IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
FORT WORTH DIVISION

STATE OF TEXAS, ET AL., Plaintiffs, v. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, ET AL., Defendants. EMANUEL MCCRAY, *On Behalf of Himself and All Others Similarly Situated*, Intervenors-Plaintiffs.	**Case No.: 4:23-cv-00066-Y** **INTERVENORS' REPLY TO [DOC. 10]**

Perry Mason once said: "Murder is usually very simple. It's the getting away with it that's real complicated and tricky".[1]

In their Response, Doc. 10, Defendants advance several legal theories and precedents in opposition to the motions to intervene and for class certification.

[1] Perry Mason. *The Case of the Frantic Flyer*. Season 3, Episode 12. @ 50:36. Available from https://www.amazon.com/gp/video/detail/B077LXZRSX/ref=atv_dp_season_select_s3.

Defendants' arguments, like those advanced by the Plaintiffs, are akin to an elegantly decorated inedible cake.

Defendants argue that "McCray's motion to intervene should be denied because he cannot represent the class that he purports to represent", Doc. 10 at 3, and "McCray's motion to intervene should be denied because he cannot show that he meets the requirements for intervention." (Doc. 10 at 4)

The Defendants are confused. McCray filed his motions pursuant to Rule 24 of the Federal Rules of Civil Procedure (Fed. R. Civ. P.), the Declaration of Independence, our sovereign power reserved to the People in the Tenth Amendment, and our power as a group acting as a class pursuant to *Bond v. United States*, 572 U.S. 844, 853 (2014),[2] and *Califano v. Yamasaki*, 442 U.S. 682, 700, (1979).[3] (Doc. 5 at 2).

Defendants further argue that "McCray's motion to intervene should be denied for failure to comply with the Local Civil Rules" regarding "a certificate of conference". (Doc. 10 at 6)

Again, the Defendants are confused. N.D. TEX. L.R. 7.1(a), in part, provides that: "Conferences are not required. . .when a conference is not possible." N.D. Tex. L.R. 7.1(b)(3) further provides that:

[2] Holding that: "'An individual may 'assert injury from governmental action taken in excess of the authority that federalism defines.'"

[3] Holding that "class relief is appropriate in civil actions brought in federal court, including those seeking to overturn determinations of the departments of the Executive Branch of the Government in cases where judicial review of such determinations is authorized…. Indeed, a wide variety of federal jurisdictional provisions speak in terms of individual plaintiffs, but class relief has never been thought to be unavailable under them."

> "If a conference was not held, the certificate must explain why it was not possible to confer, in which event the motion will be presumed to be opposed."

McCray provided the certification required by Local Rule 7.1(a) and (b)(3), as follows:

> "In accordance with Local Rule 7.1(b)(3), a conference was not held because the Defendants have not made an appearance as of January 29, 2023. The last action on the Docket occurred on January 19, 2023 with the issuance of the Summons as to all Defendants. This motion must be presumed to be opposed." (Doc. 6 at 2.)

To state differently, Defendants concede that, after being served on the dates indicated in Doc. 4 with Summons and a copy of the Complaint filed by Texas and Oklahoma, they did not file a Notice of Attorney Appearance until March 3, 2023, which simply left no one with whom to confer regarding McCray's motions filed on February 10, 2023. See Doc. 10 ¶¶ 2-3.

The question before the Court is very important due to recent developments in the ongoing COVID-19 pandemic. On March 2, 2023, McCray filed a Motion to Intervene ("Delaware Intervention") in *Arbutus Biopharma Corporation et al. v. Moderna, Inc. et al*, Case No. 1:22-cv-00252-MSG, in the U.S. District Court District of Delaware (Wilmington).

The Delaware Intervention was sought after the United States (the Government) appeared "on behalf of its Department of Health and Human Services and Department of Defense" to assert as an affirmative defense, the fact that the

United States granted Moderna, Inc. and ModernaTX, Inc. "its 'authorization and consent' to manufacture and use inventions covered by United States patents under Contract No. W911QY-20-C-0100 (the '-0100 Contract)".

The Delaware Intervention sought a narrow declaration that "the '-0100 Contract" and 28 U.S.C. § 1498, were unavailable for use by Moderna, Defendant HHS and the Department of Defense to shift (1) Moderna's liabilities for infringements of patents owned by Arbutus Biopharma and (2) Moderna's liabilities for the safety and efficacy of the vaccine products made from these infringements" to the People of the United States. (*Id.* D.I. 60-1 ¶ 6.)

On March 8, 2023, the Honorable Judge Mitchell S. Goldberg denied McCray's Motion To Intervene after finding, *inter alia*, that standing to intervene was unavailable to McCray in patent cases and that "even if Defendants are ultimately successful in having part of the current patent litigation transferred to the Court of Federal Claims, there will be no impact on McCray's tort claims against Defendants in another jurisdiction." (*Id.* D.I. 63 ¶¶ 6, 8, attached hereto as Intervenors' Reply Exhibit 1). Judge Goldberg next gave the Plaintiffs permission to discover the '-0100 Contract unredacted. (*Id.* D.I. 64, attached hereto as Intervenors' Reply Exhibit 2).

The redacted version of the '-0100 Contract and its amendments were filed by Moderna with the Securities and Exchange Commission as part of its Form 10-K

filings for the years ending December 31, 2020 and December 31, 2021. These contracts were executed pursuant to Public Law 115–92, §1(a), 131 Stat. 2023 [21 U.S.C. §360bbb–3(b)(1)(B)], a "counterterrorism" legislation:

> "An Act To amend the Federal Food, Drug, and Cosmetic Act to authorize additional emergency uses for medical products to reduce deaths and severity of injuries caused by agents of war, and for other purposes."

To state differently, the use of Public Law 115–92, §1(a) by Moderna and Defendant HHS to develop COVID-19 vaccines converted "SARS-COV-2" into an "agent[] of war" and the COVID-19 pandemic into a declaration of biological war by the World Health Organization and the Communist Party of China, in violation of the Biological Weapons Anti-Terrorism Act of 1989 (the "Biological Weapons Act"), Pub. L. No. 101-298, 104 Stat. 201 (1990) (codified as amended at Chapter 10, 18 U.S.C. §§ 175 - 178 (2021).

On April 30, 2020, President Trump confirmed during a White House Press Conference[4] that the Communist Party of China and the WHO attacked the United States with a virus that originated with the Wuhan Institute of Virology. When asked whether he had seen anything that gave him a "high degree of confidence that the Wuhan Institute of Virology was the origin of this virus", President Trump

[4] *Remarks by President Trump on Protecting America's Seniors.* White House East Room. April 30, 2020. Available from https://trumpwhitehouse.archives.gov/briefings-statements/remarks-president-trump-protecting-americas-seniors/.

responded: "Yes, I have. Yes, I have…. I think the World Health Organization should be ashamed of themselves."

When pressed on his "high degree of confidence", President Trump responded: "I can't tell you that. I'm not allowed to tell you that."

For its counterclaim, Moderna cited a non-peer reviewed Preprint[5] which was co-authored by Moderna, Inc. and the National Institute of Allergy and Infectious Diseases (NIAID), among others. The Preprint, which was funded by Defendant HHS and the NIAID, made no reference to the full genome sequence of the SARS-CoV-2 virus which was first submitted by the Shanghai Public Health Clinical Center & School of Public Health, Fudan University, Shanghai, China to the U.S. National Institutes of Health (NIH) on January 5, 2020 as "Primary Locus Genome Sequence GenBank No. MN908947" (Severe acute respiratory syndrome coronavirus 2 isolate Wuhan-Hu-1, complete genome).[6]

On January 10, 2020, after the genome sequence was made public in the NIH's "GenBank", Edward "Eddie" C. Holmes, an acquaintance of Anthony Fauci, who was the Director of the NIAID, posted a link to GenBank on the Virological.org website.[7]

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[5] *SARS-CoV-2 mRNA Vaccine Development Enabled by Prototype Pathogen Preparedness*, bioRvix.org, at 5–6 (June 11, 2020) ("Moderna/NIH Preprint"). Available from https://www.biorxiv.org/content/10.1101/2020.06.11.145920v1.full.

[6] Available from https://www.ncbi.nlm.nih.gov/nuccore/MN908947.

[7] Novel 2019 coronavirus genome. January 10, 2020. Available from https://virological.org/t/novel-2019-coronavirus-genome/319

On January 11, 2020, news of the genome sequence posted by Eddie Holmes was reported by Science Magazine.[8]

The NIH NIAID Grant No. T32-AI007151, referenced in Moderna's Preprint, is commonly associated with research conducted at the University of North Carolina at Chapel Hill, which has been funded by the NIAID since at least 1985 under the "Project Narrative" titled "Infectious Disease Pathogenesis Research Training Program",[9] and is the same funding mechanism used by Moderna to prepare the Preprint and develop a "prototype pathogen" for its COVID-19 vaccines.[10]

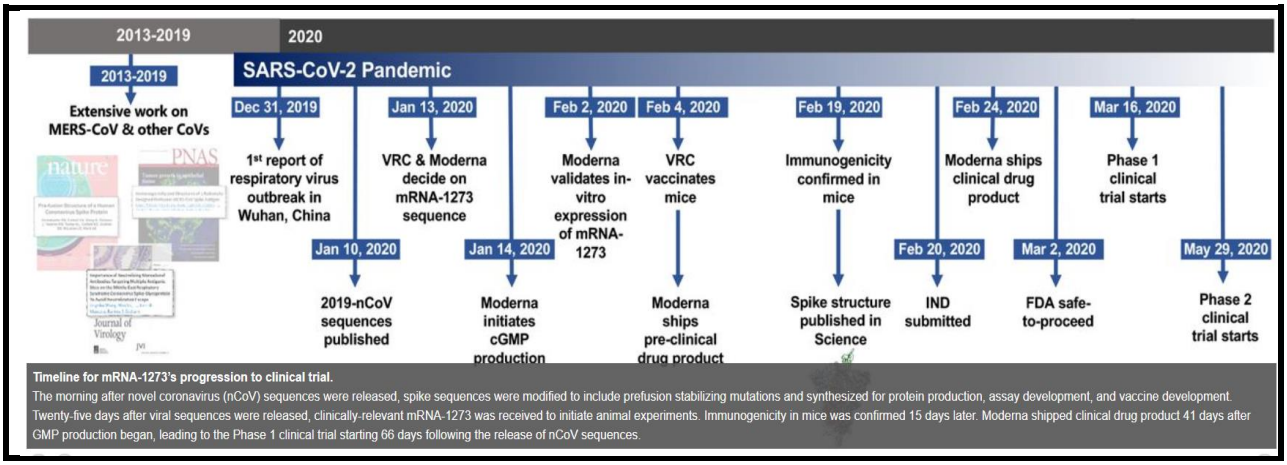
In its Preprint, Moderna claims that within 5 days of sequence release on January 10, 2020, current Good Manufacturing Practice (cGMP) production of "mRNA/LNP expressing the SARS-CoV-2 S-2P as a transmembrane-anchored protein with the native furin cleavage site (mRNA-1273)" had been initiated in parallel with preclinical evaluation. This, Moderna claims, "led to the start of a first in human Phase 1 clinical trial on March 16, 2020, 66 days after the viral sequence was released, with a Phase 2 that began 74 days later on May 29, 2020. The

[8] Jon Cohen. *Chinese researchers reveal draft genome of virus implicated in Wuhan pneumonia outbreak.* January 11, 2020. Available from https://www.sciencemag.org/news/2020/01/chinese-researchers-reveal-draft-genome-virus-implicated-wuhan-pneumonia-outbreak.

[9] Available from https://reporter.nih.gov/search/1DhNG2eJl0a_pl96ntZZrQ/projects.

[10] *SARS-CoV-2 mRNA Vaccine Development Enabled by Prototype Pathogen Preparedness,* bioRvix.org, at 5–6 (June 11, 2020) ("Moderna/NIH Preprint"). Available from https://www.biorxiv.org/content/10.1101/2020.06.11.145920v1.full.

complete "prototype pathogen" timeline for Moderna's mRNA-1273's progression to clinical trial in 2020 started seven years earlier in 2013:[11]



To state differently, Moderna claimed its COVID-19 vaccines are based on a "Prototype Pathogen": "This is fundamental to the prototype pathogen approach for pandemic preparedness",[12] a "prototype pathogen" program funded by Anthony Fauci while serving as the Director of the NIAID.[13] In September 2022, the "Prototype Pathogen" approach of Moderna and the NIAID was heralded as an advancement in pandemic preparedness by the Biden Administration.[14]

The biological agent of war, a planned "prototype pathogen" given the name "SARS-CoV-2", constitutes false or misleading information and a hoax which

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[11] *Id.* Extended Data Figure 2 to "Moderna/NIH Preprint". Available from https://www.biorxiv.org/content/10.1101/2020.06.11.145920v1.full.pdf.

[12] *Id.* at 5, lines 73-74.

[13] Anthony Fauci, *et al.*, *Prototype Pathogen Approach for Vaccine and Monoclonal Antibody Development: A Critical Component of the NIAID Plan for Pandemic Preparedness.* J Infect Dis. 2022 Jul 25:jiac296. doi: 10.1093/infdis/jiac296. Epub ahead of print. PMID: 35876700; PMCID: PMC9384504. Available from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9384504/;

[14] See *First Annual Report on Progress Towards Implementation of the American Pandemic Preparedness Plan* ("The U.S. Government continues to expand its capabilities for development of next-generation COVID vaccines and vaccines against other high-priority viruses…utilizing the prototype pathogen approach…." Available from https://www.whitehouse.gov/wp-content/uploads/2022/09/09-2022-AP3-FIRST-ANNUAL-REPORT-ON-PROGRESS.pdf

violates 18 U.S.C. §1038(a), for which a civil cause of action is provided under 18 U.S.C. §1038(b).

On or about March 5, 2023, the House Select Subcommittee on the Coronavirus Pandemic Majority Staff released its Report[15] pointing to "new evidence" that on February 1, 2020, Dr. Anthony Fauci, Dr. Francis Collins, and at least eleven other scientists convened a conference call to discuss how to conceal the fact that the biological agent of war, a planned "prototype pathogen" given the name "SARS-CoV-2" "leaked from a lab in Wuhan, China and, further, may have been intentionally genetically manipulated". See Intervenors' Reply Exhibit 3.

The "new evidence" revealed Dr. Fauci "prompted" the drafting of "Proximal Origin",[16] a science paper that would "disprove" the lab leak theory, and where Fauci and the authors of this paper "skewed available evidence to achieve that goal", is consistent with the allegations in ¶¶ 21-23, 26, and 37-110 of Intervenors' proposed Complaint. (Doc. 7).

In *State v. Rosado*, 134 Conn. App. 505, 517 n.4 (Conn. App. Ct. 2012), the Court made reference to "[t]he dog that didn't bark in the night", which was a point made by Sherlock Holmes in "Silver Blaze", a story by Sir Arthur Conan Doyle. The fact that the watch dog did not bark while the racehorse was being stolen led

[15] *New Evidence Resulting from the Select Subcommittee's Investigation into the Origins of COVID-19 – "The Proximal Origin of SARS-CoV-2"*. March 5, 2023. Available from https://oversight.house.gov/wp-content/uploads/2023/03/2023.03.05-SSCP-Memo-Re.-New-Evidence.Proximal-Origin.pdf.

[16] Andersen KG, Rambaut A, Lipkin WI, Holmes EC, Garry RF. The proximal origin of SARS-CoV-2. Nat Med. 2020 Apr;26(4):450-452. doi: 10.1038/s41591-020-0820-9. PMID: 32284615; PMCID: PMC7095063. Available from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7095063/.

Holmes to conclude that: "Obviously the midnight visitor was someone whom the dog knew well."

Here, Defendant HHS knew the WHO and the Communist Party of China declared biological war against the United States and its citizens by converting a "gain-of-function" coronavirus into a planned biological "agent of war" given the name "SARS-CoV-2", but remained silent, as did the watch dog in Silver Blaze.

Defendants' opposition makes the case for both intervention and class certification for declaratory relief given recent developments regarding the true nature and origin of the bioterrorist attack disguised as a pandemic.

CONCLUSION

For the reasons set forth above, the proposed Intervenors-Plaintiffs respectfully request that the Court grant their motion to intervene as of right, or, in the alternative, allow the Proposed Intervenors-Plaintiffs to intervene permissively.

Respectfully submitted this 12th day of March 2023.

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INTERVENORS' REPLY EXHIBIT 1

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.,	:	

ORDER

AND NOW, this 8th day of March, 2023, upon consideration of the Motion to Intervene filed by Emanuel McCray (D.I. 60), I find the following:

1. On March 2, 2023, McCray filed a Motion to Intervene in this matter along with a proposed class action complaint. The proposed complaint seeks "a declaration that Moderna's failure to procure a contract for production" of its COVID-19 vaccines before infringing Plaintiffs' patents "precludes and prevents Moderna and the United States from shifting Moderna's liabilities for infringing Plaintiffs' patents to the United States." (D.I. 60-1 ¶ 94.)

2. Federal Rule of Civil Procedure 24 sets forth the standard for intervention. The Rule provides, in pertinent part:

> **(a) Intervention of Right.** On timely motion, the court must permit anyone to intervene who:
> . . .
> **(2)** claims an interest relating to the property or transaction that is the subject of the action, and is so situated that disposing of the action may as a practical matter impair or impede the movant's ability to protect its interest, unless existing parties adequately represent that interest.
> . . .
> **(b) Permissive Intervention**.
>
> **(1) In General.** On timely motion, the court may permit anyone to intervene who:
> . . .

> **(B)** has a claim or defense that shares with the main action a common question of law or fact.

Fed. R. Civ. P. 24.

3. To intervene as of right under Federal Rule of Civil Procedure 24(a), a party must show "(1) a sufficient interest in the litigation; (2) 'a threat that the interest will be impaired or affected, as a practical matter, by the disposition of the action'; *and* (3) that its interest is not adequately represented by the existing parties to the litigation." Commonwealth of Pa. v. President United States of America, 888 F.3d 52, 57 (3d Cir. 2018) (emphasis added) (quotation omitted).

4. McCray fails to establish either the first or the second element. McCray's allegations against Defendants generally contend that the vaccines were released to the public with known serious health risks. (D.I. 60-1 ¶¶ 34, 57, 67.) He seeks intervention both as of right and permissively "solely to challenge Moderna's attempt to shift liability for its . . . vaccines to the United States." (D.I. 60 at p. 3.) More specifically, the proposed Intervenor Complaint seeks "a narrow declaration that Contract No. W911QY-20-C-0100 (the '-0100 Contract) and 28 U.S.C. § 1498 are unavailable for use by the United States to shift Moderna's liability to the People of the United States for its infringements of Plaintiffs' patents and Moderna's liability for the safety and efficacy of the vaccine products made from these infringements." (D.I. 60-1 ¶ 6.)

5. To the extent McCray seeks to challenge the use of § 1498 in the underlying patent litigation, McCray is not the patentee and, therefore, does not have standing to challenge Defendants' efforts to use § 1498 and shift patent infringement liability to the United States. See 35 U.S.C. § 281 (noting that a civil action for patent infringement may be brought only by a "patentee."); see also 35 U.S.C. § 100(d) (defining "patentee" as "not only the patentee to whom the patent was issued but also the successors in title to the patentee.").

6. To the extent McCray is concerned that Defendants' reliance on 28 U.S.C. § 1498 in the underlying case will preclude him from obtaining tort liability against Defendants in a separate

suit, his concerns are unfounded. Section 1498 pertains only to patent and copyright cases. See Richmond Screw Anchor Co. v. United States, 275 U.S. 331, 345 (1928) (noting that the "intention and purpose of Congress" in enacting this statute was "to stimulate contractors to furnish what was needed" by the government, "without fear of becoming liable themselves for infringements to inventors or the owners or assignees of patents."). As such, even if Defendants are ultimately successful in having part of the current patent litigation transferred to the Court of Federal Claims, there will be no impact on McCray's tort claims against Defendants in another jurisdiction.

7. Likewise, I do not find that McCray is entitled to permissive intervention under Rule 24(b). Permissive intervention is discretionary and may be given to any party who "(A) is given a conditional right to intervene by a federal statute; or (B) has a claim or defense that shares with the main action a common question of law or fact." Fed. R. Civ. P. 24(b)(1); see also United States v. Territory of Virgin Islands, 748 F.3d 514, 524 (3d Cir. 2014). The United States Court of Appeals for the Third Circuit has previously upheld the denial of permissive intervention for the same reasons that a district court denied a motion for intervention by right. See id. at 524; Brody By & Through Sugzdinis v. Spang, 957 F.2d 1108, 1124 (3d Cir. 1992) ("[I]f intervention as of right is not available, the same reasoning would indicate that it would not be an abuse of discretion to deny permissive intervention as well.").
8. Because McCray has not asserted a claim or defense that shares a common question of law or fact with the main action, I will also deny permissive intervention.

WHEREFORE, Emanuel McCray's Motion to Intervene (Doc. No. 60) is **DENIED**.

BY THE COURT:

/s/ Mitchell S. Goldberg
MITCHELL S. GOLDBERG, J.

INTERVENORS' REPLY EXHIBIT 2

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.

INTERVENORS' REPLY EXHIBIT 3

Congress of the United States

Washington, DC 20515

MEMORANDUM

TO: Select Subcommittee on the Coronavirus Pandemic Members

FROM: Select Subcommittee on the Coronavirus Pandemic Majority Staff

DATE: March 5, 2023

RE: New Evidence Resulting from the Select Subcommittee's Investigation into the Origins of COVID-19 – "The Proximal Origin of SARS-CoV-2"

On February 1, 2020, Dr. Anthony Fauci, Dr. Francis Collins, and at least eleven other scientists convened a conference call to discuss COVID-19.[1] It was on this conference call that Drs. Fauci and Collins were first warned that COVID-19 may have leaked from a lab in Wuhan, China and, further, may have been intentionally genetically manipulated.[2]

Only three days later, on February 4, 2020, four participants of the conference call authored a paper entitled "The Proximal Origin of SARS-CoV-2" (Proximal Origin) and sent a draft to Drs. Fauci and Collins.[3] Prior to final publication in *Nature Medicine*, the paper was sent to Dr. Fauci for editing and approval.[4]

On April 16, 2020, slightly more than two months after the original conference call, Dr. Collins emailed Dr. Fauci expressing dismay that Proximal Origin—which they saw prior to publication and were given the opportunity to edit—did not squash the lab leak hypothesis and asks if the NIH can do more to "put down" the lab leak hypothesis.[5] The next day—after Dr. Collins explicitly asked for more public pressure—Dr. Fauci cited Proximal Origin from the White House podium when asked if COVID-19 leaked from a lab.[6]

New evidence released by the Select Subcommittee today suggests that Dr. Fauci "prompted" the drafting of a publication that would "disprove" the lab leak theory, the authors of this paper skewed available evidence to achieve that goal, and Dr. Jeremy Farrar went uncredited despite significant involvement.

[1] E-Mail from Jeremy Farrar to Anthony Fauci, et. al. (Feb. 1, 2020) (On file with Comm. Staff).
[2] Letter from Hon. James Comer, Ranking Member, H. Comm. on Oversight & Reform, & Hon. Jim Jordan, Ranking Member, H. Comm. on the Judiciary, to Hon. Xavier Becerra, Sec'y, U.S. Dep't of Health & Human Servs. (Jan. 11, 2022).
[3] E-Mail from Jeremy Farrar to Anthony Fauci & Francis Collins (Feb. 4, 2020) (On file with Comm. Staff)
[4] E-Mail from Kristian Andersen to Anthony Fauci, Francis Collins, & Jeremy Farrar (Mar. 6, 2020) (On file with Comm. staff).
[5] E-Mail from Francis Collins to Anthony Fauci, et. al. (Apr. 16, 2020) (On file with Comm. Staff).
[6] John Haltiwanger, *Dr. Fauci throws cold water on conspiracy theory that coronavirus was created in a Chinese lab,* BLOOMBERG (Apr. 18, 2020).

New Evidence:
The Drafting and Publication of "The Proximal Origins of SARS-CoV-2"

I. "Prompted by…Tony Fauci"

The evidence available to the Select Subcommittee suggests that Dr. Anthony Fauci "prompted" Dr. Kristian Andersen, Professor, Scripps Research (Scripps), to write Proximal Origin and that the goal was to "disprove" any lab leak theory.

On August 18, 2021, Scripps responded to then-Committee on Oversight and Reform Ranking Member, James Comer, and then-Committee on the Judiciary Ranking Member, Jim Jordan's, July 29, 2021, letter to Dr. Andersen.[7] In this letter, Scripps asserts that Dr. Andersen "objectively" investigated the origins and that Dr. Anthony Fauci did not attempt to influence his work.[8] Both statements do not appear to be supported by the available evidence.

The Goal of Proximal Origin Was to "Disprove" A Lab Theory

In Scripps' August 18 letter, on behalf of Dr. Andersen, it stated:

> In January 2020, Dr. Andersen began investigating the origins of SARS-CoV-2. At every point, ***Dr. Andersen has objectively weighed all of the evidence available to him***…Dr. Andersen's view evolved consistent with the evidence at his disposal…Scientists must make conclusions supported by the available evidence, even when it conflicts with earlier assessments.[9]

According to previously released e-mails, this assertion is also demonstrably false. On February 8, 2020, Dr. Andersen stated:

> Our main work over the last couple of weeks has been focused on ***trying to disprove any type of lab theory***…[10]

This e-mail directly contradicts Scripps' earlier statement that Dr. Andersen "objectively" weighed all the evidence regarding the origins of COVID-19. Instead, it appears that Dr. Andersen was given direction and sought to formulate a paper, regardless of available evidence, that would disprove a lab leak.

[7] Letter from Hon. James Comer, Ranking Member, H. Comm. on Oversight & Reform, & Hon. Jim Jordan, Ranking Member, H. Comm. on the Judiciary, to Kristian Andersen, Professor, Scripps Research (July 29, 2021).
[8] Letter from Counsel for Scripps Research, to Hon. James Comer, Ranking Member, H. Comm. on Oversight & Reform, & Hon. Jim Jordan, Ranking Member, H. Comm. on the Judiciary (Aug. 18, 2021) (emphasis added).
[9] *Id* (emphasis added).
[10] E-Mail from Kristian Andersen, Professor, Scripps Research, to Christian Drosten, et. al., Professor, German Cent. For Infection Research (Feb. 8, 2020) (emphasis added).

Dr. Anthony Fauci "Prompted" the Drafting of "The Proximal Origin of SARS-CoV-2"

In Scripps' August 18 letter, on behalf of Dr. Andersen, it stated:

> As for the conference call of February 1, ***Dr. Fauci did not, in Dr. Andersen's view, attempt to influence Dr. Andersen*** or any other member of the *ad hoc* working group of international subject matter experts with respect to any aspect of the discussion.[11]

According to new evidence obtained by the Select Subcommittee, this assertion is demonstrably false. On February 12, 2020, Dr. Andersen wrote to *Nature* to request the publication of what would become Proximal Origin. In this e-mail, Dr. Andersen wrote:

> There has been a lot of speculation, fear mongering, and conspiracies put forward in this space and we thought that bringing some clarity to this discussion might be of interest to Nature [sic].
>
> ***Prompted by Jeremy Farrah [sic], Tony Fauci, and Francis Collins,*** Eddie Holmes, Andrew Rambaut, Bob Garry, Ian Lipkin, and myself have been working through much of the (primarily) genetic data to provide agnostic and scientifically informed hypothesis around the origins of the virus.[12]

This e-mail directly contradicts Scripps' earlier statement that Dr. Fauci did not influence Dr. Andersen.

II. The False Narrative of the Pangolin Sequences

It remains unclear what science changed, or new evidence was discovered to change the minds of the authors of Proximal Origin between the February 1 conference call and the February 4 draft. In a July 14, 2021 interview with *The New York Times*, Dr. Andersen was asked about how his view changed from possible lab leak to definitely zoonotic, "[c]an you explain how the research changed your view?" He replied:

> The features in SARS-CoV-2 that initially suggested possible engineering were identified in related coronaviruses, meaning that features that initially looked unusual to us weren't…Yet more extensive analyses, significant additional data and thorough investigations to compare genetic diversity more broadly across coronaviruses led to the peer-reviewed study published in Nature Medicine [sic]. ***For example, we looked at data from coronaviruses found in other species, such as bats and pangolins,***

[11] Letter from Counsel for Scripps Research, *supra* note 8 (emphasis added).
[12] E-Mail from Kristian Andersen, Professor, Scripps Research, to Claire Thomas, Team Manager, Nature (Feb. 12, 2020) (emphasis added) (On file with Select Subcomm. Staff).

> ***which demonstrated that the features that first appeared unique to SARS-CoV-2 were in fact found in other, related viruses.***[13]

According to new evidence obtained by the Select Subcommittee, while Proximal Origin was going through peer review with *Nature Medicine* more than a year earlier, Dr. Andersen actually did not find the pangolin data compelling.

The first referee asked:

> There are two recent reports about coronaviruses in pangolins. The authors might want to comment on these.[14]

Dr. Andersen replied:

> We have included these references as well as several others that have investigated pangolin CoV. ***In addition…we should point out that these additional pangolin CoV sequences do not further clarify the different scenarios discussed in our manuscript.*** There is nothing in these reports that changes our statements regarding a potential role of pangolins.[15]

The second referee asked:

> The paper itself is interesting, but unnecessarily speculative. It's not clear why the authors do not refute a hypothetical lab origin in their coming publication on the ancestors of SARS-CoV-2 in bats and pangolins…Once the authors publish their new pangolin sequences, a lab origin will be extremely unlikely. It is not clear why the authors rush with a speculative perspective if their central hypothesis can be supported by their own data. Please explain.[16]

Dr. Andersen replied:

> Our manuscript is written to explore the potential origin of SARS-CoV-2. We do not believe it is speculative…***Unfortunately, the newly available pangolin sequences do not elucidate the origin of SARS-CoV-2 or refute a lab origin.*** Hence, the reviewer is incorrect on this point…***[T]here is no evidence on present data***

[13] James Gorman & Carl Zimmer, *Scientist Opens Up About His Early Email to Fauci on Virus Origins,* THE N.Y. TIMES (June 14, 2021) (emphasis added).
[14] Referee #1 Document (Feb. 21, 2020) (On file with Select Subcomm. Staff).
[15] *Id* (emphasis added).
[16] Referee #2 Document (Feb. 21, 2020) (On file with Select Subcomm. Staff).

> ***that the pangolin CoVs are directly related to the COVID-19 epidemic.***[17]

Privately, Dr. Andersen did not believe the pangolin data disproved a lab leak theory despite saying so publicly. It is still unclear what intervening event changed the minds of the authors of Proximal Origin in such a short period of time. Based on this new evidence, the pangolin data was not the compelling factor; to this day, the only known intervening event was the February 1 conference call with Dr. Fauci.

III. Uncredited Involvement of Dr. Jeremy Farrar

The evidence available to the Select Subcommittee suggests that Dr. Farrar, the former Director of the Wellcome Trust and current Chief Scientist at the World Health Organization, was more involved in the drafting and publication of Proximal Original than previously known.

Dr. Eddie Holmes Sought Permission from Dr. Farrar to Involve Dr. W. Ian Lipkin

Dr. Lipkin, Professor of Epidemiology, Columbia University, was not on the February 1 conference call and was not involved in the drafting of Proximal Origin in the early stages. However, on February 10, 2020, Dr. Holmes sent a draft of Proximal Origin to Dr. Lipkin for his review. Dr. Holmes stated:

> Here's the document we wrote a few days ago. Things are moving so quickly that is hard [sic] to keep up. Comments welcome. I favour natural evolution myself, but the furin cleavage site is an issue. ***I'll have a chat with Jeremy [Farrar] in a little while to see if can [sic] get you more directly involved***.[18]

Dr. Lipkin responded with his thoughts on the draft of Proximal Origin:

> It's well reasoned and provides a plausible argument against genetic engineering. ***It does not eliminate the possibility of inadvertent release following adaptation through selection in culture at the institute in Wuhan. Given the scale of the bat CoV research pursued there and the site of emergence of the first human cases we have a nightmare of circumstantial evidence to assess***.[19]

Dr. Holmes agreed with Dr. Lipkin's assessment of the possibility of a lab leak and reiterated that he was asking Dr. Farrar about including Dr. Lipkin in the drafting process:

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[17] *Id* (emphasis added).
[18] E-Mail from Edward Holmes, Professor, University of Sydney, to W. Ian Lipkin, Professor, University of Columbia (Feb. 10, 2020) (emphasis added) (On file with Select Subcomm. Staff).
[19] E-Mail from W. Ian Lipkin, Professor, University of Columbia, to Edward Holmes, Professor, University of Sydney (Feb. 11, 2020) (emphasis added) (On file with Select Subcomm. Staff).

> I agree. ***Talking to Jeremy (Farrar) in a few minutes and I'll get back in touch after.*** It is indeed striking that this virus is so closely related to SARS yet is behaving so differently. ***Seems to have been pre-adapted for human spread since the get go.*** It's the epidemiology that I find most worrying.[20]

Dr. Farrar Led the Drafting Process and Made At Least One Uncredited Direct Edit to Proximal Origin

Dr. Farrar is not credited as having any involvement in the drafting and publication of Proximal Origin. According to new evidence obtained by the Select Subcommittee, Dr. Farrar led the drafting process and in fact made direct edits to the substance of the publication.

Right before publication, on February 17, 2020, Dr. Lipkin emails Dr. Farrar to thank him for leading the process of drafting Proximal Origin:

> ***Thanks for shepherding this paper.*** Rumors of bioweaponeering are now circulating in China.[21]

Dr. Farrar responds, confirming and saying that he will pressure *Nature* to publish:

> Yes I know and in US – why so keen to get out ASAP. ***I will push nature.***[22]

In addition to leading the drafting and publication process, Dr. Farrar made at least one direct edit to Proximal Origin. On February 17, 2020, the day Proximal Origin was first published publicly, Dr. Farrar made an edit to the draft:

> ***Sorry to micro-manage/microedit!*** But would you be willing to change one sentence?
>
> From
>
> ***It is unlikely*** that SARS-CoV-2 emerged through laboratory manipulation of an existing SARS-related coronavirus.
>
> To
>
> ***It is improbable*** that SARS-CoV-2 emerged through laboratory manipulation of an existing SARS-related coronavirus.[23]

[20] E-Mail from Edward Holmes, Professor, University of Sydney, to W. Ian Lipkin, Professor, Columbia University (Feb. 10, 2020 (emphasis added) (On file with Select Subcomm. Staff).
[21] E-Mail from W. Ian Lipkin, Professor, Columbia University, to Jeremy Farrar, Dir., Wellcome Trust (Feb. 17, 2020) (emphasis added) (On file with Select Subcomm. Staff).
[22] E-Mail from Jeremy Farrar, Dir., Wellcome Trust, to W. Ian Lipkin, Professor, Columbia University (Feb. 17, 2020) (emphasis added) (On file with Select Subcomm. Staff).

To which, Dr. Andersen responds:

> Sure, attached.[24]

This evidence suggests that Dr. Farrar was more involved in the drafting and publication of Proximal Origin than previously known and possibly should have been credited or acknowledged for this involvement.

[23] E-Mail from Jeremy Farrar, Dir., Wellcome Trust, to Kristian Andersen, et. al., Professor, Scripps Research (Feb. 17, 2020) (On file with Select Subcomm. Staff).
[24] E-Mail from Kristian Andersen, Professor, Scripps Research, to Jeremy Farrar, Dir., Wellcome Trust (Feb. 17, 2020) (On file with Select Subcomm. Staff).