IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARBUTUS BIOPHARMA CORPORATION and GENEVANT SCIENCES GMBH,	:	
	:	**CIVIL ACTION**
Plaintiffs,	:	
v.	:	
	:	**NO. 22-252**
MODERNA, INC. and MODERNATX, INC.,	:	

MEMORANDUM OPINION

Goldberg, J. **March 10, 2023**

Context is important. This is particularly so in litigation and in considering the stage of a proceeding. In the patent infringement matter before me, which is at the pleading stage, the parties, now joined by the United States and several *Amici Curiae*, hotly contest the application of 28 U.S.C. § 1498(a). This statute instructs that whenever it is alleged that a patent has been used by the United States in an infringing manner, litigation shall occur in the United States Court of Federal Claims, which is where Defendants Moderna, Inc. and Modernatx, Inc. (collectively, "Moderna") urge that a majority of this case must be decided.

It is well settled that an accused infringer, such as Moderna, bears the burden of establishing under § 1498(a) that the infringing use is "for the Government" and "with authorization and consent of the Government." Sevenson Envt'l Servs., Inc. v. Shaw Envt'l, Inc., 477 F.3d 1361, 1365 (Fed. Cir. 2007). These standards clearly implicate factual considerations, and in the context of the pleading stage of this case, where I am obligated to assume the veracity of the facts pled in the Complaint, weighing facts is inappropriate. Burtch v. Milberg Factors, Inc., 662 F.3d 212, 221 (3d Cir. 2011). Consequently, the Government's recently filed Statement of Interest does not change

my view that Moderna's request to transfer a portion of this matter to the Federal Claims Court is premature and must be denied at this time. My brief reasoning follows.

Most of the necessary background regarding § 1498(a) is set forth in my November 2, 2022 Opinion that addressed Moderna's partial motion to dismiss. That motion asserted that some of Plaintiff's patent infringement claims should proceed in the Court of Federal Claims pursuant to 28 U.S.C. § 1498(a). I denied that request on November 2, 2022, finding that Moderna's Rule 12(b)(6) motion was not an appropriate vehicle to resolve the § 1498(a) issue. Arbutus Biopharma Corp. v. Moderna, Inc., No. 22-cv-252, 2022 WL 16635341, at *7–8 (D. Del. Nov. 2, 2022). Following submission of the parties' Answers and Counterclaims, I set a Rule 16 scheduling conference to be held on February 16, 2023.

Two days prior to that conference, the United States Government filed a Statement of Interest, asserting that any doses of the vaccine produced by Moderna pursuant to the terms of Contract No. W911QY-20-0100 (the '-0100 Contract) were "for the Government" and "with the authorization and consent of the Government." During the Rule 16 conference, counsel for the parties and the Government (who I invited to participate) addressed the import of this Statement of Interest. Letter briefs, including those of *Amici*, have subsequently been submitted and considered.

As set out in my November 2, 2022 Opinion, § 1498(a) establishes an affirmative defense, not a jurisdictional bar. Manville Sales Corp. v. Paramount Sys., Inc., 917 F.2d 544, 554 (Fed. Cir. 1990). Importantly, I also noted that a § 1498(a) affirmative defense presents a highly factual determination. Toxgon Corp. v. BNFL, Inc., 312 F.3d 1379, 1382–83 (Fed. Cir. 2002). Viewing as true the well-pled facts in the Complaint, I found that Moderna had not established as a matter of law that § 1498(a) applied, and that the issue was best resolved after discovery.

Moderna continues to press its point that § 1498(a) requires transfer of part of this case to the Court of Federal Claims. Now, heavily relying on the recently filed Statement of Interest,

Moderna urges that, "the Government is in the best position to decide what is for its benefit." (Moderna Letter brief, p. 2.) But neither the Government nor Moderna have provided any authority suggesting that the Government's interpretation of § 1498(a) trumps a court's analysis of this issue. And I note that the very contract that Moderna relies upon also states that vaccine was to be developed to "improve *patient care*," thereby "mitigating the impact of COVID-19 on the nation and *its people*." (D.I. 17-1, Ex. A (emphasis added)); see Larson v. United States, 26 Cl. Ct. 365 (Cl. Ct. 1992) ("[M]edical care is provided for the benefit of the patient, not the government.").

While the Statement of Interest does point to certain evidence that Moderna's sales under the '-0100 Contract may have been with the "authorization and consent" of the Government, Moderna offers no evidence that sales were "for the Government" which is also a necessary factor under §1498(a). But in any event, examination of evidence in the context of Fed. R. Civ. P. 12(b)(6) is not proper. Rather, I will consider the § 1498(a) issue after both parties have engaged in discovery, which will provide Plaintiff an opportunity to review the entire unredacted version of the '-0100 Contract and discover facts regarding that Contract.

The recent submissions by the parties underscore why discovery on this issue is needed. Moderna originally moved to dismiss Plaintiffs' claims as to *all* of its sales of COVID-19 vaccine doses to the U.S. Government. But now, both the Government and Moderna acknowledge that claims regarding sales under a second Government contract (W58P05-22-C-0017 (the '-0017 Contract)) were not with the authorization and consent of the Government and should not be dismissed. Had I granted the relief Moderna sought in its original motion to dismiss, this fact would not have come to light and the relief ordered could have been incorrect. Discovery is necessary to ensure that any application of § 1498(a) is based upon developed facts and not solely on the Government's say-so.

I reaffirm the analysis and conclusions set forth in my November 2, 2022 Memorandum Opinion and again conclude that the Complaint should not be partially dismissed based on 28 U.S.C. § 1498(a). An appropriate Order follows.