IN THE UNITED STATES DISTRICT COURT FOR THE

DISTRICT OF DELAWARE

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

STATEMENT OF INTEREST OF THE UNITED STATES

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The United States (the Government) appears on behalf of its Department of Health and Human Services and Department of Defense pursuant to 28 U.S.C. § 517[1] to inform the Court of its interest in this litigation. The Government is aware of the Court's resolution of Moderna's motion to dismiss, D.I. 31 at 15–16, where the Court noted that the Government had not provided a statement of interest. In light of the Court's hesitance to find authorization and consent absent a statement of interest from the United States, the United States appears to present its position.[2]

I. THE INTEREST OF THE UNITED STATES

In accordance with 28 U.S.C. § 1498, the United States granted Moderna, Inc. and ModernaTX, Inc. ("Moderna")[3] its "authorization and consent" to manufacture and use inventions covered by United States patents under Contract No. W911QY-20-C-0100 (the '-0100 Contract), which is at issue in this litigation. The Government granted its authorization and consent by inserting the Federal Acquisition Regulation (FAR) clauses 52.227-1 and 52.227-1, Alternate I, in the contract. The Government's acceptance of liability in this instance is limited to the '-0100 Contract and does not extend to all of Moderna's allegedly infringing activity as described in the Complaint.

In pertinent part, section 1498 provides:

[1] Section 517 provides, in pertinent part, that "any officer of the Department of Justice[] may be sent by the Attorney General to any … district to attend to the interests of the United States in a suit pending in a court of the United States…or to attend to any other interest of the United States."

[2] The United States is prepared to appear, should the Court have questions regarding this statement of interest or require other assistance with respect to this statement.

[3] For the purposes of this statement of interest, the Government refers to Moderna, Inc. and ModernaTX, Inc. collectively as "Moderna."

> 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. . . .
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> . . . .
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> 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. . . .

(emphasis added). As explained below, the effect of the Government's "authorization and consent" is to relieve Moderna of any liability for patent infringement resulting in performance of the '-0100 Contract and to transfer to the United States any liability for the manufacture or use of the inventions claimed in the Patents-in-Suit resulting from the authorized and consented acts.[4] Accordingly, and to the extent that liability exists for such acts, the patentee is limited to pursuing a claim against the United States in the Court of Federal Claims pursuant to 28 U.S.C. § 1498.

The inclusion of FAR clauses 52.227-1 and 52.227-1, Alternate I in the '-0100 Contract constitutes the Government's express authorization and consent. Section 1498(a), therefore, provides the exclusive remedy for any infringement occurring in the course of Moderna's performance of the '-0100 Contract. The Government is not aware of any other contract at issue in this litigation where it granted authorization and consent, and therefore its authorization and consent does not extend to any other procurement of vaccine in this litigation beyond what has

[4] As used in this Statement, "liability" is defined as having legal responsibility for any acts that may constitute the alleged infringement; it is not an admission that the vaccine infringes. All issues relating to the merits of Arbutus's claim and the Government's defenses must be presented to, and addressed by, the Court of Federal Claims.

been procured under the '-0100 Contract. Accordingly, claims for infringement in the course of performance of the '-0100 Contract should be dismissed.

II. BACKGROUND

In response to the SARS-CoV-2 (COVID-19) pandemic, the United States engaged in a multi-agency effort to ensure the availability of medical supplies needed to alleviate shortages and to counteract the contagion; that effort was known as "Operation Warp Speed" (OWS). As part of OWS, the Department of Health and Human Services (HHS) and the Department of Defense (DOD) collaborated to coordinate the nation's efforts to accelerate the development, acquisition, and distribution of COVID-19 vaccines. Pursuant to a memorandum of understanding between HHS and DOD, COVID-19 vaccines were to be procured through contracts issued by DOD, with HHS providing subject-matter expertise and support in inspecting and accepting vaccine deliveries.

On August 11, 2020, the U.S. Army, on behalf of HHS and DOD, executed the '-0100 Contract[5] with ModernaTX, Inc. to purchase production quantities of Moderna's mRNA-1273 vaccine for prevention of COVID-19, which was then under development. *See* D.I. 17-1 at 2. The '-0100 Contract incorporates by reference standardized "authorization and consent" clauses: FAR clauses 52.227-1 (also referred to as the base or "narrow" clause) and 52.227-1, Alternate I (the Alternate I or "broad" clause). D.I. 17-1 at 47. Although there were multiple modifications to that contract, none removed or revised these FAR clauses.

[5] The '-0100 Contract contains information that Moderna considers proprietary and other information that may be sensitive government information. We understand that the Court has not issued a protective order in this case. The United States, however, is prepared to produce an unredacted copy of the '-0100 Contract either for the Court's inspection *in camera* or under a suitable protective order, should the Court find it useful.

The base version of FAR clause 52.227-1, 48 C.F.R. § 52.227-1, in pertinent part, provides that "(a) [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 – (1) [e]mbodied in the structure or composition of any article the delivery of which is accepted by the Government under this contract; . . . ." The Alternate I version of FAR clause 52.227-1 is broader in scope than the base version by omitting the requirement that the patented invention be "embodied" in the structure or composition of a delivered article. The Alternate I version provides, in pertinent part: "(a) [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."

The U.S. Army also entered into Contract No. W58P05-22-C-0017[6] (the '-0017 Contract) on July 28, 2022. This contract procures additional quantities of Moderna's COVID-19 vaccine. The '-0017 Contract contains neither FAR clause 52.227-1 nor FAR clause 52.227-1, Alternate I. The United States has not granted its authorization and consent, either explicitly or by implication, for use of patented inventions in the performance of the '-0017 Contract. To the contrary, the '-0017 Contract contains a special provision, H.14, that states the contracting parties' express agreement that the terms of the contract do not constitute express or implied Government authorization or consent under section 1498.

At this time, the Government is only aware of these two procurement contracts between the Government and Moderna that relate to the purchase of Moderna's mRNA-1273 vaccine at

[6] The '-0017 Contract will be administered by HHS pursuant to a modification recently executed by the parties.

issue here. And, as stated, only the '-0100 Contract grants the Government's authorization and consent.

III. ANALYSIS

In a suit between private parties, the invocation of 28 U.S.C. § 1498 is an affirmative defense. *Sperry Gyroscope Co. v. Arma Eng'g Co.*, 271 U.S. 232, 235–36 (1926); *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 554–55 (Fed. Cir. 1990). However, the Federal Circuit has also recognized that section 1498 "relieves a third party from patent infringement liability, and 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). The Federal Circuit has noted that these two views of the statute are not inconsistent:

> Without deciding, we see no inconsistency between interpreting section 1498(a) as a jurisdictional statute (waiving sovereign immunity) in suits against the United States and as merely codifying a defense that private parties who are alleged infringers may raise on the merits. That two different effects occur depending on the party raising section 1498(a) is the clear implication of *Sperry* [271 U.S. 232], and the other cases [*Trojan, Inc. v. Shat–R–Shield, Inc.*, 885 F.2d 854 (Fed.Cir.1989), and *W.L. Gore & Associates v. Garlock, Inc.*, 842 F.2d 1275, (Fed.Cir.1988)], read together.

Manville Sales, 917 F.2d at 555 n.6. In providing this statement of interest, the United States defines the parameters of its waiver of sovereign immunity with respect to this litigation and the liability that, if proven, the Government has consented to accept.

The origins of section 1498 began with the Act of June 25, 1910, 61st Cong., 2d Sess., 36 Stat. 851–52, which permitted a suit in the Court of Claims to recover for uses of the owner's patent by the Government. That statute was subsequently found to be limited to use of the invention by the Government, but not government contractors. *See Cramp & Sons Ship & Engine Bldg. Co. v. Int'l Curtis Marine Turbine Co.*, 246 U.S. 28, 42, 45 (1918).

Faced with the prospect that patent suits against government contractors may prevent the Government from procuring necessary war materials at the advent of this country's entry into World War I, Congress amended the 1910 Act to provide that the owner could sue to recover for "use or manufacture by or for the United States without license of the owner." Naval Appropriations Act of July 1, 1918, 65 Cong. 2d Sess., 40 Stat. 704, 705. In reviewing the statutory history, the Supreme Court concluded that,

> [t]he purpose of the amendment was to relieve the contractor entirely from liability of every kind for the infringement of patents in manufacturing anything for the government, and to limit the owner of the patent and his assigns and all claiming through or under him to suit against the United States in the Court of Claims[7] for the recovery of his reasonable and entire compensation for such use and manufacture.

Richmond Screw Anchor Co. v. United States, 275 U.S. 331, 345 (1928); *Leesona Corp. v. United States*, 599 F.2d 958, 967 (Ct. Cl. 1979) (en banc).[8]

The statute was further amended at the beginning of World War II by the Act of October 31, 1942, Pub. L. 768, § 6, 77th Cong. 2d Sess., 56 Stat. 1013, 1014 (The Royalty Renegotiation Act). That Act provided, in pertinent part, that,

> for the purposes of the Act of June 25, 1910, as amended [now section 1498] . . ., the use or manufacture of an invention described in or 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.

The purpose of the "authorization and consent" provision "was to broaden the scope of the act of June 25, 1910, as amended, so to remove any further doubt that subcontractors and other suppliers

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[7] The trial division of the Court of Claims became the Court of Federal Claims.

[8] Upon its creation, the Court of Appeals for the Federal Circuit adopted "the holdings of the Court of Claims and the Court of Customs and Patent Appeals announced before the close of business on September 30, 1982 . . . within the substantive jurisdiction" of the court as its precedent. *S. Corp. v. United States*, 690 F.2d 1368, 1370 (Fed. Cir. 1982).

of goods and materials to the government were included within the terms of that act to the same extent as prime contractors to the government were . . . ." *Bereslavsky v. Esso Stand. Oil Co.*, 175 F.2d 148, 150–51 (4th Cir. 1949) (quoting 2 Bulletin of the Judge Advocate General of the Army, 75–76 (1943) (internal quotation marks omitted)).

The Federal Circuit reads section 1498 broadly "so as not to limit the Government's freedom in procurement by considerations of private patent infringement." *TVI Energy Corp. v. Blane*, 806 F.2d 1057, 1060 (Fed. Cir. 1986). The structure of the statute describes the conditions that must be met for its invocation. Where the use or manufacture of the invention is "by the Government"—which is not the case here—the application of the statute is automatic and no further inquiry is required. *Hughes Aircraft Co. v. United States*, 534 F.2d 889, 902 (Ct. Cl. 1976) (direct and exclusive control of British satellite for launch in Florida was sufficient to meet "use by the Government").

Where the use or manufacture is "by a contractor, a subcontractor, or any person, firm, or corporation for the Government," a two-part inquiry is employed: whether "(1) the [allegedly infringing] use is 'for the Government' and (2) the [allegedly infringing] use is 'with 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).

The "for the Government" requirement is met if the allegedly infringing manufacture or use is "for the benefit of the Government," and not merely an incidental benefit from private activity. *IRIS Corp. v. Japan Airlines Corp.*, 769 F.3d 1359, 1362 (Fed. Cir. 2014); *see also Hughes Aircraft*, 534 F.2d at 897 (equating "for the Government" with "for the Government's benefit"). The Federal Circuit has cautioned against attempting to fathom the "primary purpose" of a contract. *Sevenson Env't*, 477 F.3d at 1365. Rather, the inquiry is focused on whether the

alleged infringing activity is addressed to a policy interest or objective of the United States. *See generally Adv. Software Design Corp. v. Fed. Rsrv. Bank of St. Louis*, 583 F.3d 1371, 1379 (Fed. Cir. 2009) ("benefits to the government of using the seal encoding technology on Treasury checks are not incidental effects" of private activity where the Government participated in providing the Treasury checks with the required technology); *Hughes Aircraft*, 534 F.2d at 898–99, 901 (stating the broad policy objectives of interoperability and common defense of Great Britain and United States were sufficient to meet "for the Government" standard); *cf. Riles v. Amerada Hess Corp.*, 999 F. Supp. 938, 940 (S.D. Tex. 1998) (finding that, while the oil lease may have satisfied "Congressional statements of national policy" of making the offshore oil field available for public use, the oil drilling activities carried out under the lease served only the interests of the lessee).

Under section 1498(a), authorization and consent may be either express or implied. *TVI Energy Corp.*, 806 F.2d at 1060. And "it is plain that the Government can limit its authorization and consent" in its contracts. *Carrier Corp. v. United States*, 534 F.2d 244, 249 (Ct. Cl. 1976). Thus, where the Government expressly states the limits of its authorization and consent in the contract, those limits will generally control. *Id.*; *see also Madey v. Duke Univ.*, 413 F. Supp. 2d 601, 608 (M.D.N.C. 2006) ("When the Government provides express consent, that consent may be very broad, extending to any patented invention and any infringing use, or may be limited to only certain patented inventions or to only those uses that are necessary or are specifically consented to by the Government.").

The '-0100 Contract contains express "authorization and consent" in the form of the well-established FAR clauses 52.227-1 and 52.227-1, Alternate I. Where, pursuant to a contract containing these FAR clauses, the Government accepts goods that allegedly infringe on a patent, those clauses typically "bring[ ] the matter within Section 1498 even if the contract could be

fulfilled with other noninfringing products." *Saint-Gobain Ceramics & Plastics, Inc. v. II-VI Inc.,* 369 F. Supp. 3d 963, 980 (C.D. Cal. 2019) (quoting 5 *Chisum on Patents* § 16.06 (2019)).[9]

As *Sevenson Environmental* further explains, the "for the Government" inquiry collapses into the "authorization and consent" inquiry where the Government directly contracts for goods or services and that contract provides the Government's authorization and consent. 477 F.3d at 1365 ("where infringing activity has been performed by a government contractor pursuant to a government contract and for the benefit of the government, courts have all but bypassed a separate inquiry into whether infringing activity was performed 'for the Government.'"). Accordingly, where the Government elects to include a contract provision expressly providing its authorization and consent, as it has done here, that decision is appropriately viewed as reflecting the Government's determination that the contract is for the Government's benefit.

In this instance, the United States submits that the truncated inquiry is appropriate. The Army procured substantial quantities of mRNA-1273 vaccine during the COVID-19 pandemic. The vehicle for purchasing that vaccine was the '-0100 Contract which contains the broad FAR clause 52.227-1, Alternate I, as well as the narrower base clause 52.227-1. And there is no question here that the Government paid for the vaccine as required by the contract and that the vaccine was delivered in accordance with the contract (indeed, Arbutus's claim of patent infringement presumes that vaccine was manufactured and distributed, and therefore it claims to be damaged). No further "for the Government" inquiry is required under these circumstances: the contract's

[9] Where the Government has granted express authorization and consent, the limits of that grant will generally control. *Carrier*, 534 F.2d at 249. To the extent that implied authorization and consent could be found, it would generally act to broaden the scope of the Government's liability, not to restrict it. *See id.* (discussing how the decision in *Croll-Reynolds Co. v. Perini-Leavell-Jones-Vinell*, 399 F.2d 913 (5th Cir. 1968), could be read to expand a "narrow" express authorization and consent clause through implied consent where equipment was specially assembled to comply with contractual provision to cool concrete).

provisions demonstrate that the contract was "for the Government" and therefore "for the benefit of the Government."

Where, as here, the Government directly contracts to procure the allegedly infringing goods or services in a contract that grants authorization and consent, the "benefit to the Government" is inherent. Indeed, the contractor's compliance with the contract's obligations alone demonstrate the benefit: that the Government obtains goods and services for which it pays is alone sufficient to demonstrate the procurement is "for the Government" and "for the benefit of the Government." Consequently, even if the Court chooses to examine the "benefit to the Government" prong, the Government has received the benefit of its contract, namely, procuring the vaccine that it then offered for free public distribution in an effort to thwart the COVID-19 pandemic. *See Hughes Aircraft*, 534 F.2d at 901 (finding benefit in meeting governmental objectives or interests).

Finally, we turn to the authorities and argument presented by the parties and addressed by the Court in its Order, D.I. 31. The Court noted that, given the early stage of this litigation and based on the allegations in the Complaint (which must be taken as true at the motion to dismiss stage), the case before it was more akin to *Larson*, where no authorization and consent was found and any benefit to the Government was merely incidental, rather than *Advanced Software Design* or *Saint-Gobain,* where the Government's authorization and consent was found to be implied or express, and the Government received a benefit. D.I. 31 at 12–13. As explained below, the Government submits that of the three cases discussed, *Saint-Gobain* is on point here and *Advanced Software Design*'s discussion of authorization and consent guides the present inquiry.

Like the present case, *Saint-Gobain* involved express contractual authorization and consent. 369 F. Supp. 3d at 969–70 (stating that contracts by which II-VI Inc. sold products to Lockheed contained an authorization and consent clause, and that Lockheed's prime contracts also

contained an authorization and consent clause). The court found the benefit to the Government was clear because the Government contracted with Lockheed for aircraft, while granting its authorization to Lockheed and its subcontractors. *Id.* The benefit in *Saint-Gobain* was the production of the aircraft that the Government contracted to buy. Indeed, the present case is even clearer in that the Government directly contracted with Moderna to procure a specific vaccine, and there is no intermediate contractor.

On the other hand, in both *Advanced Software Design* and *Larson*, the party claiming the benefit of section 1498 could not point to a contract with the Government. *Adv. Software Design Corp.*, 583 F.3d at 1374 (no contract between Government and Federal Reserve Bank); *Larson v. United States*, 26 Cl. Ct. 365, 367–68 (1992) (government contracts were with carriers and fiscal intermediaries, not doctors). As a result, the courts in those cases had to engage in a more detailed inquiry into whether the Government had granted authorization and consent. *Cf. IRIS Corp*, 769 F.3d at 1362 (providing that "a governmental grant of authorization or consent does not mean that the alleged use or manufacture is done 'for the United States' under § 1498(a)" where the court determined that a *regulatory statute*, rather than a *direct procurement contract*, provided authorization and consent).

In *Larson*, plaintiff owned patents for plastic medical splints. 26 Cl. Ct. at 367. Health care providers participating in government programs including Medicare, Medicaid, and the medical health plan for military families provided medical treatment to patients using splints that allegedly infringed plaintiffs' patents. *Id.* The healthcare providers submitted claims for reimbursement, and the programs "through their carriers and fiscal intermediaries, determine the rates and amounts of payments to providers, and reimburse health care providers for the procedure rendered to the patient." *Id.*

The *Larson* court began by addressing the "authorization and consent" prong. *Id.* at 369. Plaintiffs conceded that the Government had not expressly granted authorization and consent, but asserted implied authorization and consent based on the provision of "reasonable and necessary" medical services to patients that government health plans reimbursed. *Id.* at 370. Based on that record, the trial court found that the Government did not grant its authorization and consent by implication. *Id.* at 371. While the health plans reimbursed "reasonable and necessary" medical services, only "code numbers" were provided to the government programs, the "details of the treatment . . . remain[ed] with the patient and his or her provider." *Id.* In rejecting Larson's argument that the reimbursement of these medical devices was "for the Government" under section 1498, the court noted that the Government "has no interest in the particular medical products used in treatment . . . [and] [t]he 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 the purposes underlying § 1498." *Id.* at 369. Moreover, the court noted that "mere reimbursement is not authorization to infringe on patent rights." *Id.* Nor could such authorization to infringe "be reasonably inferred" from the public health statutes at issue in that case. *Id.* at 370. Further, the facts demonstrated that the doctor—not the Government—determined the type of splinting material to be used from a variety of available types. *Id.* at 370–71 (stating that 16 types of splints and casts were available and describing reimbursement of medical expenses as a "billing arrangement"). And, importantly, in *Larson* the Government affirmatively denied the existence of authorization and consent in the litigation.

Advanced Software Design also presents a factually different scenario because no contract existed between the Federal Reserve Bank or its supplier and the United States. 583 F.3d at 1376. Nonetheless, the trial court found, and the Federal Circuit affirmed, that the Bank had been granted

the Government's authorization and consent by means of correspondence between the Treasury and the Bank, both before and after the infringement claim arose. *Id.* at 1377. Importantly, in *Advanced Software Design*, the Federal Circuit also recognized that, to the extent that the Government's earlier statements were ambiguous, the Government's appearance and assertion of authorization and consent before that court resolved the issue. *Id.* at 1378.

Under the facts of this case, the sales of the vaccine to the Government pursuant to the terms of the '-0100 Contract, which expressly includes the FAR clauses granting the Government's authorization and consent, satisfy the requirements of 28 U.S.C. § 1498(a) that the procurement was "for the Government" and with its authorization and consent. And to the extent that any doubt otherwise existed, the Government's filing of this statement of interest and confirmation of its authorization and consent should resolve the issue. Accordingly, to the extent that any liability exists for infringement of the Patents-in-Suit by the manufacture or use of vaccine procured under the '-0100 Contract, the patentee is limited to pursuing a claim against the United States in the Court of Federal Claims under 28 U.S.C. § 1498(a).

Respectfully submitted,

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