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BY CM/ECF
The Honorable Mitchell S. Goldberg
United States District Court
Eastern District of Pennsylvania
James A. Byrne U.S. Courthouse, Room 17614
601 Market Street
Philadelphia, PA 19106-1797

Re: *Arbutus Biopharma Corporation, et. al. v. Moderna, Inc., et. al.*
C.A. No. 22-252-MSG

Dear Judge Goldberg:

We write on behalf of Plaintiffs Arbutus and Genevant pursuant to Your Honor's order directing the parties to submit letter briefs regarding the impact of the Government's Statement of Interest on the scheduling of this matter. D.I. 51. The Government's Statement (D.I. 49) does not change the scope of this case or disturb the Court's holding last November that the resolution of Moderna's affirmative defense under 28 U.S.C. § 1498(a) "is not appropriate . . . in a Rule 12(b)(6) motion." D.I. 31 at 13. Indeed, as discussed below, both Moderna and the Government concede that regardless of § 1498(a), Plaintiffs' claims related to significant sales to the Government, as well as significant non-governmental sales, must be adjudicated here and not in the Court of Federal Claims. And in any event, the Government's Statement is merely one piece of evidence that the Court or jury eventually may consider, but it is not dispositive, particularly on the pleadings, of the crucial contested issue here: whether the accused manufacture, offers for sale, sale, and use of Moderna's COVID-19 vaccine was "for the Government" or for the U.S. population. Adjudication of that question is reserved for this Court. The Government's view is mere attorney argument entitled to no deference and, in any event, contradicts binding precedent that this Court previously followed and should not now ignore.

In denying Moderna's partial motion to dismiss, the Court correctly observed that § 1498(a) requires Moderna to make two independent showings: that its infringement of Plaintiffs' patents was (1) "for the Government," *and* (2) with the Government's "authorization or consent." 28 U.S.C. § 1498(a); *Sevenson Evnt'l Servs., Inc. v. Shaw Envt'l, Inc.*, 477 F.3d 1361, 1365 (Fed. Cir. 2007); D.I. 31 at 8. Despite the uniform body of precedent requiring both prongs of § 1498(a) to be met, the Government urges the Court to perform a "truncated inquiry" focusing entirely on the inclusion of "FAR 52.227-1" in the -0100 Contract between Moderna and the Government, without considering any other evidence. D.I. 49 at 9. According to the Government, FAR 52.227-1 definitively resolves the "authorization or consent" inquiry, and the Court has no further role to play regarding the other prong of § 1498(a)—whether Moderna's infringement was "for the Government"—simply because Moderna "compli[ed] with the contract's obligations." *Id.* at 10.

That is a radical departure from the law. Even if the Court could consider a single,

selectively produced document at the Rule 12 stage, the Government's "truncated inquiry" finds no support in *Sevenson*, the sole case cited in the Government's Statement for that proposition, nor anywhere else. The Government's reading, and the expansive application of § 1498(a) it now urges, is contrary to the statute's text and history, and also to *Larson v. United States*, 26 Cl. Ct. 365 (1992), as this Court found in denying Moderna's motion. D.I. 31 at 9–13 (analyzing *Larson*, *Advanced Software Design Co. v. Fed. Reserve Bank of St. Louis*, 583 F.3d 1371 (Fed. Cir. 2009), and *Saint-Gobain Ceramics & Plastics, Inc. v. II-VII Inc.*, 369 F.Supp.3d 963 (C.D. Cal. 2019)). As the Court held, whether Moderna's infringement was for the benefit of the U.S. population or the Government is a factual dispute that can only be resolved on a fully developed record. D.I. 31 at 13–14. The Government is not the trier of fact, and its opinion on the case law regarding § 1498(a), the subject of the majority of its Statement, is entitled to no deference.

If anything, the Government's Statement makes clear why Plaintiffs should be afforded an opportunity to develop a full factual record. Astonishingly, the Government's submission reveals that Moderna knew—while its motion "to dismiss *with prejudice* Plaintiffs' claims based on Moderna's sale and provision of COVID-19 doses to the U.S. Government" was pending, D.I. 17 at 14 (emphasis added)—that the Government had disclaimed authorization and consent under one of the two contracts between them. Even Moderna now agrees that Plaintiffs' claims regarding sales under the second contract should not be dismissed, Feb. 16, 2023 Tr. (Ex. 1) 28:7–14, such that its initial motion (never amended even upon execution of the second contract) sought improper relief. Yet Moderna never brought this fact to either Plaintiffs' or the Court's attention. Had the Court granted Moderna's motion without discovery—an approach Moderna advocated and still advocates—neither the Court nor Plaintiffs ever would have known that Moderna's request was, by its own belated admission, improper. The Government's revelation is precisely why courts routinely hold that the application of § 1498(a) should be decided at summary judgment, rather than on the pleadings. *Toxgon Corp. v. BNFL, Inc.*, 312 F.3d 1379, 1382 (Fed. Cir. 2002).

Nor would waiting to decide the application of § 1498(a) have a material impact on the scope of discovery in the case. While there is certainly discovery to be taken as to the application of § 1498(a) itself, *see infra* at 7, the core issues in the case—infringement, invalidity, and the reasonable royalty—will be unchanged irrespective of whether the Court ultimately determines that some damages should be collected in the Court of Federal Claims. For these reasons and the reasons that follow, Plaintiffs request that the Court resolve the parties' disagreements in the proposed case schedule, D.I. 46, and enter a scheduling order setting a date for trial.

I. Background and Procedural Posture

Plaintiffs filed their Complaint over a year ago asserting patents covering the lipid nanoparticle ("LNP") technology in Moderna's COVID-19 vaccine. Plaintiffs' LNP technology solved the key challenge underlying the new class of medicines to which Moderna's mRNA-based vaccine belongs: the protection of the fragile mRNA (and other nucleic acids) from degradation in the human body and the delivery of those molecules into human cells where they can exert their therapeutic effect. D.I. 1 ¶¶ 21–28. This lawsuit followed not only Moderna's refusal to negotiate a reasonable license to Plaintiffs' patents, but also its failed effort to invalidate certain claims of the patents-in-suit in *inter partes* review proceedings before the USPTO. D.I. 1 ¶¶ 31–38, 55–64. Moderna's failed IPR attacks and unsuccessful efforts to reverse them on appeal to the Federal

Circuit, 18 F.4th 1352 (Fed. Cir. 2021); 18 F.4th 1364 (Fed. Cir. 2021), leave Moderna statutorily estopped from advancing in this lawsuit its primary arguments against Plaintiffs' patents. 35 U.S.C. § 315. Moderna's effort to avert the estoppel flowing from those failed proceedings provide important clues as to why the Government and Moderna, as part of their ongoing, politically-charged negotiations,[1] would seek (improperly) to shift the billions of dollars of liability at issue away from Moderna and to the Government. *See infra* at 7.

Moderna moved for partial dismissal of Plaintiffs' Complaint on May 6, 2022, on the basis that all of its COVID-19 vaccine sales to the U.S. Government were subject to the so-called "government contractor defense" under 28 U.S.C. § 1498(a). Section 1498(a) is an affirmative defense that requires Moderna to prove that its infringement be (1) "for the Government" and (2) with "the authorization and consent of the Government." D.I. 17 at 10–11; 28 U.S.C. § 1498(a). In an effort to meet its burden, Moderna requested the Court take judicial notice of its "-0100 Contract" with the Government, including the incorporation of FAR 52.227-1. D.I. 17 at 7–8. Plaintiffs opposed because, as alleged in the Complaint, Moderna's vaccines sales, while funded *by* the Government, were not *for* the Government—but "for the benefit of individual vaccine recipients in the United States." *E.g.*, D.I. 21 at 3, 7, 9–16; D.I. 1 ¶ 51; *see also Larson*, 26 Cl. Ct. at 369. Plaintiffs also pointed out that, in addition to the sufficiency of their allegations, discovery would be needed to ascertain whether in fact all of Moderna's government sales were both "for the Government" and with the Government's "authorization or consent." D.I. 21 at 17–20.

On November 2, 2022, the Court denied Moderna's motion, agreeing that "this case [is] more akin to *Larson* than *Advanced Software Design* or *Saint-Gobain Ceramics*" and that whether Moderna's infringement was "for the Government" and with its "authorization or consent" were disputes "best considered under a more fully developed record." D.I. 31 at 12, 16. Unbeknownst to the Court or Plaintiffs, Moderna and the Government executed the "-0017 Contract" months earlier, in July 2022 for 300 million more doses.[2] As the Government's Statement makes clear, D.I. 49 at 4, and Moderna agrees, Feb. 23, 2023 Tr. (Ex. 1) 28:7–14, § 1498(a) does not apply to the -0017 Contract, such that even if Moderna's partial motion were granted, this Court would still be left with claims to adjudicate, as to sales to the Government and others.

II. The Government's Statement Does Not Control the Application of § 1498(a) or Address the Full Scope of Its Requirements.

A. The Government improperly vitiates "for the Government" from § 1498(a).

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[1] *See, e.g.*, https://www.bostonglobe.com/2023/01/25/business/two-senators-accuse-moderna-greed-its-plan-quadruple-covid-vaccine-cost/ (**Exhibit 4**); https://www.sanders.senate.gov/wp-content/uploads/Moderna-Letter-01.09.20231.pdf **(Exhibit 5**); https://www.warren.senate.gov/imo/media/doc/2023.01.24%20Letter%20to%20Moderna%20re%20COVID%20Vaccine%20Price%20Hikes.pdf (**Exhibit 6**).

[2] https://investors.modernatx.com/news/news-details/2022/Moderna-Announces-New-Supply-Contract-With-The-U.S.-Government-For-An-Initial-66-Million-Doses-Of-A-Moderna-Bivalent-Covid-19-Booster-Vaccine-With-Options-For-U.S.-Government-To-Purchase-Up-To-An-Additional-234-Million-Doses/default.aspx (**Exhibit 7**).

The Government's Statement offers no reason to depart from the Court's prior ruling. The Government focuses heavily on the incorporation of FAR 52.227-1 in the -0100 Contract. D.I. 49 at 1–4, 8–10. But the incorporation of that provision is not new. Moderna's motion made FAR 52.227-1 its centerpiece, D.I. 17 at 6, 12–14, and the Court rejected that provision as singularly dispositive of § 1498(a)'s application, because the statute requires more than authorization and consent: the infringement must also be for the benefit of the Government, D.I. 31 at 13–14.

Rather than address that distinct legal requirement Moderna failed to meet, D.I. 31 at 13, the Government advances the unprecedented theory that when FAR 52.227-1 is present, "the 'for the Government' inquiry" under § 1498(a) should "collapse[] into the 'authorization and consent' inquiry." D.I. 49 at 9. The Government's interpretation of precedent manifestly cannot supplant the Court's. And the Government is wrong. Its sole support is *Sevenson*, a case that this Court cited for the exact *opposite* point: that "[a] defendant" like Moderna "bears the burden of establishing that '(1) the [infring]ing use is "for the Government" and (2) the [infringing] use is "with the authorization and consent of the government."'" D.I. 31 at 8.

Sevenson on its face does not support the Government's position. There, as in all of the § 1498(a) cases cited by Moderna and the Government, the Federal Circuit separately analyzed *both* prongs of the statutory inquiry. The court began its analysis by expressly rejecting the appellee's argument that "for the Government" requires the "primary purpose" of the contract be to benefit the Government. 477 F.3d at 1365–66. In doing so, the court simply adhered to the statutory text, which imposes no such requirement. *Id.* The Federal Circuit proceeded to address whether there was a genuine dispute as to the second prong—whether the infringement was "with the authorization and consent of the Government." *Id.* at 1367–68.

In doing so, the Court of Appeals did *not* find that a "truncated inquiry" under § 1498(a) would be appropriate. Instead, as the Government's own parenthetical quote from *Sevenson* makes clear, D.I. 49 at 9, to the extent courts have "bypassed a separate inquiry into whether infringing activity was performed 'for the Government,'" they have done so only "where infringing activity has been performed by a government contractor pursuant to a government contract *and for the benefit of the Government*." 477 F.3d at 1366 (emphasis added). In other words, in a case like *Sevenson* where the benefit to the Government is undisputed under the correct legal standard—the use of patented technology to remediate toxic waste *on a parcel of Government property*—and the patent owner's only argument rests on an extrastatutory requirement that the "primary purpose" of the infringement be "for the Government," there is no factual dispute that the "for the Government" prong of § 1498(a) is met. Put another way, as with all legal tests, where one prong of a two-prong test is not disputed (or not disputed under the correct legal standard), the inquiry turns on the single, disputed prong. Here, however, the parties dispute—fiercely—the "for the Government" prong. The posture in which *Sevenson* was decided—summary judgment—also confirms that resolution of the "for the Government" inquiry cannot be "truncated" merely by the Government's after-the-fact say-so. *See also infra* at 7.

Given *Sevenson*'s plain import, it is unsurprising that counsel for the United States backtracked from the Statement during the February 16, 2023 conference, stating that *Sevenson* had merely "suggested" the possibility of the Government's "truncated inquiry." Feb. 16, 2023 Tr. (Ex. 1) 26:14–19. In reality, *Sevenson* "suggested" no such thing. Every court to address the

§ 1498(a) inquiry, before *Sevenson* and after, has reiterated that two distinct prongs must be satisfied for its invocation. *E.g.*, *Sevenson*, 477 F.3d at 1365; *Advanced Software*, 583 F.3d at 1376; *Saint-Gobain*, 369 F.Supp.3d at 970; *IRIS v. Japan Airlines Corp.*, 769 F.3d 1359, 1362 (Fed. Cir. 2014); *Hughes Aircraft Co. v. United States*, 534 F.2d 889, 898 (Ct. Cl. 1976). Not even Moderna, in multiple briefs, D.I. 17, 23, has argued that the Court should ignore this avalanche of precedent or "collapse" the statute's two-pronged test into one. It is a simple matter of logic that "standing alone, 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)." *IRIS*, 769 F.3d at 1362.

During the February 16 hearing, the Government also urged the Court to look to *Advanced Software*. Feb. 16, 2023 Tr. (Ex. 1) 26:14–19. That case does not support the Government's position either. As in *Sevenson*, the court in *Advanced Software* carefully examined the factual record to ascertain whether both of the statutory requirements "for the Government" and "with the authorization or consent of the Government" were met. That analysis considered testimony from a U.S. Treasury official, as well as the benefit to the Government in the form of detecting fraudulent checks purportedly from the U.S. Treasury, to resolve summary judgment, not a motion to dismiss under Rule 12(b)(6). *Advanced Software*, 583 F.3d at 1374, 1376 (quoting *Sevenson*'s legal standard as providing "two criteria for application of § 1498(a) to activity of private parties").

The Government's belated invitation to overturn decades of precedent to erase the "for the Government" prong of § 1498(a) is as transparent as it is baseless. Rather than finding any case law support, the Government's misreading of *Sevenson* was first advanced in a 2016 Yale Law Journal article—and later by a Senator—urging the Government to pursue a price reduction scheme by invoking § 1498(a) to buy "generic versions of [approved medicines] at less than 1% of their list price plus a reasonable royalty." H. Brennan, A. Kapczynski, C.H. Monahan & Z. Rizvi, *A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health*, 18 Yale J.L. & Tech. 275, 275 (2016) ("Yale Article"); Letter from Senator Elizabeth Warren to Xavier Becerra (Apr. 22, 2022), (**Exhibit 2**). The authors of that article quoted the same portion of *Sevenson* as the Government does now to assert that "where the infringing party has shown that they are acting pursuant to a contract with the federal government, courts typically assume use 'for' the government without further inquiry.'" Yale Article at 333 & nn.271–72. A month after Moderna filed its reply brief, D.I. 23, a faction of legislators again urged the Department of Health and Human Services, the agency on behalf of which the Government submitted its Statement, to "use compulsory licensing under 28 U.S.C. § 1498(a) . . . to lower prescription drug prices." Letter to the Honorable Xavier Becerra (June 23, 2022) (**Exhibit 3**).

The reason that the Government's Statement—parroting the law review article—urges this Court to erase the "for the Government" prong of the § 1498(a) inquiry, is that medical treatments and interventions, such as Moderna's COVID-19 vaccine, fail to satisfy that prong. The law could not be clearer: "Medical care is provided for the benefit of the patient, not the government." *Larson*, 26 Cl. Ct. at 369. Moderna's inability to satisfy § 1498(a) is no reason to change it outside of the proper legislative avenue. The Government's argument is nothing more and nothing less than an invitation to rewrite the statute for political purposes, as ensuing commentators—including the former Chief Judge of the Court of Federal Claims herself—have explained. Chief Judge Braden and others have criticized a reading of *Sevenson* that permits the Government to abrogate unilaterally the statutory text requiring that the infringing conduct be "for the Government," as the

Government urges here, and endorsed this Court's interpretation of precedent. Susan G. Braden & Joshua A. Kresh, *Section 1498(a) is Not a Rx to Reduce Drug Prices*, 77 Food & Drug L.J. 274, 283 & n.53, 285 n.74 (2022) (**Exhibit 11**). Chief Judge Braden further observed that "continued pressure on the executive branch to exert 28 U.S.C. § 1498(a) should be expected." *Id.* at 275.

That "continued pressure" ostensibly has succeeded, and the executive branch (through the Government's Statement) now beseeches this Court to ignore the text of § 1498(a) and its own prior interpretation of *Sevenson* and *Larson* that are inconsistent with the Government's apparent policy goal of expanding § 1498(a) into the realm of medical care. No court has advanced the view of § 1498(a) that the Government now urges. Contra the Government's suggestion, "it is emphatically the province and duty of the judicial department," not the executive or legislative branches, "to say what the law is." *Marbury v. Madison*, 5 U.S. (1 Cranch) 137, 177 (1803).

B. This Court correctly applied the controlling precedent in *Larson* to the facts alleged in the Complaint.

Aside from erasing the "for the Government" test, the Government offers no new response to *Larson*, Plaintiffs' lead case that the Court carefully considered in denying Moderna's partial motion to dismiss, D.I. 21 at 10, D.I. 31 at 12. The *Larson* Court determined that the provision of infringing medical equipment to patients through Medicare and Medicaid was not "for the Government" because "the fact that the government has an interest in [a] 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." 26 Cl. Ct. at 369 (emphasis added). *Larson*'s reasoning applies full force, notwithstanding the Government's Statement. As in *Larson*, "the benefit and convenience," *id.*, of "free public distribution" of Moderna's vaccine, D.I. 49 at 10, funded or reimbursed by the Government, flowed to the "patient and provider, *with no benefit to the government*," 26 Cl. Ct. at 369 (emphasis added). Again, "[m]edical care is provided for the benefit of the patient, not the government." *Id.* All that Moderna and the Government have cited to date is the generalized programmatic interest in "thwart[ing] the COVID-19 pandemic," D.I. 49 at 10, which this Court properly found is insufficient. *See also Windsurfing Int'l., Inc. v. Ostermann*, 534 F.Supp.581, 588 (S.D.N.Y. 1982).

The Government downplays *Larson* by reprising Moderna's failed argument that *Larson*'s facts can be distinguished by the absence of an express government contract. *See* D.I. 49 at 12; D.I. 23 at 3–4. But that fact was irrelevant in *Larson*, and neither Moderna nor the Government cite a case where it has proven dispositive. The Government and Moderna's argument seems to be that the invocation of FAR 52.227-1 is enough on its own to definitively establish the applicability of § 1498(a). That express Government contract may be relevant to the "authorization and consent" prong of the test, but it does not change the fact that, as to the first prong, "[m]edical care is provided for the benefit of the patient, not the government." *Larson*, 26 Cl. Ct. at 369. The patient receives that benefit identically, without regard to whether the Government signed a contract or provides funding or a reimbursement. *Arlton v. Aerovironment, Inc.*, 2021 WL 1589302, at *7–8 (C.D. Cal. Apr. 22, 2021) (requiring and finding "more than incidental benefit" to the Government, notwithstanding contract with FAR 52.227-1).

In reality, the key distinction between this case and the cases relied upon by the

Government and Moderna finding § 1498(a) to be applicable is that there is (at best for Moderna) a genuine factual dispute regarding whether Moderna's infringement was "for the Government." In each of those cases, the Government benefit was indisputable. In *Saint-Gobain*, the infringing sapphire sheets were used in F-35 fighter jets; in *Advanced Software*, the technology at issue was to detect fraudulent U.S. Treasury checks; in *Sevenson*, the infringing "phosphoric-acid based stabilization system" was to remediate toxic waste at a Government-owned property. The only case analogous to the facts here—subsidized private medical treatment—is *Larson*. The Government's position that a "contractor's compliance with the contract's obligations alone" is sufficient to invoke § 1498(a) whenever a clause like FAR 52.227-1 is present, D.I. 49 at 10, fully embraces the error that the Court observed in Moderna's nearly identical position, *i.e.*, "that every government-funded product used to advance any policy goal articulated by the U.S. Government—such as IV needles to fight HIV to cancer drugs to fight the war on cancer—would be subject to a § 1498(a) defense," D.I. 31 at 13. That misapplication of § 1498(a) was wrong in Moderna's motion, and it fares no better now repeated by the Government (which apparently seeks to expand § 1498(a) to the examples identified by the Court that are plainly beyond the reach of the statute).

C. The Government's Statement does not address Plaintiffs' indirect infringement allegations.

Even as the Government's Statement errs regarding the application of § 1498(a) to the sale of Moderna's vaccine doses to the Government, it is completely silent about an entire, and distinct, category of infringement alleged in the Complaint: Moderna's indirect-infringement liability for inducing and contributing to direct infringement by the numerous non-governmental actors involved in the distribution and administration of Moderna's infringing vaccine. *E.g.*, D.I. 1 ¶ 9. None of these infringing uses are "by or for the United States"—the Government is nowhere to be found. The Government never asserts otherwise. Thus, separate and apart from any other acts of infringement addressed by the Government, there can be no doubt that these acts of infringement, *which apply to every dose of the accused vaccine* ever used in the United States, are not subject to § 1498(a). The law is clear that "section 1498(a) is a waiver of sovereign immunity only with respect to a direct governmental infringement of a patent . . . the Government is not liable for its inducing infringement by others, for its conduct contributory to infringement of others." *Decca v. United States*, 640 F.2d 1156, 1167 (Ct. Cl. 1980); *Madey v. Duke Univ.*, 307 F.3d 1351, 1359 (Fed. Cir. 2002) (§ 1498(a) "acts as a waiver of sovereign immunity" and "waivers of sovereign immunity are to be strictly construed."). The authority cited by the Government, D.I. 57 at 3, does not address liability for indirect infringement by use of a patented invention by private parties, as alleged in Plaintiffs' Complaint here. Accordingly, even were government sales under one contract somehow subject to § 1498(a) (they are not), Moderna would remain accused of indirect infringement with respect to every dose, and such allegations would *not* be subject to § 1498(a).

III. The Government's Statement Underscores that Discovery is Needed to Determine the Applicability of § 1498(a).

In denying Moderna's motion, the Court held that "this dispute is not appropriate for resolution in a Rule 12(b)(6) motion" and that the "dispute should be resolved by summary judgment rather than on a motion to dismiss." D.I. 31 at 13; *Toxgon*, 312 F.3d at 1382. In *Saint-Gobain*, a case cited by both the Government and Moderna, D.I. 49 at 10, the court "converted

defendants' motion to dismiss into a motion for summary judgment" and "directed the parties to conduct discovery and submit supplemental briefing on the applicability of § 1498." 369 F.Supp.3d at 966. The Government's Statement neither requires nor warrants departure from the Court's earlier decision. Indeed, the revelation that Moderna was seeking dismissal with prejudice of all claims relating to sales to the Government, while knowing the Government had expressly revoked any authorization and consent as to certain sales, only underscores why courts do not make legal determinations on less than a full record. Feb. 16, 2023 Tr. (Ex. 1) 28:7–14.

Discovery in this case is still needed into both prongs of Moderna's § 1498(a) defense—as it is with respect to all of the disputed issues of infringement, validity, and damages. As to the "authorization and consent" prong, although the Government has offered to produce unredacted versions of the contracts, it still has not done so. It has offered no legal basis for the Court to consider those documents—and those documents alone—in deciding whether Moderna has met its burden to establish an affirmative defense at the pleading stage. And Plaintiffs have been afforded no opportunity to take discovery into whether there are any formal or informal communications outside of the -0100 Contract that might modify or limit the scope of the Government's authorization and consent.

But even if authorization and consent were present, extensive fact discovery remains as to whether Moderna can meet the "for the Government" prong of § 1498(a). Tellingly, the Government's Statement entirely avoids the factual dispute in favor of a contorted interpretation of *Sevenson* that simply reads the inquiry out of the statute. And here, the question of whether the Government is more than an "incidental" beneficiary is hotly disputed. That distinguishes this case from those in which courts have relied on Statements of Interest. In *Arlton*, cited by the Court, D.I. 31 at 15, for example, the alleged infringement involved "Mars Helicopters" built for NASA, 2021 WL 1589302, at *7.[3] In *IRIS v. JAL*, referenced by Moderna during the hearing, Feb. 16, 2023 Tr. (Ex. 1) 20:20–21:3, the infringement involved the "uniquely governmental function" of border security and the "quasi-governmental function" of screening for fraudulent passports, 469 F.3d at 1362. As *Larson* makes clear, the alleged infringement for healthcare here is far different. And as both the Government and Moderna acknowledged at the Court's conference, the Government's Statement is not conclusive. *See* Feb. 16, 2023 Tr. (Ex. 1) 20:14–19 ("not accepted without question"), 26:1–6 ("the Court always has a role in determining whether § 1498 applies"); *see also IRIS*, 769 F.3d at 1363 ("the government's statement is not dispositive").

Plaintiffs thus intend to take discovery relevant to the application of § 1498(a) in this case, including (i) the complete and unredacted terms of Moderna's contracts with the Government and any other related agreements and communications; (ii) the negotiations that culminated in the terms of those agreements; (iii) the nature and extent of the Government's involvement in the development and specifications of the infringing vaccine, (iv) how the purchased doses were distributed and to whom—whether to customers of drug stores, grocery stores, private medical practices, or others; (v) Moderna's and the Government's respective understandings of who were

[3] *Arlton* underscores the need for discovery as the court in that case (1) vacated summary judgment after the defendant "publicly showcased" a new product that it had failed to disclose and (2) ordered limited discovery on that product. 2021 WL 4902186, at *3–5 (C.D. Cal. June 24, 2021).

the true beneficiaries of the contract; and (vi) any discussions of Plaintiffs' patents, including efforts to avoid the effects of *inter partes* review estoppel by shifting liability. *See, e.g.*, Order, *Racing Optics, Inc. v. Clear Defense, LLC*, No. 16-cv-288, D.I. 22, D.I. 23 (M.D.N.C. Sept. 30, 2016 & Oct. 13, 2016) (ordering production of "all of [defendant's] communications with the Government concerning sales of the Accused Products" and depositions of "persons with knowledge of the facts and documents related to [defendant's] § 1498(a) defense."); *Crater Corp. v. Lucent Techs., Inc.*, 1999 WL 33973795, at *2–3 (E.D. Mo. Aug. 25, 1999) (granting discovery on § 1498(a), including evaluating the Government's claim to privilege based on state secrets).

The current circumstances especially warrant discovery. The Government's Statement comes nearly a year after Moderna filed its motion, in the midst of ongoing negotiations between them, the day before Moderna announced it would make vaccines "available at no cost for insured people," and after paying $400 million to settle part of an ongoing patent dispute.[4] It would hardly be surprising, given the attendant media and political scrutiny, for the Government and Moderna to have discussed the Government's willingness to take on potentially billions of dollars of liability in exchange for concessions from Moderna. Plaintiffs, of course, can only surmise what negotiations between Moderna and the Government contain—the purpose of discovery is to establish those contents as a factual matter. Indeed, Moderna's decision not to advise Plaintiffs and the Court that the Government withdrew any potential authorization in the July 2022 contract, while continuing to seek what Moderna now acknowledges was improper dismissal of Government sales, reinforces the need for discovery. Feb. 16, 2023 Tr. (Ex. 1) 28:7–14.

IV. Judicial Efficiency Would Not Be Served by Deciding the Application of § 1498(a) Before Discovery.

Moderna does not dispute that significant allegations of infringement remain to be tried in this Court regardless of whether § 1498(a) ultimately applies to sales under the -0100 Contract. Feb. 16, 2023 Tr. (Ex. 1) 28:7–14. The Government's Statement confirms that this case will concern not only Moderna's liability for contributing to and inducing uses of its vaccine, but also its forthcoming sales in the private insurance market, and also sales to the Government for which the latter has disclaimed all patent infringement liability—*i.e.* sales pursuant to the -0017 Contract. As a result, even if the Government and Moderna's novel and unsupported interpretation of § 1498(a) were accepted, the Court would still have to preside over a case regarding infringement, validity, and damages with respect to the patents-in-suit, and no efficiency will be gained from deciding the application of § 1498(a) now as opposed to at summary judgment or trial.

Nor would proceedings in this Court be duplicative or *de minimis*. The Government's Statement does not contest that sales or offers for sales relating to hundreds of millions of doses, as well as infringing uses for every dose, must be tried in this forum. *See* note 2, *supra*. And there is no co-pending case in the Court of Federal Claims at the present time, so any case would

[4] https://investors.modernatx.com/Statements--Perspectives/Statements--Perspectives-Details/2023/Modernas-Commitment-to-Patient-Access-in-the-United-States/default.aspx (**Exhibit 8**); https://www.wsj.com/articles/moderna-considers-price-of-110-130-for-covid-19-vaccine-11673289609 (**Exhibit 9**); https://www.nytimes.com/2023/02/23/science/moderna-covid-vaccine-patent-nih.html (**Exhibit 10**).

necessarily be far behind this suit; duplicative litigation could result only if Moderna's motion were granted. As the Third Circuit has emphasized, "[i]n all cases of federal concurrent jurisdiction, the court which first ha[d] possession of the subject *must* decide it." *EEOC v. University of Pennsylvania*, 850 F.2d 969, 971 (3d Cir. 1988) (emphasis added).

Moreover, to the extent there is any risk of duplicative litigation, it favors proceeding in this Court, rather than the Court of Federal Claims, because certain issues have already been adjudicated as between Plaintiffs and Moderna. Specifically, as a result of its failed challenges in the Patent Office, Moderna is statutorily estopped from raising certain invalidity defenses under 35 U.S.C. §§ 102 and 103. *See* 35 U.S.C. 315(e)(2). Common law principles of collateral estoppel also apply to arguments that Moderna has raised and lost before the agency. *See MaxLinear, Inc. v. CF CRESPE LLC*, 880 F.3d 1373, 1376 (Fed. Cir. 2018). The effect of these estoppels would be to streamline this litigation considerably.

Revealingly, in response to this Court's query, the Government declined to agree not to re-litigate issues of infringement and validity, responding that it had not yet had occasion, in the year since this case was filed, to analyze those issues that bear on billions of dollars of liability it now seeks to inherit. Feb. 16, 2023 Tr. (Ex. 1) 24:23–25:4. The Government's refusal to commit to being bound by estoppels that apply to Moderna improperly invites duplicative litigation that Congress deemed inappropriate. Plaintiffs have prevailed on the issues of obviousness and anticipation, and the notion that the Government can step into Moderna's shoes and attempt to avoid Moderna's estoppels is as unfair as it is inefficient. Judicial efficiency is promoted best by proceeding in this Court, leaving any sales subject to § 1498(a) left at its conclusion limited to the quantification of damages owed by the Government to Plaintiffs in the Court of Federal Claims.

V. Plaintiffs Would be Prejudiced by Pursuing Relief in the Court of Federal Claims.

The tactical advantage of attempting to avoid estoppel is hardly the only reason that Moderna (and now the Government) have sought dismissal under § 1498(a). Litigation in this forum carries both procedural and substantive advantages that would not be afforded to Plaintiffs in the Court of Federal Claims, and Plaintiffs should not be deprived of their rights in this forum on an undeveloped record. For example, Plaintiffs are entitled under the Seventh Amendment to trial by jury in this Court; proceedings in the Court of Federal Claims, on the other hand, carry no such right. *E.g.*, *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 377 (1996). Plaintiffs also are seeking enhanced damages for willful patent infringement, potentially trebling the billions of dollars of compensatory liability. *E.g.*, D.I. 1 ¶¶ 31–38, 39–50, 77, 82–83, 96, 101–02, 118, 123–24, 142, 147–48, 161, 166–67, 186–87. This remedy is unavailable in a suit against the Government in the Court of Federal Claims. *See, e.g.*, *Return Mail, Inc. v. USPS*, 139 S. Ct. 1853, 1866–67 (2019). And, as above, Plaintiffs would be prejudiced by any attempt by the Government to relitigate issues of infringement and validity that had been established in other fora.

Before the Court determines whether Plaintiffs should be deprived of these aspects of litigation in this forum, Plaintiffs should be afforded a full and fair opportunity to develop a factual record for the Court to consider when deciding the important question of the application of § 1498(a) to the acts of infringement alleged in this case.

Respectfully submitted,

/s/ Nathan R. Hoeschen

Nathan R. Hoeschen (No. 6232)

cc: Clerk of the Court (by CM/ECF)
All counsel of record (by CM/ECF and e-mail)
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Exhibit 1

Exhibit 2

ELIZABETH WARREN
MASSACHUSETTS

COMMITTEES:
BANKING, HOUSING, AND URBAN AFFAIRS
ARMED SERVICES
FINANCE
SPECIAL COMMITTEE ON AGING

United States Senate

UNITED STATES SENATE
WASHINGTON, DC 20510–2105
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www.warren.senate.gov

April 22, 2022

The Honorable Xavier Becerra
Secretary
U.S. Department of Health & Human Services
200 Independence Avenue SW
Washington, DC 20201

Dear Secretary Becerra:

I write to bring to your attention to a new letter, sent to me by over 25 legal and public health experts, describing "three powerful tools that the [Biden Administration] can use to lower drug prices by breaking patent barriers and accelerating competition."[1]

According to the letter, which was led by experts from Yale Law School, Harvard Medical School, and Columbia Law School:

> High prescription drug prices in the United States are a major problem today for both patients and the sustainability of our healthcare system. Importantly, these prices do not typically reflect material factors like supply shortages, manufacturing difficulties, or labor costs. Instead, drug prices are high primarily because brand-name drug companies use government-granted exclusivities, such as patents, to prevent competition and charge high prices.
>
> Existing law gives the executive branch several tools to intervene when patients and public health are harmed by excessive drug prices. These tools can help the Administration break patent barriers, foster competition where currently there is none, and drive down prices. **Critically, using them requires no additional congressional action.**
>
> This letter describes three of these tools: the "government patent use power" codified at 28 U.S.C. § 1498, and the Bayh-Dole Act's "royalty-free license" and "march-in rights." **These tools are integral, longstanding, and legitimate parts of our patent system.** Together, their directed use can help the government obtain fair prices for prescription drugs.

[1] Letter from Legal and Public Health Experts to Senator Elizabeth Warren, April 20, 2022, https://www.warren.senate.gov/imo/media/doc/2022.4.20%20Letter%20to%20Warren%20on%20Drug%20Pricing%20Executive%20Authorities.pdf.

I have repeatedly called upon the Administration to use its executive powers to lower drug prices,[2] as explicitly contemplated by the Department of Health and Human Service's Comprehensive Plan for Addressing High Drug Prices.[3] The attached letter affirms in extraordinary detail that you have the legal authority to do so. Consistent with these experts' conclusions, I urge you to move swiftly to use your existing authorities to give sorely needed relief to the millions of Americans paying far too much for their prescription drugs.

Thank you for your attention to this important matter.

Sincerely,

Elizabeth Warren
United States Senator

Enclosure

[2] *See, e.g.*, Letter from Senator Elizabeth Warren, Senator Angus King, and Congressman Lloyd Doggett to HHS Secretary Xavier Becerra, February 17, 2022, https://www.warren.senate.gov/imo/media/doc/2022.02.17%20Letter%20to%20Sec.%20Becerra%20on%20Xtandi%20March-in%20Petition%20(2).pdf; Letter from Senator Elizabeth Warren, Senator Amy Klobuchar, and Congressman Lloyd Doggett to HHS Secretary Xavier Becerra, July 28, 2021, https://www.warren.senate.gov/imo/media/doc/2021.07.28%20Letter%20to%20Secretary%20Becerra%20re%20Drug%20Pricing%20Authorities.pdf.

[3] U.S. Department of Health & Human Services, Office of the Assistant Secretary for Planning and Evaluation, "Comprehensive Plan for Addressing High Drug Prices: A Report in Response to the Executive Order on Competition in the American Economy," September 9, 2021, p. 22, https://aspe.hhs.gov/sites/default/files/2021-09/Competition%20EO%2045-Day%20Drug%20Pricing%20Report%209-8-2021.pdf.

Exhibit 3

Congress of the United States
Washington, DC 20515

June 23, 2022

The Honorable Xavier Becerra
Secretary
Department of Health and Human Services
200 Independent Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Becerra:

We write to you today to urge you to utilize administrative authorities, including government patent use compulsory licensing under 28 U.S.C. 1498 and march-in and royalty-free rights under the *Bayh-Dole Act*, to lower prescription drug prices.

Americans pay more than two-and-a-half times as much for prescription drugs as people in other countries.[1] This is especially perverse and upsetting, given that U.S. taxpayers drive biomedical research through more than $40 billion in annual investments through the National Institutes of Health.[2] High U.S. medicine prices are the result of prescription drug corporations using their monopoly power to hike prices and pad their bottom lines. Meanwhile, U.S. law forbids direct government negotiations and other restrictions on pharmaceutical pricing.[3] This uniquely American combination of rules has led to pharmaceutical companies making more money in the U.S. than the rest of the world combined for the 20 top-selling drugs.[4]

Sky-high prices for medicines can be devastating for Americans' finances and health, leading to hardships and personal tragedies for families across the nation.

One in four Americans report they have been unable to afford their medicines, with Black and brown communities disproportionately bearing this suffering.[5] Patients confronted with exorbitant prices are forced to make difficult decisions between filling prescriptions and putting food on the table or paying rent. And people with chronic illnesses who are forced to skip or

[1] RAND, "Prescription Drug Prices in the United States Are 2.56 Times Those in Other Countries," press release, January 28, 2021, https://www.rand.org/news/press/2021/01/28.html.
[2] National Institutes of Health, "Budget," https://www.nih.gov/about-nih/what-we-do/budget#note.
[3] Kaiser Family Foundation, "Drug Price Negotiation Doesn't Mean the Government Will Restrict Access to Medicines," Juliette Cubanski and Larry Levitt, October 7, 2021, https://www.kff.org/policy-watch/drug-price-negotiation-doesnt-mean-the-government-will-restrict-access-to-medicines/.
[4] Public Citizen, "United We Spend," Rick Claypool and Zain Rizvi, September 30, 2021, https://www.citizen.org/article/united-we-spend-big-pharma-us-international-revenue-report/.
[5] Gallup, "In U.S., Large Racial Divide in COVID-19 Cost Concerns," Dan Witters, July 29, 2020, https://news.gallup.com/poll/316052/large-racial-divide-covid-cost-concerns.aspx; U.S. Department of Health and Human Services, "Prescription Drug Affordability among Medicare Beneficiaries," January 2022, p. 1, https://aspe.hhs.gov/sites/default/files/documents/1e2879846aa54939c56efeec9c6f96f0/prescription-drug-affordability.pdf.

delay medication due to cost are more likely to experience adverse health events, including death.[6]

We thank you and President Biden for your leadership in seeking relief for many of these patients by calling for Congress to finally allow Medicare to negotiate drug prices for a selection of high-priced, brand-name drugs and to prevent prices for all drugs from rising faster than the rate of inflation.[7] We stand committed to delivering on these vital legislative priorities. But to provide the urgent relief that Americans demand, including patients who would not initially benefit from Medicare drug price negotiations, you must simultaneously use the executive tools readily at your disposal.

Exercising these authorities would be extraordinarily popular – about 80 percent of voters favor breaking patent monopolies to reduce drug prices.[8] Moreover, using executive tools to lower drug prices while also supporting robust drug pricing legislation is the policy of the administration as expressed by President Biden in the executive order he signed last summer, *Promoting Competition in the American Economy*.[9] The order directs the Department of Health and Human Services to ensure that the patent system does not "unjustifiably delay generic drug and biosimilar competition," while also expressing support for "aggressive" legislative reforms.[10] It also directs the National Institute of Standards and Technology to consider not finalizing a Trump-era regulation that would prevent the government from exercising certain rights under the *Bayh-Dole Act* to lower drug prices on medicines invented with taxpayer funds.[11]

Utilizing patent licensing authorities under these statutes could introduce generic or biosimilar competition and dramatic price relief in a matter of months. In your report released in September 2021, you recognized that the federal government holds government use patent licensing rights under 28 U.S.C. 1498 and march-in rights under the *Bayh-Dole Act*.[12] The report concludes that legislative and administrative actions presented in its pages "…will protect American patients and improve their access and adherence to medications by lowering drug prices through increased competition throughout the health care system."[13]

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[6] Centers for Disease Control and Prevention, "Cost-Related Nonadherence and Mortality in Patients With Chronic Disease: A Multiyear Investigation, National Health Interview Survey, 2000-2014," Sarah C. Van Alsten, Jenine K. Harris, December 3, 2020, https://www.cdc.gov/pcd/issues/2020/20_0244.htm.

[7] The White House, "FACT SHEET: President Biden Calls on Congress to Lower Prescription Drug Prices," press release, August 12, 2021, https://www.whitehouse.gov/briefing-room/statements-releases/2021/08/12/fact-sheet-president-biden-calls-on-congress-to-lower-prescription-drug-prices/.

[8] Arnold Ventures, "Prescription Drug Prices: The Voters Speak," March 2019, https://craftmediabucket.s3.amazonaws.com/uploads/AV-Summary-of-Polling-Project_052119_FINAL.pdf.

[9] The White House, "Executive Order on Promoting Competition in the American Economy," July 9, 2021, https://www.whitehouse.gov/briefing-room/presidential-actions/2021/07/09/executive-order-on-promoting-competition-in-the-american-economy/.

[10] *Id.*

[11] *Id.*

[12] U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, "Comprehensive Plan for Addressing High Drug Prices," September 9, 2021, https://aspe.hhs.gov/sites/default/files/2021-09/Competition%20EO%2045-Day%20Drug%20Pricing%20Report%209-8-2021.pdf.

[13] *Id.*

You personally understand the value that these authorities can provide to American patients. We appreciate that as California's attorney general, you led a bipartisan initiative of state attorneys general in urging the prior administration to use its licensing authorities to ensure access to and secure a fair price for the drug remdesivir. [14] As a member of Congress, you also called on the Obama administration to use competitive licensing to lower drug prices.[15]

Now, you have the power to take on the monopoly abuses of the pharmaceutical industry and the responsibility to ensure Americans have affordable access to the medicines they need. We respectfully request a meeting with you by July 15, 2022 to discuss the Department's efforts to urgently lower drug prices for Americans using these authorities. You can provide immediate relief for millions of patients from Big Pharma's price gouging and show millions more Americans that you, President Biden, and his administration are on their side. Please do so without delay.

Sincerely,

Elizabeth Warren
United States Senator

Lloyd Doggett
Member of Congress

Angus S. King, Jr.
United States Senator

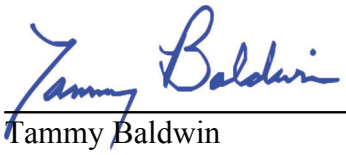
Joaquin Castro
Member of Congress

[14] State of California Department of Justice, "Attorneys General Becerra and Landry Lead Bipartisan Coalition Urging Federal Government Action to Increase Access and Affordability for Remdesivir," press release, August 4, 2020, https://oag.ca.gov/news/press-releases/attorneys-general-becerra-and-landry-lead-bipartisan-coalition-urging-federal.

[15] Knowledge Ecology International, "2016: 51 members of Congress have asked the NIH to use March-In rights to rein in high drug prices," James Love, January 11, 2016, https://www.keionline.org/22983.

Sara Jacobs
Member of Congress

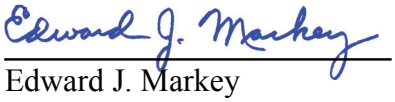
Katie Porter
Member of Congress



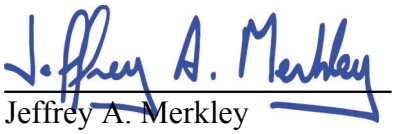
Tammy Baldwin
United States Senator

Sherrod Brown
United States Senator

Cory A. Booker
United States Senator



Edward J. Markey
United States Senator



Jeffrey A. Merkley
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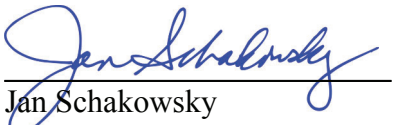
Bernard Sanders
United States Senator



Jan Schakowsky
Member of Congress

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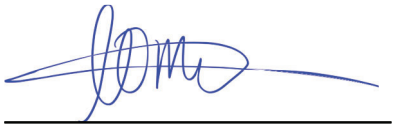

Ilhan Omar
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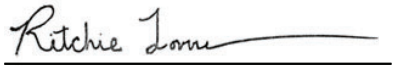
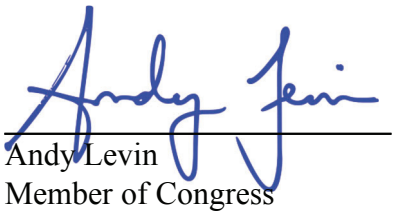
Maxine Waters
Member of Congress



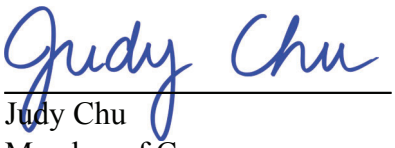
Ritchie Torres
Member of Congress



Andy Levin
Member of Congress

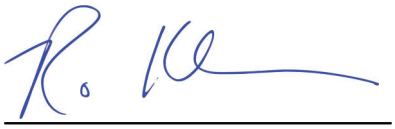
Brenda L. Lawrence
Member of Congress

Adriano Espaillat
Member of Congress



Judy Chu
Member of Congress

Mark Pocan
Member of Congress



Ro Khanna
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Raúl M. Grijalva
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Michael F. Q. San Nicolas
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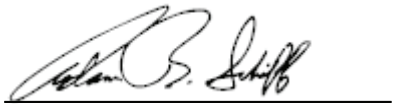
Pramila Jayapal
Member of Congress



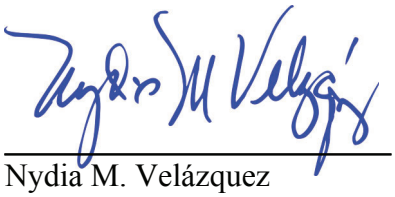
Adam B. Schiff
Member of Congress

John Garamendi
Member of Congress

Rashida Tlaib
Member of Congress

Al Green
Member of Congress

Carolyn B. Maloney
Member of Congress



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Ann McLane Kuster
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Peter Welch
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Frederica S. Wilson
Member of Congress

David N. Cicilline
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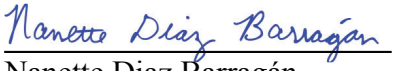

Nanette Diaz Barragán
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John Yarmuth
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Adam Smith
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Sylvia R. Garcia
Member of Congress

Debbie Dingell
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Ayanna Pressley
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Mark Takano
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Barbara Lee
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Chellie Pingree
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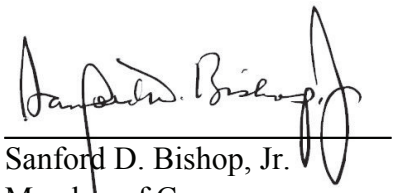
Matt Cartwright
Member of Congress



Sanford D. Bishop, Jr.
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Jamaal Bowman, Ed.D.
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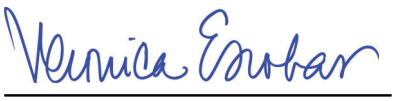

Veronica Escobar
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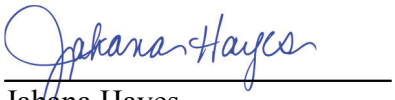
Cori Bush
Member of Congress

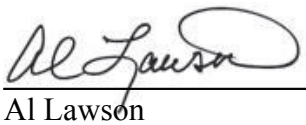
Jerrold Nadler
Member of Congress



Jahana Hayes
Member of Congress

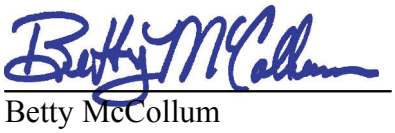
Marie Newman
Member of Congress

Karen Bass
Member of Congress



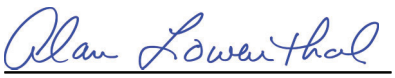
Al Lawson
Member of Congress

Salud Carbajal
Member of Congress



Betty McCollum
Member of Congress

Melanie Stansbury
Member of Congress



Alan Lowenthal
Member of Congress

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Member of Congress

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Terri A. Sewell
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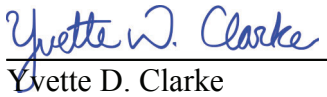
Troy Carter
Member of Congress

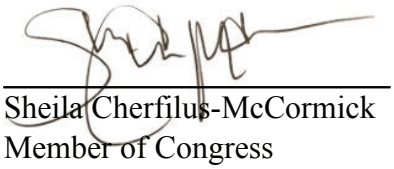
Dean Phillips
Member of Congress



Yvette D. Clarke
Member of Congress

Dina Titus
Member of Congress

Alexandria Ocasio-Cortez
Member of Congress



Sheila Cherfilus-McCormick
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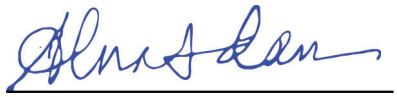
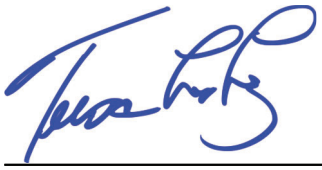
Grace F. Napolitano
Member of Congress

Norma J. Torres
Member of Congress



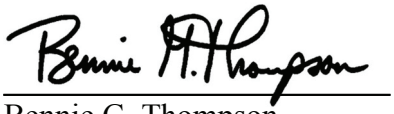
Alma S. Adams, Ph.D.
Member of Congress



Teresa Leger Fernández
Member of Congress

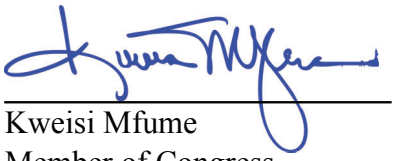
Anthony G. Brown
Member of Congress

Emanuel Cleaver, II
Member of Congress



Bennie G. Thompson
Member of Congress

Ted Lieu
Member of Congress



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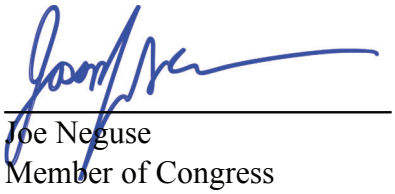
Member of Congress



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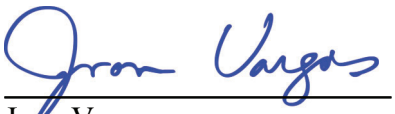
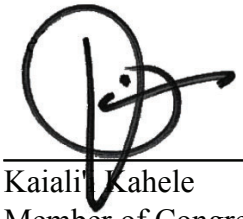
Member of Congress



Juan Vargas
Member of Congress



Kaiali'i Kahele
Member of Congress

Eddie Bernice Johnson
Member of Congress

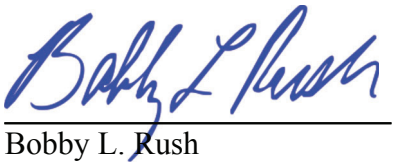
Kathy Manning
Member of Congress

Brad Sherman
Member of Congress

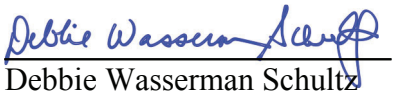
Earl Blumenauer
Member of Congress

Sean Casten
Member of Congress

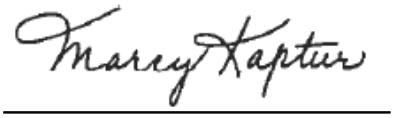
Mary Gay Scanlon
Member of Congress



Bobby L. Rush
Member of Congress



Debbie Wasserman Schultz
Member of Congress



Marcy Kaptur
Member of Congress

Ed Perlmutter
Member of Congress

Exhibit 4

Two senators accuse Moderna of 'greed' for its plan to quadruple COVID vaccine cost

Elizabeth Warren of Massachusetts and Peter Welch of Vermont say that shots could become unaffordable for some Americans.

By **Jonathan Saltzman** Globe Staff, Updated January 25, 2023, 6:00 a.m.

Moderna building in Cambridge. BLAKE NISSEN FOR THE BOSTON GLOBE/FILE

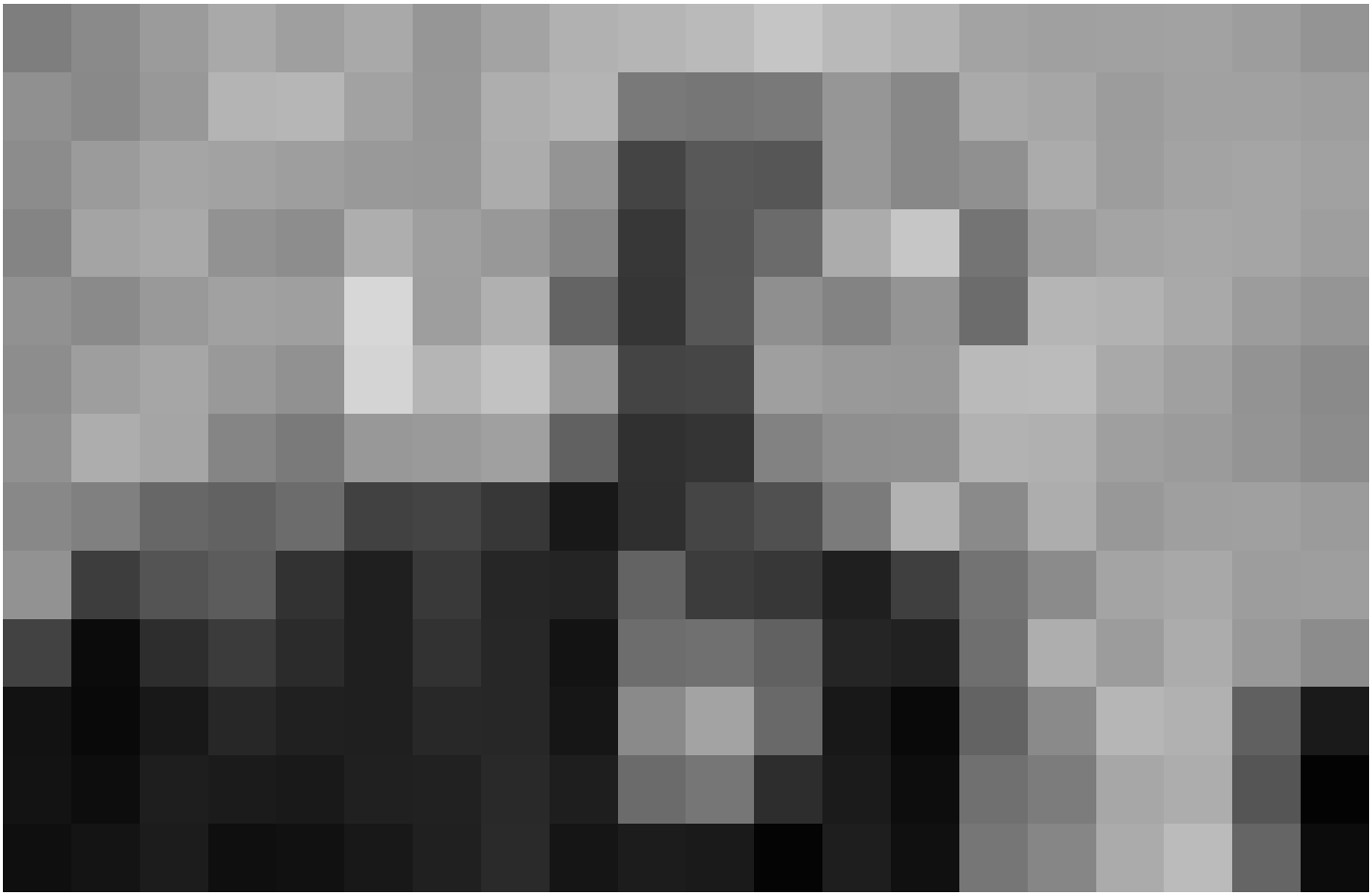
US Senators Elizabeth Warren of Massachusetts and Peter Welch of Vermont are urging Moderna's chief executive to reconsider a plan to quadruple the cost of its COVID-19

vaccine, saying the Cambridge firm’s “greed” threatens to make the shots unaffordable to some Americans.

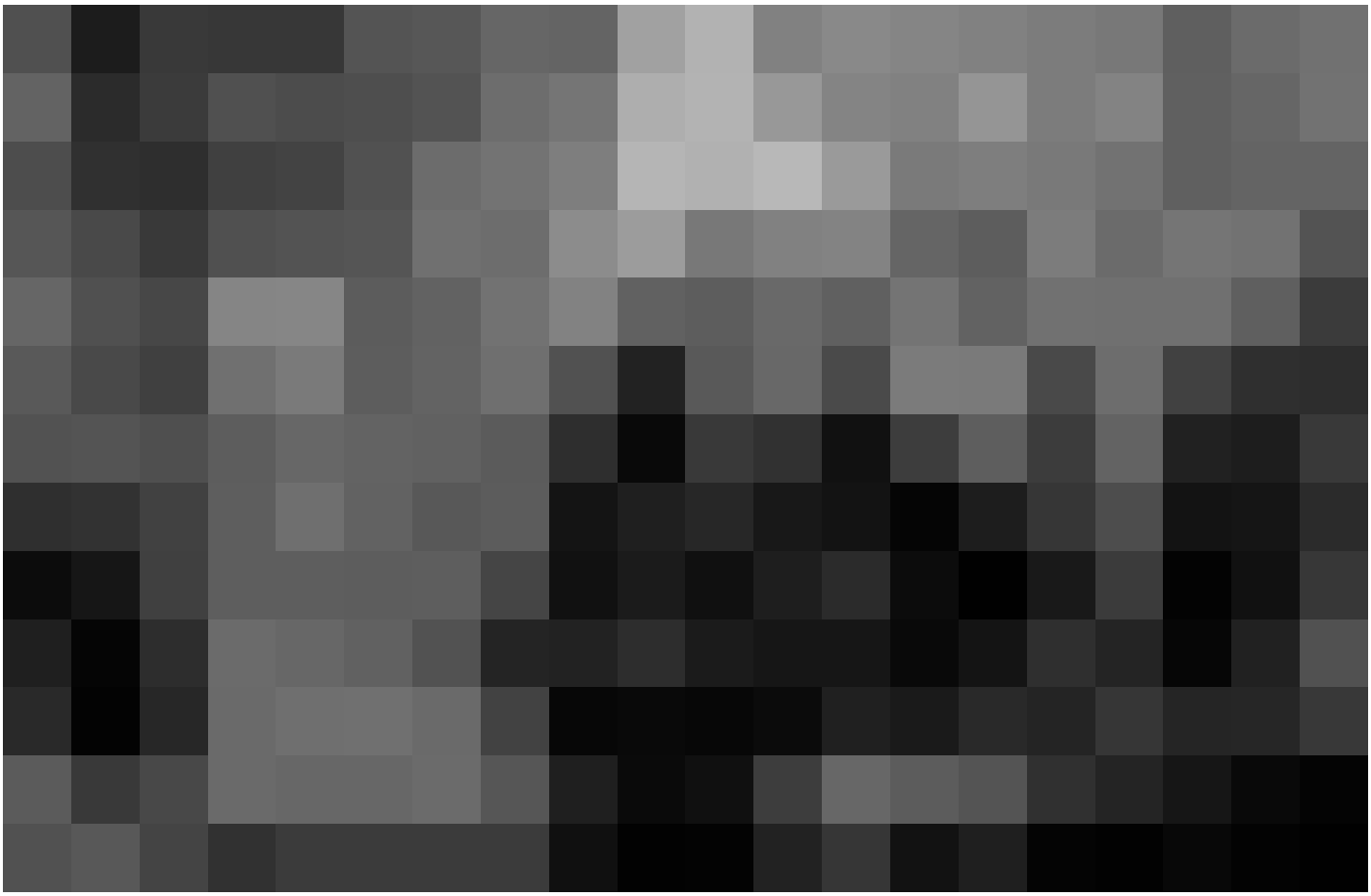
In a firmly worded letter to CEO Stéphane Bancel, the Democratic senators denounced the proposal to quadruple the price from about $26 per dose to between $110 and $130. They said the biotech received billions of dollars from US taxpayers for research, development and advance purchases and that the company has used the resulting outsized profits to reward company executives and shareholders.

Although the Cambridge-based biotech’s messenger RNA vaccine has helped to tame the pandemic, the senators wrote Wednesday, “this progress may be put at risk because of Moderna’s greed, which has the potential to increase vaccination costs for millions of un- and underinsured Americans.”

In a statement, Moderna said its vaccines have saved the lives of hundreds of millions of people around the world and that their prices reflect their value. The firm also said most Americans won’t notice the difference because insurers will cover the cost.



Senator Elizabeth Warren JACQUELYN MARTIN/ASSOCIATED PRESS



Senator Peter Welch J. SCOTT APPLEWHITE/ASSOCIATED PRESS

"It is important to note that, upon transition to a commercial market and consistent with preventive services coverage requirements, Moderna's COVID-19 vaccines and boosters will continue to be available at no cost for the vast majority of people in the United States," the company said.

Warren and Welch sent a similar letter to Pfizer chief executive Albert Bourla last month after he said the pharmaceutical giant planned to raise the price of its rival mRNA vaccine to the same range. At a conference hosted by STAT in November, Bourla said the vaccine will still be "free for all Americans" because insurers will pick up the cost. But critics said the higher cost borne by insurers will be passed on in the form of higher premiums.

In the case of Moderna, Bancel told The Wall Street Journal on Jan. 9 that his company was considering raising the price when the federal government's contract ends and the vaccine shifts to commercial distribution. The government currently distributes the shots for free.

Bancel's announcement prompted a swift denunciation from Vermont's senior senator, Bernie Sanders, an independent and the incoming chair of the Senate's health committee. In a letter of his own to Moderna's head, he said Bancel's plan was "outrageous" and amounted to "unacceptable corporate greed."

In this week's letter, Warren and Welch asked Bancel to respond to a series of nine questions by Feb. 7, including whether Moderna executives consulted Pfizer executives about planning similar price increases, raising the specter of a possible anti-trust violation.

Jonathan Saltzman can be reached at jonathan.saltzman@globe.com.

Show 51 comments

Exhibit 5

United States Senate
WASHINGTON, DC 20510

January 10, 2023

Stéphane Bancel
Chief Executive Officer
Moderna
200 Technology Square
Cambridge, MA 02139

Dear Mr. Bancel:

Yesterday, the Wall Street Journal reported that Moderna is considering more than quadrupling the price of its COVID vaccine after the supply that the U.S. government purchased, and distributed to Americans at no cost, is depleted. Instead of charging $26.36 per dose, the price that the government paid, Moderna has indicated that the commercial price will go up to as much as $130 per dose.

I have very deep concerns about that decision and the impact that it will have on the federal budget, the cost of private insurance and the unnecessary deaths that may occur because millions of Americans may not be able to afford the vaccine at the new cost.

I am writing to ask you to reconsider your decision and refrain from any price increases.

The huge increase in price that you have proposed will have a significantly negative impact on the budgets of Medicaid, Medicare and other government programs that will continue covering the vaccine without cost-sharing for patients. Your decision will cost taxpayers billions of dollars. Your outrageous price boost will also increase private health insurance premiums. Perhaps most significantly, the quadrupling of prices will make the vaccine unavailable for many millions of uninsured and underinsured Americans who will not be able to afford it. How many of these Americans will die from COVID-19 as a result of limited access to these lifesaving vaccines? While nobody can predict the exact figure, the number could well be in the thousands. In the midst of a deadly pandemic, restricting access to this much needed vaccine is unconscionable.

I find your decision particularly offensive given the fact that the vaccine was jointly developed in partnership with scientists from the National Institutes of Health (NIH), a U.S. government agency that is funded by U.S. taxpayers. The federal government directly provided $1.7 billion to your company for research and development, and guaranteed your company billions more in sales. In other words, you propose to make the vaccine unaffordable for the residents of this country who made the production of the vaccine possible. That is not acceptable.

Mr. Bancel: In the last two years, Moderna made over $19 billion in profits and used those profits to provide incredibly extravagant compensation packages to you and other top officials at

your company. It is reported that you, yourself, became a multi-billionaire as a direct result of Moderna's COVID vaccine with Forbes currently estimating your wealth at $6.1 billion.

Moreover, Noubar Afeyan, Moderna's chairman and co-founder is currently worth $2.1 billion. Robert Langer, another co-founder of Moderna, is now worth $2.2 billion. Timothy Springer, a founding investor in Moderna is now worth $2.6 billion. Further, my understanding is that Moderna approved a $926 million golden parachute for you once you leave the company along with $160 million for Stephen Hoge (Moderna's president) and $53 million for Juan Andres (Moderna's chief technical officer).

I should point out that all of this corporate welfare and profiteering has taken place in the midst of the worst public health crisis in America in 100 years. In the last three years, nearly 1.1 million Americans died from COVID-19 and over 100 million more have become ill. It has also been estimated that the cost of producing the vaccine is now as low as $2.85 per dose – 2.2% of what Moderna has suggested charging to the public.

Let's be clear: The purpose of the recent taxpayer investment in Moderna was to protect the health and lives of the American people, not to turn a handful of corporate executives and investors into multi-billionaires.

As you know, the federal government, over the years, has supported Moderna every step of the way going back to 2013 when your company reportedly only had three employees. Now, in the midst of a continuing public health crisis and a growing federal deficit, is not the time for Moderna to be quadrupling the price of this vaccine. Now is not the time for unacceptable corporate greed.

As the incoming Chairman of the Committee on Health, Education, Labor and Pensions in the United States Senate, I look forward to hearing your response in the very near future.

Sincerely,

Bernard Sanders
United States Senator

Exhibit 6

United States Senate

WASHINGTON, DC 20510

January 24, 2023

Stéphane Bancel
Chief Executive Officer
Moderna
200 Technology Square
Cambridge, MA 02139

Dear Mr. Bancel:

We write to you today regarding reports that Moderna is considering plans to dramatically increase the price of its COVID-19 vaccine, charging between $110 and $130 per dose for commercial distribution.[1] Your company has already earned billions in profits from the vaccine, which benefited from extensive taxpayer support for research and development,[2] and your proposed price increase threatens to reduce access to a life-saving vaccine while boosting your company's profits. In addition, your price increase closely follows Pfizer's October 2022 proposed increase for its COVID-19 vaccine,[3] raising questions about whether, and if so how, Pfizer's announcement has influenced Moderna's conversations around vaccine pricing. Moderna's reported plans to charge as much as $130 per dose for its COVID-19 vaccines could prolong the public health crisis caused by COVID-19 and leave many uninsured Americans simply unable to afford the vaccine. We are writing today to request additional information.

Moderna's planned price hikes come after both Moderna and Pfizer raked in billions during the COVID-19 pandemic.[4] Moderna earned $12 *billion* in net income in 2021,[5] and earlier this

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[1] Wall Street Journal, "Moderna Considers Price of $110-$130 for Covid-19 Vaccine," Peter Loftus, January 9, 2023, https://www.wsj.com/articles/moderna-considers-price-of-110-130-for-covid-19-vaccine-11673289609.

[2] Boston Globe, "The U.S. Government Has Now Paid Moderna $6b for Vaccine Effort," Jonathan Saltzman, April 29, 2021, https://www.bostonglobe.com/2021/04/29/nation/us-government-has-now-given-moderna-6b-vaccine-effort/;
U.S. Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, "COVID-19 Medical Countermeasure Portfolio," https://www.medicalcountermeasures.gov/app/barda/coronavirus/COVID19.aspx?filter=vaccine.

[3] Reuters, "Pfizer COVID vaccine price hike to boost revenue for years, rivals may follow," Michael Erman, October 21, 2022, https://www.reuters.com/business/healthcare-pharmaceuticals/pfizer-covid-vaccine-price-hike-seen-giving-revenue-boost-years-2022-10-21/.

[4] Reuters, "Pfizer, Moderna seen reaping billions from COVID-19 vaccine booster market," Michael Erman, August 13, 2021, https://www.reuters.com/business/healthcare-pharmaceuticals/pfizer-moderna-seen-reaping-billions-covid-19-vaccine-booster-market-2021-08-13/.

[5] Securities and Exchange Commission, Moderna, Inc., Form 10-K, p. 106, February 25, 2022, https://www.sec.gov/ix?doc=/Archives/edgar/data/1682852/000168285222000012/mrna-20211231.htm.

month, Moderna projected that 2023 sales of the COVID-19 vaccine would be "at least" $5 billion.[6] Moderna used these outsized profits to richly reward company executives and shareholders. Your compensation jumped 41 percent in 2021 to $18.2 million due to "unprecedented growth."[7] In addition, Moderna announced a $3 billion buyback program in August 2022.[8]

When Pfizer announced plans to raise the price of its COVID-19 vaccine in October 2022,[9] we warned that these hikes could "pave the way for other vaccine manufacturers […] to raise the prices of their vaccines."[10] Moderna's price hikes, aside from threatening public health, also raise questions about how Pfizer's similar announcement of vaccine price hikes in October 2022 may have influenced Moderna's decision-making process regarding its vaccine prices.

The production of the COVID-19 vaccine was an extraordinary achievement that saved more than 3 million lives in the United States and helped the world escape from the worst ravages of the pandemic.[11] But your company didn't achieve this milestone alone: nearly every step of the vaccine development benefited from taxpayer funding, from basic research investment to absorbing manufacturing investment and market risk.[12] Moderna's vaccine "grew out of a four-year collaboration between Moderna and the National Institute of Health,"[13] and the vaccine relies on basic technology developed from federally funded research.[14] And the company itself accepted $10 billion in taxpayer money for research, development, and advanced purchases of the vaccine between April 16, 2020 and June 15, 2021.[15]

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[6] Fierce Pharma, "JPM23: Moderna reaped $18.4B in COVID vaccine sales last year, projects at least $5B in 2023," Kevin Dunleavy, January 9, 2023, https://www.fiercepharma.com/pharma/moderna-covid-vax-scarfed-sales-184b-2022-company-says#:~:text=The%20company%20said%20it%20had,reach%20at%20least%20%245%20billion..

[7] Fierce Pharma, "Moderna CEO's pay jumps 41% to $18.2M as COVID vaccine giant expands globally," Angus Liu, March 10, 2022, https://www.fiercepharma.com/pharma/moderna-ceo-stephane-bancel-pay-jumps-41-182m-covid-vaccine-giant-expands-globally.

[8] Bloomberg, "Moderna Plans $3 Billion Buyback With Covid Market Shifting," Angelica Peebles, August 3, 2022, https://www.bloomberg.com/news/articles/2022-08-03/moderna-to-buy-back-shares-with-covid-shot-outlook-steady?leadSource=uverify%20wall.

[9] Reuters, "Pfizer COVID vaccine price hike to boost revenue for years, rivals may follow," Michael Erman, October 21, 2022, https://www.reuters.com/business/healthcare-pharmaceuticals/pfizer-covid-vaccine-price-hike-seen-giving-revenue-boost-years-2022-10-21/.

[10] Letter from Senator Elizabeth Warren to Pfizer CEO Albert Bourla, December 12, 2022, https://www.warren.senate.gov/imo/media/doc/2022.12.12%20Letter%20to%20Pfizer%20on%20Vaccine%20Price%20Hikes.pdf.

[11] CNN, "Covid-19 vaccines have saved more than 3 million lives in US, study says, but the fight isn't over," Jen Christensen, December 13, 2022, https://www.cnn.com/2022/12/13/health/covid-19-vaccines-study/index.html.

[12] Health Affairs, "It Was The Government That Produced COVID-19 Vaccine Success," Richard G. Frank, Leslie Dach, and Nicole Lurie, May 14, 2021, https://www.healthaffairs.org/do/10.1377/forefront.20210512.191448/.

[13] New York Times, "Moderna and U.S. at Odds Over Vaccine Patent Rights," Sheryl Gay Stolberg and Rebecca Robbins, November 9, 2021, https://www.nytimes.com/2021/11/09/us/moderna-vaccine-patent.html.

[14] Scientific American, "For Billion-Dollar COVID Vaccines, Basic Government-Funded Science Laid the Groundwork," Arthur Allen, November 18, 2020, https://www.scientificamerican.com/article/for-billion-dollar-covid-vaccines-basic-government-funded-science-laid-the-groundwork/.

[15] Pharmaceutical Technology, "Top Ten Pharma Companies in 2020," Updated June 1, 2021,

Thanks to billions of federal dollars used to support production and delivery of Moderna's vaccine product, Moderna's COVID-19 vaccine is currently free for patients in the United States. Over 665 million doses of the COVID-19 vaccine have been administered in the U.S., and many million more worldwide, and more 80 percent of the total U.S. population has received at least one dose.[16] This is a landmark public health achievement. But this progress may be put at risk because of Moderna's greed, which has the potential to increase vaccination costs for millions of un- and underinsured Americans. We urge you to reconsider your proposed price increases and ensure COVID-19 vaccines are reasonably priced and accessible to people across the United States. And we request answers to the following questions by February 7, 2023.

1. How much revenue is Moderna expected to earn from the COVID-19 vaccine for the full 2022 calendar year?
2. How much revenue does Moderna estimate it would earn from the COVID-19 vaccine in 2023 if it does not increase the vaccine's price?
3. How much revenue does Moderna estimate it will earn from the COVID-19 vaccine in 2023 factoring in the increase in the vaccine's price?
4. How much profit did Moderna earn from the COVID-19 vaccine in 2021? How much profit is the company expected to earn from its vaccine for the full 2022 calendar year?
5. How much profit does Moderna estimate it would earn from the COVID-19 vaccine in 2023 if it does not increase the vaccine's price?
6. How much profit does Moderna estimate it will earn from the COVID-19 vaccine in 2023 factoring in the increase in the vaccine's price?
7. How much will Moderna charge Medicare, Medicaid, and the VA for the COVID-19 vaccine in 2023? How much does Moderna estimate that it will charge private insurers for the vaccine?
8. Did Moderna executives, officials, or any other Moderna-affiliated individual have any direct or indirect communication with Pfizer about the companies' price increases for their COVID-19 vaccines? If so, please describe the timing and nature of these discussions.

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https://www.pharmaceutical-technology.com/features/top-ten-pharma-companies-in-2020/; Boston Globe, "The U.S. Government Has Now Paid Moderna $6b for Vaccine Effort," Jonathan Saltzman, April 29, 2021, https://www.bostonglobe.com/2021/04/29/nation/us-government-has-now-given-moderna-6b-vaccine-effort/; U.S. Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, "COVID-19 Medical Countermeasure Portfolio," Accessed October 4, 2021, https://www.medicalcountermeasures.gov/app/barda/coronavirus/COVID19.aspx?filter=vaccine.

[16] Centers for Disease Control and Prevention, "COVID-19 Vaccinations in the United States," https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-total-admin-rate-total.

9. Did Moderna employees have any internal discussions about the Pfizer price increase when determining Moderna's proposed price increase for its COVID-19 vaccine? If so, please describe the timing and nature of these discussions.

Sincerely,

Elizabeth Warren
United States Senator

Peter Welch
United States Senator

Exhibit 7

NEWS RELEASE

Moderna Announces New Supply Contract With The U.S. Government For An Initial 66 Million Doses Of A Moderna Bivalent Covid-19 Booster Vaccine With Options For U.S. Government To Purchase Up To An Additional 234 Million Doses

7/29/2022

New U.S. government contract includes an award up to $1.74 billion for 66 million doses to be delivered in 2022; additional options, if exercised, may raise total to 300 million doses

CAMBRIDGE, MA / ACCESSWIRE / July 29, 2022 / Moderna, Inc., (Nasdaq:MRNA) a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines, today announced that the U.S. government has secured 66 million doses of a Moderna COVID-19 vaccine booster candidate, mRNA-1273.222, a bivalent booster candidate containing Spikevax™ plus the Omicron BA.4/5 strain mRNA.

The contract includes an award of up to $1.74 billion for the manufacture and delivery of 66 million doses of mRNA-1273.222, as well as options to purchase up to an additional 234 million doses of COVID-19 vaccine booster candidates from Moderna.

"We are pleased to extend our successful collaboration with the U.S. government," said Stéphane Bancel, Chief Executive Officer of Moderna. "Moderna's mRNA platform is enabling us to rapidly create mRNA-1273.222, a bivalent vaccine that specifically targets Omicron subvariants BA.4 and BA.5, the most prevalent variants of concern in the U.S. today. We remain fully committed to leveraging our innovative technology platform to offer tailored vaccines that help protect communities against COVID-19."

On July 11, 2022, **Moderna announced that it is advancing two bivalent candidates for the fall** based on different population health security strategies in different countries. mRNA-1273.222 contains the BA.4/5 Omicron strain and is being developed in accordance with recent FDA recommendations, while mRNA-1273.214 contains the BA.1 Omicron strain, which may be of benefit **as noted by the WHO.** These updated bivalent vaccines, if authorized, may offer higher, broader and more durable protection against COVID-19.

The contract announced today is supported by federal funds from the U.S. Department of Health and Human Services, Administration for Strategic Preparedness and Response (ASPR), Biomedical Advanced Research and Development Authority (BARDA) and awarded by the Department of Defense Joint Program Executive Office for Chemical, Biological, Radiological Nuclear Defense (JPEO-CBRND) and the Army Contracting Command under contract number W58P05-22-C-0017.

INDICATION (U.S.)

SPIKEVAX (COVID-19 Vaccine, mRNA) is a vaccine indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older.

IMPORTANT SAFETY INFORMATION

Do not administer to individuals with a known history of severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine.

Appropriate medical treatment to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the vaccine.

Postmarketing data demonstrate increased risks of myocarditis and pericarditis, particularly within 7 days following the second dose. The observed risk is higher among males under 40 years of age than among females and older males. The observed risk is highest in males 18 through 24 years of age.

Syncope (fainting) may occur in association with administration of injectable vaccines. Procedures should be in place to avoid injury from fainting.

Immunocompromised persons, including individuals receiving immunosuppressive therapy, may have a diminished response to the vaccine.

The vaccine may not protect all vaccine recipients.

Adverse reactions reported in clinical trials following administration of the vaccine include pain at the injection site, fatigue, headache, myalgia, arthralgia, chills, nausea/vomiting, axillary swelling/tenderness, fever, swelling at the injection site, and erythema at the injection site, and rash.

The vaccination provider is responsible for mandatory reporting of certain adverse events to the Vaccine Adverse Event Reporting System (VAERS) online at **https://vaers.hhs.gov/reportevent.html** or by calling 1-800-822-7967.

Please see the SPIKEVAX Full Prescribing Information. For information regarding authorized emergency uses of the Moderna COVID-19 Vaccine, please see the EUA Fact Sheet.

About Moderna

In over 10 years since its inception, Moderna has transformed from a research-stage company advancing programs in the field of messenger RNA (mRNA), to an enterprise with a diverse clinical portfolio of vaccines and therapeutics across seven modalities, a broad intellectual property portfolio in areas including mRNA and lipid nanoparticle formulation, and an integrated manufacturing plant that allows for both clinical and commercial production at scale. Moderna maintains alliances with a broad range of domestic and overseas government and commercial collaborators. Most recently, Moderna's capabilities have come together to allow the authorized use and approval of one of the earliest and most effective vaccines against the COVID-19 pandemic.

Moderna's mRNA platform builds on continuous advances in basic and applied mRNA science, delivery technology and manufacturing, and has allowed the development of therapeutics and vaccines for infectious diseases, immuno-oncology, rare diseases, cardiovascular diseases, and autoimmune diseases. Moderna has been named a top biopharmaceutical employer by Science for the past seven years. To learn more, visit **www.modernatx.com**.

Forward Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including regarding: the Company's development of bivalent vaccine candidates against COVID-19 (mRNA-1273.214 and mRNA-1273.222); the U.S. government's purchase of doses of mRNA-1273.222 and potential for further option exercises for the purchase of this vaccine; and the potential for bivalent vaccines to offer higher, broader and more durable protection against COVID-19. The forward-looking statements in this press release are neither promises nor guarantees, and you should not place undue reliance on these forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, many of which are beyond Moderna's control and which could cause actual results to differ materially from those expressed or implied by these forward-looking statements. These risks, uncertainties, and other factors include those other risks and uncertainties described under the heading "Risk Factors" in Moderna's most recent Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (SEC) and in subsequent filings made by Moderna with

the SEC, which are available on the SEC's website at **www.sec.gov**. Except as required by law, Moderna disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this press release in the event of new information, future developments or otherwise. These forward-looking statements are based on Moderna's current expectations and speak only as of the date of this press release.

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Exhibit 8

moderna

VIEW ALL NEWS ⟶

MODERNA'S COMMITMENT TO PATIENT ACCESS IN THE UNITED STATES

02/15/2023

DOWNLOAD

Moderna's vaccines have protected the lives of hundreds of millions of people around the world from COVID-19 and have dramatically lessened the burden of the pandemic to society.

As the public health emergency ends, the United States government will no longer be providing vaccines at no cost. Moderna remains committed to ensuring that people in the United States will have access to our COVID-19 vaccines regardless of ability to pay.

Moderna's COVID-19 vaccines will continue to be available at no cost for insured people whether they receive them at their doctors' offices or local pharmacies. For uninsured or underinsured people, Moderna's patient assistance program* will provide COVID-19 vaccines at no cost.

Everyone in the United States will have access to Moderna's COVID-19 vaccine regardless of their ability to pay.

*Available after the expiry of the COVID-19 Public Health Emergency on May 11, 2023.

VIEW ALL NEWS ⟶

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Exhibit 9

https://www.wsj.com/articles/moderna-considers-price-of-110-130-for-covid-19-vaccine-11673289609

◆ WSJ NEWS EXCLUSIVE HEALTH

Moderna Considers Price of $110-$130 for Covid-19 Vaccine

Commercial price is similar to Pfizer's plans for after government contracting ends

Even at higher per-dose pricing, sales of Moderna's Covid-19 vaccine are expected to decline.
PHOTO: AMIR HAMJA FOR THE WALL STREET JOURNAL

By Peter Loftus Follow

Jan. 9, 2023 1:40 pm ET

Moderna Inc. said it is considering pricing its Covid-19 vaccine in a range of $110 to $130 per dose in the U.S. when it shifts from government contracting to commercial distribution of the shots.

The range is similar to the one Pfizer Inc. said in October it was considering for the Covid-19 vaccine it developed with BioNTech SE.

"I would think this type of pricing is consistent with the value" provided by the vaccine, Moderna Chief Executive Officer Stephane Bancel said in an interview Monday on the sidelines of the J.P. Morgan Healthcare Conference in San Francisco.

The expected price for commercial insurers would be significantly higher than the per-dose cost in Moderna's supply contracts with the federal government. Moderna's updated booster

shots cost about $26 per dose in a federal supply contract signed in July 2022. The original vaccine cost about $15 to $16 per dose in earlier supply contracts.

To date, the federal government has purchased all doses of Covid-19 vaccines and made them available at no cost to consumers. U.S. officials have said that after the supply secured under federal contracts runs out, companies should switch to standard commercial distribution.

Moderna is in discussions with hospital systems, pharmacies and pharmacy-benefit managers to line up distribution of its vaccine ahead of a potential fall booster shot campaign, Mr. Bancel said.

Any booster shots distributed in the fall may be updated to match circulating variants of the coronavirus, Mr. Bancel said.

Even at higher per-dose pricing, sales of Moderna's Covid-19 vaccine are expected to decline. The Cambridge, Mass., company said Monday it expects minimum Covid-19 vaccine sales of about $5 billion for 2023, with the potential for more. For full-year 2022, it recorded about $18.4 billion in Covid-19 vaccine sales.

The company is increasing its focus on potential new products beyond the Covid-19 vaccine, such as a vaccine for respiratory syncytial virus, or RSV. Moderna expects to report results from a large study for its RSV vaccine soon, Mr. Bancel said.

Write to Peter Loftus at peter.loftus@wsj.com

Appeared in the January 10, 2023, print edition as 'Moderna Eyes Range for Covid Shot Pricing'.

EXHIBIT 10

The New York Times https://www.nytimes.com/2023/02/23/science/moderna-covid-vaccine-patent-nih.html

After Long Delay, Moderna Pays N.I.H. for Covid Vaccine Technique

Moderna has paid $400 million to the government for a chemical technique key to its vaccine. But the parties are still locked in a high-stakes dispute over a different patent.

By Benjamin Mueller

Feb. 23, 2023

5 MIN READ

As Moderna racked up tens of billions of dollars in sales of its coronavirus vaccine, the company held off on paying for the rights to a chemical technique that scientists said it had borrowed from government-funded research and used in its wildly successful shot.

But Moderna and the government have now reached an agreement. The company said on Thursday that it had made a $400 million payment for the technique that will be shared by the National Institutes of Health and two American universities where the method was invented.

The payment, disclosed in Moderna's latest earnings report, represented a small victory for the experts and activists who long argued that the company had resisted acknowledging its debt to the government and academic researchers.

"If pharmaceutical companies are going to make billions of dollars, it seems reasonable that the scientists who helped generate some of the initial intellectual property and the universities also share some of the gains," said Jason McLellan, a structural biologist who in 2017 led efforts to devise the technique in question as a researcher at the Geisel School of Medicine at Dartmouth. "A lot of that will now be reinvested for future development and research."

Moderna is still locked in a separate high-stakes dispute with the N.I.H. over who invented the central component of the vaccine, the genetic sequence that helps recipients produce an immune response.

The N.I.H. said its scientists, some of whom had been collaborating for years with Moderna, had helped to design that sequence. Moderna also received nearly $10 billion in taxpayer funding to develop and test the vaccine, and to provide doses to the federal government. The company has sold roughly $36 billion worth of coronavirus vaccines worldwide.

But even as the fight over the sequence attracted public attention, including suggestions from the N.I.H. that it might consider legal action, another standoff played out largely in private, this one concerning the chemical tweak that was the subject of the payments announced on Thursday.

That technique was integral to a number of coronavirus vaccines, including Moderna's, scientists said. It entailed changing the mRNA code within the vaccines so that they would help people generate an immune response to the version of spike proteins present on the surface of the coronavirus before they fused with

human cells.

It appeared indisputable to legal experts that government and academic researchers had invented the technique. Scientists at Dartmouth, Scripps Research, in California, and the N.I.H. published findings in 2017 and filed for a patent. A patent was issued in 2021.

Other vaccine makers, too, acknowledged relying on those researchers' work. By the end of 2021, seven pharmaceutical companies had agreed to pay the three institutions for the use of their technique. Among them was BioNTech, whose coronavirus vaccine made with Pfizer became the main competitor to Moderna's.

But negotiations with Moderna were slower. The delay in licensing the spike technology became another sore point between the company and the government.

"Moderna has benefited richly from government largess, and it does owe a public duty, but it's been very begrudging and slow in acknowledging that public duty," said Lawrence Gostin, a professor of global health law at Georgetown University.

Mr. Gostin said the agreement announced on Thursday, which was finalized in December, was "a small token in the right direction."

Chris Ridley, a Moderna spokesman, said in a statement that the company and the government "have been engaged in productive discussions since 2020 regarding the licensing of certain patents related to Covid-19 vaccines." He added, "It was always our intention to reach an agreement, and we were pleased to have done so this past December."

The N.I.H. did not immediately answer questions about negotiations with Moderna or whether it was still awaiting licensing fees from any other vaccine makers.

Under the agreement with Moderna, the company made what it described as a $400 million "catch-up payment" to the N.I.H. The government will share that money with Dartmouth and Scripps. The individual scientists who helped invent the technique are also likely to receive a portion of the payment, experts said. Moderna said the agreement also required royalty payments representing low single-digit percentages of future Covid-19 vaccine sales.

The company has forecast Covid vaccine sales of $5 billion for 2023.

The N.I.H. tends to be uneasy about aggressively asserting legal rights to its work, experts said, a stance that some activists believe hurts taxpayers who face high prices for medicines developed with government funding and research. In the case of the dispute over the spike-protein technique, experts said, the N.I.H. was in a particularly tricky position because of its parallel fight over who ultimately invented the vaccine.

That put more of the onus on Dartmouth and Scripps to encourage the government and Moderna to reach an agreement. For those institutions, the potential licensing fees represented a significant opportunity to pour money into the very same kinds of research that revealed how to modify the spike protein in the first place.

"We're doing it not to benefit shareholders," said Kim Rosenfield, Dartmouth's director of technology transfer. "This money is going to go right back into the kind of research that enables further lifesaving drugs and into educating people."

For a university of Dartmouth's size, she said, the payments were "game-changing." Royalty payments for an earlier drug developed in part at Dartmouth helped the university set up the research program where Dr. McLellan worked, Ms. Rosenfield said. Now the payments for Dr. McLellan's findings could help cultivate future discoveries.

The university said that it had already received $117 million from vaccine makers that had reached earlier agreements to license the spike technique.

Dr. McLellan had been working at Dartmouth to respond to an outbreak of an earlier coronavirus — one that causes Middle East Respiratory Syndrome, or MERS — when he developed the trick for modifying the spike. The spikes on the surface of that virus, too, were squirmy and unstable, taking one form before invading a cell and another afterward.

Dr. McLellan's team, working with Dr. Barney Graham at the N.I.H. and Andrew Ward at Scripps, knew that the spike needed to be locked in place if it was to elicit the strongest possible immune response. After several attempts failed, they zeroed in on a particularly loose joint of the spike and added two stiff amino acids, a tweak that made the entire thing more rigid.

Philip Hanlon, the president of Dartmouth, said that it had been a "thrilling moment" when the research had been harnessed for the coronavirus vaccines. Ensuring that the university and its scientists were paid for the work, he said, would set the stage for future research, especially experiments risky and uncertain enough that pharmaceutical companies would generally not think it worthwhile to carry them out themselves.

"I think this gives you a model for partnerships where the basic, curiosity-based research did happen on a campus, and led to eventually creating a product which saved millions of lives," he said.

EXHIBIT 11

Section 1498(A) is Not a Rx to Reduce Drug Prices

SUSAN G. BRADEN & JOSHUA A. KRESH*

ABSTRACT

On June 20, 2018, *The New York Times* published an editorial captioned "How the Government Can Lower Drug Prices," announcing that "a possible solution involves an obscure part of federal law known as Section 1498. The provision acts as a sort of eminent domain for patented inventions allowing the government to circumvent patent protections if the patent holder is compensated. In the case of a pharmaceutical, the Department of Health and Human Services (HHS) can authorize a drug maker to produce a low-cost generic version, which it would then buy in bulk."[1] The authority cited by *The New York Times* for this proposition was a 2016 law review article published in the *Yale Journal of Law & Technology* (Yale Article).[2]

Fast forward to March 23, 2021. Within weeks of President Biden's inauguration, Senator Bernie Sanders delivered the Opening Statement at a Senate Committee on Health, Education, Labor, and Pensions Subcommittee hearing citing *The New York Times* editorial as support for the introduction of S. 909, the Prescription Drug Price Relief Act of 2021, proposed legislation that would authorize the HHS Secretary to infringe on pharmaceutical patents or require pharmaceutical patent owners to enter compulsory licenses at royalty rates established by HHS should those patent owners be found to have charged excessive rates for the drug in question.[3]

On February 17, 2022, Senators Elizabeth Warren and Angus S. King, Jr., with Congressman Lloyd Doggett, wrote a letter to HHS Secretary Xavier Becerra urging

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[1] *How the Government Can Lower Drug Prices*, N.Y. TIMES: EDITORIALS (June 20, 2018), https://www.nytimes.com/2018/06/20/opinion/prescription-drug-costs-naloxone-opioids.html.

[2] Hannah Brennan, Amy Kapczynski, Christine H. Monahan & Zain Rizvi, *A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health*, 18 YALE J.L. & TECH. 275 (2016).

[3] Prescription Drug Price Relief Act of 2021, S. 909, 117th Cong. (2021); *Why Does the U.S. Pay the Highest Prices in the World for Prescription Drugs*, *Hearing Before the Subcomm. on Primary Health and Ret. Sec.*, 116th Cong. (Mar. 23, 2020), https://www.help.senate.gov/hearings/why-does-the-us-pay-the-highest-prices-in-the-world-for-prescription-drugs (opening statement of Senator Bernie Sanders).

him to use "existing executive authority" to lower drug prices.[4] On March 24, 2022, eight public interest groups forwarded the HHS Secretary a "Petition To Make Drugs More Affordable," citing the Yale Article.[5] On April 22, 2022, Senator Warren again wrote to the HHS Secretary attaching an April 22, 2022 letter from "over 25 legal and public health experts" describing 28 U.S.C. § 1498 as the "government patent use power," i.e., a "tool" that can be used "to intervene when patients and public health are harmed by excessive drug prices."[6] The chief author of this letter is none other than one of the authors who penned the 2016 Yale Article. And, on June 23, 2022, eight Senators and 103 members of Congress sent a letter to the HHS Secretary to "utilize . . . government use compulsory licensing under 28 U.S.C. 1498 . . . to lower prescription drug prices."[7] In light of the close margins in the 118th Congress, continued pressure on the executive branch to exert 28 U.S.C. § 1498 (a) should be expected.

In *Richmond Screw Anchor Co. v. United States*, 275 U.S. 331, 345 (1928), however, the United States Supreme Court held that the "intention and purpose of Congress in the act of 1918 [(the predecessor to Section 1498)] was to stimulate contractors to furnish what was needed for [World War I], without fear of becoming liable themselves for infringements to inventors or the owners or assignees of patents." In 1949, Congress amended the Act of 1918 to precisely limit Section 1498(a) solely as a waiver of sovereign immunity to provide a private party with standing and a judicial forum in which to sue the government for patent infringement.[8] No federal court, however, has held that the government has an absolute *right* to infringe privately held patent rights and therefore, historically, they have narrowly and strictly construed Section 1498(a), as we discuss below.

I. INTRODUCTION

This Article argues that the authors of the Yale Article have misled some legislators and members of the public to believe government infringement of pharmaceutical

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[4] Letter from Senator Elizabeth Warren, Senator Angus S. King, Jr., and Congressman Lloyd Doggett to Xavier Becerra, Sec'y, U.S. Dep't of Health & Hum. Servs. (Feb. 17, 2022), https://www.warren.senate.gov/imo/media/doc/2022.02.17%20Letter%20to%20Sec.%20Becerra%20on%20Xtandi%20March-in%20Petition%20(2).pdf.

[5] Letter from Action Center on Race & the Economy, Center for Popular Democracy Action, Indivisible, People's Action, PrEP4All, Public Citizen, Social Security Works, and T1International, to Xavier Becerra, Sec'y, U.S. Dep't of Health & Hum. Servs. 3 n. 9 (Mar. 24, 2022), https://www.citizen.org/article/make-meds-affordable-petition/ (introducing and including petition).

[6] Letter from Senator Elizabeth Warren to Xavier Becerra, Sec'y, U.S. Dep't of Health & Hum. Servs. (Apr. 22, 2022), https://www.warren.senate.gov/imo/media/doc/2022.4.22%20Letter%20to%20Becerra%20on%20Drug%20Pricing%20Executive%20Authorities.pdf; Letter from Amy Kapczynski, JD, Aaron S. Kesselheim, MD, JD, MPH, Christopher J. Morten, JD, PhD, David Herman, Christopher Umanzor, to Senator Elizabeth Warren (Apr. 22, 2022), https://www.warren.senate.gov/imo/media/doc/2022.4.20%20Letter%20to%20Warren%20on%20Drug%20Pricing%20Executive%20Authorities.pdf.

[7] Letter from Elizabeth Warren et al. to Xavier Becerra, Sec'y, U.S. Dep't of Health & Hum. Servs. (June 23, 2022), https://www.warren.senate.gov/imo/media/doc/Bicameral%20Letter%20Urging%20HHS%20to%20Lower%20Drug%20Prices%20FINAL1.pdf.

[8] 28 U.S.C. § 1498(a); *see* Brennan et al., *supra* note 2, at 301 n.128; *see generally* Sean M. O'Connor, *Taking, Tort, or Crown Right? The Confused History of Government Patent Policy*, 12 J. MARSHALL REV. INTELL. PROP. L. 145 (2012).

patent rights is sanctioned by Section 1498(a) and will reduce drug prices. First, we take issue with the Yale Article for its failure to cite empirical evidence that government infringement of pharmaceutical patents will lower drug prices. Next, we critique the Yale Article's proposal that HHS engage in the unprecedented misuse of executive authority to infringe on pharmaceutical patents, ignoring the history and limited scope of Section 1498(a), as reflected in decades of case law. Consequently, we believe that any unilateral executive action authorizing infringement of pharmaceutical patents or compelling owners of pharmaceutical patents to license them at royalty rates set by HHS, or another federal agency, should be nullified by the federal courts. If not, Section 1498(a) will require the government to pay pharmaceutical patent owners "reasonable and entire compensation" as damages, including lost profits. And those damages will be paid from congressional appropriations. As such, the misuse of Section 1498(a) is not a Rx for reducing drug prices, but in effect is a tax imposed on American citizens.

II. NO EMPIRICAL EVIDENCE SHOWS THAT GOVERNMENT INFRINGEMENT OF PHARMACEUTICAL PATENTS WILL REDUCE DRUG PRICES

The Yale Article states with alarm that the cost of pharmaceuticals in the United States is "soaring," but admits the "increase in prescription spending can be attributed almost entirely to recently approved drugs that treat the Hepatitis C virus (HVC)."[9] The drug at issue was HARVONI™, a breakthrough patented pharmaceutical developed and manufactured by Gilead Sciences, Inc. (Gilead). The Yale Article asserts, based on inferences and assumptions, that "Gilead's prices vastly exceed the cost of producing these drugs."[10] The Yale Article accurately reports the initial list price of HARVONI™ was approximately $100,000 for a twelve-week regimen.[11] This initial price, however, was reduced by 46% within twelve months; by 2018, Gilead released its own generic drug, EPCLUSA™.[12] The myopic focus on the introductory price of these drugs, hyped by the Yale Article as an example of "one of the most pressing domestic policy issues in the United States today,"[13] however, did not take into account that new competition on the horizon could have a significant downward effect on these drug prices—which happened.

In 2017, the U.S. Food and Drug Administration (FDA) approved AbbVie, Inc.'s MAVYRET™, which reduced HCV treatment time to eight weeks at an estimated wholesale cost of $26,400.[14] A few months later, MAVYRET™ weekly new

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9 Brennan et al., *supra* note 2, at 277.

10 *Id.* at 278.

11 *Id.* at 277.

12 Richard Staines, *Gilead Launches Generics of Own Hepatitis C Drugs in US to Cut Health Costs*, PHARMAPHORUM (Sept. 25, 2018), https://pharmaphorum.com/news/gilead-launches-generics-of-own-hepatitis-c-drugs-in-us-to-cut-health-costs/.

13 Brennan et al., *supra* note 2, at 277.

14 Ned Pagliarulo, *AbbVie Surprised Investors with its Hepatitis C Success. Will it Last?* BIOPHARMADIVE (Aug. 2, 2018), https://www.biopharmadive.com/news/abbvies-surprised-investors-mavyret-hepatitis-c-success-will-it-last/529158/; *see also* Press Release, AbbVie, AbbVie Receives U.S. FDA Approval of MAVYRET™ (glecaprevir/pibrentasvir) for the Treatment of Chronic Hepatitis C in All Major Genotypes (GT 1-6) in as Short as 8 Weeks, https://news.abbvie.com/news/abbvie-receives-us-fda-

prescriptions "outpaced" Gilead's HARVONI™ and EPCLUSA™.[15] As a result of these drugs, Hepatitis C virus-caused disease has steadily declined, leaving a "smaller and smaller pool of patients."[16] While the Yale Article was published in 2016 and subsequently did not have the benefit of this information, we are skeptical of the authors' contention that the price of HVC drugs raises "the problem that economists have long identified with patent-based drug pricing: the potential for massive social 'deadweight' losses that stem from supra-marginal cost pricing"[17] that must be remedied by the government's infringement of these patented pharmaceuticals. The *raison d'être* advanced for the federal government "breaking" pharmaceutical companies' patent rights is the promise of "significant social gains to be had from bringing compensation in line with the risk-adjusted cost of developing a drug."[18] Of course, these "social gains" are not identified, nor how the government will determine the "risk-adjusted cost of drug development," nor who within the government will decide when these "significant social gains" require infringing a patent issued by the United States Patent and Trademark Office (USPTO), the sole federal agency authorized by Congress "[t]o promote the Progress of Science . . . by securing for limited Times to . . . Inventors the exclusive Right to their respective . . . Discoveries."[19]

The Yale article also did not account for the subsequent development that both list and net prices of pharmaceuticals, primarily those composed of small-molecule drugs, began to fall around the time of its publication; a trend that has continued.[20] Biologics have become "the driver behind overall drug spending in the United States in recent years.[21] In inflation-adjusted terms, biologic drug spending increased from $291 to $435 per capita from 2014 to 2018, while small-molecule drug spending fell from $689 to $610 per capita during this same period."[22]

The following chart, based on data obtained and compiled by Drug Channels Institute, an organization that collects and reports on approximately 1,000 brand-name

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approval-mavyret-glecaprevirpibrentasvir-for-treatment-chronic-hepatitis-c-in-all-major-genotypes-gt-1-6-in-as-short-as-8-weeks.htm.

15 Pagliarulo, *supra* note 14.

16 *Id.*

17 Brennan et al., *supra* note 2, at 279.

18 *Id.* at 282.

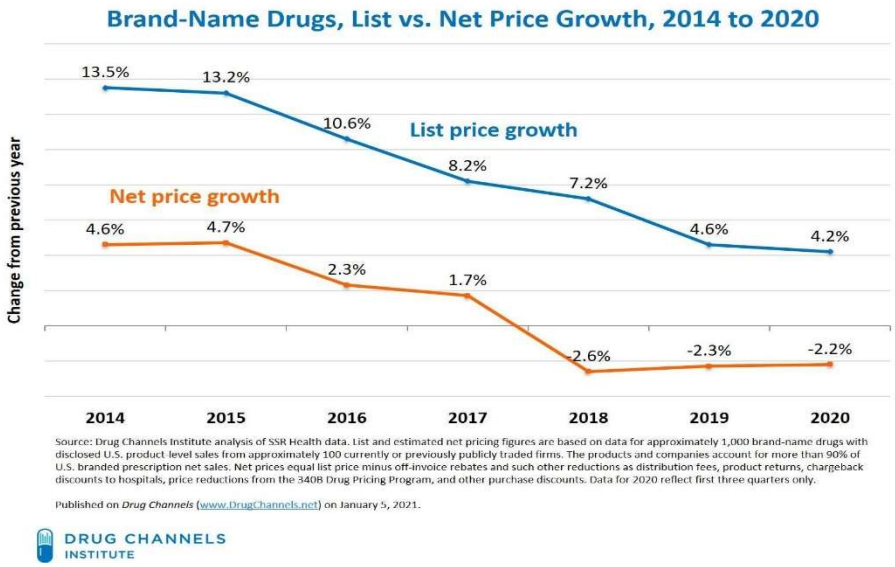
19 U.S. CONST. art. I., § 8, cl. 8.

20 A "small-molecule drug" is composed of "organic compounds affecting molecular pathways by targeting important proteins. These compounds have a low molecular weight, making them penetrate cells easily." Qingxin Li & CongBao Kang, *Mechanics of Action for Small Molecules Revealed by Structural Biology in Drug Discovery*, 21 INT'L. J. MOLECULAR SCI. 5262 (2020).

21 *What Are "Biologics" Questions and Answers*, U.S. Food and Drug Admin. (Feb. 6, 2018), https://www.fda.gov./about-fda/center-biologics-evaluation-and-research-cber/what-are-biologics-questions-and-answers (defining a "biologic drug" as being composed of "sugars, proteins, or nucleic acids or complex combinations of these substances, or may be living entities such as cells and tissues." Biologic drugs are not easily identified or characterized and are extremely sensitive to environmental factors such as heat and microbiological contamination); *see also Why Does the US Pay the Highest Prices in the World for Prescription Drugs*? *Hearing Before the Subcomm. on Primary Health and Retir. Sec.*, 117th Cong. 2 (Mar. 23, 2021) (statement of Alex Brill, Resident Fellow, American Enterprise Institute) (pointing to biologics as the current driver of overall drug spending in the United States) [hereinafter Statement of Brill].

22 Statement of Brill, *supra* note 21 at 2.

drug prices,[23] shows the list price growth of brand-name pharmaceutical drugs decreased from 13.5% in 2014 to 4.2% in the first three quarters of 2020. In addition, net price growth declined -2.2% in 2020; the gross-to-net gap in prices was -6.4%.



The most important takeaway from this chart is that, by 2018, at least 90% of all prescriptions in the United States were filled with generic drugs, a trend attributed by some to "the concentration of purchasing power by payers and the aggressive use of utilization management tools to rapidly shift utilization towards generics."[24] Moreover, the price of certain generic drugs "more than doubled prices," including one from Exelan Pharmaceuticals, Inc. that treated high blood pressure "by 536% . . . depending on the dosage and package size."[25] In contrast, during the same year, pharmaceutical manufacturers raised prices by 6.6%, but even this increase did not allow those firms to "realize all or any of the benefit from price increases because of the discounts they provide to health insurers and pharmacy-benefit managers, the companies that oversee drug benefits for employers."[26]

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[23] DRUG CHANNELS INST., https://drugchannelsinstitute.com/. The CEO of Drug Channels Institute, Dr. Adam J. Fein, Ph.D, is an expert in the U.S. pharmaceutical industry and a regular contributor to the *Wall Street Journal*, *The New York Times*, and *Forbes*. *Leadership*, DRUG CHANNELS INST., https://drugchannelsinstitute.com/about/leadership/.

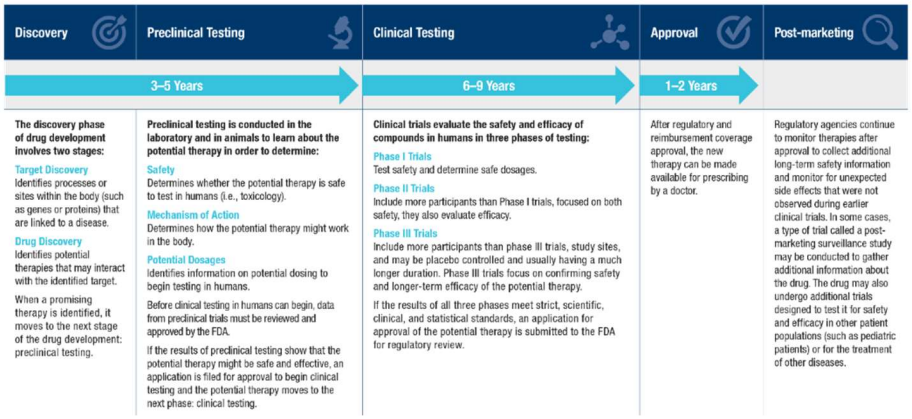
[24] *Intellectual Property and the Price of Prescription Drugs: Balancing Innovation and Competition*, *Hearing Before the S. Comm. on the Judiciary*, 116th Cong. 4 (May 7, 2019) (statement of James Stansel, Executive Vice President and General Counsel, Pharmaceutical Research and Manufacturers of America); *see also id.* at 6 (citing projections by IQVIA, a provider of analytics and clinical research services to the life sciences industry, that between 2019 and 2023, IQVIA estimates "annual net price growth for brand-name drugs will be just 0 to 3 percent.").

[25] Joseph Walker, *Prescription Drugs List Prices Rise Average of 6.6%*, WALL ST. J., Jan. 30, 2022, at A7.

[26] *Id.*; *see also*, Andrew Brownlee & Jordan Watson, *The Pharmaceutical Supply Chain, 2013–2020*, BERKELEY RSCH. GRP. (Jan. 7, 2022), https://www.thinkbrg.com/insights/publications/pharmaceutical-supply-chain-2013-2020/ ("Brand manufacturers retain just 37 percent of total spending on prescription

The Yale Article also gives short shrift to the time-consuming and expensive U.S. Food and Drug Administration (FDA) regulatory approval process.[27] As the following chart shows, this process can take many years, during which the twenty-year statutory term of a patent continues to run and while the patent holder receives no revenue.

Drug Development and Clinical Trial Process[28]



To address the time and cost of drugs receiving approval from FDA, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (informally known as the Hatch–Waxman Act)[29] to establish a "unified framework to coordinate drug approval and resolution of patent rights relating to generic versions of patented drugs."[30] On one hand, the Hatch–Waxman Act provides pharmaceutical patent owners with the potential for up to a five-year extension (restoration) on a patent's term, which is supposed to compensate patent owners for lost market opportunity.[31] The Act also provides for a data package exclusivity period, during

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medicines (brand and generic medicines)."); *see also id.* ("2020 marks the first year on record where nonmanufacturer stakeholders—including PBMs, health plans, hospitals, the government, pharmacies, and others—received the majority of total spending on brand medicines."). PEW CHARITABLE TRS., THE PRESCRIPTION DRUG LANDSCAPE, EXPLORED 1 (Mar. 2019), https://www.pewtrusts.org/-/media/assets/2019/03/the_prescription_drug_landscape-explored.pdf [hereinafter PEW CHARITABLE TRS.] (finding pharmaceutical manufacturer rebates increased from $39.7 billion in 2021 to $89.5 billion in 2016 only "partially offsetting increases in list prices"); *compare* PEW CHARITABLE TRS. at 14 (finding pharmaceutical manufacturers' net revenue on retail prescriptions grew only an average of 3.6% annually from 2012–2016), *with* PEW CHARITABLE TRS. at 14 (finding pharmacy net revenue on retail prescriptions increased from $30.8 billion to $76.9 billion in 2016); Letter from Senator Thom Tillis to Janet Woodcock, MD, Acting U.S. Food & Drug Comm'r and Drew Hirshfeld, Acting Comm'r for Patents (Jan. 31, 2022) (questioning the accuracy of drug price research from the Initiative for Medicine, Access & Knowledge and a project from the University of California Hastings Law School); Adam Mossoff, *Unreliable Data Have Infected the Policy Debates Over Drug Patents*, HUDSON INST. (Jan. 19, 2022).

[27] *See* 21 U.S.C. § 355(a)–(b) (2012).

[28] *See Drug Development, Review & Lifecycle Management*, BIOTECHNOLOGY INNOVATION ORG., https://www.bio.org/policy/human-health/drug-development-review-lifecycle-management.

[29] *See* Pub. L. No. 98-417, 98 Stat. 1585(1984) (codified at 21 U.S.C. § 30; 21 U.S.C. §§ 355, 360cc).

[30] FEDERAL JUDICIAL CENTER, PATENT CASE MANAGEMENT 10-2 (3d ed. 2016).

[31] A study conducted of 170 top-selling drugs which had a first generic equivalent approved between 2000–2012, found that only 49% (or eighty-three drugs) received a patent term restoration. The median

which a generic manufacturer is prohibited from referencing any proprietary regulatory data of a pharmaceutical "originator" for five years in pursuit of obtaining FDA approval for a competing drug.[32] On the other hand, after this period expires, a generic manufacturer can accelerate approval for a "follow-on" drug, if it is the "bioequivalent" of a patented drug, among other criteria.[33] As a prerequisite, the generic manufacturer must file an Abbreviated New Drug Application (ANDA) and a statement certifying the patents that claim the listed drug have expired, will expire, are invalid, unenforceable, or will not be infringed (or there are no listed patents).[34] Next, if the generic manufacturer wants to market its product prior to the expiration of a patent, it must provide the "originator" with notice and certification attesting to the same requisites as the ANDA filing.[35] Then, an "originator" has forty-five days in which to lodge an infringement action challenging the certification in a federal district court, thereby triggering an automatic thirty-month stay of FDA's approval of the ANDA.[36] During the stay, FDA may not approve the ANDA unless: the patent expires; a federal district court determines the "originator's" patent is invalid, unenforceable, or not infringed; or the thirty-month stay expires, whichever comes first.[37]

After the Yale Article was published, the Technology Law & Policy Clinic of New York University School of Law, co-published with PrEP4All, released a student publication (NYU Student White Paper), parroting the same rhetoric: "[P]atents permit [pharma] companies to set and keep prices astronomically high—much higher than needed to fund future drug development, and much, much higher than the manufacturing cost."[38] Like the Yale Article, the NYU Student White Paper, cites no empirical data to support the assertion that pharmaceutical prices exceed costs incurred to conduct research, develop, and obtain a patent, or much less garner FDA approval to manufacture, market, and distribute a pharmaceutical drug and then educate the

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extension length was only 2.75 years. *See Unsustainable Drug Prices (Part III), Hearing Before the H. Comm. on Oversight and Reform*, 117th Cong. (2021) (statement of Dr. Aaron S. Kesselheim, Professor of Medicine, Harvard Medical School and Director, Program on Regulation Therapeutics and Law, Department of Medicine, Brigham and Women's Hospital (citing Reed F. Beall, Jonathan J. Darrow & Aaron S. Kesselheim, *Patent Term Restoration for Top-selling Drugs in the United States*, 24 DRUG DISCOVERY TODAY 20–25 (2019).

[32] 21 U.S.C. 355 § (3)(ii)–(iv).

[33] *See id.* § 355(j)(4)(F) ("bioequivalence" requires a generic manufacturer to demonstrate its drug delivers approximately the same amount of active ingredients into the bloodstream as the same amount of the reference drug).

[34] These drugs are listed in an annual FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations," known as the Orange Book. *Approved Drug Products with Therapeutic Equivalence Evaluations | Orange Book*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book. *See* 21 U.S.C. §§ 355(b)(2)(A)(ii)–(iv), (j)(2)(A)(vii)(IV).

[35] *See id.* §§ 355 (b)(3)(C), (j)(2)(B)(iii).

[36] *See id.* §§ 355(c)(3)(C), (j)(5)(B)(iii); *see also* 35 U.S.C. § 271(e)(2).

[37] *See* 21 U.S.C. § 355(j)(5)(B)(iii)(1); *see also id.* § 355 (c)(3)(C)(i).

[38] JOSEPH ADAMCZYK, ADRIENNE LEWIS & SHIVANI MORRISON, N.Y.U. TECH. L. & POL'Y CLINIC, § 1498: A GUIDE TO GOVERNMENT PATENT USE: A PATH TO LICENSING AND DISTRIBUTING GENERIC DRUGS (2020–2021), https://static1.squarespace.com/static/5e937afbfd7a75746167b39c/t/60099e3582c53f4f1b6a4a57/1611243061897/P4A++1498+A+Guide+to+Government+Patent+Use.pdf%22%20%5Ct%20%22_blank; *Id.* at 9.

medical community and patients about a new drug.[39] It is well established, however, that "[i]t takes on average over 2 billion dollars and close to 10 years of R&D, at a 90% failure rate, before a new investigational drug can be approved and made available for patient care."[40] The authors of the NYU Student White Paper tout the "versatility" of Section 1498(a), as "leverage" the government can use in negotiating pharmaceutical prices, by assuming "reasonable and entire compensation generally will be less than the cost of acquiring the patented technology on the open market—sometimes significantly so."[41] The NYU Student White Paper, however, cites no empirical data to support the authors' contention that Section 1498(a) damages for infringement of pharmaceutical patents will be less than paying for a license or that it "generally reimburses the patent holder for the fair market value of the patent rights over the life of the patent."[42]

Another reckless idea of the NYU Student White Paper suggests, if an "originator" files a Hatch–Waxman Act case against a generic manufacturer in a federal district court, HHS promptly should license the generic to infringe the pharmaceutical patent.[43] The NYU Student White Paper then recommends HHS intervene in the Hatch–Waxman case to seek dismissal and transfer the case to United States Court of Federal Claims under Section 1498(a), effectively divesting the pharmaceutical "originator" of the Hatch–Waxman Act thirty-month automatic stay.[44] This scenario would have an Executive Department interfere with a Hatch–Waxman action authorized by Congress and should be rejected by a federal court as a violation of the Administrative Procedure Act (APA),[45] not to mention raising separation of powers

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[39] Letter from Drew Hirshfeld, Acting Comm'r for Patents to Senator Elizabeth Warren and Congresswoman Pramila Jayapal 9–10 (Aug. 13, 2021) ("Developing the dossier of data necessary to obtain marketing approval for a new drug or biologic product in the U.S. is a complex, lengthy, and very costly endeavor, often taking years to complete[.] In 2020, HHS's Center for Drug Evaluation and Research reported than a total of just 53 'novel drugs' were approved."); *see also* Dr. Eric Topol, *The Hyper-Acceleration of the Life Sciences*, WALL ST. J., Mar. 19, 2021, at C4 ("[T]he average time in the life sciences for translating research into clinical practice is 17 years . . . . The successful mRNA vaccines that set such a high bar of efficacy and safety so early in the pandemic were not conceived in 2020. The use of mRNA was pioneered in the basic research of Katalin Karikó and Drew Weissman at the University of Pennsylvania three decades ago.").

[40] Letter from James C. Greenwood, President and CEO, Biotechnology Innovation Organization, Letter to Alex M. Azar, Secretary, U.S. Dep't of Health & Hum. Servs. 2–3 (Mar. 12, 2018); *see also Unsustainable Drug Prices (Part III), Hearing Before the H. Comm. on Oversight and Reform*, 117th Cong. 5 (2021) (statement of Dr. Carl L. Garthwaite, Herman Smith Research Professor in Hospital and Health Care Services Management and Director of Program on Healthcare at the Kellogg School of Management, Northwestern University) ("The development of pharmaceuticals is a long and risky process where firms make investments that only expect to payoff [sic] over a potentially decades long time horizon.") [hereinafter Statement of Garthwaite]; Joseph A. DiMasi, Henry G. Grabowski & Ronald W. Hansen, *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. HEALTH ECON. 20, 31 (2016) (estimating $2.87 billion in "capitalized cost" (2013 dollars) to bring a new drug to market).

[41] ADAMCZYK ET AL., *supra* note 38, at 24.

[42] *Id.*

[43] *Id.* at 34.

[44] *Id.*

[45] *See* 5 U.S.C. § 706(2)(A) (federal agency action is subject to judicial review under, among others, an "arbitrary, capricious, an abuse of discretion or otherwise not in accordance with law" standard); *see also* Motor Vehicle Mfg. Ass'n v. State Farm Auto Mut. Ins. Co., 463 U.S. 29, 43 (1983) (emphasis added) (stating that a federal agency's decision is *arbitrary*, if it "has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation

issues. In the alternative, having the HHS Secretary contract with a generic to infringe a pharmaceutical patent or intervening *sua sponte* in a Hatch–Waxman case to deprive a patent holder of the thirty-month automatic stay granted by Congress could be well viewed by a federal court as unlawful because it is "not one of those areas traditionally committed to agency discretion."[46]

A particularly problematic suggestion of the NYU Student White Paper is for the government "to coordinate with generic manufacturers to work around . . . non-patent exclusivities."[47] Generic manufacturers that engage in "coordinating" price or supply, however, risk violating the antitrust law and facing private treble damage actions.[48]

III. FEDERAL COURTS SHOULD HOLD THAT SECTION 28 U.S.C. § 1498(A) IS NOT APPLICABLE TO GOVERNMENT INFRINGEMENT OF PHARMACEUTICAL PATENTS TO REDUCE DRUG PRICES

The Yale Article also proclaims: "28 U.S.C. § 1498[(a)] permits the government to 'use' patents at any time without permission of the patent holder, as long as reasonable compensation is provided."[49] Not quite.

In 1949, Congress amended 28 U.S.C. § 1498 to clarify the parameters of the waiver of sovereign immunity in the event the government infringed a patent:

> 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 . . . . 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.[50]

The first federal appellate court to consider Section 1498(a) held:

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for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.").

[46] Dep't of Com. v. New York, 139 S. Ct. 2551, 2568 (2019); *see also* Liesegang v. Sec'y of Veterans Affs., 312 F.3d 1368, 1372 (2002) ("This court reviews questions of statutory interpretation without deference.").

[47] ADAMCZYK ET AL., *supra* note 38, at 3.

[48] 15 U.S.C. § 1 (*prohibiting* "[e]very contract, combination . . . or conspiracy, in restraint of trade or commerce among the several States"); *see also* 15 U.S.C. §15(a) ("[A]ny person who shall be injured in his business or property by reason of anything forbidden in the antitrust laws may sue therefor in any district court of the United States[.];") 15 U.S.C. § 15c (authorizing state Attorneys General to file federal antitrust actions on behalf of their citizens).

[49] Brennan et al., *supra* note 2, at 279–80.

[50] *See* 28 U.S.C. § 1498.

> Nowhere [therein] is active inducement of infringement or contributory infringement mentioned, either directly or by cross reference to 35 U.S.C. §§ 271 (b) and (c). ***A waiver of sovereign immunity must be strictly construed.*** Stated differently, the Government is not to be regarded as having waived its sovereign immunity by implication. Hence, we hold that 35 U.S.C. §§ 271 (b) and (c) are not incorporated by implication in section 1498. It is our view that the ***Government has agreed under section 1498 merely to assume liability for its direct infringement of a patent; it has not agreed thereunder to assume liability for its active inducement of infringement or for its contributory infringement***.[51]

The strict application of Section 1498(a) has not changed over the years and, in the last decade, was reaffirmed en banc by the United States Court of Appeals for the Federal Circuit (Federal Circuit).[52]

The statutory term "use for the Government" has two elements: "use that is both 'for the Government' *and* 'with the authorization and consent of the Government.'"[53] Nevertheless, the Yale Article states "where the infringing party has shown that they are acting pursuant to a contract with the federal government, courts typically assume use 'for' the government without further inquiry."[54] The Federal Circuit, however, has been clear that this analysis is incorrect.[55] Instead,

> use "for the United States" is defined as use that is both "for the Government" and "with the authorization and consent of the Government." In context, the "for the Government" prong of the definition appears to impose only a requirement that the use or manufacture of a patented method or apparatus occur *pursuant to a contract with the government* and for the benefit of the government.[56]

Nevertheless, the Yale Article insists that the two separate elements of Section 1498(a) can be conflated as "government use,"[57] citing three cases where the Federal Circuit held Section 1498(a) applied.[58] Each of these cases is *sui generis* and the analysis of questionable precedential effect.

In the first case, the government's participation in the Skynet satellite program was found to be "for the Government's benefit" because the program was considered "critical" to the military defense and security of the United States.[59] Military defense

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[51] Decca Ltd. v. United States, 640 F.2d 1156, 1169–70 (Ct. Cl. 1980) (emphasis added).

[52] Zoltek Corp. v. United States, 672 F.3d 1309, 1320 (Fed. Cir. 2012) (en banc) ("The court [in *Decca*] explained that inducement and contributory infringement are outside § 1498(a) because they 'do not involve *the Government's* making or using a patented invention[.]'") (emphasis in original) (quoting *Decca*, 640 F.2d at 1170 & n.31).

[53] Sevenson Envt'l Servs., Inc. v. Shaw Envt'l, Inc. 477 F.3d 1361, 1365 (Fed. Cir. 2007) (emphasis in original).

[54] Brennan et al., *supra* note 2, at 333.

[55] *Sevenson Envt'l Servs., Inc*., 477 F.3d at 1365.

[56] *Id.* (underscore in original, emphasis added).

[57] Brennan et al., *supra* note 2, at 332.

[58] *Id.* at 332 n.266; *see also id.* at 333 nn.269, 272.

[59] Hughes Aircraft Co. v United States*,* 534 F.2d 889, 898 (Ct. Cl.1976).

and national security, however, are not at issue in the event the government infringes a pharmaceutical patent.

The second case involved an airline's use of a patent that improved the detection of fraudulent passports and reduced demands on government resources.[60] The infringing use was viewed as a "quasi-governmental function" and "for the Government's benefit" since a federal entity otherwise would be required to examine passports for fraud.[61] In addition, this use was found to be "in furtherance and fulfillment of a stated Government policy," i.e., "enhances border security and improves the government's ability to monitor the flow of people in and out of the country."[62] Government infringement of a pharmaceutical patent certainly is not a "quasi-governmental function."

In the third case, a Federal Reserve Bank entered a contract with a private company to use its encoded technology in a pilot project to ferret out fraudulent checks.[63] The Treasury Department participated in the project by printing checks that used the encoded technology. It turned out this technology violated another company's patent. The Federal Circuit was satisfied that this was "use for the Government," even though there was no contract with Treasury, based on the involvement of two federal agencies, "reinforced by" a government amicus in a private Title 35 case attesting that Treasury's "use" was "for the Government."[64] The appellate court also seemed impressed that the infringing activity conferred "significant benefits to the United States," although the record below on this issue was not fully developed.[65]

The second element of Section 1498(a), i.e., "the scope of the government's authorization and consent to liability naturally hinges on the language of that clause."[66] Today, most government contracts contain "authorization and consent" clauses. For example, supply contracts routinely incorporate Federal Acquisition Regulation (FAR) 52.227-1 authorizing contractors or subcontractors to "use and manufacture" a patented invention where it is 1) embodied in the structure or composition of any article delivered to and accepted by the government related to a government contract; or 2) used in machinery, tools, or methods necessary for a contractor to comply with the Specifications of a contract, or if such use is directed by a contracting officer's specific written instructions. Research and development contracts include FAR 52.227-1 Alternative I to express "authorization and consent" in the event of patent infringement. "Authorization and consent" also have been found "by contracting officer instructions, by specifications and drawings which impliedly sanction and necessitate infringement, or by *post hoc* intervention by the Government in pending infringement litigation against individual contractors."[67]

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[60] Iris Corp. v. Japan Airlines Corp., 769 F.3d 1359, 1362 (Fed. Cir. 2014).

[61] *Id.* at 1362–63 (stating the government's amicus "reinforce[d] [the court's] conclusion that the United States has waived sovereign immunity in this case").

[62] *Id.* at 1362.

[63] Advanced Software Design Corp. v. Fed. Rsrv. Bank of St. Louis, 583 F.3d 1371, 1376–79 (Fed. Cir. 2009).

[64] *Id.*

[65] *Id.*

[66] *Id.* at 1367.

[67] Hughes Aircraft Co. v United States*,* 534 F.2d 889, 901 (Ct. Cl.1976).

The Federal Circuit has considered only one case where it found "implied authorization and consent" without a government contact.[68] There, a bidder for a government contract was required to provide a "specimen" of equipment and a live demonstration to show its ability to perform if it were awarded a contract.[69] Since the government was aware this requirement would infringe another bidder's patent, the appellate court was satisfied that this evidenced sufficient "authorization and consent" to invoke Section 1498(a).[70] The equitable issues presented in that case, however, are far different from government infringement of a pharmaceutical patent.

More importantly, as a matter of law, if the government infringes a pharmaceutical patent to reduce Medicare and Medicaid costs, Section 1498(a) will not apply. This is so because the predecessor to the United States Court of Appeals for the Federal Circuit soundly rejected a medical device company's Section 1498(a) claim that selling infringing splints was "for the benefit of the Government," even though their costs were reimbursed under Medicare and other federal programs.[71] Notably, the court's holding emphasized the fact that the government has an "interest in [a] 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."[72] Clearly, the court recognized that, if every federal program is deemed to be "for the Government," there would be no end to cases asserting Section 1498(a)—a statute to be construed "strictly."[73] Likewise, government infringement of a pharmaceutical patent could be viewed as "not the type of activity that Congress, by enacting Section 1498(a), intended to cloak with immunity from injunction."[74] This reasoning is akin to the Supreme Court's recent invocation of the "major questions" doctrine to invalidate "agencies asserting highly consequential power beyond what Congress

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[68] TVI Energy Corp. v. Blane, 806 F.2d 1057 (Fed. Cir. 1986).

[69] *Id.* at 1059.

[70] *Id.* at 1060.

[71] Larson v. United States, 26 Cl. Ct. 365, 369 (1992).

[72] *Id.* (emphasis added); *see also* MATTHEW RIZZOLO, FILKO PRUGO, CHARLOTTE JACOBEN, RYAN SULLIVAN & BRENDAN MCLAUGHLIN, ROPES & GRAY LLP, CAN THEY REALLY DO THAT? THE SPECTER OF GOVERNMENT-AUTHORIZED INFRINGEMENT OF PHARMACEUTICAL PATENTS 8 (Apr. 27, 2020), https://www.ropesgray.com/en/newsroom/alerts/2020/04/Can-They-Really-Do-That-The-Specter-of-Government-Authorized-Infringement-of-Pharmaceutical-Patents ("Medicaid is primarily run by the states, with complex systems of rebates and reimbursements for prescription drugs, and Medicare provides outpatient prescription drugs though Medicare Part D private insurance. Because of the [federal] government's indirect role in these programs, . . . any use of § 1498 would likely rest on uncertain legal ground[.]").

[73] Decca Ltd. v. United States, 640 F.2d 1156, 1169 (Ct. Cl. 1980).

[74] Carrier Corp. v. United States, 534 F.2d 244, 250 (Ct. Cl. 1976). A recent decision echoes this concern, where the District Court of Delaware denied a partial motion to dismiss a case asserting that any royalties on the sale and provision of COVID-19 vaccine doses to the United States were governed by 28 U.S.C. § 1498(a) and therefore subject to the jurisdiction of the United States Court of Federal Claims. *See* Arbutus Biopharma Corp. et al. v. Moderna, Inc. et al., Case No. 22-252, slip op. (D. Del. Nov. 22, 2022). Notably, the court found "this case more akin to Larson than Advanced Software Design[.] Based on the allegations of the Complaint, which I must accept as true, the development and sale of the vaccines was for the benefit of the vaccine's recipients. According to the Complaint, the U.S. Government was an incidental beneficiary who borne an interest in ensuring the safety of its citizens." *Id.* at 12. The court also rejected argument that inclusion of FAR 52,227-1 in the contract was dispositive evidence of "authorization and consent" of the government as, "it remains unsettled whether the Government, in seeking to hasten the development of a vaccine, actually consented to the use of a patented invention and agreed to accept any liability for such use." *Id.* at 15. Obviously, the final disposition of this case bears watching.

could reasonably understood to have granted."[75] Therefore, government infringement of a pharmaceutical patent should be struck down on that basis, particularly since the effect would be to divest a patent owner of a property right conveyed by the USPTO, without a judicial determination of invalidity.[76]

Nevertheless, the Yale Article proposes that HHS, *sua sponte*, announce the names of the patented pharmaceutical drugs it intends to displace,[77] so that federal procurement officers can proceed to contract directly with generic manufacturers. The Yale Article concedes that the government will be obliged to offer pharmaceutical patent owners "modest or nominal compensation," such as a royalty on the price of the generic.[78] The Yale Article adds, if a pharmaceutical patent owner is not satisfied, it can file an administrative claim or suit under 28 U.S.C. § 1498(a).[79] The Yale Article naively envisions this process would be "legally uncontroversial" and "quickly implemented,"[80] without considering that government infringement of a pharmaceutical patent would require the Federal Circuit to overrule precedent *en banc* and, even if that happened, a petition for certiorari to the United States Supreme Court would be inevitable. And, as we next discuss, if government infringement of a pharmaceutical patent were able to satisfy the elements of Section 1498(a), multi-million-dollar damage awards likely will result.

IV. IF GOVERNMENT INFRINGEMENT OF PHARMACEUTICAL PATENTS IS SUBJECT TO SECTION 1498(A), AMERICAN TAXPAYERS WILL ULTIMATELY FOOT THE BILL FOR MULTI-MILLION DOLLAR DAMAGE AWARDS

The rationale for Section 1498(a) is not complicated. As the predecessor to the Federal Circuit explained: "[the Government] is deemed to have 'taken' the patent license under an eminent domain theory, and compensation is the just compensation required by the fifth amendment. Title 28 U.S.C. § 1498 *contains no directions or limitations as to the grant of damages* other than its mandate of 'reasonableness' and 'entirety.'"[81] In other words, "reasonable compensation" should equate to "what the owner has lost, not what the taker has gained."[82] As Justice Breyer has observed,

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[75] In light of the Supreme Court's recent decision in *West Virginia v. EPA*, whether the government, via the HHS Secretary, can deny or shorten a pharmaceutical patent owner's statutory right to exclude competition for a limited time period and/or divest a pharmaceutical patent owner of the exclusivities granted by Congress under the Hatch–Waxman Act, without explicitly repealing that statute, may well be considered by a federal appellate court as under the "major question doctrine" in light of the "economic and political significance" of such executive action, instead of conducting an APA review. *See* West Virginia v. EPA, 142 S. Ct. 2587, 2609 (2022).

[76] *See id.* at 20; *see also* 35 U.S.C. §§ 282(a), (b)(2) (reflecting congressional intent that all patents are presumed to be valid, unless a federal court determines otherwise).

[77] Brennan et al., *supra* note 2, at 346 (This scenario is suggested for HCV drugs but is "common to all options of our § 1498 strategy."); *see also id.* at 282 (suggesting the government also should "import" generic drugs from a foreign country "maximizing social benefit").

[78] *Id.* at 347.

[79] *Id.*

[80] *Id.*

[81] Leesona Corp. v. United States, 599 F.2d 958, 964 (Ct. Cl. 1979) (emphasis added).

[82] *Id.* at 969 (citing United States v. Chandler-Dunbar Co., 229 U.S. 53, 76 (1913).

"patent infringement suits against the Government . . . threaten to impose large damage awards."[83]

The Federal Circuit has endorsed three methods for determining "reasonable compensation": a reasonable royalty; government savings achieved by use of an infringed patent; or the patent owner's lost profits,[84] although the latter two methods primarily have been used to evaluate the "reasonableness" of royalty awards.[85]

For many years, Section 1498(a) damages have been determined by federal trial judges evaluating and balancing the same factors as private patent infringement cases under 35 U.S.C. § 271.[86] The Federal Circuit, however, has expressed concern about using these factors to determine an appropriate royalty rate describing them as "[a] comprehensive (but unprioritized and often overlapping) list of relevant factors for a reasonable royalty calculation."[87] Shortly thereafter, the appellate court also rejected the past practice of using a "rule of thumb" approach to determine a "reasonable royalty rate."[88] Consequently, most trial judges now set a "reasonable royalty" either at a rate that is comparable to prior license terms or by replicating an arms-length negotiation.[89] Two caveats: the Federal Circuit has rejected royalty rates where the license was not specifically "linked" to an infringed product.[90] The appellate court also has rejected license terms entered after litigation was threatened or underway.[91]

Where an infringed patent previously has not been licensed, determining a "reasonable royalty" has been described as "a difficult judicial chore, seeming often

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[83] Return Mail, Inc. v. U.S. Postal Serv., 139 S. Ct. 1853,1871 (2019) (Breyer, J., dissenting).

[84] *Leesona Corp*., 599 F.2d at 964.

[85] *Id.* at 973.

[86] Gargoyles, Inc. v. United States, 113 F.3d 1572, 1580–81 (Fed. Cir. 1997) (citing fifteen factors listed in Georgia-Pacific Corp. v. U.S. Plywood Corp., 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970), *modified and affirmed sub. nom*, Ga-Pac. Corp. v. U.S. Plywood-Champion Papers, Inc., 446 F.2d 295, 302 (2d Cir. 1971).

[87] ResQNet.com, Inc. v. Lansa, Inc., 594 F.3d 860, 869 (Fed. Cir. 2010); *see, e.g.*, Christopher B. Seaman, *Reconsidering the Georgia-Pacific Standard for Reasonable Royalty Patent Damages*, 2010 BYU L. REV. 1661, 1726 (2010) (concluding that the *Georgia-Pacific* test has "outlived its usefulness" and "is no meaningful standard at all"); Stuart Graham, Peter Menell, Carl Shapiro & Tim Simcoe, *Final Report of the Berkeley Center for Law & Technology Patent Damages Workshop*, 25 TEX. INTEL. PROP. L.J. 115, 117 (2016).

[88] Uniloc USA, Inc. v. Microsoft Corp., 632 F.3d 1292, 1315 (Fed. Cir. 2011) (holding "the 25 percent rule of thumb is a fundamentally flawed tool for determining a baseline royalty rate in a hypothetical negotiation. Evidence relying on the 25 percent rule of thumb is inadmissible under *Daubert* and the Federal Rules of Evidence, because it fails to tie a reasonable royalty base to the facts of the case at issue.").

[89] *Leesona Corp*., 599 F.2d at 973. ("The comparative royalty technique is the preferred method of determining just compensation."); *see also* Unisplay S.A. v. Am. Elec. Sign Co., Inc., 69 F.3d 512, 519 (Fed. Cir. 1995) (existing licenses "carry considerable weight in calculating a royalty rate").

[90] Lucent Techs., Inc. v. Gateway, Inc., 580 F.3d 1301, 1327–28 (Fed. Cir. 2009) (rejecting reliance on licenses that were "radically different from the hypothetical agreement under consideration"); *See also* Trell v. Marlee Elecs. Corp., 912 F.2d 1443, 1446 (Fed. Cir. 1990) (rejecting licenses that "conveyed rights more broad in scope than those covered by the [infringed] patent").

[91] Hanson v. Alpine Valley Ski Area, Inc., 718 F.2d 1075, 1078–79 (Fed. Cir. 1983) ("license fees negotiated in the face of a threat of high litigation costs may be strongly influenced by a desire to avoid full litigation"); *see also* Nickson Indus., v. Rol Mfg. Co., 847 F.2d 795, 798 (Fed. Cir. 1988) (stating a higher figure may be awarded when evidence shows that established royalties are artificially depressed by widespread infringement).

to involve more the talents of a conjurer than those of a judge."[92] Therefore, trial courts typically use the "entire market rule" to ascertain a compensation base that reflects "the value of an entire apparatus containing several features, when the feature patented constitutes the basis for customer demand."[93] Once a compensation base is determined, an appropriate royalty rate is determined considering what would happen in a hypothetical license negotiation between a willing seller and willing buyer. In reviewing various negotiation scenarios, the Federal Circuit also has allowed trial courts to consider a range of royalty rates, if supported by credible expert testimony.[94]

The Federal Circuit also has endorsed determining "reasonable compensation" by having the trial court construct a hypothetical "ceiling" and "floor," within which the royalty rate will be deemed "reasonable."[95] In that case, the "ceiling" was set as the total savings difference "between what it paid [an infringing government contractor]" and the patent owner's price.[96] The "floor" was set as the "reasonable" development expenses incurred,[97] amortized over the life of the patent and also a "reasonable profit."[98] In this case, the royalty rate also included the "special value of the exclusive manufacturing rights, their importance to the diversification plans [of the patent owner], made their worth much greater and thus the hypothetical royalty charged would have been . . . higher."[99] Therefore, if the government infringes a pharmaceutical patent, the damage "ceiling" could equal the government's estimated total savings achieved by infringing the pharmaceutical patent[100] and the "floor" could equal the pharmaceutical company's reasonable amortized development costs and the "claimed invention's foot print in the marketplace"[101] or "commercial success."[102] The

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[92] Fromson v. W. Litho Plate & Supply Co., 853 F.2d 1568, 1574 (Fed. Cir. 1988).

[93] TWM Mfg., Co. v. Dura Corp. 789 F.2d 895, 901 (Fed. Cir. 1986); *see also* Rite-Hite Corp. v. Kelley Co., Inc., 56 F.3d 1538, 1549 (Fed. Cir. 1995) (en banc) (The entire market rule "permits recovery of damages based on the value of a patentee's entire apparatus containing several features when the patent-related feature is the basis for customer demand.").

[94] Bayer HealthCare LLC. V. Baxalta, Inc., 989 F.3d 964, 983 (Fed. Cir. 2021) (holding damages may be determined within a "range of possible hypothetical negotiation royalty rates[; however,] we are aware of no precedent that requires an expert to provide a single proposed royalty rate").

[95] Leesona Corp. v. United States, 599 F.2d 958, 977–78 (Ct. Cl. 1979).

[96] *Id.* at 977.

[97] *Id.*

[98] *Id.*

[99] *Id.* at 978.

[100] *Id.* at 971 ("Savings to the government may be considered in determining reasonable and entire compensation. Its most proper use [however] . . . is in estimating what royalty willing buyers and sellers would agree to.").

[101] ResQNet.com, Inc. v. Lansa, Inc., 594 F.3d 860, 869 (Fed. Cir. 2010). *See also* Grain Processing Corp. v. Am. Maize-Prods. Co., 185 F.3d 1341, 1350 (Fed. Cir. 1999) ("To prevent the hypothetical from lapsing into pure speculation, this court requires sound economic proof of the nature of the market and likely outcomes with infringement factored out of the economic picture.").

[102] Rahul Guha, Jian Li & Andrea L. Scott, *The Economics of Commercial Success in Pharmaceutical Patent Litigation*, 1:5 LANDSLIDE 8, 13 at n.10 (May/June 2009) ("The level and growth of sales as a share of sales by competing drugs is another important indicator of commercial success because it speaks to the success of the product relative to its competitors . . . . Pricing of the drug relative to competing drugs may also be a relevant indicator of commercial success. In particular, the ability to command a price premium over other competing drugs and still enjoy sales and share growth suggests that a drug provides unique therapeutic benefits. Other possible indicators of a drug's commercial success include rapid and widespread international diffusion and widespread favorable coverage for the drug in prescription drug plans."); *see*

resulting damage award in a Section 1498(a) case involving government infringement of a pharmaceutical patent using this analysis would no doubt be significant.

In contrast, the Yale Article proposes that federal trial judges in Section 1498(a) cases should determine "reasonable compensation" by "establishing a baseline reasonable royalty calculated as a percentage of the generic drug price."[103] No case supports finding a "reasonable royalty" based on a competitor's price which necessarily will entail discovery about R&D, manufacturing, distribution, sales costs, and profit allocation. The Yale Article further suggests, if appropriate evidence is proffered by the patent owner, the trial court could simply "adjust this compensation award upwards to account for the patentee's risk-adjusted R&D costs and to ensure a reasonable profit."[104] Of course, the Yale Article does not explain how a pharmaceutical manufacturer's "risk-adjusted R&D costs" would be determined, although we assume it would exclude the value of any unexpired patent term.[105] Nor does the Yale Article consider that calculating a "reasonable profit" for a pharmaceutical drug necessarily requires extensive discovery and necessarily be a highly subjective exercise.[106]

In the alternative, the Yale Article surmises that a "residual royalty" could be determined by a generic manufacturer's earnings, even though this likely would result in a "very low baseline."[107] To solve this problem, the Yale Article envisions that the trial judge could just "gross up" the "residual royalty" by some arbitrary amount to "ensure adequate incentives for innovation."[108] In determining the "gross up," the Yale Article assures us that "courts need not make these calculations perfectly: even with a sizable margin of error, the social gains in these cases will likely far exceed the possible losses."[109] There is absolutely no basis in case law for the federal courts to dispense what amounts to Robin Hood-type justice.

A more reliable way to measure damages for government infringement of a pharmaceutical patent would be lost profits, i.e., multiplying the units of the generic drugs sold by the profit margin of the infringed patented drug.[110] Although the appellate court initially was skeptical of awarding lost profits as damages in Section

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also id. at 9–10 ("Commonly used indicators of commercial success, include significant sales levels, significant sales growth, price premiums, and other indicators. Pharmaceutical sales can be measured by dollars of sales revenue, prescriptions, or daily doses.").

[103] Brennan et al., *supra* note 2, at 283.

[104] *Id.*

[105] *Leesona Corp.*, 599 F.2d at 979 ("Although we can and do heavily stress the importance of exclusivity when determining the applicable royalty rate, we cannot say that § 1498 provides compensation for its loss independently of the statutory defined bases for compensation.").

[106] Guha et al., *supra* note 102, at 10 (Determining profitability by the return of invested capital to discover and develop drugs "is difficult to obtain because R&D costs may be incurred over a long period of time and may not easily be allocated to a particular drug. In addition, a lack of positive return on capital investment should not necessarily undermine a conclusion of commercial success. A few 'blockbuster' drugs generate the majority of profits for the drug companies. That means the majority of smaller drugs may not be profitable in the sense of recouping all the costs of their discovery and development, even if they have therapeutic value.").

[107] Brennan et al., *supra* note 2, at 315.

[108] *Id.*

[109] *Id.* at 282.

[110] Guha et al., *supra* note 102, at 10 ("Because pharmaceuticals have low production costs, sales revenue is a good proxy for gross profitability.").

1498(a) cases,[111] that is no longer so.[112] Even, the Yale Article agrees that lost profits are an appropriate measure of damages if the government infringes pharmaceutical patents and suggests what it describes as a "10 to 30% bounty [to] approximate average profits in the pharmaceutical industry."[113] Anticipating a negative public reaction to what would be a significant damage award, the Yale Article informs us: "[C]ourts must play a role in setting damages. That role might, however, be merely a backstop. Agencies can establish guidelines that will shape any bargaining around the courts' powers, thereby influencing courts' calculations and reducing uncertainty about how courts would assess damages."[114] The Federal Circuit certainly would not allow an agency's "guidance" to trump the primacy of the courts in assessing patent infringement damages: "[G]uidance 'is not, itself, the law . . . , does not carry the force of law, and is not binding on our . . . analysis.' And to the extent the guidance 'contradicts or does not fully accord with our caselaw [sic], it is our caselaw [sic], and Supreme Court precedent it is based upon, that must control.'"[115]

Nevertheless, the Yale Article claims its damage analysis is "[i]n line with the goals of § 1498 and patent protection more broadly, [as] our proposed compensation methodology tethers patent compensation to the risk-adjusted costs of innovation."[116] It is difficult to imagine how government infringement of patents can be conceived as a "goal of patent protection." In addition, the Yale Article's view that the "goal of patent protection" is to provide "compensation" for "the risk-adjusted cost of innovation" appears nowhere in the text of patent law nor any judicial decision that the authors have identified. Moreover, the Yale Article fails to acknowledge that the United States, unlike other developed countries, heavily relies on private markets to finance pharmaceutical research and development,[117] as the following chart shows.[118]

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[111] Tektronix, Inc. v. United States, 552 F.2d 343, 348–49 (Cl. Ct. 1997), *opinion modified on denial of remand*, 557 F.2d 265 (Cl. Ct. 1977) (ruling that when the federal government is the infringer, lost profits must be established by the "strictest proof").

[112] Leesona Corp. v. United States, 599 F.2d 958, 971 (Ct. Cl. 1979) ("[O]ur suggestion in *Tektronix* [was] lost profits might be used in some circumstances to measure just compensation.") *See also* Gargoyles, Inc. v. United States, 113 F.3d 1572, 1576 (Fed. Cir. 1997) ("[L]ost profits should be recoverable in at least some infringement actions against the government[.]").

[113] Brennan et al., *supra* note 2, at 315; *see also id.* at 284, n.35 (citing Liyan Chen, *Best of the Biggest: How Profitable Are the World's Largest Companies*, FORBES (May 13, 2014)); *see also id.* at 315 n.196; *see also* Guha et al., *supra* note 102, at 10 ("Because pharmaceuticals have low production costs, sales revenue is a good proxy for gross profitability.").

[114] *Id.* at 326.

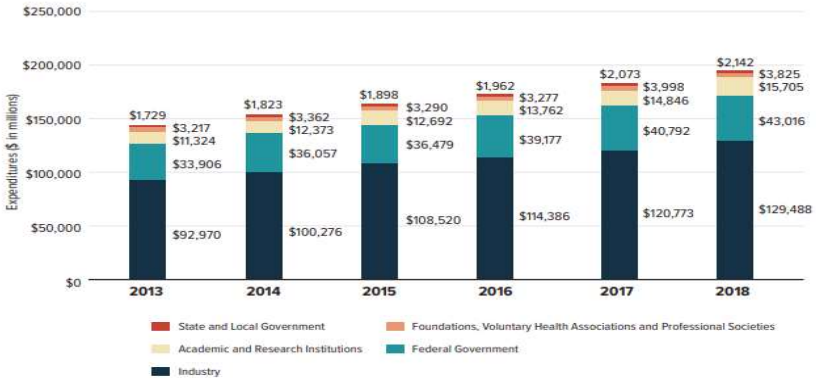
[115] cxLoyalty, Inc. v. Maritz Holdings, Inc., 986 F.3d 1367, 1375, n.1 (Fed. Cir. 2021) (citation omitted).

[116] Brennan et al., s*upra* note 2, at 353.

[117] *See* Statement of Garthwaite, *supra* note 40, at 2 ("In contrast to most other developed countries, the United States relies more heavily on private markets to finance and provide healthcare services. While this is a source of consternation for some, this use of economic markets is not a policy accident and instead reflects a belief that there are many advantages to market-based healthcare. A large and diverse country such as the United States has a wide variety of preferences and meaningful differences in the willingness to pay for quality. In this setting, the central planning inherent to regulated prices is unlikely to maximize welfare, and an economic market is the superior method of allocating goods and services. This is even more true once we consider the variety of economic actors necessary for the development of innovative new healthcare products and services.").

[118] *See* RESEARCH!AMERICA, U.S. INVESTMENTS IN MEDICAL AND HEALTH RESEARCH AND DEVELOPMENT 2013–2018 5 fig. 3 (2019).

Figure 3: Estimated U.S. Medical and Health R&D Expenditures ($ in millions), 2013-2018



5 Research!America

Numerous life-saving drugs have been brought to market as a result of private investment in the pharmaceutical industry.[119] A recent example is ABECMA™, a cell therapy developed by Bristol-Myers Squibb Co. and bluebird bio, Inc., with great promise in curing multiple myeloma where other drugs have not worked.[120] This therapy collects patient T cells that are sent to a laboratory where specialized molecular hooks are inserted into the T cells. The T cells are then reinjected into the patient where they attach to a marker found in cancerous cells.[121] After 2017, when this therapy was approved by FDA, venture capital contributed over $3.83 billion to accelerate availability to the public, even though new competitors already were on the scene.[122] Although the initial wholesale price of a one-time infusion was $419,500, that cost is expected to be reduced and covered by Medicare and commercial insurers.[123] To be sure, this still will be an expensive therapy, but previously there was no cure for multiple myeloma.

Another example is LUMAKRAS™, a pill developed by Amgen, Inc., which treats a genetic mutation found in lung cancer. This drug received FDA approval in May 2021, having "sped through clinic trials since the first encouraging results in 2019."[124] About 13% of patients with non-small cell lung cancer, or approximately 25,000 individuals annually, now have a drug where previously no treatment was available.[125] It is expected that LUMAKRAS™ will cost $17,900 a month, but its commercial success will depend on whether it works either as a first-line treatment or in

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[119] *Id.* at 5 (reporting that in 2018, the biopharma industry spent approximately $129.5 billion or 66.7% of all such R&D expenditures).

[120] Brian Gormley, *Cancer Therapies Draw Venture Cash*, WALL ST. J., May 14, 2021, at B11.

[121] *Id.*

[122] *Id.*

[123] *Id.*

[124] Joseph Walker, *Amgen's Lung Cancer Pill Wins Approval*, WALL ST. J. (last updated May 28, 2021), https://www.wsj.com/articles/amgen-wins-approval-for-pathbreaking-lung-cancer-drug-11622220249.

[125] *Id.* at A6.

combination or sequentially with other medicines. LUMAKRAS™, however, faces imminent competition from Mirati Therapeutics, Inc., Eli Lilly & Co., and Revolution Medicines, Inc., each of which is advancing toward clinical trials with similar drugs.[126] The bottom line is none of these patented pharmaceuticals is guaranteed to provide private investors with any financial return. As an industry analyst observed: "[T]he jury's still out."[127] And that is after forty years of largely private funding in this one area of cancer research.[128]

To state the obvious, investing in the research, development, and obtaining FDA approval to bring a pharmaceutical drug to market entails a great deal of risk, often over decades. Therefore, if the return on such investment is not commensurate with these economic realities, there are other options for a rational investor to obtain a modest profit with little risk. The inevitable result will be a dearth of funds needed to develop drugs to cure disease, particularly those that affect only a small segment of the population. The Yale Article does not begin to discuss the consequences to the health of American citizens if private capital begins to move out of the pharmaceutical space.

Finally, the Yale Article does not consider that the Court of Federal Claims rarely adjudicates Section 1498(a) cases. The court's website reflects that from June 20, 2003 to March 1, 2022, approximately ninety cases invoking Section 1498(a) were filed; almost all, however, were dismissed or settled.[129] Another relevant fact not considered by the Yale Article is that in the last thirty-eight years, the Federal Circuit has considered only four cases where awarded Section 1498(a) damages were subject to an appeal; all were affirmed.[130] Three other Section 1498(a) cases were settled

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[126] *Id.*

[127] *Id.*

[128] *Id.*; *see also* J.P. Carroll, *How Long Does it Take to Get a Drug Approved?* BIOTECHNOLOGY INNOVATION ORG.: BIOTECHNOW (Feb. 16, 2021), https://www.bio.org/blogs/how-long-does-it-take-get-drug-approved ("From 2011–2020, a drug in a Phase I clinical trial had a 7.9% likelihood of approval."); DiMasi et al., *supra* note 40, at 23 (reporting only approximately 12% of investigational medicines that reach clinical trials receive approval from FDA).

[129] *See U.S. Court of Federal Claims Opinion Search*, U.S. CT. OF FED. CLAIMS, https://www.uscfc.uscourts.gov/opinion-search (June 20, 2003 is the earliest date on the website of the United States Court of Federal Claims issuing a Section 1498(a) opinion.).

[130] *See* FastShip, LLC v. United States, 892 F.3d 1298, 1310 (Fed. Cir. 2018) (affirming a $7,117,271.82 award, calculated on a base of "the cost of the elements of LCS-1 covered by the [Patents-in-Suit] as of the date of the license" at a 3% royalty rate plus interest); Paymaster Techs., Inc. v. United States, 180 F. App'x 942, 945 (Fed. Cir. 2006) (affirming $55,923,969.47 award, calculated on a base of "postal money orders," determined, but not reported by the parties, at 3.5% royalty rate); Gargoyles, Inc. v. United States, 113 F.3d 1572, 1574 (Fed. Cir. 1997) (affirming damage award (amount not reported) calculated on a base representing the bulk of B/LPS units acquired by the Army at a 10% royalty and a 50% royalty on a small portion of the of the contract representing the development phase); Hughes Aircraft Co. v. United States, 140 F.3d 1470 (Fed. Cir. 1998) (on remand affirming Hughes Aircraft Co. v. United States, 86 F.3d 1566, 1569, 1574 (Fed. Cir. 1996) (affirming an award of $3.577 billion calculated on a royalty base of "total spacecraft cost," i.e., the total procurement cost, including payload costs, to the government for eighty-one spacecraft at a 1% royalty rate determined by comparing three other Hughes license offers)).

reporting damage awards,[131] although there may be a few others.[132] The Yale Article also fails to take into account that government infringement would be ongoing and require pharmaceutical patent owners to file new cases every six years to satisfy the statute of limitations.[133] Consequently, the complexity of determining "reasonable compensation" in these cases will consume a large part of the resources of the Court of Federal Claims and transform it into a de facto price control agency. Finally, the Yale Article breezes over the fact that Section 1498(a) damage awards are paid from monies appropriated by Congress to the Judgment Fund.[134] Therefore, it is the American taxpayer who will foot the bill for the government's infringement of pharmaceutical patents.

V. LEGISLATIVE PROPOSALS TO "BREAK" PHARMACEUTICAL PATENTS OR COMPEL COMPULSORY LICENSING AT ROYALTY RATES SET BY THE GOVERNMENT WILL FACE SIGNIFICANT LEGAL CHALLENGES

The Prescription Drug Price Relief Act of 2019, Senate Bill 102, which Senator Sanders introduced, if enacted, would authorize the HHS Secretary to infringe pharmaceutical patents or require the owners thereof to enter compulsory licenses at royalty rates established by HHS.[135] Other pending legislation proposals include similar remedial measures directed to address the COVID emergency.[136]

The purpose of Senate Bill 102, as set forth in the title of Section 3, is: "Ending Government-Granted Monopolies for Excessively Priced Drugs."[137] The premise of this proposed legislation is incorrect as a matter of law. As the first Chief Judge of the Federal Circuit pronounced:

> **A patent, under [35 U.S.C. § 262] is property. Nowhere in any statute is a patent described as a monopoly**. The patent right is but the right to

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[131] Honeywell Int'l, Inc. v. United States, 114 Fed. Cl. 637, 639 (Fed. Cl. 2014) (Stipulated Final Judgment awarding plaintiff $75 million); *see also* Jenna Greene, *Judgment Fund: Feds Paid $87M in Patent Cases*, NAT'L L. J. (Apr. 6, 2015). Two other Section 1498(a) cases also were settled. Advanced Aerospace Techs., Inc. v. United States, 132 Fed. Cl. 696 (Fed. Cl. 2017) (final judgment order awarding plaintiff $12.5 million after trial, but before a final decision was issued) and CANVS Corp. v. United States, No. 10-540 C, 2016 U.S. Claims LEXIS 1248 (Fed. Cl. Sept. 7, 2016) (final judgment order awarding plaintiff $14 million after claim construction).

[132] *See, e.g.*, Boeing Co. v. United States, 86 Fed. Cl. 303, 321–22 (Fed. Cl. 2009) (determining the royalty base corresponded to the value of external tanks sold to the National Aeronautics and Space Administration to which a 1.25% royalty was applied to derive "income flows" of "approximately $16.9 million"); *see also* Securitypoint Holdings, Inc. v. United States, 156 Fed. Cl. 750, 793 (Aug. 31, 2021) (establishing an interim royalty of $103,685,510).

[133] *See* 28 U.S.C. § 2501.

[134] *See* 31 U.S.C. § 1304; *see also* Brennan et al., *supra* note 2, at 347 n.336.

[135] *See* Prescription Drug Price Relief Act of 2019, S. 102, 116th Cong. (2019).

[136] *See* Pandemic Emergency Manufacturing Act of 2021, S.187, 117th Cong. (2021) (establishing an Emergency Office within HHS to manufacture and distribute medical products to address COVID-19 or medical products that are in short supply or vulnerable to shortage); *see also* Pandemic Emergency Manufacturing Act of 2021, H.R. 728, 117th Cong. (2021) (same).

[137] S. 102.

> exclude others, the very definition of 'property.' . . . Patents are valid or invalid under the statute, 35 U.S.C. It is but an obfuscation to refer to a patent as 'the patent monopoly[.]'[138]

Other federal appellate courts also have recognized that "[t]he loose application of the pejorative term 'monopoly,' to the property right of exclusion represented by a patent, can be misleading. Unchecked it can also destroy the constitutional and statutory scheme reflected in the patent system."[139] This reflects the primacy of patent law, which "antedate[s] the Sherman Act by a century, [and is] not an 'exception' to the antitrust laws [because] patent rights are not legal monopolies in the antirust sense of that word."[140] A patent grants "the right to exclude others from profiting by [a] patented invention."[141] Therefore, patent law is viewed as an "exception to antitrust law, and the scope of the patent—i.e., the rights conferred by the patent—forms the zone within which the patent holder may operate without facing antitrust liability."[142]

It is unfortunate that public discourse often overlooks that the right to exclude others from making, using, or selling a patented product affords the patent owner only a limited period to sell or license its work, nothing more.[143] Indeed "[t]he sphere that a patent holder can occupy is circumscribed by prior art, shared with those who have overlapping patent rights, frustrated by limitations of the market, and ultimately, truncated by the passage of time. These limitations are essential elements of the patent grant that keep its power in check."[144]

For these reasons, the Supreme Court has recognized that "Congress, the antitrust enforcement agencies, and most economists have all reached the conclusion that a patent does not necessarily confer market power upon the patentee. Today, we reach the same conclusion[.]"[145] If a patent does not convey market power, *ipso facto* it does not convey monopoly power. Since the premise of Senate Bill 102[146] is that patents

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[138] Schenck v. Nortron Corp., 713 F.2d 782, 786 n.3 (Fed. Cir. 1983) (emphasis added).

[139] Panduit Corp. v. Stahlin Bros. Fibre Works, Inc., 575 F.2d 1152, 1160 n.8 (6th Cir. 1978).

[140] Am. Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1367 (Fed. Cir. 1984); *see also* Ames v. Howard, 1 F. Cas. 755, 756 (C.C. D. Mass. 1833) (stating that patents are "not to be treated as mere monopolies odious in the eyes of the law, and therefore not to be favored").

[141] Dawson Chem. Co. v. Rohm & Haas Co., 448 U.S. 176, 215 (1980).

[142] FTC v. Actavis, Inc., 570 U.S. 136, 161 (2013) (Roberts, C.J., dissenting).

[143] Robin Feldman, *Patent and Antitrust Different Shades of Meaning*, 13 VA. J.L. & TECH. 5, 4, 11 (2008).

[144] *Id.* at 12.

[145] Ill. Tool Works, Inc. v. Indep. Ink, Inc., 547 U.S. 28, 45–46 (2006); *see also* U.S. DEP'T OF JUST. & FED. TRADE COMM'N, ANTITRUST GUIDELINES FOR THE LICENSING OF INTELLECTUAL PROPERTY 4 (Apr. 6, 1995) (footnote omitted), https://www.justice.gov/sites/default/files/atr/legacy/2006/04/27/0558.pdf (announcing that neither enforcement agency will presume that "a patent . . . necessarily confers market power upon its owner. Although the intellectual property right confers the power to exclude with respect to the specific product, process, or work in question, there will often be sufficient actual or potential close substitutes . . . to prevent the exercise of market power. If [an intellectual property right] does confer market power, that market power does not by itself offend the antitrust laws. As with any other . . . asset that enables its owner to obtain significant supracompetitive profits, market power (or even a monopoly) that is solely 'a consequence of a superior product, business acumen, or historic accident' does not violate the antitrust laws. Nor does such market power impose on the intellectual property owner an obligation to license the use of that property to others.").

[146] Prescription Drug Price Relief Act of 2019, S. 102, 116th Cong. (2019).

are monopolies, the bill is contrary to antitrust law, and actions by HHS to implement Senate Bill 102 likely would face a direct challenge under the APA.[147]

For example, Section 2(b)(1)(A) of Senate Bill 102 mandates: "The Secretary shall determine that any name brand drug for which the domestic average manufacturing price exceeds the median price[148] charged for such drug in the 5 reference countries to have an excessive price."[149] Once a drug is deemed to be excessively priced, under Section 3(a)(1) and (2), the Secretary "shall waive or void any government-granted exclusivities with respect to such drug [granted under the Hatch–Waxman Act] . . . and shall grant open, non-exclusive licenses allowing any person to make, use, offer to sell or sell, or import into the United States such drug[.]"[150]

Without specifying how a "median price"[151] would be determined,[152] or simply leaving the decision whether a drug's price is "excessively priced" to the unfettered discretion of HHS, would be considered by the federal courts as classic examples of "arbitrary" agency action.[153]

Section 3 of Senate Bill 102 also provides that if a brand name drug price is excessive, the HHS Secretary shall 1) waive or void any exclusive rights granted to the drug's manufacturer by the government to make or sell the drug; and 2) regardless of any applicable patents, grant open, non-exclusive licenses so that any person, organization, or company may make, import, or sell the drug in the United States.[154]

Thus, Senate Bill 102 authorizes the HHS Secretary to "void" or "waive" pharmaceutical patents in direct conflict with the only two laws by which a patent may be declared invalid. First, 28 U.S.C. § 1338(a) specifies: "The district courts shall have original jurisdiction of any civil action arising under any Act of Congress relating to patents." Second, the America Invents Act, provides for inter partes Review[155] and post-grant review[156] of patent validity before the Patent Trial and Appeal Board, subject to review by the Federal Circuit.[157] Authorizing an executive department with no responsibility for the issuance of a patent to invalidate one, without judicial review,

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147 *See* 5 U.S.C. § 706(2)(A).

148 *See* S. 102.

149 *Id.*

150 *Id.*

151 A "median price" is a price in the middle *i.e.,* "an ordered set of [prices] below and above which there is an equal number of [prices]." *Median*, MERRIAM-WEBSTER, https://www.merriam-webster.com/dictionary/median (last visited Sept. 12, 2022).

152 Since the price of the like-kind drugs selected by the HHS Secretary for the data set will determine the "median," using this methodology is subjective and the results can be skewed. For example, if four like-kind drug prices are used to determine the median, e.g., $4.50, $5.75, $6.00, and $6.25, the median would be $5.87. If the price of only two like-kind drugs is used to determine the median, e.g., $5.00 and $7.00, the median would be $6.00.

153 *See* 5 U.S.C. § 706 (2)(A).

154 *See* S. 102.

155 *See* Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011).

156 *Id.* at § 321, 125 Stat. 306.

157 Oil States Energy Services, LLC v. Greene's Energy Group, LLC, 138 S. Ct. 1365, 1373–74 (2018) (holding that the procedural similarities used by federal trial courts and the USPTO Patent Trial and Appeal Board during inter partes review did not violate Article III because the substantive decisions of both are subject to review by the United States Court of Appeals for the Federal Circuit).

would be an unprecedented and serious encroachment on the jurisdiction of Article III judges.[158]

Finally, Section 3 of Senate Bill 102 authorizes the HHS Secretary to grant "open, non-exclusive licenses" allowing others to manufacture, import, or sell patented drugs within the United States.[159] Again, nothing in the history of Section 1498(a) or case law supports such an arbitrary exercise of executive authority, nor should federal courts countenance it.

VI. CONCLUSION

As a prominent Research Professor and Director in one of the nation's most prestigious healthcare and business institutions testified at a recent congressional hearing:

> [I]t is tempting to cave to the crass political calculus that purports to increase access [to pharmaceutical drugs] in a visible way today and obscures the potential long-term costs[, but] . . . once we observe the magnitude of those costs most elected officials making these decisions will have moved on to other careers. But the goal of policy is to carefully weigh those future costs and not believe snake oil promises that strict and large price regulations can cure all of our ills with no side effects.[160]

Although initial prices of some patented pharmaceutical drugs in the past have been higher in the United States than in countries with price controls and less rigorous regulatory requirements,[161] it would be an extremely dangerous undertaking for the government to upend a patent system that has enabled millions of lives to be saved

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[158] *See id.* at 1380–86 (2018) (Gorsuch, J., dissenting) ("'It has been settled by repeated decisions of this court that when a patent has [been issued by] the Patent Office, it . . . is not subject to be revoked or cancelled by the President, or any other officer of the Government. It has become the property of the patentee, and as such is entitled to the same legal protection as other property.'" (quoting McCormick Harvesting Machine Co. v. Aultman, 169 U.S. 606, 608–09 (1898)); *see also* Minerva Surgical, Inc. v. Hologic, Inc., 141 S. Ct. 2298, 2318 (2021) (Barrett, J., dissenting) ("'[A patent] was manifestly intended by Congress to surround the conveyance of patent property with safeguards resembling those usually attaching to that of land.'" (quoting Westinghouse Elec. & Mfg. Co. v. Formica Insulation Co., 266 U.S. 342, 349 (1924)); Adam Mossoff, *The Constitutional Protection of Intellectual Property*, THE HERITAGE FOUND. (Mar. 8, 2021) (reviewing "Founding Era" and 19th Century court decisions and other source material documenting that patents historically have been treated the same in law as private property).

[159] *See* S. 102.

[160] Statement of Garthwaite, *supra* note 40, at 7.

[161] PHRMA, MODERNIZING DRUG DISCOVERY, DEVELOPMENT, AND APPROVAL 1 (Mar. 31, 2016), https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/P-R/proactive-policy-drug-discovery.pdf ("Developing an innovative medicine is a lengthy and complex process, taking an average of 10 or more years. The clinical trial component alone takes roughly six to seven years. With just 12 percent of drugs that enter clinical trials resulting in an approved medicine, the average research and development cost for each successful drug is estimated at $2.6 billion (including the cost of failures). Against this backdrop . . . reforms at the [FDA] would enhance the competitive market for biopharmaceuticals, drive efficiency in drug development and discovery and help hold down costs."); *see also A Prescription for Change: Cracking Down on Anticompetitive Conduct in Prescription Markets*, *Hearing Before the S. Comm. on the Judiciary, Subcomm. on Competition Policy, Antitrust, and Consumer Rights*, 117th Cong. (2021) (statement of Alden F. Abbott, Senior Research Fellow, Mercatus Center, George Mason University) ("Without significant regulatory reform, significant distortions of competition will remain in pharmaceutical markets.").

and has made substantial contributions to the growth of the American economy over the last century.

Section 1498(a) is not a Rx to reduce drug prices![162]

[162] Some policymakers in the current Administration agree. *See* U.S. DEP'T OF HEALTH & HUM. SERVS., OFF. OF THE ASSISTANT SEC'Y FOR PLAN. & EVALUATION, COMPREHENSIVE PLAN FOR ADDRESSING HIGH DRUG PRICES: A REPORT IN RESPONSE TO THE EXECUTIVE ORDER ON COMPETITION IN THE AMERICAN ECONOMY 10 (Sept. 9, 2021) (Neither HHS infringement of pharmaceutical patents nor mandating compulsory licenses set at a royalty rate determined by HHS is recommended to reduce drug prices.).