

IN THE UNITED STATES DISTRICT COURT FOR THE  
DISTRICT OF DELAWARE

AR BUTUS BIOPHARMA CORPORATION  
AND GENEVANT SCIENCES GMBH,

Plaintiffs,

v.

MODERNA, INC. and MODERNATX, INC.

Defendants.

C.A. No. 22-252 (MSG)

**UNITED STATES' LETTER IN RESPONSE TO THE COURT'S ORDER, D.I. 51**

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Dear Judge Goldberg:

The Government writes in response to the Court’s Order (D.I. 51), which directed the Government and the parties to address “the impact of the Government’s Statement of Interest on the scheduling in this matter.” As noted in the Initial Pretrial Conference, the Government submits that the Statement of Interest fully resolves the questions raised by the Court and Plaintiffs at the conference with respect to the applicability of 28 U.S.C. § 1498 to Contract No. W911QY-20-C-0100 (the ’-0100 Contract).

As restated during the conference, the Government asserts that Moderna acted with Government’s *express* authorization and consent in its performance of the ’-0100 Contract, as evidenced by the inclusion of FAR clauses 52.227-1 and 52.227-1, Alternate I, and as expressed in the Statement of Interest. The Government contracted for and received delivery of vaccine as prescribed in the ’-0100 Contract, demonstrating that such procurement was “for the Government.” The vaccine so produced was made with the authorization and consent of the Government and accepted by the Government. Accordingly, the requirements of section 1498 are satisfied, and Plaintiffs’ infringement claims against Moderna relating to vaccine delivered under the ’-0100 Contract are properly before the United States Court of Federal Claims.

During the conference, Plaintiffs argued that discovery is required to determine “whether Moderna was under the Government’s control” during development and testing of the accused vaccines, and that this would elucidate whether the vaccine was “for the Government.” This is incorrect. Whether a contractor was under “Government control” is only an issue where implied authorization and consent is alleged. In such cases, authorization and consent may be “implied by necessity” where the action of the Government causes the infringement, although no express contract provision grants authorization and consent. *See also IRIS Corp. v. Japan Airlines Corp.*, 769 F.3d 1359, 1362 (Fed. Cir. 2014) (“[The contractor] cannot comply with its legal obligations without engaging in the allegedly infringing activities.”); *Bereslavsky v. Esso Standard Oil Co.*, 175 F.2d 148, 149 (4th Cir. 1949) (compliance with government directives resulted in infringement); *see generally Auerbach v. Sverdrup Corp.*, 829 F.2d 175, 180 (D.C. Cir. 1987) (discussing copyright authorization and consent provision of section 1498(b)).

Here, the ’-0100 Contract itself—an *express* procurement contract between Moderna and the Government—demonstrates that the procurement of vaccine doses was for the “benefit of the Government,” regardless of whether the Government “controlled” Moderna. Indeed, where there is an express grant of authorization and consent, the question of whether a procurement contract is for the benefit of the Government is a truncated inquiry. *Sevenson Env’t Servs., Inc. v. Shaw Env’t, Inc.*, 477 F.3d 1361, 1365–66 (Fed. Cir. 2007) (holding that the Government’s contracts for and receipt of waste remediation services were the only facts relevant to the “for the Government” inquiry when the contracts included express authorization and consent clauses). “[W]here 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 the separate inquiry into whether infringing activity was performed ‘for the Government.’” *Id.* No further discovery as to “Government control” is necessary.

We also understood Plaintiffs to argue that there may be claims arising from the '-0100 Contract related to indirect infringement (either contributory or induced infringement) notwithstanding the applicability of section 1498. This is incorrect under the facts alleged in the Complaint, as Moderna's obligations were outlined in the '-0100 Contract, and any liability for patent infringement performed in fulfilment of the '-0100 Contract to produce vaccine falls to the Government. The effect of 28 U.S.C. § 1498 is to *entirely* relieve the contractor of liability for claims of patent infringement arising from the fulfillment of its contractual obligations, and as such, the contractor cannot be held liable for inducing or contributing to related infringement when section 1498 applies. *See* 28 U.S.C. § 1498(a) ("[T]he use or manufacture of an invention described in and covered by a patent of the United States by a contractor...or any person...shall be construed as use or manufacture for the United States."); *Richmond Screw Anchor Co. v. United States*, 275 U.S. 331, 343 (1928); *Crozier v. Fried. Krupp Aktiengesellschaft*, 224 U.S. 290, 302, 305 (1912); *Leesona Corp. v. United States*, 599 F.2d 958, 966–69 (Ct. Cl. 1979) (explaining § 1498 and its history).

While we agree that the Court is the final authority as to whether to dismiss Plaintiffs' claim where the Government has granted its authorization and consent, section 1498 and the binding precedent interpreting it makes clear that the Government's express grant of authorization and consent should generally be determinative of the issue. *See Advanced Software Design Corp. v. Fed. Reserve Bank of St. Louis*, 583 F.3d 1371, 1376 (Fed. Cir. 2009). Indeed, we are not aware of any case where a district court has refused to grant dismissal of claims after the Government asserted its "authorization and consent" pursuant to section 1498. *See, e.g., IRIS Corp. v. Japan Airlines Corp.*, 769 F.3d 1359 (Fed. Cir. 2014); *Arlton v. Aerovironment, Inc.*, No. 20-cv-7438, 2021 WL 1589302 (C.D. Cal. Apr. 22, 2021).

As the Court correctly noted at the Initial Pretrial Conference, the Government is not a party to these proceedings. Accordingly, the Government takes no position on how the case should proceed with respect to scheduling or Plaintiffs' remaining claims.

Respectfully submitted,

*/s/ Philip Charles Sternhell*  
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cc: Clerk of the Court (by CM/ECF)  
All counsel of record (by CM/ECF)