D Techs.*, 2021 WL 2194601, at *2 (granting Rule 12(b)(6) motion, dismissing claims involving sales to the U.S. Government under § 1498); *IRIS Corp.*, 769 F.3d at 1283 (affirming Rule 12(b)(6) dismissal under § 1498).

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May 6, 2022

CERTIFICATE OF SERVICE

I hereby certify that on May 6, 2022, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on May 6, 2022, upon the following in the manner indicated:

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