

## Don't Count On PREP Act To Defend Pandemic IP Infringement

By Joseph Evall, Richard Mark and Amanda First (July 2, 2020, 2:38 PM EDT)

As COVID-19 cases continue to rise worldwide, the demand for products used to test for, prevent and treat the virus has grown.

Both established businesses and new enterprises are serving the market by producing, supplying, distributing and/or administering products that combat COVID-19.

Some of those businesses may invoke, or plan to invoke, the Public Readiness and Emergency Preparedness Act, or PREP, Act to protect against certain product-based lawsuits relating to COVID-19 countermeasures.

Although the PREP Act's applicability to product liability claims is clear, whether or not companies may invoke the act as a defense against intellectual property infringement claims remains unsettled. That uncertainty could affect supply chains for personal protective equipment, COVID-19 tests and other in-demand countermeasures as companies evaluate potential exposure.

Because the question of whether the PREP Act extends to IP claims has not yet been resolved by courts, companies embarking on new product ventures in response to COVID-19 should carefully evaluate associated IP infringement risks.

Similarly, anyone contemplating a technology transfer, including licensing intellectual property rights for use in COVID-19 countermeasures, should consider including appropriate breach and damages clauses in the contracts, to provide contractual remedies rather than reliance on infringement claims — in the event such claims are subject to a PREP Act defense.

The ultimate determination of whether the act extends to IP claims will likely reflect a number of the considerations set forth below, which summarize anticipated arguments for and against a PREP Act defense to a potential infringement claim.

### PREP Act Overview

The PREP Act, enacted in 2005, provides immunity from liability for tort claims relating to the manufacture, distribution, sale or administration of qualified countermeasures during public health



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crises. Immunity applies only after the secretary of the U.S. Department of Health and Human Services declares a public health emergency and invokes the act.[1]

On March 17, the HHS secretary issued a declaration under the PREP Act, retroactive to Feb. 4, relating to the COVID-19 pandemic.[2] The PREP declaration immunizes entities and individuals from liability with respect to their efforts to combat COVID-19 and the virus that causes it, SARS-CoV-2, extending to activities relating to covered countermeasures.[3]

Individuals covered under the declaration include manufacturers, suppliers and distributors of, and health care providers authorized to use, qualifying products that treat or help prevent COVID-19.[4]

The act contains certain limitations: Covered countermeasures include only U.S. Food and Drug Administration-approved or authorized drugs, vaccines, diagnostics or devices used to treat, prevent or mitigate COVID-19 or the virus that causes it.[5] Further, immunity is limited to activities relating to federal contracts or activities authorized by federal, state or local authorities as part of a public health response.[6]

And the scope of covered countermeasures is in flux: Protected countermeasures are limited to products or treatments approved or authorized for use by the FDA or the National Institute for Occupational Safety and Health, and emergency use authorizations are subject to revocation at any time.[7]

### **The PREP Act and IP Immunity**

Neither the PREP Act nor the PREP declaration directly addresses whether immunity under the act extends to IP claims. Interested parties may be expected to raise various arguments as to whether IP rights may or may not be enforced against potentially infringing COVID-19 countermeasures.

#### ***1. Why the PREP Act May Extend to IP Claims***

Those seeking to invoke the PREP Act against IP lawsuits may point to the fact that Congress intended the act to grant broad protection to anyone providing covered countermeasures during public health crises. In a recent advisory opinion regarding the PREP declaration, HHS took particular note of the broad scope of PREP immunity.[8]

Indeed, the act states that immunity extends to all claims for loss under federal or state law. Loss is defined to mean any type of loss, including "loss of or damage to property, including business interruption loss." [9]

Commentators have interpreted this broad language to mean that PREP Act confers absolute liability for all tort suits other than claims of willful misconduct, regardless of the type of loss involved.[10] Because IP infringement claims are considered statutory tort claims, they could involve a type of loss within the meaning of the PREP Act.[11]

Similarly, the act's definition of "covered persons" could be used to further support a reading that it contemplates protecting parties against IP infringement claims. Coverage extends to manufacturers of covered countermeasures, which include "a supplier or licensor of ... intellectual property ... used in the design, development, clinical testing, investigation, or manufacturing of a covered countermeasure." [12]

Further, the PREP Act takes care to limit immunity in some areas, but includes no express limitations on the types of loss covered. Under the act and declaration, covered countermeasures are limited to FDA-approved or authorized products, and covered activities include only those conducted pursuant to a federal contract or official public health response effort.[13]

Despite these apparent limitations on the types of products and activities that may be immune from suit, Congress undertook no such effort to limit immunity for any category of damages. In fact, the act expressly states that the sole exception for tort immunity under the PREP Act is for claims involving willful misconduct.[14] Given that Congress took care to solely exempt claims for willful misconduct, courts could interpret the act's comparative silence on IP claims as intentional.[15]

## ***2. Why the PREP Act May Not Extend to IP Claims***

IP owners seeking to enforce their rights during the COVID-19 pandemic may take note of the PREP Act and declaration's language, especially in light of guidance by HHS suggesting that IP infringers may not be immune from liability.

While the PREP Act and declaration do not expressly refer to IP claims, the HHS April 14 advisory opinion notes that the act's protections do not extend to claims under federal law for equitable relief.[16] Such a statement appears to cover IP infringement actions seeking injunctions, leaving only claims for damages subject to possible immunity.

And even those claims may not be covered: The advisory opinion states that immunity under the act is limited to claims for personal injury or damage to property.[17] Although lost profits or other economic losses due to infringement may potentially be considered damage to property, purely economic loss does not encompass the most natural reading of the term.[18]

In contrast, patent infringement damages are usually calculated based on the cost of a reasonable royalty to the patent-holder for use of the patented technology or to profits the patent-holder would have made if infringement had not occurred.[19]

Further, we have found no instance of the PREP Act actually being invoked to block an IP infringement claim. In fact, IP suits relating to COVID-19 countermeasures are currently being litigated in federal courts around the country, and IP owners have already obtained relief against COVID-19-related acts of infringement, although the relief was injunctive.[20] Companies should monitor recent IP infringement suits as they develop to see if relief in the form of damages is awarded.

Finally, one might argue that application of the PREP Act to IP lawsuits amounts to a taking of property without just compensation, making any extension of the act to IP claims unconstitutional. The U.S. Supreme Court's decision last term in *Oil States Energy Services LLC v. Greene's Energy Group LLC*, relating to the constitutionality of inter partes review proceedings, is instructive.

In that case, the court held that IPR proceedings do not violate Article III of the Constitution but noted that its holding "should not be misconstrued as suggesting that patents are not property for purposes of the Due Process Clause or the Takings Clause." [21]

In fact, the opposite may be true: The Supreme Court found in *Horne v. U.S. Department of Agriculture* that patents are property subject to protection under the takings clause of the Fifth Amendment, and any appropriation or use of a patent by the government without just compensation is

unconstitutional.[22] IP owners may argue that statutory immunity from infringement amounts to a government taking of property rights.

In sum, no clear guidance exists in the PREP Act or declaration, or in interpretive guidance or case law, regarding IP immunity. Well-reasoned arguments may be made for immunity, given the PREP Act's broad scope.

However, HHS' recent guidance, the recent rise in COVID-19-related IP lawsuits and underlying constitutional considerations suggest that parties cannot rely with certainty on the PREP Act to protect against IP infringement claims. As a result, entities involved with the manufacture, distribution or use of COVID-19 countermeasures should proceed with caution before conducting activities that may infringe existing IP rights.

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[1] 42 U.S.C. § 247d-6d.

[2] Declaration Under the Public Readiness and Preparedness Act for Medical Countermeasures Against COVID-19 ("PREP Declaration"), 85 FR 15198-01 ("PREP Declaration") (March 17, 2020).

[3] *Id.* at Section III ("Activities Covered by this Declaration Under the PREP Act's Liability Immunity").

[4] *Id.* at Section V ("Covered Persons").

[5] *Id.* at Section VI ("Covered Countermeasures").

[6] *Id.* at Section VII ("Limitations on Distribution").

[7] See Letter from Denise M. Hinton, Chief Scientist, U.S. Food & Drug Admin., to Gary L. Disbrow Ph.D., Director of Medical Countermeasure Programs (June 15, 2020) (revoking emergency use authorization for chloroquine phosphate and hydroxychloroquine sulfate to treat COVID-19).

[8] Department of Health and Human Services, Advisory Opinion on the Public Readiness and Emergency Preparedness Act and the March 10, 2020 Declaration Under the Act (Apr. 14, 2020), available at <https://www.hhs.gov/sites/default/files/prep-act-advisory-opinion-april-14-2020.pdf>.

[9] 42 U.S.C. § 247d-6d (a)(2)(A)(iv) (emphasis added).

[10] See John D. Winter et. al., Toward a Global Solution on Vaccine Liability and Compensation, 74 Food & Drug L. J. 1, 11 (2019) ("Once a PREP Act Declaration is published, immunity from tort lawsuits is absolute for the prescribed time period and within the designated area.").

[11] See *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 786 F.3d 899, 905 (Fed. Cir. 2015) (noting that

patent infringement is a "tort defined by statute").

[12] 42 U.S.C. § 247d-6d (i)(4)(B).

[13] 42 U.S.C. § 247d-6d (i)(1)(C), (D); PREP Declaration at Section VI ("Limitations on Distribution").

[14] 42 U.S.C. § 247d-6d(d)(1).

[15] See *Helfman v. GE Grp. Life Assur. Co.*, 489 Fed. Appx. 112, 114-15 (6th Cir. 2012) (finding statute's express exclusion of "certain money and benefits" to defined class requires inclusion of all other benefits).

[16] *Id.*

[17] *Id.*

[18] See, e.g., *Berry Plastics Corp. v. Illinois Nat'l Ins. Co.*, 903 F.3d 630, 636 (7th Cir. 2018) (distinguishing economic losses from "property damage or bodily injury;" noting that purely economic losses are usually unrecoverable in "torts such as negligence"); *Polytech, Inc. v. Affiliated FM Ins. Co.*, 21 F.3d 271, 275-76 (1994) (defining "business interruption loss" in insurance policy as "future prospective earnings," i.e., after destruction of production facility).

[19] 35 U.S.C. § 284 (allowing for patent infringement damages equal to "a reasonable royalty for the use made of the invention by the infringer"); see *Mentor Graphics Corp v. EVE-USA Inc.*, 851 F.3d 1275, 1285 (Fed. Cir. 2017) (noting that lost profits consist of "[the profits] the patent holder [would] have made if the infringer had not infringed").

[20] See, e.g., *3M Co. v. Performance Supply, LLC*, --- F. Supp. 3d ---, 2020 WL 2115070 (S.D.N.Y. May 4, 2020) (granting preliminary injunction against defendant); Tamara Frazier Ph.D. and Steven M. Auvil, Patent Litigation Filings on the Increase with the COVID-19 Pandemic, *Nat'l. L. Rev.* (May 4, 2020), <https://www.natlawreview.com/article/patent-litigation-filings-increase-covid-19-pandemic>; Sarah Morgan, 3M ramps up U.S. mask litigation, secures injunction, *Life Sci. Intell. Prop. Rev.* (May 5, 2020), <https://www.lifesciencesipreview.com/news/3m-ramps-up-us-mask-litigation-secures-injunction-4016>.

[21] *Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC*, 138 S. Ct. 1365, 1379 (2018) (citing *Florida Prepaid Postsecondary Ed. Expense Bd. v. College Savings Bank*, 527 U.S. 627, 642 (1999)).

[22] See *Horne v. Dep't of Agriculture*, 135 S. Ct. 2419, 2427 (2015); see also *Cascades Projection LLC v. Epson America, Inc.*, 864 F.3d 1309, 1312-23 (Fed. Cir. 2017) (O'Malley, J., dissenting) (dissenting from court's refusal to consider en banc whether a patent right is a public right; arguing that patents are property subject to the Takings Clause).