**UNITED STATES DISTRICT COURT**
**DISTRICT OF MAINE**

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| **COPAN ITALIA S.P.A., et al.,** | ) | |
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| **Plaintiffs,** | ) | |
| | ) | |
| **v.** | ) | **1:18-cv-00218-JDL** |
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| **PURITAN MEDICAL PRODUCTS COMPANY, LLC, et al.,** | ) | |
| | ) | |
| | ) | |
| **Defendants.** | ) | |

**ORDER ON DEFENDANTS' PARTIAL MOTION TO DISMISS**

Defendants Puritan Medical Products Company LLC, Puritan Diagnostics LLC, Hardwood Products Company LP, and Hardwood Products Company LLC (collectively, "Puritan") move to partially dismiss (ECF No. 212) the amended complaint (ECF No. 84) filed by Plaintiffs Copan Italia S.p.A. and Copan Diagnostics, Inc. (collectively, "Copan Italia"). This case pertains to flocked swabs: small rods tipped with fibers used for taking and releasing biological samples. Copan Italia alleges patent infringement, false advertising under the Lanham Act, and violations of Maine's Uniform Deceptive Trade Practices Act. Puritan's motion seeks the dismissal of all of the counts with respect to flocked swabs manufactured at Puritan's P3 factory, citing the immunity provision of the Public Readiness and Emergency Preparedness Act (the "PREP Act"). *See* 42 U.S.C.A. § 247d-6d (West 2022). Puritan's motion also contains a request for leave to amend Puritan's answer. For reasons I will explain, the Partial Motion to Dismiss is denied, and the embedded motion for leave to amend the answer is granted.

## I. BACKGROUND

The PREP Act provides protections from liability upon the declaration of a public health emergency by the Secretary of the Department of Health and Human Services. *See id.* § 247d-6d(a)(1), (b)(1). The key subsection states that those protections apply to certain claims related to "covered countermeasure[s]":

> Subject to the other provisions of this section, a covered person shall be immune from suit and liability under Federal and State law 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.

*Id.* § 247d-6d(a)(1).

There are four ways for a product to qualify as a covered countermeasure under the PREP Act. *Id.* § 247d-6d(i)(1). Puritan argues that the first of the four ways to qualify applies here: Covered countermeasures include "a qualified pandemic or epidemic product." *Id.* § 247d-6d(i)(1)(A). That phrase is itself defined, and Puritan invokes the portions of the definition providing that a product is a qualified pandemic or epidemic product when it is (1) a "device" that is (2) "manufactured, used, designed, developed, modified, licensed, or procured" to "diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic" *and* is (3) "authorized for emergency use in accordance with section 564, 564A, or 564B of the Federal Food, Drug, and Cosmetic Act." *Id.* § 247d-6d(i)(7).

In response to the COVID-19 pandemic, the Secretary issued a PREP Act declaration on March 17, 2020. Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15198 (Mar. 17, 2020). As alluded to in the block quotation above, PREP

Act immunity exists only for those covered countermeasures identified by the Secretary's declaration, which might be a narrower set of products than would satisfy the statutory definition of "covered countermeasure." *See* 42 U.S.C.A. § 247d-6d(a)(1), (b)(1). As subsequently amended, the declaration makes explicit that immunity applies to all qualified pandemic and epidemic products under the PREP Act, i.e., the portion of the definition of "covered countermeasure" that Puritan relies on. 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, 79193, 79196 (Dec. 9, 2020).[1]

The PREP Act also requires the Secretary to specify whether immunity "is effective only to a particular means of distribution . . . for obtaining the countermeasure." 42 U.S.C.A. § 247d-6d(b)(2)(E). Here, the declaration specifies three means of distribution. Fourth Amendment to the Declaration Under the Public

[1] The original declaration has been amended 10 times, but the sections relevant to the resolution of Puritan's Partial Motion to Dismiss have not changed since the fourth amendment went into effect. *See* Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 21012 (Apr. 15, 2020); Second Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 35100 (June 8, 2020); Third Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 52136 (Aug. 24, 2020); 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 (Dec. 9, 2020); Fifth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 86 Fed. Reg. 7872 (Feb. 2, 2021); Sixth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 86 Fed. Reg. 9516 (Feb. 16, 2021); Seventh Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 86 Fed. Reg. 14462 (Mar. 16, 2021); Eighth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 86 Fed. Reg. 41977 (Aug. 4, 2021); Ninth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 86 Fed. Reg. 51160 (Sept. 14, 2021); Tenth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 87 Fed. Reg. 982 (Jan. 7, 2022).

Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 and Republication of the Declaration, 85 Fed. Reg. at 79194, 79196-97. Puritan appears to rely on the first: "(a) Covered Countermeasures that are related to present or future federal contracts, cooperative agreements, grants, other transactions, interagency agreements, memoranda of understanding, or other federal agreements." *Id.* at 79196.

In its motion to dismiss, Puritan alleges that on July 29, 2020, Puritan entered into a contract with the U.S. Air Force to increase production of flocked swabs for COVID-19 testing. The contract does not obligate Puritan to provide flocked swabs to the Air Force, only to expand Puritan's manufacturing capacity. It specifies that Puritan will procure or produce 15 Ultra Flock Tipping machines and six packaging machines with funds provided by the Air Force (plus another five Puritan-funded Ultra Flock Tipping machines) and implement facility upgrades to accommodate them. The contract mentions that Puritan intended to procure a new facility via capital investment.

Puritan further alleges that the contract was supplemented on October 2, 2020. The supplemental agreement discusses PREP Act immunity:

> In accordance with the [PREP Act] as well as the Secretary of HHS's Declaration[,] . . . this Agreement is being entered into for purposes of production capability expansion for "Covered Countermeasures" for responding to the COVID-19 public health emergency . . . . Therefore, . . . 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.

ECF No. 214 at 6-7 (citation omitted). According to Puritan, it built the P3 factory to meet its contractual obligations and, therefore, immunity exists with respect to any flocked swabs produced there.

## II. ANALYSIS

### A. Leave to Amend

PREP Act immunity is an affirmative defense because it is a statutory limitation on liability. "While a statutory limitation on liability is not enumerated among the listed [affirmative] defenses [of Federal Rule of Civil Procedure 8(c)(1)], we think it falls within the Rule's residuary clause" because the "defense shares the common characteristic of a bar to the right of recovery even if the general complaint were more or less admitted to." *Jakobsen v. Mass. Port Auth.*, 520 F.2d 810, 813 (1st Cir. 1975); *accord Knapp Shoes, Inc. v. Sylvania Shoe Mfg. Corp.*, 15 F.3d 1222, 1226 (1st Cir. 1994); *Carrasquillo-Serrano v. Mun. of Canovanas*, 991 F.3d 32, 43 (1st Cir. 2021); *see also Tonkinson v. Walmart, Inc.*, Case No. 21-2588, 2022 WL 425868, at *2 (D. Kan. Feb. 11, 2022) ("As many courts have held, the immunity from suit afforded under the PREP Act is considered an affirmative defense . . . ."); *Mackey v. Tower Hill Rehab., LLC*, No. 21 C 2608, 2021 WL 5050292, at *7 (N.D. Ill. Nov. 1, 2021); *Colpits v. NHC Healthcare Clinton, LLC*, Case No. 6:20-cv-04065, 2021 WL 5332436, at *1 n.1 (D.S.C. July 1, 2021); *Thomas v. Century Villa Inc.*, Case No. 2:21-cv-03013, 2021 WL 2400970, at *6 (C.D. Cal. June 10, 2021).

Puritan did not plead PREP Act immunity in its answer (ECF No. 96), as is required for affirmative defenses under Federal Rule of Civil Procedure 8(c)(1) ("In responding to a pleading, a party must affirmatively state any avoidance or

affirmative defense . . . ."). However, Puritan's motion to dismiss includes a request for leave to amend its answer to assert PREP Act immunity, as well as a proposed amended answer.

Puritan filed its answer before the COVID-19 pandemic and thus had no reason to plead PREP Act immunity then. Puritan's request for leave to amend was made diligently and within the deadline imposed by the Scheduling Order. Accordingly, leave to amend is granted and PREP Act immunity is presented as an affirmative defense to the complaint.

**B. PREP Act Immunity**

"As a general rule, a properly raised affirmative defense can be adjudicated on a motion to dismiss so long as (i) the facts establishing the defense are definitively ascertainable from the complaint and the other allowable sources of information, and (ii) those facts suffice to establish the affirmative defense with certitude." *Rodi v. S. New Eng. Sch. of L.*, 389 F.3d 5, 12 (1st Cir. 2004); *see also Garcia v. Welltower OpCo Grp. LLC*, 522 F. Supp. 3d 734, 745 (C.D. Cal. 2021) ("As an affirmative defense, immunity via the PREP Act can provide a basis for dismissal at the pleadings stage under Rule 12(b)(6) provided the elements of the defense appear on the face of the complaint."), *abrogated on other grounds by Saldana v. Glenhaven Healthcare LLC*, 27 F.4th 679 (9th Cir. 2022). "[R]eview of the complaint, together with any other documents appropriately considered under Fed. R. Civ. P. 12(b)(6), must 'leave no doubt' that the plaintiff's action is barred by the asserted defense." *Blackstone Realty LLC v. FDIC*, 244 F.3d 193, 197 (1st Cir. 2001) (quoting *LaChapelle v. Berkshire Life Ins.*, 142 F.3d 507, 509 (1st Cir. 1998)).

Copan Italia urges the Court to deny the motion to dismiss because the motion is premised on facts that do not appear in the operative complaint, which was filed in March 2019 before the pandemic began. Copan Italia contends that it has not yet had an opportunity to conduct discovery into Puritan's allegations about PREP Act immunity because this case was stayed for most of the pandemic and discovery resumed only last October.

Puritan seeks to supplement the motion-to-dismiss record by requesting judicial notice of its agreements with the Air Force. *See* Fed. R. Evid. 201(b) ("The court may judicially notice a fact that is not subject to reasonable dispute because it . . . can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned."). Puritan also impliedly seeks judicial notice of a letter appearing on the Food and Drug Administration's website that Puritan describes as an emergency use authorization for a COVID-19 diagnostic kit with a nasal swab. Copan Italia opposes the request for judicial notice, seemingly because it believes that these documents are not the types of documents of which a court may take judicial notice. As I will explain, I need not resolve the parties' dispute regarding judicial notice because, even if it were assumed that judicial notice of both agreements and the letter is appropriate, the motion-to-dismiss record would not establish Puritan's affirmative defense with the certitude required to partially dismiss the complaint.

As previously noted, Puritan argues that the flocked swabs manufactured at the P3 factory have been authorized for emergency use in accordance with section 564, 564A, or 564B of the Federal Food, Drug, and Cosmetic Act. Under Puritan's theory for why PREP Act immunity exists here, that emergency authorization is one

of the three requirements that must be satisfied for flocked swabs from the P3 factory to be a qualified pandemic or epidemic product and thus a covered countermeasure. Puritan offers the aforementioned letter from the Food and Drug Administration as evidence that the flocked swabs from P3 are authorized for emergency use. However, the document does not mention Puritan, the P3 factory, or even flocked swabs. Instead, it appears to authorize emergency use of the OraRisk COVID-19 RT-PCR, a test to detect whether COVID-19 is present on a swab, at a laboratory in Minnesota.[2] Additionally, because the letter is unsigned, I cannot discern from its four corners whether it was intended to be final and binding. Further, Puritan has not presented any argument as to why the Food and Drug Administration's emergency approval of a test capable of detecting COVID-19 on a swab also constitutes emergency approval of the swabs used in conjunction with the test.

Puritan's other evidence that the flocked swabs from the P3 factory are covered countermeasures is the Air Force's statement to that effect in the supplemental agreement. Again, that agreement states:

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[2] In relevant part, the letter states:

> I am authorizing the emergency use of your product . . . . Your product is a qualitative test for the detection of nucleic acid from SARS-CoV-2 in nasopharyngeal swab and nasal swab specimens collected in universal transport media, nasal swabs collected in saline oral rinse, and saline oral rinse specimens from individuals suspected of COVID-19 by their healthcare provider. This test is also for use with nasal swab specimens that are collected using the binx health At-home Nasal Swab COVID-19 Sample Collection Kit when used consistent with its authorization. Testing is limited to Access Genetics, LLC laboratory, located at 7400 Flying Cloud Drive, Eden Prairie, MN 55344, which is certified under CLIA 42 U.S.C. §263a, and meets the requirements to perform high complexity tests.

Letter from Rear Admiral Denise Hinton, Chief Scientist, Food and Drug Administration, to Ronald C. McGlennen, President and Medical Director, Access Genetics, LLC, d.b.a. OralDNA Labs 2-3 (July 28, 2021), https://www.fda.gov/media/140290/download.

> In accordance with the [PREP Act] as well as the Secretary of HHS's Declaration[,] . . . this Agreement is being entered into for purposes of production capability expansion for "Covered Countermeasures" for responding to the COVID-19 public health emergency . . . . Therefore, . . . 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.

ECF No. 214 at 6-7 (citation omitted). This statement is offered without any explanation as to why the swabs meet the statutory definition of "covered countermeasure," and Puritan has not developed any argument as to why the Air Force's stated opinion merits deference. Moreover, the Air Force does not administer the PREP Act. Thus, its unexplained conclusion stated in the supplemental agreement is not entitled to judicial deference. *See United States v. Mead Corp.*, 533 U.S. 218, 228 (2001) ("The fair measure of deference to an agency administering its own statute has been understood to vary with circumstances, and courts have looked to the degree of the agency's care, its consistency, formality, and relative expertness, and to the persuasiveness of the agency's position." (footnotes omitted) (citing *Skidmore v. Swift & Co.*, 323 U.S. 134, 139-40 (1944))). Because the Air Force's statement leaves some doubt as to whether the flocked swabs from P3 are covered countermeasures, I cannot credit Puritan's affirmative defense at the motion-to-dismiss stage.

Additionally, recall that (1) the PREP Act requires the Secretary to specify whether immunity is effective only as to particular means of distribution for obtaining covered countermeasures; (2) Puritan relies on the first of the means specified in the Secretary's declaration: covered countermeasures related to federal contracts or other federal agreements; and (3) Puritan seeks the dismissal of all

counts with respect to flocked swabs manufactured at Puritan's P3 factory. But Puritan's proposed evidence does not establish that Puritan carried through with its contractual obligations, that it did so at its P3 factory, or that all of the flocked swabs from its P3 factory (as opposed to some subset) are produced in relation to its government contract. The agreements and the letter do not mention the P3 factory or what transpired after the agreements were entered into. The original Air Force contract merely states that Puritan intended to procure an unspecified new facility via capital investment. Accordingly, without a more fulsome record of the relevant facts, I cannot conclude with certainty that all of the flocked swabs manufactured at the P3 factory are related to a federal agreement.

In light of the evidentiary gaps I have noted, the dismissal of the amended complaint is not supported because the limited record before me does not show that the PREP Act affirmative defense has been proven. For that reason, I do not decide the subsidiary question of whether judicial notice of the relevant documents is proper, nor do I evaluate Copan Italia's other arguments challenging Puritan's assertion of PREP Act immunity.

## III. CONCLUSION

Puritan's Motion for Leave to Amend (ECF No. 212) is **GRANTED**, and Puritan's Partial Motion to Dismiss (ECF No. 212) is **DENIED.**

**SO ORDERED.**

**Dated: June 1, 2022**

**/s/ JON D. LEVY**
**CHIEF U.S. DISTRICT JUDGE**