

UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

No. 1:24-cv-01151

Northwestern University,
Plaintiff,

v.

Moderna, Inc. et al.,
Defendants.

OPINION AND ORDER

In this patent-infringement action, Northwestern alleges that Moderna's lipid-nanoparticle vaccines infringe three of Northwestern's patents: a method patent (No. 9,216,155) and two product patents (Nos. 10,328,026 and 8,323,686). The products accused in the complaint are Spikevax and mResvia, and Northwestern's briefing also accuses mNexspike. Northwestern seeks at least a reasonable royalty plus enhanced damages for willful infringement.

The core disputes are in discovery after trimming on a prior motion to dismiss. The court dismissed the '155 patent direct-infringement theories based on providers administering the vaccine ("delivery" and "divided infringement") and, on Northwestern's concession, the 35 U.S.C. § 271(f) supplying-components-abroad claim as to that patent. Doc. 24. Direct, induced, and contributory infringement and willfulness are live on all three patents, as is § 271(f) infringement on the product patents.

Moderna's response has two tracks: the merits broadly and issues specific to sales to the government. The merits of claim construction, invalidity, and noninfringement and associated declaratory counterclaims are under development. But Moderna also has a set of defenses and counterclaims arguing that it cannot be held liable for around 500 million Spikevax doses that it sold to the federal government. The two pending motions concern that government-sales track of Moderna's case.

That track invokes the government’s license to the patents in suit under the Bayh–Dole Act, which arose because Northwestern’s research was funded federally. That track also invokes the doctrines of breach of contract (i.e., that Northwestern breached its patent-licensing agreement with the government), third-party beneficiary, patent exhaustion (the first-sale doctrine), unclean hands, and the defense under 28 U.S.C. § 1498(a) for channeling to another court claims regarding work done for the government.

Northwestern brings two motions challenging that track of Moderna’s case. First, Northwestern moves (Doc. 38) to dismiss or strike the license counterclaim (Count VII), the breach-of-contract counterclaim (Count IX), and the defenses of unclean hands, third-party beneficiary, exhaustion, and license. Northwestern’s core argument is that a private company cannot invoke the federal government’s license arising from its research funding. For the reasons stated below, Northwestern’s motion is granted. Because amendment would be futile, the dismissal is with prejudice and leave to amend is denied.

Second, Northwestern moves (Doc. 80) to strike Moderna’s § 1498(a) defense, and for partial judgment on Moderna’s corresponding counterclaim, in light of this court’s decision in a different case rejecting a materially identical defense as to doses distributed to the public. The parties stipulate that any ruling should await Moderna’s appeal of that ruling. Doc. 86 (citing *Arbutus Biopharma Corp. v. Moderna, Inc.*, No. 26-1581 (Fed. Cir.)). The court agrees with the central premise of the stipulation and elects to deny this motion without prejudice to refiling.

I. Background

The asserted patents relate to synthetic nanostructures related to delivering mRNA into human cells for therapeutic applications. Doc. 1 at 16–22. Defendants are Moderna, Inc., ModernaTX, Inc., and Moderna US, Inc. (collectively, “Moderna”). Northwestern accuses Moderna’s Spikevax and mResvia products of infringing the asserted patents. *Id.* at 33–44. Moderna markets Spikevax as a vaccine for the SARS-CoV-2 virus, which may

cause COVID-19, and markets mResvia as a vaccine for respiratory syncytial virus, commonly known as RSV. Doc. 36 at 7–11.

Moderna asserts counterclaims for: (1) a declaratory judgment that the U.S. government’s license to the asserted patents shields Moderna from liability for any supply to the U.S. government and (2) breach of said license by Northwestern. *Id.* at 25–28.

Moderna alleges that the “U.S. Government has a license from Northwestern to ‘practice and have practiced’ each Asserted Patent.” *Id.* at 25. In Moderna’s view, because the U.S. government allegedly contracted with Moderna “for supply of hundreds of millions of doses of” an accused product, Moderna “cannot be held liable for any patent infringement related to its supply or sales to the U.S. Government” under the government’s licensing agreement with Northwestern. *Id.* at 26. Moderna does not allege that it was a party to this licensing agreement.

Moderna also accuses Northwestern of breaching the licensing agreement with the government. The breach of contract allegations mirror the declaratory-judgment allegations: the government procured a license to the asserted patents and then Moderna allegedly practiced the patents on behalf of the government under a supply agreement. *Id.* at 27–28. One clause in the licensing agreement allegedly bolsters that counterclaim: “[t]he licenses’ language of ‘practiced for or on behalf of the United States’ explicitly indicates that third parties are intended beneficiaries of the licenses.” *Id.* at 28. In Moderna’s view, Northwestern’s bringing this suit against Moderna for supplying the government with Spikevax is a breach of that license agreement. *Id.*

Moderna also asserts four affirmative defenses that Northwestern moves to strike: (1) unclean hands, (2) third-party beneficiary, (3) patent exhaustion, and (4) license. *Id.* at 80–87.

Moderna asserts that Northwestern’s bringing of this suit is “unconscionable conduct and/or in bad faith” because Northwestern was aware of the government’s license to the asserted patents and that Moderna was an intended beneficiary of it. *Id.* at

82–83. Thus, according to Moderna, Northwestern’s claims are barred by the equitable doctrine of unclean hands. *Id.* at 81.

Relatedly, Moderna also asserts that it is “an intended and foreseeable third-party beneficiary of the licenses between Northwestern and the U.S. Government,” which independently bars or offsets Northwestern’s recovery for the alleged patent infringement. *Id.* at 83–84. On this theory, the license immunizes Moderna’s allegedly infringing sales of Spikevax to the government. *Id.* at 84.

Additionally, Moderna asserts that Northwestern exhausted its patent rights. *Id.* at 85. Moderna alleges that its sale of Spikevax to the U.S. government “is an authorized sale” under the government’s license agreement with Northwestern. *Id.* Following that sale, Moderna alleges, Northwestern’s “patent rights in those vaccine doses are exhausted, and any further activities downstream of Moderna—such as use of the vaccines by health care providers and patients—are not infringing.” *Id.* at 85–86. Moderna also alleges that the government’s distribution of the vaccine doses transfers title that independently exhausts Northwestern’s patent rights. *Id.* at 86. Moderna alleges that any indirect infringement was exhausted by the government’s license and transfer of title of those doses to the healthcare providers and patients. *Id.* If healthcare providers and patients are not directly infringing under the exhaustion doctrine, there is no predicate infringement to hold Moderna liable for indirect infringement. *Id.*

Lastly, Moderna asserts that it cannot be liable because the government has a license to the asserted patents. *Id.* Under that license theory, Moderna argues that Northwestern is “barred from asserting that Moderna’s manufacture for, and sales of SPIKEVAX® to, the U.S. Government pursuant to advance purchase agreements infringes the Asserted Patents.” *Id.*

II. The Bayh–Dole Act and 28 U.S.C. § 1498

Congress may enact legislation “[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and

Discoveries.” U.S. Const. art. I, § 8, cl. 8. Congress may also “lay and collect Taxes, Duties, Imposts and Excises, to pay the Debts and provide for the common Defence and general Welfare of the United States.” *Id.* cl. 1. That “spending power must be in pursuit of the general welfare.” *South Dakota v. Dole*, 483 U.S. 203, 207 (1987) (citation modified). This case lies at the intersection of those two congressional powers: promoting technological innovation and spending for the general welfare.

Congress promotes technological innovation through the funding and issuance of federal research grants. “Unlike normal contractual undertakings, federal grant programs originate in and remain governed by statutory provisions expressing the judgment of Congress concerning desirable public policy.” *Bennett v. Ky. Dep’t of Educ.*, 470 U.S. 656, 669 (1985). Previously, grantees and contractors had to cede patent rights for inventions obtained from federal funding to the federal agency issuing the grant. S. Rep. No. 96-480, at 2 (1979). To retain patent rights, inventors had to complete “lengthy waiver procedures.” *Id.* This stifled commercialization of patentable inventions developed through federal research for two reasons: (1) the government only licensed 4% of its patent portfolio while university patentees licensed 33% of their patent portfolios, and (2) the waiver provisions to retain patent rights varied from agency to agency, creating a “policy maze” that small businesses, nonprofits, and universities could not navigate. *Id.* at 2–3. The grants designed to promote innovation were stifling commercialization due to corporate uncertainty of patent ownership and regulatory hurdles. But despite those hurdles, the government was still entitled to practice patented technology discovered through its spending power. *See id.* at 3.

To alter the balance between government use of federally funded research and commercialization of innovation, Congress passed the University and Small Business Patent Procedures Act of 1980, commonly known as the Bayh–Dole Act. 35 U.S.C. §§ 200–212. “Congress passed the Bayh–Dole Act to ‘promote the utilization of inventions arising from federally supported

research,’ ‘promote collaboration between commercial concerns and nonprofit organizations,’ and ‘ensure that the Government obtains sufficient rights in federally supported inventions.’” *Bd. of Trs. of Leland Stanford Junior Univ. v. Roche Molecular Sys., Inc.*, 563 U.S. 776, 782 (2011) (quoting 35 U.S.C. § 200) [hereinafter *Stanford*].

The Bayh–Dole Act allocates patent rights for federally funded inventions between the federal government and “contractor[s],” defined as “any person, small business firm, or nonprofit organization that is a party to a funding agreement.” 35 U.S.C. § 201(c); *see also id.* § 201(b) (defining “funding agreement” as “any contract, grant, or cooperative agreement entered into between any Federal agency . . . and any contractor for the performance of experimental, developmental, or research work funded in whole or in part by the Federal Government”). The Act distinguishes between an “invention,” which is “any invention or discovery which is or may be patentable,” and a “subject invention,” which is “any invention of the contractor conceived or first actually reduced to practice in the performance of work under a funding agreement.” *Id.* § 201(d), (e).

The Bayh–Dole Act allows “nonprofit organizations and small business firms to elect to retain title to any” subject invention, as defined by § 201(e). *Campbell Plastics Eng’g & Mfg., Inc. v. Brownlee*, 389 F.3d 1243, 1247 (Fed. Cir. 2004). However, even when the contractor elects to retain patent rights in the subject invention, the government retains “a nonexclusive, nontransferrable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world.” 35 U.S.C. § 202(c)(4). Accordingly, the Act states that “all funding agreements” made under the Bayh–Dole Act, “including those with other than small business firms and nonprofit organizations, shall include the requirements established in section 202(c)(4) and section 203.” *Id.* § 210(c). In other words, the licensing agreement between the contractor and the government shall include the Act’s express requirements.

The Act thus provides a benefit for the contractor—the right to retain title—and a benefit to the government for funding the contractor’s research. The contractor may retain patent rights to inventions developed through federal funding by complying with one set of regulations, regardless of the federal agency issuing the grant. *See id.* §§ 202–204. That provides researchers with a consistent regulatory scheme “to encourage maximum participation of small business firms in federally supported research and development efforts . . . [and] to promote collaboration between commercial concerns and nonprofit organizations.” *Id.* § 200. The government, through all of its funding arrangements, retains a nonexclusive license to practice or have practiced on behalf of the government any invention developed through federal grants. *Id.* § 202(c)(4). That “ensure[s] that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect[s] the public against nonuse or unreasonable use of inventions.” *Id.* § 200.

Third parties accused of patent infringement for providing products or services to the government are not without statutory defense. Under 28 U.S.C. § 1498(a):

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.

Unlike the Bayh–Dole Act, this provision “relieves a third party from patent infringement liability, and it acts as a waiver of sovereign immunity and consent to liability by the United States.” *Madey v. Duke Univ.*, 307 F.3d 1351, 1359 (Fed. Cir. 2002).

Section 1498(a) thus provides (1) a cause of action against the United States for aggrieved patent holders in the U.S. Court of Federal Claims, and (2) an affirmative defense for accused infringers in any other forum. *See id.* Congress enacted § 1498 “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.” *Richmond Screw Anchor Co. v. United States*, 275 U.S. 331, 345 (1928). Section 1498 encourages companies to supply the government with essential products in times of great public need by shifting liability for their infringement to the United States. *See Astornet Techs. Inc. v. BAE Sys., Inc.*, 802 F.3d 1271, 1277 (Fed. Cir. 2015) (citing *Richmond Screw Anchor*, 275 U.S. at 345).

Thus, a patentee’s sole remedy for infringement arising from work performed for the government and with the authorization or consent of the government is “a suit against the United States in the Court of Claims.” *TVI Energy Corp. v. Blane*, 806 F.2d 1057, 1059–60 (Fed. Cir. 1986). In that instance, the private party cannot be held liable for patent infringement under § 1498(a). *Crater Corp. v. Lucent Techs., Inc.*, 255 F.3d 1361, 1364 (Fed. Cir. 2001).

III. Legal standard

The Federal Circuit applies the regional circuit’s law when reviewing a motion to dismiss for failure to state a claim. *FairWarning IP, LLC v. Iatric Sys., Inc.*, 839 F.3d 1089, 1092 (Fed. Cir. 2016). “Courts use the same standard in ruling on a motion to dismiss a counterclaim under Rule 12(b)(6) as they do in assessing a claim in a complaint.” *Lieberman v. BeyondTrust Corp.*, No. 1:19-cv-01730, 2020 WL 1815547, at *1 (D. Del. Apr. 9, 2020) (cleaned up). When presented with a Rule 12(b)(6) motion to dismiss for failure to state a claim, a district court conducts a two-part analysis. *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009).

First, the court separates the factual and legal elements of a claim, “accept[ing] all of the complaint’s well-pleaded facts as true, but . . . disregard[ing] any legal conclusions.” *Id.* at 210–11. Second, the court determines whether the facts pleaded are sufficient to show that the counter-claimant has a “plausible claim for relief.” *Id.* at 211 (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009)). A claim has facial plausibility when the claimant pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. *Iqbal*, 556 U.S. at 678 (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556 (2007)).

“To decide a motion to dismiss, courts generally consider only the allegations contained in the complaint, exhibits attached to the complaint and matters of public record.” *Pension Benefit Guar. Corp. v. White Consol. Indus., Inc.*, 998 F.2d 1192, 1196 (3d Cir. 1993). “However, an exception to the general rule is that a document integral to or explicitly relied upon in the complaint may be considered” *Schmidt v. Skolas*, 770 F.3d 241, 249 (3d Cir. 2014) (cleaned up).

“The court may strike from a pleading an insufficient defense or any redundant, immaterial, impertinent, or scandalous matter.” Fed. R. Civ. P. 12(f). “A grant or denial of a motion to strike is not an issue unique to patent law, and we therefore apply the law of the regional circuit.” *Anchor Wall Sys., Inc. v. Rockwood Retaining Walls, Inc.*, 340 F.3d 1298, 1313 (Fed. Cir. 2003). “[A] court should not grant a motion to strike a defense unless the insufficiency of the defense is ‘clearly apparent.’” *Cipollone v. Liggett Grp., Inc.*, 789 F.2d 181, 188 (3d Cir. 1986) (citation omitted). District courts in this circuit apply a standard akin to Rule 12(b)(6)’s standard, but shaded by the Third Circuit’s “clearly apparent” modifier. *Corteva Agriscience LLC v. Inari Agric., Inc.*, No. 1:23-cv-01059, 2025 WL 1380763, at *2 (D. Del. May 13, 2025). Courts disfavor motions to strike and consider “equitable and practical considerations more often than with Rule 12(b)(6).” *Id.*

IV. Analysis

For the reasons explained below, the court concludes that the Bayh–Dole Act provides no counterclaim or defense for third parties as opposed to the government. Accordingly, Northwestern’s motion to dismiss and to strike is granted.

Northwestern frames part of its motion as a challenge to Moderna’s “standing” under Rule 12(b)(1), arguing that Moderna is neither a party to nor an intended beneficiary of the government’s licenses. Doc. 39 at 5, 7–8. But whether a litigant may enforce a contract or invoke a license—like whether a statute supplies a cause of action—goes to the merits, not to the court’s power to hear the case. *See Steel Co. v. Citizens for a Better Env’t*, 523 U.S. 83, 89, 96 (1998); *Lexmark Int’l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 128 & n.4 (2014). Moderna has Article III standing to defend against Northwestern’s damages claims and to seek relief from those claims. The court therefore resolves the motion under Rules 12(b)(6) and 12(f), and its rulings are on the merits.

A. License counterclaim and affirmative defense

The Bayh–Dole Act, or a license created pursuant to the conditions of the Bayh–Dole Act, does not create a cause of action or defense for third parties. Moderna provides no case law holding otherwise. Doc. 46 at 7–9.

Moderna takes the view, however, that its cause of action can assert that the *license* under the Bayh–Dole Act shields Moderna from liability even though the *Act* itself does not provide a cause of action. *Id.* at 8. On that view, the license is the shield, not the statute under which the license was made. The court finds that view inconsistent with the text of the Bayh–Dole Act.

The Act requires “that all funding agreements, including those with other than small business firms and nonprofit organizations, shall include the requirements established in section 202(c)(4) and section 203.” 35 U.S.C. § 210(c). So the language of the licensing agreement cannot be considered in a vacuum. The language of a Bayh–Dole Act license must come from the language

of the Act itself—as § 210(c) demands. Thus, to interpret the licensing agreement, the court must interpret the Act.

Consistent with other courts, this court holds that the Bayh–Dole Act does not create a cause of action for third parties. *See, e.g., Madey v. Duke Univ.*, 413 F. Supp. 2d 601, 613 (M.D.N.C. 2006) (“[T]he Government License created by the Bayh–Dole Act is designed to regulate the relationship between the Government and its funding recipients, but it would not be available to a private third party as the basis for a private right of action or private defense.”); *United States v. Cytogel Pharma, LLC*, No. 2:16-cv-13987, 2018 WL 5297753, at *4 (E.D. La. Oct. 25, 2018) (finding no cases support “the proposition that a nongovernmental entity may raise the Government License in its own defense”); *Fenn v. Yale Univ.*, 393 F. Supp. 2d 133, 137–38 (D. Conn. 2004) (collecting cases) (“The Bayh–Dole Act does not provide for a private cause of action to enforce its provisions.”).

That being said, Moderna’s alleged facts may warrant a separate defense. Both the Bayh–Dole Act and 28 U.S.C. § 1498 recognize that the government has the right to allow a third party to practice a patented invention on behalf of the government. *Compare* 35 U.S.C. § 202(c)(4) *with* 28 U.S.C. § 1498(a). But only § 1498 provides the third party with an affirmative defense. *Madey*, 307 F.3d at 1360; *Madey*, 413 F. Supp. 2d at 613–15. Despite snippets of similar statutory language, the Bayh–Dole Act does not recodify the § 1498 defense. To rule otherwise would require courts “to infer a duplicative Government License defense in suits between private parties, where both defenses would require the private party to establish a use ‘for the United States.’” *Madey*, 413 F. Supp. 2d at 614.

Moderna’s reliance on the license’s “have practiced” language does not change the analysis. *See* Doc. 46 at 7–8 (citing *Cyrrix Corp. v. Intel Corp.*, 77 F.3d 1381, 1387–88 (Fed. Cir. 1996), and *Intel Corp. v. Broadcom Corp.*, 173 F. Supp. 2d 201, 228 (D. Del. 2001)). Those cases construed privately negotiated “have made” clauses, whose scope depends on the contracting parties’

bargain. The “have practiced” language here is not a bargained-for term, however, but a statutory requirement that every funding agreement must include. 35 U.S.C. §§ 202(c)(4), 210(c). Congress has separately specified when a contractor’s work for the government shields it from infringement liability: when the work is done “for the Government and with the authorization or consent of the Government,” in which case the patentee’s remedy runs against the United States. 28 U.S.C. § 1498(a). Reading § 202(c)(4) to give contractors a parallel defense would let them bypass § 1498(a)’s conditions and remedy, so the court finds Moderna’s reading unpersuasive. Nor does rejecting the license theory leave Moderna without protection for genuine government work: the license reaches only practice “for or on behalf of the United States,” and whether Moderna’s doses were made and used for the government is the question presented by its § 1498(a) defense, which remains pending. *See Madey*, 413 F. Supp. 2d at 614.

For the same reasons, it is “clearly apparent” that the government’s Bayh–Dole Act license provides Moderna itself with no defense in this court. Accordingly, the court strikes Moderna’s license affirmative defense.

Moderna’s noninfringement counterclaims repeat the same theory. Each alleges that, to the extent Northwestern accuses vaccines made for and sold to the government, “those activities are covered by the U.S. Government’s license” and “therefore are not infringing.” Doc. 36 at 23 ¶ 81, 24 ¶ 86, 25 ¶ 91. For the reasons just given, that theory fails as a matter of law. So Counts IV through VI may proceed only on Moderna’s other noninfringement allegations, not on the theory that the government’s license authorizes Moderna’s conduct.

B. Breach-of-contract counterclaim and third-party-beneficiary affirmative defense

Moderna’s breach-of-contract counterclaim fails for similar reasons. “Before a stranger can avail himself of the exceptional privilege of suing for a breach of an agreement to which he is not a party, he must, at least, show that it was intended for his direct

benefit.” *German All. Ins. Co. v. Home Water Supply Co.*, 226 U.S. 220, 230 (1912). “For third party beneficiary status to be conferred on a party, the ‘contract must reflect the express or implied intention of the [contracting] parties to benefit the third-party.’” *Sullivan v. United States*, 625 F.3d 1378, 1380 (Fed. Cir. 2010) (alteration in original) (quoting *Montana v. United States*, 124 F.3d 1269, 1273 (Fed. Cir. 1997)). “Merely because a third party may derive a benefit, purely incidental and not contemplated by the contracting parties, from the performance of a contract does not entitle that party to enforce the contract.” *Id.* (quoting Williston on Contracts § 37:7) (citation modified).

The Bayh–Dole Act lists its “policy and objective” expressly in 35 U.S.C. § 200. “[T]he Bayh–Dole Act . . . ‘promote[s] the utilization of inventions arising from federally supported research,’ ‘promote[s] collaboration between commercial concerns and nonprofit organizations,’ and ‘ensure[s] that the Government obtains sufficient rights in federally supported inventions.’” *Stanford*, 563 U.S. at 782 (quoting 35 U.S.C. § 200). “[T]he intended beneficiaries of the Bayh–Dole Act are the institutions themselves and the government.” *Platzer v. Sloan-Kettering Inst. for Cancer Rsch.*, 787 F. Supp. 360, 364–65 (S.D.N.Y. 1992), *aff’d per curiam*, 983 F.2d 1086 (Fed. Cir. 1992) (unpublished table decision). Third parties are neither provided a cause of action nor intended beneficiaries of a Bayh–Dole license. Indeed, the Act provides that the government’s license is “nontransferrable” to a third party. 35 U.S.C. § 202(c)(4). Congress protects companies that contract with the government through 28 U.S.C. § 1498, not through Bayh–Dole Act licenses. *See Madey*, 413 F. Supp. 2d at 615 (“[Section] 1498 and the provisions of the Bayh–Dole Act at 35 U.S.C. § 202(c)(4) should be read in tandem as part of an overall scheme”). Because Moderna has no rights under the government’s Bayh–Dole Act license, Moderna’s breach-of-contract counterclaim is dismissed.

For the same reasons, it is “clearly apparent” from the text of the Bayh–Dole Act that Moderna is not a third-party beneficiary

of the government's licenses. So the court strikes Moderna's third-party-beneficiary affirmative defense.

C. Unclean hands

Unclean hands is an equitable defense with five elements: “(1) the party seeking affirmative relief (2) is guilty of conduct involving fraud, deceit, unconscionability, or bad faith (3) directly related to matter in issue (4) that injures other party (5) and affects balance of equities between litigants.” *Sonos, Inc. v. D&M Holdings Inc.*, No. 1:14-cv-01330, 2016 WL 4249493, at *5 (D. Del. Aug. 10, 2016), *report and recommendation* adopted, 2016 WL 4581078, at *1 (D. Del. Sept. 1, 2016).

Moderna's unclean-hands theory is based on its argument that the Bayh–Dole Act license protects Moderna's conduct. Doc. 36 at 82–83; Doc. 46 at 14–15. But Moderna is neither a party to the license nor an intended beneficiary of the license as just explained. Filing a patent suit against which a disputed, license-based defense exists is not unconscionable conduct. Accordingly, the court strikes Moderna's unclean-hands defense.

D. Patent exhaustion

“The longstanding doctrine of patent exhaustion provides that the initial authorized sale of a patented item terminates all patent rights to that item.” *Quanta Computer, Inc. v. LG Elecs., Inc.*, 553 U.S. 617, 625 (2008). “When a patentee sells one of its products . . . the patentee can no longer control that item through the patent laws—its patent rights are said to ‘exhaust.’” *Impression Prods., Inc. v. Lexmark Int’l, Inc.*, 581 U.S. 360, 366 (2017). “This well-established exhaustion rule marks the point where patent rights yield to the common law principle against restraints on alienation.” *Id.* at 370–71. “Exhaustion is triggered *only* by a sale *authorized* by the patent holder.” *Quanta*, 553 U.S. at 636 (emphasis added).

Moderna's exhaustion defense fails. Exhaustion is triggered only by a sale that the patentee authorized, and it protects the purchaser and those downstream of that sale—not an unauthorized maker and seller. *See Impression Prods.*, 581 U.S. at 376–77;

Quanta, 553 U.S. at 636. Moderna alleges that it manufactured the accused Spikevax doses and sold them to the government. Doc. 36 at 85. Moderna is therefore the maker and initial seller of those doses, not a purchaser downstream of any authorized sale.

Moderna contends that its own sales were authorized because the government holds a license to “have the Asserted Patents practiced by third parties for or on its behalf.” *Id.* at 85. But as explained above, the government’s Bayh–Dole Act license gives Moderna no defense of its own. For better or worse, the protection that Congress provided for those who supply the government is § 1498(a). Absent authorization from Northwestern, Moderna’s manufacture and sale cannot trigger exhaustion. *See Impression Prods.*, 581 U.S. at 377 (“[I]f a patentee has not given authority for a licensee to make a sale, that sale cannot exhaust the patentee’s rights.”); *Auto. Body Parts Ass’n v. Ford Glob. Techs., LLC*, 930 F.3d 1314, 1322 (Fed. Cir. 2019) (holding that exhaustion did not protect sales of replacement parts that the patentee had not authorized: “ABPA’s members’ sales are not authorized by Ford; it follows that exhaustion does not protect them.”).

Moderna’s alternative theory is that the government’s later distribution of doses to healthcare providers was itself an authorized sale that exhausted Northwestern’s rights before any administration occurred, leaving no direct infringement on which Northwestern’s indirect-infringement claims could rest. Doc. 36 at 86. That theory adds nothing to Moderna’s § 1498(a) defense. The government’s license extends only to practice “for or on behalf of the United States.” 35 U.S.C. § 202(c)(4). To the extent that the government’s distribution of doses to the public falls outside that phrase, it was not an authorized sale and exhausted nothing. To the extent it falls within that phrase, the question is the same one that Moderna’s pending § 1498(a) defense presents—whether the doses were made and used “for the Government.” *See Madey*, 413 F. Supp. 2d at 614 (noting that both a government-license defense and § 1498 “would require the private party to establish a use ‘for the United States’”). So the exhaustion theory

is either legally insufficient or redundant. *See* Fed. R. Civ. P. 12(f). And exhaustion could not reach Northwestern's claims that Moderna itself directly infringes by making, using, and testing the accused products.

Because Moderna's pleaded facts cannot establish an authorized sale by Moderna, and its downstream theory duplicates its § 1498(a) defense, the insufficiency of the exhaustion defense is clearly apparent. The court strikes it.

E. Leave to amend

Moderna asks for leave to amend if any counterclaim or defense is dismissed or struck. Doc. 46 at 19. Leave to amend should be freely given "when justice so requires," Fed. R. Civ. P. 15(a)(2), but may be denied when amendment would be futile. *Shane v. Fauver*, 213 F.3d 113, 115 (3d Cir. 2000). The defects identified above are legal, not factual. Moderna has already amended once in response to Northwestern's first motion to strike, *see* Doc. 36, and it does not identify any fact it would add. Whether a private party may invoke the government's Bayh-Dole Act license, whether Moderna is an intended beneficiary of licenses whose text is before the court, and whether Moderna's own sales were authorized do not turn on potential additional facts. Amendment would therefore be futile. As noted, however, the court's ruling does not affect Moderna's § 1498(a) defense and counterclaim, which remain pending.

V. Conclusion

Northwestern's motion to dismiss and strike (Doc. 38) is granted. Moderna's counterclaims for a declaratory judgment based on the government's license (Count VII) and for breach of contract (Count IX) are dismissed with prejudice. Moderna's affirmative defenses of unclean hands (defense 11), third-party beneficiary (defense 12), patent exhaustion (defense 14), and license (defense 15) are struck without leave to amend. Moderna's non-infringement counterclaims (Counts IV–VI) may not proceed on the theory that the government's license authorizes Moderna's conduct. *See* Doc. 36 at 23 ¶ 81, 24 ¶ 86, 25 ¶ 91.

Northwestern's motion (Doc. 80) for partial judgment on the pleadings on Moderna's § 1498(a) counterclaim (Count VIII) and on the § 1498(a) portion of Moderna's affirmative defense 13 is denied without prejudice to refiling after the Federal Circuit decides *Arbutus Biopharma Corp. v. Moderna, Inc.*, No. 26-1581. The parties' stipulation regarding those issues (Doc. 86) is approved as modified by this order. As stipulated, 500,001,540 doses of Spikevax were sold under the C0100 contract, 6,244,340 of those doses were administered to U.S. government employees, and Northwestern does not seek damages from Moderna for those 6,244,340 doses. The parties are directed to file a joint report proposing how this case should proceed on Moderna's § 1498(a) defense and counterclaim within seven days after the Federal Circuit issues its decision in *Arbutus* or, if no decision has issued by then, by April 7, 2027.

So ordered by the court on September 30, 2026.



J. CAMPBELL BARKER
United States District Judge