

UNITED STATES DISTRICT COURT

DISTRICT OF MAINE

COPAN ITALIA S.P.A., et al.,)

Plaintiffs,)

v.)

Case No. 1:18-cv-00218-SDN

PURITAN MEDICAL PRODUCTS)

COMPANY, LLC, et al.,)

Defendants.)

**ORDER ON DEFENDANTS' MOTION FOR PARTIAL SUMMARY
JUDGMENT**

Plaintiffs Copan Italia S.P.A. and Copan Diagnostics Inc. (collectively, “Copan”) initiated this patent infringement suit against Defendants Puritan Medical Products Company, LLC, and its affiliated companies (collectively, “Puritan”), alleging Puritan infringed upon Copan’s flocked swab technology and methods for use. Puritan now moves for partial summary judgment, alleging that any flocked swabs it produced past the start of the COVID-19 pandemic are immunized from patent infringement claims pursuant to the Pandemic Readiness and Emergency Preparedness Act (“PREP Act”). For the reasons below, Defendants’ motion for partial summary judgment is denied.

PROCEDURAL HISTORY AND BACKGROUND¹

The facts of this suit between Copan and Puritan have developed over nearly seven years of litigation before this Court. *See* Pls.' Compl. (ECF No. 1). Essentially, Copan claims Puritan infringed upon its flocked swab technology and methods of using the flocked swabs. Puritan filed a motion for partial dismissal of this matter, claiming the flocked swabs Puritan produced in response to the COVID-19 pandemic are immunized by the PREP Act (ECF No. 212). Puritan's motion was unsuccessful (ECF No. 230). Puritan filed an interlocutory appeal to the United States Court of Appeals for the Federal Circuit challenging this Court's decision (ECF No. 237). Since this Court refrained from deciding whether PREP Act immunity applied to patent infringement claims, the Federal Circuit dismissed the case for lack of jurisdiction pursuant to the collateral order doctrine and remanded the matter back to this Court (ECF Nos. 269, 270). The Federal Circuit also advised this Court to structure the issues in a manner that warranted a determination on Puritan's PREP Act immunity defense (ECF No. 270 at 14).

As a result, Puritan is now moving for partial summary judgment, alleging the record reveals PREP Act immunity shields the portion of flocked swabs Puritan produced after the PREP Act came into effect (ECF No. 288). Following Local Rule 56(h), the parties have submitted their respective versions of factual allegations, as well

¹ The summary judgment facts are drawn from the parties' stipulations, if any, and from their statements of material facts submitted in accordance with Local Rule 56. The Court will adopt a statement of fact if it is admitted by the opposing party and is material to the dispute. If a statement is denied or qualified by the opposing party, or if an evidentiary objection is raised concerning the record evidence cited in support of a statement, the Court will review those portions of the summary judgment record cited by the parties, and will accept, for summary judgment purposes, the factual assertion that is most favorable to the party opposing the entry of summary judgment, provided that the record material cited in support of the assertion is of evidentiary quality and is capable of supporting the party's assertion, either directly or through reasonable inference. D. Me. Loc. R. 56; *Boudreau v. Lussier*, 901 F.3d 65, 69 (1st Cir. 2018).

as responded to one another's factual allegations (ECF Nos. 289, 296, 298). Since the issue before me is limited to determining whether PREP Act immunity is intended to protect entities from claims of patent infringement, I relay only the facts that contribute to interpreting the PREP Act and whether it covers Puritan's production of flocked swabs during the COVID-19 pandemic.

I. The PREP Act and COVID-19 Declaration

Congress passed the PREP Act in 2005 "to encourage the expeditious development and deployment of medical countermeasures during a public health emergency by allowing" the Secretary of Health and Human Services ("HHS Secretary") "to limit legal liability for losses relating to the administration of medical countermeasures such as diagnostics, treatments, and vaccines." *Cannon v. Watermark Ret. Communities, Inc.*, 45 F.4th 137, 139 (D.C. Cir. 2022) (quotation modified); see 42 U.S.C. § 247d-6d. The PREP Act offers immunity from suit and liability to "covered persons" for claims of loss "caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure." 42 U.S.C. § 247d-6d(a)(1).

The PREP Act provides the types of entities who may be considered "covered persons" and the types of products that may be considered "covered countermeasures." *Id.* § 247d-6d(i)(1)–(2). However, Congress delegated authority to the HHS Secretary to make recommendations and state the boundaries of PREP Act immunity with respect to the public health emergency at hand, such as which countermeasures are immunized and how they should be administered, the time periods that immunity is in effect for each countermeasure, and the populations that can be immunized:

[I]f the Secretary makes a determination that a disease or other health condition or other threat to health constitutes a public health emergency, or that there is a credible risk that the disease, condition, or threat may in the future constitute such an emergency, the Secretary may make a declaration, through publication in the Federal Register, recommending, under conditions as the Secretary may specify, the manufacture, testing, development, distribution, administration, or use of one or more covered countermeasures, and *stating that subsection (a) [the immunity provision] is in effect with respect to the activities so recommended.*

Id. (emphasis added).

Accordingly, immunity only takes effect upon the HHS Secretary issuing a declaration of a public health emergency and delineating the particular covered countermeasures immunized. *Id.* § 247d-6d(b)(1). Therefore, PREP Act immunity is not without limitation. *See Cannon*, 45 F.4th at 139 (“A court should deny the immunity if, for example, the defendant is not a covered person, the measure administered is not covered, or the claim otherwise falls beyond the scope of the Secretary’s declaration.”).

In light of the COVID-19 pandemic, on March 17, 2020, the HHS Secretary issued a PREP Act Declaration of a public health emergency (the “Declaration”). Statement of Material Facts (“SMF”) ¶ 18 (ECF No. 296)²; Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15198 (Mar. 17, 2020). Pursuant to 42 U.S.C. § 247d-6d(b)(1), in Section VI of the Declaration, the HHS Secretary identified the covered countermeasures immunized by the PREP Act as “any antiviral, any other drug, any biologic, any diagnostic, any other device, or any vaccine, used to treat, diagnose, cure, prevent, or mitigate COVID-19.” 85 Fed. Reg. at 15202. Section V of the Declaration reincorporates the PREP Act’s definition of “Covered Person,” which includes a “manufacturer,” that is “a supplier or

² In their Statement of Material Fact, Defendants inscribe March 10, 2020, as the date the HHS Secretary issued the Declaration. However, the correct date is March 17, 2020. *See* 85 Fed. Reg. 15198.

licenser of . . . intellectual property . . . used in the design, development, clinical testing, investigation or manufacturing of a covered countermeasure.” *Id.* at 15201–02; 42 U.S.C. § 247-6d(i)(4)(A)–(B).

The HHS Secretary is authorized to limit immunity to covered countermeasures obtained through a particular means of distribution. *See id.* § 247d-6d(b)(2)(E) (“The Secretary shall identify, for each covered countermeasure specified in the declaration . . . whether [immunity] is effective only to a particular means of distribution as provided in subsection (a)(5) for obtaining the countermeasure, and if so, the particular means to which such subsection is effective.”); *see also id.* § 247d-6d(a)(5) (“The provisions of this section apply to a covered countermeasure . . . obtained by donation, commercial sale, or any other means of distribution, except to the extent that . . . the declaration under [subsection (b)] provides that [immunity] applies only to covered countermeasures obtained through a particular means of distribution.”). Here, the HHS Secretary did just that. In the Declaration, the HHS Secretary limited immunity to covered countermeasures obtained through

(a) Present or future federal contracts, cooperative agreements, grants, other transactions, interagency agreements, memoranda of understanding, or other federal agreements; or (b) Activities authorized in accordance with the public health and medical response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures following a Declaration of an emergency.

85 Fed. Reg. at 15202.

The PREP Act also authorizes the HHS Secretary to “amend any portion of a declaration.” 42 U.S.C. § 247d-6d(b)(4). On December 9, 2020, the HHS Secretary issued its “Fourth Amendment to the Declaration” to add a new means of distribution for covered countermeasures that are:

Licensed, approved, cleared, or authorized by the [Food and Drug Administration] (or that are permitted to be used under an Investigational New Drug Application or an Investigational Device Exemption) under the FD&C Act or PHS Act to treat, diagnose, cure, prevent, mitigate, or limit the harm from COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom

Fourth Amendment to the Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 and Republication of the Declaration, 85 Fed. Reg. 79190, 79196 (Dec. 9, 2020); SMF ¶ 21. The Fourth Amendment also provided that immunity for the covered countermeasures newly identified in the amendment began on the date the HHS Secretary issued the amendment and expired either on the final day that the Declaration was in effect or October 1, 2024, whichever came first. 85 Fed. Reg. at 79198; SMF ¶ 22.³

II. The Air Force Contract with Puritan

The federal government by way of the U.S. Air Force sent Puritan an offer, through an “Undefinitized Contract Action” (“UCA”), to “expand the domestic production of flock tipped swabs required by medical professionals for COVID-19 testing.” SMF ¶¶ 1–3; ECF No. 289-2 at 66. Puritan signed and accepted the offer on July 29, 2020, thereby forming a contract between the Air Force and Puritan (the “P3 Contract”). ECF No. 289-3. In the “Contract Terms and Conditions” section, the P3 Contract contained an indemnification clause which stated:

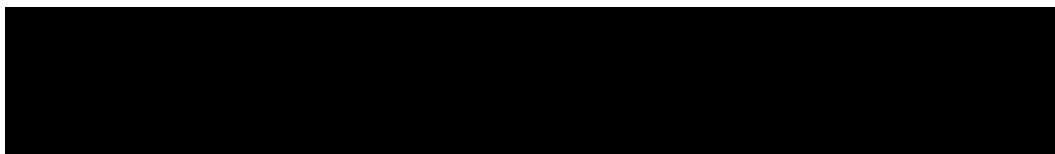
The Contractor shall indemnify the Government and its officers, employees and agents against liability, including costs, for actual or alleged direct or contributory infringement of, or inducement to infringe, any United States or foreign patent, trademark or copyright, arising out of

³ In the Eleventh Amendment to the Declaration, the HHS Secretary extended the October 1, 2024, deadline to December 31, 2024. *See* 88 Fed. Reg. 30769, 30775 (May 12, 2023); SMF ¶ 23. The Eleventh Amendment also provided manufacturers with an additional 12 months of liability protection after expiration of the prescribed immunity period. SMF ¶ 24.

the performance of this contract, provided the Contractor is reasonably notified of such claims and proceedings.

ECF No. 289-2 at 16; Plaintiff's Statement of Additional Facts ("PSAF") ¶¶ 22–21 (ECF No. 300-1). In the "Background" section, the P3 Contract stated that "[i]n order to meet domestic demand of 50 million flock tip swabs per month, [Puritan] will have to install and run an additional 20 Ultra Flock Tipping machines and 6 Automated Packaging Machines." ECF No. 289-2 at 66. The Background section also stated the Air Force would "fund [Puritan's] required upgrades of the facility and the balance of the machines." *Id.* Puritan planned to procure a new facility and five Ultra Flock Tipping machines on its own, through capital investments, to fulfill the requirements of the P3 Contract. SMF ¶ 5; ECF No. 289-2 at 66. The P3 Contract required Puritan to perform "Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ) testing and equipment performance testing" to "ensure that ultra flock tipped swabs produced in the upgraded facility [were] in compliance with requirements." ECF No. 289-2 at 67–68. The P3 Contract contained a condition that the government would issue a written acceptance and verification that Puritan's new facility was capable of producing "45 million flock tipped swabs per month" to fulfill the P3 Contract requirements. SMF ¶ 10; ECF No. 289-2 at 68.

During the negotiation stage, Puritan questioned the Air Force about the inclusion of language on PREP Act immunity into the P3 Contract, PSAF ¶ 26; ECF No. 294-6, and Puritan drafted and proposed the specific language to the Air Force, *id.* The Air Force clarified to Puritan that:




PSAF ¶¶ 25–26; ECF No. 294-7.

On October 2, 2020, the Air Force sent Puritan a modification of the UCA that served as the definitized version of the P3 Contract. SMF ¶ 15; ECF No. 289-5. The definitized version of the P3 Contract stated, “In accordance with the . . . PREP Act” the “Agreement is being entered into for purposes of production capability expansion for ‘Covered Countermeasures’ for responding to the COVID-19 public health emergency, in accordance with Section VI of the PREP Act Declaration” and that Puritan’s “performance of this Agreement falls within the scope of the ‘Recommended Activities’ for responding to the COVID-19 public health emergency.” ECF No. 289-5 at 6–7. The definitized version of the P3 Contract identified Puritan as a “‘Covered Person’ to the extent it is a person defined in Section V of the PREP Act Declaration,” and stated that “the Air Force expressly acknowledges and agrees that [Puritan] shall be immune from suit and liability to the extent and as long as [Puritan’s] activities fall within the terms and conditions of the PREP Act and the PREP Act Declaration.” *Id.* at 7.

In accordance with the P3 Contract, Puritan built a new facility in Maine (the “P3 Facility”). SMF ¶ 6. The Air Force visited the P3 Facility on June 20, 2021, and shortly after confirmed in writing that Puritan met the P3 Contract acceptance criteria. *Id.* ¶¶ 12–13; ECF No. 289-4. Puritan began producing flocked swabs at the P3 Facility in 2021. SMF ¶ 16.

III. Food and Drug Administration’s Emergency Use Authorization

On March 27, 2020, the FDA issued an Emergency Use Authorization (“EUA”) for the ID NOW COVID-19 device (“ID NOW device”). SMF ¶ 38; ECF No. 289-17. The

EUA letter explained the FDA issued its authorization so the ID NOW device could be used “for the qualitative detection of nucleic acid from the SARS-CoV-2 virus in direct nasal, nasopharyngeal or throat swabs from individuals who are suspected of COVID-19.” SMF ¶ 38; ECF No. 289-17 at 1. In the “Scope of Authorization”, the EUA letter stated:

Testing of direct nasal, nasopharyngeal or throat swabs from individuals using your product run on the ID NOW Instrument, as outlined in the “ID NOW COVID-19” Package Insert and “ID NOW COVID-19 Quick Reference Guide,” is authorized to be used in laboratories certified under [the Clinical Laboratory Improvement Amendments of 1988 (“CLIA”)] that meet the requirements to perform high, moderate, or waived complexity tests. This test is authorized for use at the POC, i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation using the ID NOW Instrument outside of the clinical laboratory environment.

ECF No. 289-17 at 3–4; SMF, ¶ 39. The EUA letter also stated that, when accompanied with the Package Insert, the ID Now device “is authorized to be distributed to and used by authorized laboratories.” ECF No. 289-17 at 4; SMF ¶¶ 40–41. The Package Insert stated, “[f]or optimal test performance [regarding throat swabs], use the swabs provided in the test kit. Alternatively, foam, polyester, HydraFlock® and nylon flocked throat swabs can be used to collect throat swab samples.” ECF No. 289-18 at 4; SMF ¶ 43. The Package Insert also stated that “rayon, foam, HydraFlock® Flocked swab (standard tip), HydraFlock® Flocked swab (mini tip), Copan Mini Tip Flocked Swab, or Copan Standard Flocked swabs can be used to collect nasal swab samples” as an alternative to the swab provided in the test kit. ECF No. 289-18 at 5; SMF ¶ 44.

On June 23, 2020, the FDA issued an EUA for the HealthQuest Esoterics TaqPath SARS-CoV-2 Assay (“TaqPath Assay”). SMF ¶ 34; ECF No. 289-13. The FDA’s EUA letter explained the TaqPath Assay is for the “[q]ualitative detection of nucleic acid

from SARS-CoV-2 in nasopharyngeal, oropharyngeal, anterior nasal, and mid-turbinate nasal swabs” ECF No. 289-13 at 1. The FDA’s EUA Summary for the TaqPath Assay stated that “[t]he swabs that were used for assay validation include Puritan PurFlock Ultra Collection swabs Other flocked swabs with plastic shafts . . . are also acceptable for testing with the [TaqPath Assay].” ECF No. 289-14 at 2; SMF ¶ 35.

On February 13, 2021, the FDA issued an EUA for the Assurance SARS-CoV-2 Panel DTC (“Assurance Panel”). SMF ¶ 36; ECF No. 289-15. The FDA’s EUA letter explained the Assurance Panel was used “as a direct to consumer product for testing of anterior nasal swab specimens self-collected at home using either: (1) the Simplicity COVID-19 Home Collection Kit or (2) the Everlywell COVID-19 Test Home Collection Kit DTC” ECF No. 289-15 at 1; SMF ¶ 36. The FDA’s EUA Summary for the Assurance Panel listed “Miraclean or Puritan” as the Material Suppliers of flocked nasal swabs. ECF No. 289-16 at 6; SMF ¶ 37.

On March 25, 2021, the FDA issued an EUA for the Amazon Real-Time RT-PCR Test for Detecting SARS-CoV-2 (“RT-PCR Test”). SMF ¶ 31; ECF No. 289-11. The letter specified that the FDA authorized the RT-PCR Test “for the qualitative detection of nucleic acid from SARS-CoV-2 in anterior nasal swab specimens that are self-collected by any individuals” SMF ¶ 32; ECF No. 289-11 at 2 n.2. The FDA’s EUA Summary identified Puritan as the supplier for nasal swabs used in the RT-PCR Test. SMF ¶ 33; ECF No. 289-12 at 10. The EUA Summary described the nasal swabs as “[i]ndividually wrapped sterile flocked nylon swab for anterior nasal specimen collection.” SMF ¶ 33; ECF No. 289-12 at 10.

LEGAL STANDARD

Summary judgment is appropriate “if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a). As cautioned by the Supreme Court, “the mere existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no *genuine* issue of *material* fact.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247–48 (1986). A material fact is one that has the potential to determine the outcome of the litigation. *Id.* at 248; *Oahn Nguyen Chung v. StudentCity.com, Inc.*, 854 F.3d 97, 101 (1st Cir. 2017). To raise a genuine issue of material fact, the party opposing the summary judgment motion must demonstrate that the record contains evidence that would permit the finder of fact to resolve the material issues in its favor. *See Triangle Trading Co. v. Robroy Indus., Inc.*, 200 F.3d 1, 2 (1st Cir. 1999) (“Unless the party opposing a motion for summary judgment can identify a genuine issue as to a material fact, the motion may end the case.”).

DISCUSSION

Puritan argues the PREP Act immunizes it from Copan’s patent infringement claims with respect to any flocked swabs Puritan produced after the HHS Secretary issued the Declaration in response to the COVID-19 pandemic. Puritan further asserts that PREP Act immunity applies to its production of flocked swabs because they constitute a covered countermeasure, Puritan is a covered person, and Puritan satisfied two means of distribution outlined in the Declaration. Copan asserts that PREP Act immunity does not apply to Copan’s claims against Puritan because Puritan’s production of flocked swabs does not count as an individual’s administration or use of a

countermeasure under the statute, and because applying PREP Act immunity to patent infringement claims would result in an unconstitutional taking in violation of the Fifth Amendment. The parties do not dispute that flocked swabs are a covered countermeasure or that Puritan is a covered person under the PREP Act.

In the PREP Act, Congress authorizes the HHS Secretary to determine the guidelines of immunity. 42 U.S.C. § 247d-6d(b)(1) (providing that the HHS Secretary must state in the declaration that PREP Act immunity “is in effect with respect to the activities so recommended,” such as “the manufacture, testing, development, distribution, administration, or use of one or more covered countermeasures”); *see Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 395 (2024) (“When the best reading of a statute is that it delegates discretionary authority to an agency, the role of the reviewing court under the [Administrative Procedure Act] is, as always, to independently interpret the statute and effectuate the will of Congress subject to constitutional limits.”). Additional provisions in the PREP Act detail the HHS Secretary’s authority to limit immunity “to covered countermeasures obtained through a particular means of distribution,” 42 U.S.C. § 247d-6d(a)(5), identify in the declaration “(A) the category or categories of diseases, health conditions, or threats to health for which the Secretary recommends the administration or use of the countermeasure;” (B) the time period for which immunity is in effect; (C) the population of individuals for which immunity is in effect with respect to the administration or use of the countermeasure; and (D) the geographic areas for which immunity is in effect with respect to the administration or use of the countermeasure, *id.* § 247d-6d(b)(2), and limit the effective time period of immunity with respect to the manufacture of certain countermeasures, *id.* § 247-6d(b)(3)(A)–(B). Thus, I will draw on the Declaration to

interpret the terms at issue here where permissible and relevant. *See, e.g., Sutherland v. Peterson's Oil Serv., Inc.*, 126 F.4th 728, 739 n.5 (1st Cir. 2025) (finding a statute that authorizes agency “to issue regulations implementing the definitions of disability . . . including rules of construction” is a “quintessential example” of a permissible delegation under *Loper Bright*).

I. The PREP Act immunizes only claims involving an individual person's administration or use of a covered countermeasure.

The PREP Act provides immunity to a “covered person . . . with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure if a declaration under subsection (b) has been issued with respect to such countermeasure.” 42 U.S.C. § 247d-6d(a)(1). According to Copan, since Puritan is not an individual person, Puritan's production of flocked swabs falls outside of the meaning of the phrase “administration to or the use by an individual” in the PREP Act immunity provision. In other words, Copan asserts the meaning of the phrase “administration to or the use by an individual” encompasses only the physical application of a covered countermeasure to a recipient. Puritan, focusing more on the phrase “use by” an individual, argues for a more expansive meaning that would render its production of flocked swabs pursuant to the P3 Contract as an immunized “use” of a covered countermeasure.

The PREP Act authorizes the HHS Secretary to give meaning to the terms “administration” and “use.” 42 U.S.C. § 247d-6d(b)(1) (“[T]he Secretary may make a declaration . . . recommending, under conditions as the Secretary may specify, the . . . administration, or use of one or more covered countermeasures, and *stating that [immunity] is in effect with respect to the activities so recommended.*” (emphasis

added)). Here, in the Declaration, the HHS Secretary defined “administration” to mean the “physical provision of the countermeasures to recipients, or activities and decisions directly relating to public and private delivery, distribution and dispensing of the countermeasures to recipients” 85 Fed. Reg. at 15202. The Description of the Declaration explains further that the phrase “physical provision” includes activities “such as vaccination or handing drugs to patients, and to activities related to management and operation of programs and locations for providing countermeasures to recipients, such as decisions and actions involving security and queuing, but only insofar as those activities directly relate to the countermeasure activities.” *Id.* at 15200.

The HHS Secretary did not define the term “use” in the Declaration. Relatedly, the PREP Act also does not define the term “individual,” and it does not authorize the HHS secretary to do so. Thus, with respect to interpreting “use” and “individual,” I turn to the traditional principles of statutory interpretation. *See In re Fin. Oversight & Mgmt. Bd. for P.R.*, 919 F.3d 121, 128 (1st Cir. 2019) (“It is elementary that in resolving a dispute over the meaning of a statute [courts] begin with the language of the statute itself.” (citing *Landreth Timber Co. v. Landreth*, 471 U.S. 681, 685 (1985))); *see also Loper Bright*, 603 U.S. at 400 (“[W]hen faced with a statutory ambiguity in such a case [where congressional delegation is not applicable], the ambiguity is not a delegation to anybody, and a court is not somehow relieved of its obligation to independently interpret the statute.”).

Accordingly, I begin with the plain language of the PREP Act. My first inquiry is whether the statutory provision “at issue has a plain and unambiguous meaning with regard to the particular dispute in the case.” *Fin. Oversight*, 919 F.3d at 128 (quoting *Robinson v. Shell Oil Co.*, 519 U.S. 337, 340 (1997)). “[I]f the statutory language is

unambiguous and the statutory scheme is coherent and consistent, then [my] inquiry must cease.” *Penobscot Nation v. Frey*, 3 F.4th 484, 490 (1st Cir. 2021) (quotation modified). I may consider legislative history only if the language of the statute is not plain and unambiguous. *Fin. Oversight*, 919 F.3d at 128.

The language of the PREP Act explains that immunity applies to “all claims for loss caused by, arising out of, relating to, or resulting from the *administration to or the use by an individual* of a covered countermeasure.” 42 U.S.C. § 247d-6d(a)(1) (emphasis added). The PREP Act further explains that “immunity . . . applies to any claim for loss that has a causal relationship with the *administration to or use by an individual* of a covered countermeasure, including a causal relationship with the . . . manufacture [or] . . . distribution . . . of such countermeasure.” *Id.* § 247d-6d(a)(2)(B) (emphasis added).

“As a noun, ‘individual’ ordinarily means ‘[a] human being, a person.’ *Mohamad v. Palestinian Auth.*, 566 U.S. 449, 454 (2012) (quoting 7 Oxford English Dictionary 880 (2d ed. 1989)); *FCC v. AT&T Inc.*, 562 U.S. 397, 403 (2011) (“When a statute does not define a term, we typically give the phrase its ordinary meaning.”). The Supreme Court “routinely uses ‘individual’ to denote a natural person, and in particular to distinguish between a natural person and a corporation.” *Mohamad*, 566 U.S. at 454 (citing *Goodyear Dunlop Tires Operations, S.A. v. Brown*, 564 U.S. 915, 924 (2011)).

Defining the term “individual” according to its ordinary meaning is consistent with the PREP Act’s statutory scheme for two reasons. *Redd v. Amazon.com, Inc.*, No. 20 C 6485, 2024 WL 2831463, at *3 (N.D. Ill. June 4, 2024) (“It is a fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme.”). First, nothing in the PREP

Act indicates Congress intended for the term “individual” to have a broader meaning than natural person. Second is Congress’s inclusion of both the terms “person” and “individual” in the statute. *See id.* § 247d-6d(a)(1). The PREP Act defines the term “person,” and does so to include “an individual, partnership, corporation, association, entity, or public or private corporation, including a Federal, State, or local government agency or department.” 42 U.S.C. § 247d-6d(i)(5). “[I]t is a well-established canon of statutory interpretation that the use of different words or terms within a statute demonstrates that Congress intended to convey a different meaning for those words.” *S.E.C. v. McCarthy*, 322 F.3d 650, 656 (9th Cir. 2003). Because the PREP Act defines “person” expansively to include “individuals” and “corporate entities,” the meaning of “individual” can only be understood as distinct from corporate entities and referring to a natural person. *See Aziz v. Alcolac, Inc.*, 658 F.3d 388, 393 (4th Cir. 2011) (“[W]hen Congress uses the noun ‘individual’—rather than the broader term ‘person’—it should ordinarily be construed to mean a human being or natural person.”).

Courts that have addressed whether or not the PREP Act shields an alleged injury caused by an entity’s failure to administer a countermeasure similarly indicate their adoption of the premise that the “physical provision” of the countermeasure requires an individual person receive the countermeasure *See Casabianca v. Mount Sinai Med. Ctr.*, 2014 WL 10413521, at *4–*5 (N.Y. Sup. Ct. Dec. 2, 2014). (“The language makes clear that the [countermeasure] must be administered to or used by a patient.”); *Mackey v. Tower Hill Rehab., LLC*, 569 F. Supp. 3d 740, 746 (N.D. Ill. 2021) (finding no causal relationship existed between the plaintiff’s claim and defendant’s use of a covered countermeasure where the individual person failed to use the countermeasure);

DeAngelo v. Artis Senior Living of Elmhurst, LLC, No. 22 C 02538, 2022 WL 3357276, at *3 (N.D. Ill. Aug. 15, 2022) (similar).

In one case, the Northern District of Illinois interpreted PREP Act immunity expansively to cover claims pursuant to the Biometric Information Privacy Act (“BIPA”). *Redd*, 2024 WL 2831463, at *3 (“Section 247d-6d(a)(2)(a) defines ‘loss’ in sweeping terms to mean ‘any type of loss, *including*’—not limited to—the enumerated examples.”). Even then, however, the question of immunity rested on the defendant’s physical provision of the countermeasure to an individual to bring forth the plaintiff’s injury. *See id.* at *4 (reasoning that the defendant’s administration of a thermal camera system—a covered countermeasure—to check employees’ temperatures in order to mitigate the spread of COVID-19 “without informed consent clearly played some role in bringing about or contributing to [the plaintiff’s alleged] injury” and thus the claim fell within the parameters of PREP Act immunity (quotation modified)); *Eaton v. Big Blue Healthcare, Inc.*, No. 2:20-CV-2291, 2020 WL 4815085 (D. Kan. Aug. 19, 2020) (describing a case in which “[t]here was no question that the claim of loss—administration of a vaccine without consent—was ‘caused by, arose out of, related to, or resulted from the administration to . . . an individual of a covered countermeasure’” because a vaccine was administered to a child (quotation modified) (quoting *Parker v. St. Lawrence Cty. Pub. Health Dept.*, 102 A.D.3d 140, 143 (N.Y. App. Div. 2012))); *see also Hogan v. Lincoln Med. Partners*, 2025 ME 22, 331 A.3d 463 (holding PREP Act immunity applied to defendants that administered a COVID-19 vaccine to children without parental consent). Thus, I am able to deduce that the PREP Act requires the relationship between manufacturing a countermeasure and administering a

countermeasure to an individual to include some step towards physically providing the countermeasure to a person to bring forth the immunized claim.

Defining the term “individual” to encompass only an individual person is also consistent with the regulatory scheme of the Declaration. As stated, the Declaration prescribes that the term “administration” of a covered countermeasure requires “physical provision of the countermeasure to a recipient.” 85 Fed. Reg. 15198 at 15200. As such, the object of the phrase “administration to” must be an individual recipient for the action to be covered by PREP Act immunity. *Casabianca*, 2014 WL 10413521, at *4 (concluding the PREP Act did not apply to an injury that was not “caused by physical provision of a countermeasure to a recipient”). The HHS Secretary’s definition of “administration” clarifies that administration involves the physical provision of a countermeasure, and, through the examples provided in the Declaration, the physical provision of a countermeasure must be connected to an individual person receiving the countermeasure. These examples include administering vaccinations to patients, handing drugs to patients, and managing and overseeing distribution sites where patients are physically provided with the countermeasures—such as providing security, queuing, and other similar activities. 85 Fed. Reg. at 15200. All of these examples involve providing a countermeasure to an individual person and support the notion that the object of the term “administration” is an individual person. Accordingly, I conclude the term “individual” in the PREP Act refers to an individual person.

Puritan argues its production of flocked swabs amounts to the immunized *use*, rather than an administration, of a countermeasure. Under Puritan’s interpretation of the statute, the phrase “use by an individual” includes a corporate entity manufacturing or distributing a covered countermeasure. Puritan’s argument is unavailing for two

reasons, however. First, Puritan’s interpretation is premised on an incorrect interpretation of the term “individual” in Section 247d-6d(a)(1), which I have already dispelled. Second, courts interpreting the PREP Act distinguish the term “use” from the term “administration” only to address or identify the operator of the covered countermeasure; that is a whether an entity “administered” a covered countermeasure to an individual, such as through on-site diagnostic testing or vaccination performed by those hired to do so, or whether an individual person “used” the covered countermeasure themselves, such as at-home diagnostic testing or masking. *See, e.g., Lopez v. Life Care Ctrs. of Am., Inc.*, No. CV 20-0958, 2021 WL 1121034, at *10 (D.N.M. Mar. 24, 2021) (assessing simultaneously whether the plaintiff’s alleged injury constitutes as an “administration or use” of a covered countermeasure). Ultimately, the focus of the language is whether the alleged harm is causally connected to the countermeasure as it relates to the individual. What distinguishes the terms is whether a covered person administered the countermeasure to the individual or whether a covered person provided an individual with the countermeasure for the individual’s own use. Because Puritan’s production of flocked swabs does not fall into either category, it is not a “use” of a covered countermeasure by an individual.

II. The PREP Act’s meaning of “loss” does not include patent infringement.

The PREP Act immunizes “all claims of loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure.” 42 U.S.C. 247d-6d(a)(1). Puritan argues that the term “loss” in the PREP Act immunity provision is broad and covers patent infringement claims. Puritan supports its claims with its interpretation of the PREP Act’s legislative history. Copan, drawing on the context of the provisions in the PREP Act and its understanding of the

legislative history, argues that applying PREP Act immunity to patent infringement claims falls outside the bounds of immunity and Congress's intent. Further, Copan argues that including patent infringement claims under the shield of immunity would render the PREP Act unconstitutional. According to Copan, the meaning of "loss" in the immunity provision refers only to claims that concern physical injury, such as medical malpractice, wrongful death, and causes of action concerning product liability or negligence.

The PREP Act grants immunity to "all claims for loss," 42 U.S.C. § 247d-6d(a)(1), and defines "loss" only as "any type of loss, including "(i) death; (ii) physical, mental, or emotional injury, illness, disability, or condition; (iii) fear of physical, mental, or emotional injury, illness, disability, or condition, including any need for medical monitoring; and (iv) loss of or damage to property, including business interruption loss." *Id.* In *Happel v. Guilford Cnty. Bd. of Educ.*, the North Carolina Supreme Court found that the types of losses covered by PREP Act immunity are claims "ordinarily associated with tort law." 913 S.E.2d 174, 193 (N.C. 2025). Drawing on the United States Supreme Court's opinion in *Fischer v. United States*, the *Happel* court employed the canons of *noscitur a sociis* and *ejusdem generis*, which led to the conclusion that, while non-exhaustive, the examples provided in the PREP Act suggest that immunity is limited to claims for personal injury. *Id.*; see *Fischer v. United States*, 603 U.S. 480, 487 (2024) ("The canon of *noscitur a sociis* teaches that a word is given more precise content by the neighboring words with which it is associated. And under the related canon of *ejusdem generis*, a general or collective term at the end of a list of specific items is typically controlled and defined by reference to the specific classes . . . that precede it." (quotation modified)). I agree. All of the examples listed in the statute of the

types of losses covered by the PREP Act relate to some form of tortious injury involving personal injury or property damage. Particularly, the examples in the first three paragraphs, 42 U.S.C. § 247-6d(a)(2)(A)(i)–(iii), identify losses as those that are manifestations of personal injury. Those three paragraphs contextualize the respective class of “loss” that the PREP Act is intended to protect—tortious physical injuries. As I explain further below, the inclusion of “business interruption loss” does not reference a distinct injury that cuts against this understanding of the types of losses able to receive PREP Act immunity. Although this list is non-exhaustive, the examples Congress delineated in the first three paragraphs of the PREP Act illustrate that immunity is limited to claims that involve some form of tortious physical injury.

The exception to PREP Act immunity in the statute also provides contextual support for determining the limits of the term “loss.” *See* 42 U.S.C. § 247d-6d(d)(1). According to the terms of the exception provision, PREP Act immunity does not shield claims for “death or serious physical injury proximately caused by willful misconduct.” *Id.* With this specific reference to physical injury in mind, it is unlikely Congress intended the PREP Act to reject the use of the immunity shield for claims of willful misconduct resulting in physical injury but otherwise extend immunity to claims for willful misconduct that leads to other types of injuries. This focus on bodily injury in the sole exception to broad liability immunity reinforces the notion that PREP Act immunity is primarily concerned with shielding claims that arise from physical harm, and that the term “loss” in the immunity provision is best understood as referring to tortious physical injuries rather than abstract or purely economic harms.

The PREP Act compensates “loss” through the Covered Countermeasure Process Fund (“CCPF”) for “eligible individuals for covered injuries directly caused by the

administration or use of a covered countermeasure pursuant to such declaration.” *Id.* § 247d-6e(a). Under the CCPF, “covered injur[ies]” are those resulting in “serious physical injury or death.” *Id.* § 247-6e(e)(3). Similar to the statutory exception to covered losses, the CCPF refers specifically to coverage for physical injuries resulting from the administration or use of a covered countermeasure. *Id.* Furthermore, the determination of compensation eligibility and amounts under the CCPF must be premised on “reliable, valid, medical and scientific evidence.” *Id.* § 247d-6e(b)(4)–(5)(A). The guidelines explaining what constitutes a covered injury and the evidence that a claimant can use to obtain compensation further supports my determination that covered losses must be a form of physical injury. Like the exception provision, the CCPF provides context to an understanding of the PREP Act that immunizes claims involving some form of tortious personal injury or property damage, not patent infringement. Viewed together, the examples mentioned above, *see* 42 U.S.C. § 247d-6d(a)(2)(A)(i)–(iii), the exception provision, and boundaries of the CCPF all support the notion that the term “loss” in the PREP Act’s immunity provision encompasses tortious claims involving physical injury.

Now, I turn back to the last example provided in the statute—“business interruption loss.” *Id.* § 247d-6d(a)(2)(A)(iv). Puritan argues Congress’s inclusion of “business interruption loss” in the examples of the losses covered by the PREP Act supports the notion that PREP Act immunity applies to economic damages resulting from patent infringement claims. Copan takes the position that since the phrase “business interruption loss” is connected to “loss of or damage to property,” the harm must fall in the category of physical damage to property. Copan further construes “business interruption loss” consistent with the economic loss rule in tort law and its

requirement that personal injury or property damage exist for recovery to be permissible.

The relevant provision explains that “loss” in the PREP Act includes “loss of or damage to property, including business interruption loss.” *Id.* The provision itself uses “business interruption loss” as a derivative of “loss of or damage to property.” *See Fischer*, 603 U.S. at 488 (“[A] general phrase can be given a more focused meaning by the terms linked to it.”). Thus, the plain language signifies that PREP Act immunity applies to loss of or damage to property resulting in business interruption loss, not that the PREP Act considers and protects business interruption loss as a distinct, broader form of loss outside the context of loss of or damage to property. The distinction between “loss of” property and “damage to” property is relevant only in the sense that the harm to the property must result in either an *entire* “loss of” the property or *partial* “damage to” the property. It does not posit a meaning that would thrust under the shield of immunity a distinct class of losses that entail purely economic losses. *E.g.*, *Lawrence Gen. Hosp. v. Cont’l Cas. Co.*, 90 F.4th 593, 600 (1st Cir. 2024) (noting that an insurance policy covering “‘direct physical loss of or damage to’ property requires some ‘distinct, demonstrable, physical alteration of the property.’”). Reading the provision in context, the only plausible understanding of the type of property losses protected by PREP Act immunity are those involving tortious claims for physical damage to property, including claims for business interruption loss.

Other court decisions hold consistently that all claims receiving PREP Act immunity rest in some form of tortious personal injury or property damage. *See, e.g.*, *Casabianca*, 2014 WL 10413521, at *4 (stating PREP Act immunity extends to losses related to “slip and fall injuries and vehicle accidents that are connected to the

vaccination process, be it at a retail store or some other facility.”); *Maney v. Brown*, 91 F.4th 1296, 1301 (9th Cir. 2024) (holding PREP Act immunity applied to the plaintiff’s Eighth Amendment claims arising out of death of inmates due to vaccine prioritization); *Hudak v. Elmcroft of Sagamore Hills*, 58 F.4th 845, 856 (6th Cir. 2023) (finding the plaintiff did not allege the defendant’s administration or use of a countermeasure caused the plaintiff’s illness or death); *see also Brown v. Watson*, 21-CV-138-JPG, 2023 WL 2788693, at *2 (S.D. Ill. Apr. 5, 2023) (“The scope of this immunity is broad in that it includes any type of physical, mental, or emotional loss or property damages that has ‘a causal relationship with the administration to or use by an individual of a covered countermeasure.’” (quoting 42 U.S.C. § 247d-6d(a)(2))). This line of cases further supports the notion that Congress did not intend for the economic losses that a plaintiff suffers through patent infringement to be shielded by PREP Act immunity. As patent infringement does not involve any form of personal injury or physical property damage, it cannot be understood to fit within the meaning of “loss” in the PREP Act.

The “causal relationship” requirement for immunity protection under the PREP Act provides further support for my conclusion. Immunity applies to “any claim for loss that has a causal relationship with the administration to or use by an individual of a covered countermeasure” 42 U.S.C. § 247-6d(a)(2)(B). As such, Puritan’s manufacture of flocked swabs must have more than a distant link in the chain of events leading to the claim of loss for immunity to apply. There must be a causal connection between a covered person administering the countermeasure to an individual person or an individual person’s use of a covered countermeasure, and the claim for personal injury. The phrases “relating to,” “caused by,” “arising out of,” and “resulting from” in the immunity provision, *id.* § 247-6d(a)(1), all “take[] on a more targeted meaning,”

Hampton, 83 F.4th at 764. (“It is not enough that some countermeasure’s use could be described as relating to the events underpinning the claim in some broad sense.”). In *Hampton*, the Ninth Circuit found an insufficient causal relationship between the administration of the countermeasure and the alleged injury where the plaintiff’s claim arose out of allegations that the defendant’s *failure* to administer COVID tests contributed to the spread of the virus and resulted in the plaintiff’s death. 83 F.4th at 763–64 (“At the very least, then, for PREP Act immunity to apply, the underlying use or administration of a covered countermeasure must have played some role in bringing about or contributing to the plaintiff’s injury.”); *cf. Maney*, 91 F.4th at 1301 (prison’s decision to prioritize vaccination distribution to protection officers had a sufficient causal connection to the administration or use of the countermeasure to invoke immunity). Consistent with this line of cases, Puritan’s manufacture of flocked swabs does not have a sufficient causal relationship with administering to an individual or an individual’s use of a covered countermeasure. To be covered, the at-issue claim must have a causal connection with the covered person physically providing the countermeasure to an individual that is beyond merely producing or distributing the countermeasure to different entities.

III. Patents are protected by the Fifth Amendment.

Copan asserts that including patent infringement claims under the shield of PREP Act immunity would result in a violation of the Fifth Amendment.⁴ Puritan argues

⁴ Puritan first challenges Copan’s ability to bring forth its constitutional challenge by raising Copan’s failure to name the United States (or one of its agencies or employees) as a party and failing to properly notify the U.S. Attorney General of its constitutional challenge to a federal statute. *See* Fed. R. Civ. P. 5.1; D. Me. Local R. 5.1; *see also Woodlands Senior Living, LLC v. MAS Med. Staffing Corp.*, 502 F. Supp. 3d 564, 570 (D. Me. 2020) (noting the judge ordered the plaintiff to comply with Rule 5.1), *vacated on other grounds*, No. 19-CV-00230, 2021 WL 2043189 (May 21, 2021); *Kenyon v. Cedeno-Rivera*, 47 F.4th 12, 24

against such a conclusion and asserts that patents are a limited monopoly subject to the boundaries provided by laws like the PREP Act.

“Statutes should be given a constitutional as opposed to an arguably unconstitutional interpretation whenever fairly possible.” *IMS Health Inc. v. Ayotte*, 550 F.3d 42, 63 (1st Cir. 2008) (citing *Arizonans for Official English v. Arizona*, 520 U.S. 43, 78 (1997) (“[Federal courts] will first ascertain whether a construction . . . is fairly possible that will contain the statute within constitutional bounds.” (quotation modified))), *abrogated on other grounds by Sorrell v. IMS Health Inc.*, 564 U.S. 552 (2011).

The Fifth Amendment provides that the government may not deprive a person of “life, liberty, or property, without due process of law” nor take private property for public use “without just compensation.” U.S. Const. Amend. V. It is well established that patents, as personal property, *see* 35 U.S.C. § 261, are protected by the Due Process and Takings Clauses of the Fifth Amendment. *See James v. Campbell*, 104 U.S. 356, 357–58 (1882) (holding the government’s appropriation or use of a patent requires just compensation under the Fifth Amendment); *Horne v. Dep’t of Agric.*, 576 U.S. 350, 358–60 (2015) (reiterating that real property and personal property receive the same protections under the Fifth Amendment); *see also Oil States Energy Servs., LLC v.*

(1st Cir. 2022) (finding it permissible for the court to analyze the constitutionality of the statute because, although untimely, Rule 5.1 notice was provided to the Attorney General); *cf. Puffer’s Hardware, Inc. v. Donovan*, 742 F.2d 12, 18 (1st Cir. 1984) (certifying the constitutional challenge of the statute to the state attorney general while still issuing a decision to uphold the statute). However, Rule 5.1(d) provides that “a party’s failure to file and serve the notice, or the court’s failure to certify, does not forfeit a constitutional claim or defense that is otherwise timely asserted.” Fed. R. Civ. P. 5.1(d). Since Copan timely filed its opposition brief in this matter, I will not treat Copan’s procedural deficiencies as a bar against its constitutional arguments. In any event, I consider the Fifth Amendment Argument here relevant only as additional support for my conclusion above that patent infringement is not within the scope of PREP Act immunity.

Greene's Energy Grp., LLC, 584 U.S. 325, 344 (2018) (stating the Court was not “suggesting that patents are not property for purposes of the Due Process Clause or the Takings Clause”). Thus, the Fifth Amendment expressly prohibits government entities from the unauthorized use of a patented invention, and these same principles apply to “the use or manufacture of a [patented] invention . . . by a contractor for the Government.” See 28 U.S.C. § 1498(a). Applying PREP Act immunity to the patent infringement claims in this case would cause such effect—Puritan, acting as a government contractor, would be immunized for any alleged infringement, or taking of Copan’s patented invention, that resulted from Puritan’s production of flocked swabs. Therefore, an interpretation of the PREP Act that includes the alleged patent infringement at issue here would constitute an unconstitutional reading of the statute.

Puritan’s assertion that the United States has waived sovereign immunity to compensate patent holders for this very situation is not convincing. See 28 U.S.C. § 1498(a) (providing a cause of action to patentees for the unauthorized use of their invention by the federal government and its contractors). The Supreme Court has held that the government’s “infringement of a patent . . . does not by itself violate the Constitution,” particularly where there exists a remedy for the patent owner to seek compensation. *Fla. Prepaid Postsecondary Educ. Expense Bd. v. College Sav. Bank*, 527 U.S. 627, 643 (1999) (analyzing whether a state infringing upon a patent constitutes a violation of the Due Process Clause of the Fourteenth Amendment where the patentee can seek compensation under Patent Remedy Act). And § 1498(a) does provide patentees an avenue for compensation resulting from the United States or its contractors’ use or manufacture of a patented invention without a license from the patentee. However, an alleged infringer’s ability to invoke this affirmative defense is

premised on the federal government's authorization or consent to the defendant's performance of the infringing acts. *TVI Energy Corp. v. Blane*, 806 F.2d 1057, 1060 (Fed. Cir. 1986) (analyzing whether the alleged infringement occurred with the United States' authorization or consent). Courts assessing whether the United States authorized or consented to a defendant's infringing actions analyze if the federal government did so either expressly or implicitly. *See* Federal Acquisition Regulation, 48 C.F.R. § 52.227-1 (2025) (hereinafter "FAR 52.227"); *TVI Energy Corp.*, 806 F.2d at 1060 ("Authorization or consent by the Government can be expressed in a form other than [an explicit] letter. In proper circumstances, Government authorization can be implied." (citation omitted)).

Here, the stipulated facts support the conclusion that, rather than authorizing or consenting to Puritan's allegedly infringing acts, the United States instead aimed to protect itself from any alleged patent infringement claims. The P3 Contract stated explicitly that Puritan would indemnify the federal government for any claim of patent infringement. *See* ECF No. 289-2 at 16. Thus, the P3 Contract cannot be understood as authorization to Puritan to infringe upon Copan's patented technology by the United States. Puritan's assertion that the government referenced the PREP Act in the definitized P3 Contract with specific regard to Puritan's pending litigation with Copan and to ensure Puritan was immune from suit is not substantiated by the undisputed facts. None of the facts here indicate that the government added the section in the P3 Contract referencing the PREP Act to specifically reference (and immunize against) Copan's patent infringement claims against Puritan. In fact, just below the section on the PREP Act, the definitized version of the P3 Contract states "[a]ll other terms and conditions remain unchanged." Thus, the indemnification clause remained in effect in

the final terms of the P3 Contract and required Puritan to indemnify the Government for any prospective patent infringement claims. *Robishaw Eng'g Inc. v. United States*, 891 F. Supp. 1134, 1141 n.11 (E.D. Va. 1995) (“Of course, the government may, and often does, shift its liability under § 1498 onto contractors by inserting a patent indemnification clause in its contracts.” (citing FAR 52.227)). [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] See ECF No. 294-7. No such procurement contract exists in the facts here. As stated, the P3 Contract does not evince the government’s authorization or consent to Puritan for its allegedly infringing acts.

I also note that while the P3 Contract did require Puritan to expand its production of flocked swabs for the government’s effort to combat the COVID-19 pandemic, Puritan’s use of flocked swabs both preceded the start of the pandemic and the formation of the P3 Contract. Copan had already commenced its suit against Puritan for allegedly infringing upon Copan’s flocked swabs, and the Court stayed the matter at the parties’ request so the parties could focus on production of COVID-19 related devices. See ECF No. 168. Because there was no resolution of whether Puritan’s flocked swabs infringed upon Copan’s patented technology, the government could not have plausibly known that Puritan’s flocked swabs resulted in infringement; the issue has not been decided. Therefore, § 1498 does not negate my conclusion. The PREP Act does not immunize Puritan from Copan’s patent infringement claims.

CONCLUSION

For the reasons above, Defendant's motion for partial summary judgment is
DENIED.

So ORDERED.

Dated this 25th day of July, 2025

/s/ Stacey D. Neumann
U.S. DISTRICT JUDGE