

No. 26-1581

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

ARBUTUS BIOPHARMA CORPORATION, GENEVANT SCIENCES, GMBH,
Plaintiffs-Appellees,

v.

MODERNA, INC., MODERNATX, INC.,
Defendants-Appellants.

On Appeal from the U.S. District Court for the District of Delaware,
The Honorable Joshua D. Wolson, Case No. 1:22-cv-000252-JDW

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FORM 9. Certificate of Interest

Form 9 (p. 1)
March 2023

**UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT**

CERTIFICATE OF INTEREST

Case Number 26-1581

Short Case Caption Arbutus Biopharma Corporation v. Moderna, Inc.

Filing Party/Entity Appellants Moderna, Inc. and ModernaTX, Inc.

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Date: 08/14/2026

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Name: William M. Jay

FORM 9. Certificate of Interest

Form 9 (p. 2)
March 2023

1. Represented Entities. Fed. Cir. R. 47.4(a)(1).	2. Real Party in Interest. Fed. Cir. R. 47.4(a)(2).	3. Parent Corporations and Stockholders. Fed. Cir. R. 47.4(a)(3).
Provide the full names of all entities represented by undersigned counsel in this case.	Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities. ☒ None/Not Applicable	Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities. ☐ None/Not Applicable
Moderna, Inc.		N/A
ModernaTX, Inc.		Moderna, Inc.

☐ Additional pages attached

FORM 9. Certificate of Interest

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March 2023

4. Legal Representatives. List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).

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Arbutus Biopharma Corporation v. Moderna, Inc.
Appeal No. 26-1581
Form 9 -- Addendum

4. Legal Representatives. In addition to the individuals listed on Form 9, Appellants Moderna, Inc. and Moderna TX, Inc. report that the following law firm appeared for Appellants in the District of Delaware proceeding:

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STATEMENT OF RELATED CASES

The following pending cases are related to this one:

Arbutus Biopharma Corp. v. United States, No. 26-cv-446 (Fed. Cl.)

Bayer CropScience LLC v. Moderna, Inc., No. 26-cv-12 (D. Del.)

CureVac SE v. Moderna, Inc., No. 26-cv-475 (D. Del.)

GlaxoSmithKline Biologicals SA v. Moderna, Inc., No. 24-cv-1135 (D. Del.)

mNG Bio, LLC v. Moderna Inc., No. 26-cv-10074 (D. Mass.)

Northwestern Univ. v. Moderna, Inc., No. 24-cv-1151 (D. Del.)

Appellants (together “Moderna”) are aware of no other related cases.

/s/ William M. Jay
William M. Jay

INTRODUCTION

Plaintiffs turn §1498 upside down. They ask the Court to decide whether a contractor manufactured “for the Government” by *ignoring* whether the Government contracted for that manufacturing. Nothing in text, structure, history, or precedent supports that counterintuitive approach. If the Government had manufactured the vaccine itself, §1498 would apply. The same protection applies to the contractor the Government hired to do the job “for” it. That has been §1498’s central purpose since World War I.

Plaintiffs claim that a “long-established” “direct-benefit test” constrains the Government’s ability to use §1498. But Plaintiffs do not point to *any* case in history holding that producing what the Government hired a contractor to produce nonetheless did not “benefit”—and therefore was not “for”—the Government. Their new, good-for-this-case-only test is not only wrong, but completely unworkable.

The Government contracted with Moderna to produce the vaccine, and Moderna delivered. It thus “manufacture[d] ... for the Government.” 28 U.S.C. §1498(a). Because it also had the Government’s authorization and consent to use any patented invention in that work, Moderna “manufactured ... for the United States.” *Id.* And even if additional benefit to the Government were necessary, Moderna showed it in spades. Of course the Government benefited from manufacturing that supplied the Government’s fight against COVID-19 and enabled

the Government to deliver on its commitment to the Nation—to protect its people, reopen the economy, and restore order to its balance sheet. Nothing in a century of §1498 practice justifies ignoring those benefits—and preventing the Government and its contractors from using patented inventions to achieve them “for the Government.”

Plaintiffs’ alternative theory, indirect infringement, is largely an afterthought. Plaintiffs never reckon with the text: indirect infringement carried out “for” the United States is no less protected than infringement “by” the United States. There is no indirect-infringement loophole.

ARGUMENT

I. Plaintiffs’ gerrymandered “direct-benefit test” has no basis in §1498.

Plaintiffs claim (Red.Br.46) “controlling authority assiduously appl[ies]” a “direct-benefit test” to assess whether government-contracted-for manufacturing falls within §1498. There is no such “controlling authority.” Plaintiffs’ “test” is a case-specific improvisation that contradicts text, precedent, and common sense.

A. Plaintiffs’ argument rests on a supposedly well-established “test” the district court never applied.

Plaintiffs’ “test” is not what the district court applied—or what they argued below. The court held that “the Government, as an entity, must be the *intended recipient of the infringing product*, as opposed to the public that the Government represents.” Appx13 (emphasis added); *see* Appx5816 (Plaintiffs argued §1498 only

covers “articles used by the Federal Government”). The court therefore categorically ignored *all* benefits to the Government from doses “that went to the general public” after the Government received them from Moderna. Appx15. It then refused even to consider Moderna’s evidence of benefit. Appx17.

Plaintiffs now run from that reasoning (Red.Br.27-29, 41-42), saying that “for the Government” does *not* require government end-use, and newly acknowledging that such a rule would contradict binding precedent. *See IRIS Corp. 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). Plaintiffs’ retreat leaves the district court’s rationale entirely undefended; Plaintiffs’ *new* atextual limit on §1498 fares no better.

B. Plaintiffs’ test is wholly atextual.

Plaintiffs have no textual evidence for their “direct-benefit test.” The statutory terms “manufactured ... for the United States”/“for the Government” say nothing about conferring some “direct” governmental “benefit.” Plaintiffs give a passing nod to the district court’s definition of “for” (“intended recipient”), but that does *not* say “direct benefit.” Red.Br.23. It is even narrower—and Plaintiffs ultimately concede it does “not always” fit “for the Government.” Red.Br.27-28, 41.

In place of that not-always-right “intended recipient” definition, Plaintiffs newly argue that “for” can introduce “that in consideration of which, in view of which, or with reference to which anything ... is done.” Red.Br.23 (quoting *For*,

Webster's New Int'l Dictionary 846 (1930)); *see id.* (citing 4 *Oxford English Dictionary* 410 (1901)).

Those newfound definitions say nothing about “direct benefit,” but they do confirm Moderna’s reading. When a contractor performs a government contract, it acts “in consideration of,” “with reference to,” and “[w]ith a view to” *the Government* that requires, directs, and pays for that performance. Doing what the Government hired it to do is how the contractor gets paid. That is precisely why Moderna was manufacturing “for the Government.”

Plaintiffs’ pizza counterexample (Red.Br.41) illustrates the point. If John orders, buys, and pays to deliver a pizza to Jane, the pizzeria still makes that pizza “for” John. It fills John’s order and follows his instructions. If it runs out of dough, it calls John, not Jane. It makes the pizza “with reference to” John as its customer and acts “with a view to” John’s instructions. All the more so if John took delivery from the pizzeria and could then decide where *he* would send the pizza. Just so here: Moderna’s contract had the vaccine delivered *to the Government* (including CDC warehouses, Appx8174-8177), which distributed it through another government contractor.

Finally, where, as here, “there is no ambiguity,” there “is no need for [the Court] to resort to the sovereign immunity canon.” *Richlin Sec. Serv. Co. v. Chertoff*,

553 U.S. 571, 590 (2008). That disposes of Plaintiffs’ fallback argument (Red.Br.43).

C. Plaintiffs’ test rests on significant misreadings of precedent.

Plaintiffs insist that “long-established” §1498 precedent requires all government contractors to satisfy a “direct-benefit test” on top of satisfying their government contract. Red.Br.1. That is wrong.

1. Plaintiffs claim support from a “long line of precedent,” but their paraphrases and one-word, context-free quotations never identify any precedential holding imposing their supposed direct-benefit requirement. *See, e.g.*, Red.Br.23-24. They fundamentally mischaracterize *Hughes* and *Advanced Software* as “procurement contract” cases that required additional showings of benefit. Red.Br.29, 49. Neither case addressed contracts with *the Government*.

In *Hughes*, the United Kingdom contracted for the manufacturing of a satellite it would own and operate. 534 F.2d at 898. The U.S. was a third-party “beneficiary” of the contract, but not “a direct party to [it].” *Id.* at 901 n.16. That benefit to U.S. national-security objectives was sufficient—not necessary—to trigger §1498. *Id.* at 898, 902. But *Hughes* was not imposing a direct-benefit element *on top of* government-contracted manufacturing, nor suggesting that a government contract is irrelevant where one exists. That is clear from how *Hughes* explicitly distinguished manufacturing pursuant to direct government contracts. *Id.* at 901 n.16.

To the same effect is *Advanced Software*, where “[t]he United States was not a party to th[e] contract.” *Advanced Software Design Corp. v. Fed. Rsrv. Bank*, 583 F.3d 1371, 1374 (Fed. Cir. 2009). Plaintiffs therefore are simply wrong in calling that case “controlling precedent analyzing the government’s benefit despite the existence of a procurement contract.” Red.Br.29. Rather, like *Hughes*, *Advanced Software* analyzed when the Government sufficiently benefits as a *third party* to bring private conduct within §1498’s scope. 583 F.3d at 1378. It explicitly recognized that “§1498(a) does not require that the government be party to any contract,” but may *also* “apply to activities by ‘any person, firm, or corporation’ for the benefit of the government.” *Id.*

2. Where, unlike in *Hughes* and *Advanced Software*, the Government itself hires a contractor to perform work, Plaintiffs’ theory collapses. Plaintiffs cannot muster *any* case holding that supplying what the Government contracted for was *not* for the Government’s “benefit”—direct or otherwise.

Attempting to fill this gap, Plaintiffs again point to *Carrier Corp. v. United States*, 534 F.2d 244 (Ct. Cl. 1976). They insist (Red.Br.36) that though *Carrier* involved a “procurement contract providing authorization and consent,” this Court’s predecessor nevertheless “found the infringement was not ‘for the Government’ because it did not benefit the government.” Not true. *Carrier* does not mention “benefit” *anywhere*. And though the contract in *Carrier* had an authorization-and-

consent clause, that clause did not cover the particular alleged infringement. *See* 534 F.2d at 247. That is an explicit boundary around §1498: *unauthorized* “use” does not qualify. *Id.*

Carrier certainly did not subject the procurement contract to an independent “benefit” analysis. As this Court has confirmed, after first holding “that infringing use of a patented device was not directly ‘by the Government’”—a different issue that Plaintiffs mischaracterize¹—*Carrier* proceeded immediately “to an analysis of whether the government authorized and consented to the infringing use.” *Sevenson Env’t Servs. v. Shaw Env’t, Inc.*, 477 F.3d 1361, 1366 (Fed. Cir. 2007).

Rather than subject government-procurement contracts to Plaintiffs’ amorphous “direct-benefit test,” this Court has done the opposite. *Sevenson* confirms that §1498’s “for the Government” inquiry is readily satisfied in procurement-contract cases. *See* 477 F.3d at 1366. So long as the Government “received” the goods or services it “sought”—which is a “benefit”—that alone shows an “infringing method was practiced ‘for the Government.’” *Id.*; *see* U.S.Br.14-16.

¹ *Carrier* mentioned the invention’s “usefulness” (Red.Br.36) only in concluding that the invention was used *by* the contractor, not *by* the Government. That passage does not address the “more difficult question” whether the contractor’s patent use was “*for* the Government with its authorization and consent.” 534 F.2d at 247 (emphasis added).

Attempting revisionist history, Plaintiffs claim (Red.Br.35) the parties in *Sevenson* “did not dispute that performing waste remediation for a government-owned facility directly benefited the government.” Wrong again. *Sevenson* insisted “there is no credible evidence that the use of phosphoric acid to treat the soil at the Site provided any benefit to the government.” Pl.-Appellant Br., 2006 WL 2188615, at *39. This Court said that was “irrelevant”: All that mattered was that the Government had “sought” the services its contractor provided. 477 F.3d at 1366. The same is true here.

3. Cases in which the Government bought goods and then gave them to allies confirm the point. None applies a direct-benefit test, contrary to Plaintiffs’ mischaracterizations. And if supplies the Government distributes to foreign governments are manufactured “for the United States,” supplies the Government distributes to its own citizens are no less so.

In *Yassin v. United States*, 76 F. Supp. 509 (Ct. Cl. 1948), the dispositive question was whether the Government contracted for the manufacturing. Plaintiffs suggest the accused bridge technology was used by *both* the United States and Great Britain. Red.Br.30. That is inaccurate, *see* 76 F. Supp. at 511 (discussing the “United States type and the British type” of portable bridge), and dodges the Court’s actual analysis. If an article was “manufactured by or for the United States in this country,” the United States “would be liable for payment of compensation under”

what is now §1498, even if it was manufactured “for disposition under the Lend-Lease Act” to Great Britain. *Id.* at 515; *see id.* at 513-14. What mattered was whether “the United States was a party to [the] contracts”: if so, that made the manufacturing “for the Government,” even if the same manufacturing would not suffice under contracts with Great Britain. *Id.* at 519.

This is confirmed by *Kaplan v. United States*, which addressed sleeping bags manufactured in the United States but used by foreign nations. 153 F. Supp. 787, 789 (Ct. Cl. 1957). Again, the Court of Claims held that the sleeping bags were made “by or for the United States” *if* manufactured pursuant to contracts with “the United States Government.” *Id.* It did not matter “that the end product, the sleeping bags, were shipped overseas and used by friendly nations.” *Id.*

Plaintiffs strain to distinguish those cases as involving “U.S. military acquisitions intended for its own use.” Red.Br.30 (double emphasis omitted). But the Government did not use them itself. If Plaintiffs mean the Government “used” them by deploying them to others, the same is true here: by controlling where *all* its C-100 purchase went, the Government likewise “used” it. Blue.Br.2, 15, 29, 47-48. Plaintiffs ignore that point.

If Plaintiffs mean *Yassin* and *Kaplan* turn on some “surprise” element about who would *ultimately* use the goods, that is also wrong. Those opinions do not turn on whether manufacturers knew the bridges and sleeping bags would be used by

allies. What mattered was that the U.S. Government hired a contractor to make them. It was then up to the Government to decide what to do with its purchase.

Broome v. Hardie-Tynes Manufacturing Co., 92 F.2d 886 (5th Cir. 1937), further reinforces the point. *Broome*’s holding is not about who “benefited” from sluicgate construction—the Government or the locality. Red.Br.31-32. It mentions “benefit” only when summarizing the plaintiff’s argument that the contracted-for sluicgates were really “for the benefit of” a local watershed district. 92 F.2d at 887. All that mattered *to the court* was that, “on its face,” “the contract was with, and was to be performed on behalf of, the United States.” *Id.* at 887-88.

Oddly, Plaintiffs also suggest that the Government always benefits from use on “public works” like the dams in *Broome*. Red.Br.31-32. But governments build “public works” like flood control or water projects to benefit the public. That only highlights the absurdity of Plaintiffs’ distinction between what the Government does to benefit “itself” versus to serve the people. No case draws any such distinction where the Government hires a contractor to manufacture goods and authorizes the use of patents to do it.

4. Without controlling precedent applying its “direct-benefit test,” Plaintiffs invoke nonbinding, trial-level decisions, which they admit concern only “incidental effects of *private* interests.” Red.Br.25 (emphasis added; citation omitted). That is the opposite of a contractor’s performance of work the Government requires.

One of Plaintiffs’ own cases (Red.Br.27, 34, 36, 48) draws exactly that contrast. In *Riles v. Amerada Hess Corp.*, 999 F. Supp. 938 (S.D. Tex. 1998), a government lease allowed Hess to drill, but did not hire Hess to do so. (Indeed, Hess paid the Government for that privilege.) To emphasize why Hess’s activity was not “for the Government” even if “the Government receive[d] some monetary benefit as a byproduct,” *id.* at 940, *Riles* contrasted *this* scenario: a “contractor making Government widgets pursuant to a contract which infringe a patent,” *Riles* confirmed, “would be making widgets *for* the Government.” *Id.* at 940 n.3.

Plaintiffs’ reliance (Red.Br.24) on *Windsurfing International, Inc. v. Fred Ostermann GmbH*, 534 F. Supp. 581 (S.D.N.Y. 1982), is similarly misplaced. The Government did not contract for the sailboards; an international body did. *Id.* at 587. The Government had only an interest in the Olympics *generally*—too “remote” to be on the hook for a third party’s choice of sailboard. *Id.* at 588.

Larson is no better for Plaintiffs. As explained (Blue.Br.42-44), the Government was held not liable for private providers’ independent decisions to prescribe infringing products to Medicare patients. *Larson v. United States*, 26 Cl. Ct. 365, 369 (1992). The Government did *nothing* to cause providers to prescribe those products, much less contract with them to do it. *Id.* As the Government explained, Medicare had “no interest in the particular medical products” patients received; the Claims Court agreed. *Id.*; AIPLA.Br.18.

This Court has distinguished *Riles*, *Larson*, and like cases as solely addressing the “incidental effects of *private* interests.” *Advanced Software*, 583 F.3d at 1379 (emphasis added). At bottom, that is why Plaintiffs’ argument misappropriates the terms “incidental beneficiary” and “direct benefit.” An “incidental beneficiary” is a *nonparty* to a contract who cannot even bring a claim as a third-party beneficiary. *E.g.*, *German All. Ins. Co. v. Home Water Supply Co.*, 226 U.S. 220, 230-31 (1912) (distinguishing “direct benefit” from “incidental benefit” for that purpose). But when a contracting party receives what it bargained for, U.S.Br.15, 22-23, it is not an “incidental” beneficiary. There is no such thing as a *party* to a contract whose bargained-for benefit is still too “incidental” to count. That is why, in the government-procurement-contract context, courts have never used Plaintiffs’ fabricated incidental/direct-beneficiary paradigm. Making precisely what the Government contracted for is the paradigmatic case of “manufacture ... for the Government.”

D. Plaintiffs’ test equates to the sole-beneficiary test this Court has rejected.

Plaintiffs’ “test” is not only unsupported by precedent; it is substantively equivalent to the sole-beneficiary test this Court has *foreclosed*.

When patentees tried to limit §1498 to situations where the Government is “a principal beneficiary” of infringement, this Court equated that position with a “sole beneficiary” requirement, then outright rejected it. *Advanced Software*, 583 F.3d at

1378. Just as §1498 imposes no “primary purpose” test, it imposes no “sole beneficiary” test. *Id.* (citing *Sevenson*, 477 F.3d at 1365-66). Thus, it did not matter that private banks “almost always” bore the cost of fraud the infringing technology prevented. *Id.* Private infringement can be “for the Government” even though the Government is *not* the “sole beneficiary” of the infringement. *Id.*; *IRIS Corp. v. Japan Airlines Corp.*, 769 F.3d 1359, 1362 (Fed. Cir. 2014) (same).

Plaintiffs simply slap a new name onto that long-rejected test. They look to who is “*the* direct beneficiary” of vaccine manufacturing—and assume there can be just *one*. Red.Br.1, 20, 28, 41 (emphasis added). Their only explanation for why the Government was *not* a “direct beneficiary” is a conclusory assertion that non-employee doses benefited “the American people.” Red.Br.45, 53 (citation omitted). They erroneously treat benefit to the people as negating, rather than coexisting with, the benefit to the Government that serves the people. That is plainly a sole-beneficiary test.

If Plaintiffs’ test were the law, the fraud-detection technology in *Advanced Software* would be for banks, *not* the Government. 583 F.3d at 1378. The passport-reading technology in *IRIS* would be for airlines, *not* the Government. 769 F.3d at 1362. And the satellite in *Hughes* would be for the U.K., *not* the United States. 534 F.2d at 901. The test is not either/or: manufacture “for the Government” does not mean nobody else benefits.

E. Plaintiffs’ test is incoherent and unworkable.

In ordinary usage, providing the Government *directly* with what *the Government* contracted for gives the Government a “direct benefit.” Plaintiffs insist that whatever it means, “direct benefit” is absent here, but they have no coherent definition of their own. That is reason enough to reject their submission.

Consider all that “benefit” apparently would exclude. “[O]wnership” and “control” of tangible property are apparently “ethereal,” “transitory,” and “legally irrelevant formalisms.” Red.Br.14, 49-50. Nothing deemed “medical care” (Red.Br.46) can bring a “direct benefit[.]” to the Government, except (apparently) when administered to a government employee, Red.Br.16. Producing a good or performing a service that “serves government interest[s]” is not enough, Red.Br.48, even though that was what *Hughes* found sufficient without a contract, 534 F.2d at 901 (“vital to U.S. interests”).

Only the thinnest veil disguises Plaintiffs’ gerrymandering. Plaintiffs suggest (Red.Br.54) that the Government *would* be “the direct beneficiary” of a vaccine it stockpiled—no matter how it later used that supply—though that would fail the district court’s ultimate-recipient test. *See Olsson v. United States*, 25 F. Supp. 495, 497-98 (Ct. Cl. 1938). So, if the Government stores its procured vaccine supply for some time before distribution (as it did here, Appx2795-2797, which Plaintiffs

ignore), the Government directly benefits. If the Government quickly distributes its supply, that somehow flunks Plaintiffs’ test. That is incoherent and unworkable.

Plaintiffs view the mere involvement of private parties as a tell-tale sign that there is no “direct” government benefit. That ignores the whole-of-nation, government-driven operation to design, produce, and distribute the first-ever COVID-19 vaccines—including the Government’s antecedent C-34 contract with Moderna to *develop* the vaccine it then manufactured under the C-100 Contract. Blue.Br.6-9. Plaintiffs try to denigrate Operation Warp Speed (“OWS”), but it undeniably *was* “the Government,” and its objectives—including moving at warp speed—were *government* objectives. Blue.Br.8-9. That they were accomplished through private contractors does not change this. After all, Congress extended §1498 to contractors precisely *because* the Government often needs to enlist private industry to achieve its goals and serve the American people. Blue.Br.30-32.

Plaintiffs claim (Red.Br.51) their framework is “[e]asily [a]dministrable.” But Plaintiffs cannot even articulate their test *now*. Their amorphous inquiry would create immense risk for the Government and contractors alike, disincentivizing capital investments essential to government contracting. NAM.Br.6-7, 21-22; U.S.Br.12. Some potential contractors will walk away rather than risk massive patent damages. NAM.Br.17; U.S.Br.26-27. Others may build the risk of treble damages into the price the Government pays up-front, *in case* performance results

in infringement allegations—leaving taxpayers with the bill regardless. NAM.Br.21-22; U.S.Br.12, 26-27. And injunctions against contractors may halt work once underway, stymying the Government’s ability to meet the Nation’s needs. U.S.Br.12. Avoiding all of this is precisely why Congress enacted §1498.

While Plaintiffs insist theirs is an “ex ante” test, it is not even *ex ante* *here*. Plaintiffs have held Moderna liable for every C-100 dose *ultimately* administered to a non-federal-employee—a numeric distribution determined only *ex post*. Plaintiffs baldly assert (Red.Br.51.n.6) that “[t]he actual distribution of doses is a proxy for the parties’ expectations.” But *why* remains entirely unclear. Nothing in the C-100 Contract said how many doses would go to federal employees, to the American people, into a stockpile, or abroad. Appx2778-2830. The Government purchased bulk supply for *it* to decide how to distribute. Appx2796; NAM.Br.15. That is a direct benefit of ownership.

Plaintiffs’ “direct-benefit” theory also turns on a false divide between what benefits the Government versus those the Government serves. That exposes the problem with Plaintiffs’ line—it is simply a question-framing exercise. *Anything* the Government buys to advance its objectives could be recast as benefiting “the people”—from satellites to security software to vaccine supply to (yes) those IRS staples. This fictitious divide certainly has no textual basis in how the statute uses

“the United States” and “Government.” Nor does it comport with a government founded by and for “the People of the United States.” U.S. Const., preamble.

Congress designed §1498 “to allow the Government to procure whatever it wished regardless of possible patent infringement.” *TVI Energy Corp. v. Blane*, 806 F.2d 1057, 1060 (Fed. Cir. 1986). Plaintiffs’ shape-shifting “direct-benefit” exception would betray that purpose and undo the work of a century.

II. Moderna’s approach applies the statute as Congress enacted it.

A. There is nothing illogical in treating government-procured manufacturing as “manufacture ... for the Government.”

Plaintiffs resort to calling Moderna’s reading “illogical.” Red.Br.34-35. Treating government-contracted manufacturing as “manufacture ... for the Government” is anything but.

Congress added “manufactured ... for the United States” in 1918 specifically to shield government *contractors*. The Supreme Court had held that the original statute covered only the Government’s own manufacturing. Blue.Br.30-32. That left contractors “exposed to expensive patent litigation, involving the possibilities of prohibitive injunction,” “royalties,” and “punitive damages,” just for making what the Government ordered. *Richmond Screw Anchor Co. v. United States*, 275 U.S. 331, 342 (1928) (quoting Acting Navy Secretary Roosevelt’s letter). By protecting manufacturing done *either* “by or for the United States,” Congress filled this gap,

treating contractors as if the Government “was doing the work itself.” 56 Cong. Rec. 7960-61 (1918) (statement of Rep. Padgett, Naval Affairs Committee Chairman).

Plaintiffs would revive the very discrepancy Congress fixed in 1918, creating unpredictability and compromising government supply lines. They do not dispute (Red.Br.37) that if government *agencies* manufactured an mRNA vaccine, §1498 would cover this work “by...the United States,” no matter who received the doses. Yet Plaintiffs say §1498’s protection evaporates if the Government tasks private-sector partners with that same work. And they *never* explain why, in §1498’s parallel structure, an atextual “direct benefit” requirement would apply to work “for” the Government but not work “by” it.

B. Moderna’s reading does not create surplusage.

Plaintiffs’ structural objections fare no better. Moderna’s position does not render “contractor” and “for the Government” redundant. Red.Br.38. Government contractors often sell products *both* to the Government and to the private market, but §1498 shields only their work “for the Government.” Without that phrase, §1498 would give a “contractor” blanket protection. And if Plaintiffs contend “contractor” is unnecessary, that is equally true of their interpretation. The statute covers manufacturing by “any person, firm, or corporation,” and that alone would cover any contractor. So “contractor” is a point of emphasis, highlighting the core “manufacturing ... for the Government” Congress sought to cover.

Nor does Moderna “collapse[] §1498’s two prongs.” Red.Br.38-39. Not all procurement contracts contain authorization-and-consent clauses, and not all infringing activity falls within one of those clauses, as *Carrier* illustrates, 534 F.2d at 247. If the Government allows (i.e., “consent[s]” to) the use or manufacture of a patented invention solely for a private party (not as part of government procurement), that consent alone does not establish use or manufacture “for the Government.” Blue.Br.39, 45.² Both prongs have “work to do.” *Nielsen v. Preap*, 586 U.S. 392, 414 (2019).

Plaintiffs argue (Red.Br.31) that Moderna’s interpretation makes surplusage of the Mutual Security Act, now codified at 22 U.S.C. §2356, but that provision confirms *Moderna’s* reading. Congress passed §2356 to respond to concerns that “in ‘many instances, materials for our allies *will not be purchased directly by the United States*[,] and in the absence of this legislation, a patent owner could enjoin a manufacturer from supplying the materials.’” *Hughes*, 534 F.2d at 913 (quoting statutory history) (emphasis added). *Kaplan* explained this—§2356 covered manufacturing under contracts with a “friendly nation,” whereas §1498 already

² Plaintiffs are incorrect that Moderna would let authorization and consent alone foreclose judicial review. Plaintiffs’ argument about “for the Government” is justiciable—but wrong.

covered goods manufactured under direct contracts with “the United States Government” but provided to allies. 153 F. Supp. at 789.

C. Applying the statute does not diminish Plaintiffs’ property or constitutional rights.

Finally, Plaintiffs are wrong that adopting their interpretation would vindicate patent rights and the separation of powers. Red.Br.56-61. They complain that a ruling for Moderna would limit them to “reasonable and entire compensation,” without a jury trial or enhanced damages. Red.Br.65.³ But Plaintiffs’ quarrel is with the statute: “given section 1498’s roots in eminent domain,” it naturally provides different remedies against the sovereign than against private defendants. *4DD Holdings, LLC v. United States*, 181 F.4th 1363, 1376 (Fed. Cir. 2026).

Plaintiffs also complain that Moderna would not “face injunctive relief” if the statute applies. Red.Br.53, 58; *accord* USIJ.Br.12.n.8. That is the point—so that patentees cannot seek injunctions to “cut the government off from sources of supply.” *Trojan, Inc. v. Shat-R-Shield, Inc.*, 885 F.2d 854, 856-57 (Fed. Cir. 1989).⁴ Plaintiffs insincerely posit (Red.Br.3) that patentees seeking injunctions will lose

³ Plaintiffs’ claim that this case involved willful infringement (Red.Br.57) is based not on anything decided below, but on a slanted story that Plaintiffs never had to present to a factfinder.

⁴ Hatch-Waxman’s provision restricting *FDA approval* of generics during patent lifetime likely presents distinct issues from injunctions.

under the “public interest” prong, but §1498 requires no factor-balancing: district courts simply may not enjoin government procurement.

Plaintiffs’ constitutionally-tinged objections are equally unpersuasive. They complain that “every functionary with contracting authority” is able to create §1498 immunity. Red.Br.60. But that is true under both sides’ interpretations. No one thinks Congress must legislate every contract individually: once Congress appropriates funds, “contracting authority” will always rest with individual officials. Even here, Plaintiffs do not dispute that the C-100 Contract was a valid contract that triggers §1498 for government-employee doses. Appx12-13.n.7, Appx15-16. All Plaintiffs’ theory would do is make contracting officers’ authority even more unpredictable—and leave contractors unable to know whether they can rely on the Government’s promises.⁵

Plaintiffs separately raise the specter of compulsory prescription-drug licensing, which they insist “is not merely hypothetical.” Red.Br.57-58. But since no one has ever tried it in a century of §1498 practice, and (as Plaintiffs recognize) “[n]o court has endorsed” it, Red.Br.57-58, it is by definition hypothetical—based

⁵ For these reasons, one amicus brief’s reliance on the major-questions doctrine does not help Plaintiffs. Novartis.Br.22-32. Plaintiffs’ reading does not limit federal contracting authority or the Government’s own ability to use patented technology to make a vaccine. Nor is there anything vague about §1498’s text. *See supra*, p. 4.

on one 2016 law-review article. No one here is claiming §1498 extends to government reimbursement, regulatory approval, or subsidies. Blue.Br.42-43.

Plaintiffs’ overwrought rhetoric about emergency powers is yet another dodge. Red.Br.61. The “context” Moderna identified as relevant is not the mere existence of an emergency, but rather the Government’s inability to itself develop and manufacture a vaccine with the necessary scale or speed. Blue.Br.28-29. It therefore hired Moderna to manufacture what it needed under its direction, oversight, and control, and authorized Moderna to use patented inventions rather than slow from warp speed. *That* is why §1498 applies.

III. Manufacturing government-owned vaccine supply to safeguard the Nation against a global threat *did* directly benefit the Government.

The Government’s successful operation to protect America from COVID-19 *did* benefit the Government. Blue.Br.49-53. Moderna made bulk vaccine supply that was vital to the Government’s pandemic response. Plaintiffs do not refute those benefits, but assert they were insufficiently “direct” to qualify. Red.Br.47.

This “direct” objection fails at the threshold because the Government was *first* in any benefit chain. Plaintiffs do not dispute the Government took title to every lot manufactured under the C-100 Contract. The C-100 clause conferring title gave the Government the right to control the lots’ disposition. Plaintiffs argue that title is “inapposite,” Red.Br.49, but tellingly rely on *Hughes*, which simply stands for the proposition that manufacture may be “for the United States” even without the

Government's taking title, *see* 534 F.2d at 895. Even if taking title is not necessary, it is sufficient, as *Kaplan* makes clear. 153 F. Supp. at 789.

Plaintiffs claim (Red.Br.50) the Government's title was somehow less valuable because the Government had McKesson take physical possession of most vaccine supply. Nonsense. McKesson did so *for the Government*. Red.Br.12-13 (acknowledging McKesson did so "under government contract"). Possession did not benefit a paid distributor rather than its customer, the Government.

Rather, the relevant §1498 conduct, which is Moderna's "manufacture" of vaccine supply, gave the Government ownership and control of *its* purchased supply, conferring a direct benefit on the Government. U.S.Br.17-18; Hepburn.Br.17-24.

Plaintiffs demand that the analysis instead look far downstream. They skip over the entire OWS apparatus (including the Government and its partners who distributed the vaccine) and suddenly land at each individual who received a shot in the arm. And *that individual*, they claim, is the sole beneficiary of each dose taken from the Government's bulk-vaccine-supply acquisition under the C-100 Contract. But that argument distorts the C-100 Contract. It rests on a theory (Red.Br.45) that the Contract divides doses into separate categories—some for "the United States Government" and others for "the US population." It does not. Consider the full quoted sentence: "The Department of Defense and Health and Human Services (HHS) require large scale manufacturing of vaccine doses in support of the national

emergency response to the Coronavirus Disease 2019 (COVID-19) for the United States Government (USG) and the US population.” Appx2796. This makes clear that it was *the Government* (DOD and HHS) purchasing bulk supply—all for *the Government’s* “national emergency response” to the pandemic. U.S.Br.17-18.

Plaintiffs’ reading even conflicts with the judgment in their favor. The Government allocated 15.52% of C-100 doses to foreign nations. Appx8180. Were Plaintiffs right that the C-100 Contract divided beneficiaries into two mutually exclusive categories, those foreign doses *must* have been “for” the Government, because they certainly were not “for” the “US population.” Plaintiffs’ reading makes clear that reversal is at minimum warranted on those doses, and further exposes why their reading of the C-100 Contract is nonsensical.

The rest of the Contract underscores the point. It confirms that DOD and HHS, through Operation Warp Speed, were “leading a whole of nation effort.” Appx2796. Its objectives were “to ensure development of promising vaccine, diagnostic and therapeutic candidates and ensure that these medical countermeasures are available in the quantities required *to reduce SARS-CoV-2 transmission*, identify prior and/or current infection, and improve patient care, thereby mitigating the impact of COVID-19 *on the nation* and its people.” *Id.* (emphases added).

Plaintiffs ignore the objective most relevant to the vaccine—reducing transmission—which was how OWS intended to “vanquish the virus” and “end the

pandemic.” Blue.Br.6-14. The Government reiterates today that it purchased the vaccine *to obtain* that benefit. U.S.Br.20. Combatting the pandemic through reduced transmission also brought other government benefits—safeguarding the Nation, reopening the economy, and mitigating the damage to the Government’s balance sheet. Blue.Br.49-53; *see also* Hepburn.Br.13-24; AIPLA.Br.17-23. These are more than sufficient benefits under *Hughes*, *Advanced Software*, and *IRIS Corp.*—even *without* considering the Government’s contractual bargain.

Plaintiffs wave these benefits away as incidental effects of private interests, but the Government confirmed—then and now—that they were the Government’s direct objectives when hiring Moderna to make the vaccine. U.S.Br.17, 20. The Government makes crystal clear that *it* (not Moderna) is “the only appropriate defendant in ... any patent-infringement suit arising out of Moderna’s performance of” the C-100 Contract. U.S.Br.11. When the Government appears in a case and *confirms* its assumption of liability for alleged patent use, this Court has always given those statements great weight. *See Iris Corp.*, 769 F.3d at 1363; *Advanced Software*, 583 F.3d at 1377-78; *Arlton v. AeroVironment, Inc.*, 2026 WL 294827, at *5 (Fed. Cir. Feb. 4, 2026).⁶ Yet the district court gave no weight to those statements here. Appx946-963.

⁶ Despite Plaintiffs’ and amici’s caricature, that does not mean the matter is unreviewable.

Finally, while Plaintiffs’ entire appellate argument hinges on the concept of government benefit, they do not dispute that the district court refused to examine *any evidence* of government benefit here. Instead, they contend (Red.Br.55.n.8) that Moderna cannot challenge that refusal, because Moderna argued “for the Government” is a legal question. That ignores the sequence below. Moderna has consistently argued that there is no need to consider any evidence of “benefit” where (as here) Moderna was producing what the Government hired it to make—that is “manufacture ... by a contractor ... for the Government.” 28 U.S.C. §1498(a). It is *Plaintiffs* who insist on a “benefit” showing *beyond* Moderna’s performance of the C-100 Contract. If the court independently assesses benefit, then it must consider evidence that the Government *did* benefit from Moderna’s work.

IV. Section 1498 also bars a standalone claim for indirect infringement against Moderna.

Plaintiffs have no meaningful response on indirect infringement. In Plaintiffs’ view, even if any direct infringement was “for the United States,” Moderna lost all §1498 protection once it packaged the vaccine with FDA-required instructions. Red.Br.63. Plaintiffs do not dispute that their indirect- and direct-infringement claims are entirely duplicative: *Every* dose they identify supports a claim under both theories. Blue.Br.59.n.8. Against that backdrop, Plaintiffs do not marshal any support to justify gutting §1498. Plaintiffs’ theory contradicts the text of the statute and flies in the face of precedent.

A. Plaintiffs’ indirect-infringement theory is atextual, unsupported, and unworkable.

1. Under Plaintiffs’ reasoning and caselaw, Moderna prevails. As Plaintiffs describe, §1498 “provides a distinct cause of action for the ‘use or manufacture’ *by or for* the government.” Red.Br.62 (emphasis added). Plaintiffs thus recognize that, in cases involving an “act of direct infringement by the government,” §1498 channels claims for all forms of infringement into a single claim for relief under the statute. *Id.* (emphases removed). But, they say, the same is not true where a private party infringes “for the United States”; in that scenario, §1498 “does not apply.” *Id.* Plaintiffs do not provide any basis for a rule that §1498 supplants all infringement claims against contractors in a case of use “by” the United States, but only claims for direct infringement in a case of use “for” the United States.

Plaintiffs appeal to precedent, but the cases they cite (Red.Br.62) *expressly adopt Moderna’s position*. In *Decca Ltd. v. United States*, the Court of Claims recognized that §1498 “shields governmental contractors from being held liable for contributory infringement.” 640 F.2d 1156, 1179 (Ct. Cl. 1980); *see also* Blue.Br.58. Plaintiffs ignore this conclusion, along with the Supreme Court’s recognition of the same. Red.Br.62; Blue.Br.57 (discussing *Marconi Wireless Tel. Co. of Am. v. Simon*, 246 U.S. 46, 56-57 (1918)). Plaintiffs also brush aside the string of cases rejecting their interpretation because they involved use “by ... the

United States.” Red.Br.63-64 (emphasis removed) (citation omitted). But, again, there is no basis for treating differently cases of use “for ... the United States.” *See supra*, p. 27.

Apparently unconcerned that *Decca* adopted the opposing position, Plaintiffs maintain (Red.Br.63) that indirect infringement falls “outside § 1498(a)” because it “do[es] not involve the Government’s making or using a patented invention.” *Zoltek Corp. v. United States*, 672 F.3d 1309, 1320 (Fed. Cir. 2012) (en banc) (emphasis removed) (quoting *Decca*, 640 F.2d at 1170 & n.31). But *Decca* was merely explaining that §1498 does not authorize a claim against the Government for the *Government’s* indirect infringement. *Decca*, 640 F.2d at 1170 & n.31. Section 1498 plainly is not limited to the Government’s making or using a patented invention; it provides a cause of action for “use[] or manufacture[] by *or for* the United States,” including use or manufacture by contractors.

At bottom, Plaintiffs have *no* case adopting their theory. Text and precedent establish that indirect-infringement claims are no exception to “the exclusive and comprehensive character” of the §1498 remedy. *Richmond Screw*, 275 U.S. at 343.

2. Like Plaintiffs’ direct-infringement theory, Plaintiffs’ indirect-infringement approach is unworkable because it turns on whether government employees would administer the vaccine. That was unknowable at the time of contracting—as was whether particular doses would be administered at all.

Blue.Br.60; U.S.Br.27-28. Plaintiffs’ objection (Red.Br.66) that Moderna did not produce evidence on which doses fall into this category misses the point: Plaintiffs’ approach blinds contractors to their potential liability.⁷

B. The Government’s sovereign-immunity waiver for its own indirect infringement is irrelevant.

Plaintiffs incorrectly argue that there can be no §1498 defense unless the Government has waived sovereign immunity *for that exact claim*. Red.Br.64-65. The statute does not endorse that premise. Rather, when §1498 applies, it “makes the remedy against the United States exclusive” of all forms of infringement liability against others. *Astornet Techs., Inc. v. BAE Sys., Inc.*, 802 F.3d 1271, 1277 (Fed. Cir. 2015); *Messerschmidt v. United States*, 29 Fed. Cl. 1, 43 (1993) (“single source of recovery” replaces what would otherwise be “a choice of suits” for direct or indirect infringement); Blue.Br.54.

Plaintiffs recognize that §1498 applies where the defendant induced or contributed to the Government’s direct infringement (as in *Astornet*, see 802 F.3d at 1277). To the extent Plaintiffs suggest §1498 applies only to cases involving “use[] or manufacture[] by or for the United States,” *every* case presenting this indirect-

⁷ Plaintiffs also misdescribe the Consent Judgment (Red.Br.66-67). Moderna consented to judgment as to particular *counts* of indirect infringement. Appx37, Appx1508. Nothing in the Consent Judgment admits liability for indirect infringement as to *all doses*—particularly doses never administered.

infringement issue requires a predicate act of direct infringement under the statute—*i.e.*, “use[] or manufacture[] by or for the United States.” That refutes Plaintiffs’ suggestion that a defendant can invoke §1498 only when *the defendant itself* “used or manufactured” a patented invention. The plain text shields defendants from any infringement claims related to use or manufacture “for” the United States.

Both this Court and its predecessor have concluded that the shield §1498 provides does not mirror the scope of the sovereign-immunity waiver. As *Decca* explained, “the Government is not liable for its inducing infringement by others, for its conduct contributory to infringement of others, or for what, *but for section 1498*, would be contributory (rather than direct) infringement of its suppliers.” 640 F.2d at 1167 (emphasis added). In other words, neither the Government *nor its suppliers* are liable for contributory infringement. *See id.* Far from “dustbin[ing] this blackletter law,” Red.Br.62, Moderna emphasized this holding, Blue.Br.55.

TVI likewise held that third-party infringement “during Government bidding activities ... is immune under” §1498. 806 F.2d at 1059. The Court rejected the patentee’s argument that this holding left it “without a judicial remedy,” explaining that it was “not ... necessary” to resolve whether the patentee had “a cause of action against the Government.” *Id.* at 1060-61. *TVI* thus rejects any notion that §1498(a) applies only when there is a corresponding claim against the Government.

The FTCA further confirms that liability protection may be broader than the corresponding sovereign-immunity waiver. Like §1498, the FTCA provides an “exclusive mode of recovery” and bars suit against employees even when the “exclusive” remedy against the government is unavailable. *United States v. Smith*, 499 U.S. 160, 166-67 (1991); *see* Blue.Br.58-59. The “two exceptions” discussed in *Smith* do not “restrict remedies,” Red.Br.66; they are specific situations where “the FTCA is *not* the exclusive remedy for torts committed by Government employees”—*i.e.*, “express preservations of employee liability,” 499 U.S. at 166-67. But where the FTCA *is* exclusive, compensation comes from the government or (where an FTCA exception applies) not at all. So too here.

Richmond Screw’s statement that §1498 “secure[s] to the owner of the patent the exact equivalent of what it was taking away from him” does not help Plaintiffs. 275 U.S. at 344-45; Red.Br.65. Plaintiffs face no gap in recovery: They can pursue their “entire” recovery against the United States in their pending Court of Federal Claims suit. Blue.Br.59.n.8; *see also Aero Prods. Int’l, Inc. v. Intex Recreation Corp.*, 466 F.3d 1000, 1017, 1019 (Fed. Cir. 2006) (barring double recovery based on the same infringing technology). The *Richmond Screw* plaintiffs would have had *no* remedy, even for *direct* infringement, had the Supreme Court not construed the Anti-Assignment Act to allow it to proceed against the Government (despite its being an assignee). That claim was barred because the 1918 Act “relieve[d] the

contractor entirely from liability *of every kind*,” 275 U.S. at 343, 345 (emphasis added). The Court’s broad interpretation of the 1918 Act supports *Moderna*, not Plaintiffs.

* * *

Plaintiffs’ reverse-engineered approach to §1498 is not anchored in text, history, practice, or practicalities. Its only guiding principle is to exclude this case. But adopting it would trample nearly a century of caselaw and deny the Government an essential tool for procuring what it needs. The Court should reverse.

CONCLUSION

The portion of the judgment awarding summary judgment to Plaintiffs on §1498 should be reversed.

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Federal Circuit Rule 32(a) because, excluding the parts of the document exempted by Federal Rule of Appellate Procedure 32(f) and Federal Circuit Rule 32(b), it contains 6,991 words.

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