

Product Liability and Intellectual Property

CORONAVIRUS

MARCH 26, 2020 • NO. 1

Special Exemptions from Product and Patent Liability for COVID-19 Countermeasures

On March 17, 2020, the U.S. Department of Health and Human Services (“HHS”) published in the Federal Register a [“notice of declaration”](#) conferring broad-based immunity from tort (including product liability) litigation for those engaging in “activities related to medical countermeasures against COVID-19.” The declaration is intended to clear the way for science-based organizations and public health professionals to take control of the situation immunized from legal second-guessing.

HHS is conferring tort immunity pursuant to 42 U.S.C. §247d-6d (the Public Readiness & Emergency Preparedness “PREP” Act) and 21 U.S.C. §§564A-B (the Pandemic and All-Hazards Preparedness Reauthorization Act or “PAHPRA”).

42 U.S.C. §247d-6d(a)(1) of the PREP Act provides immunity from liability under federal and state law. While the statute and declaration do not specifically refer to immunity from intellectual property (such as patents and copyrights), both patents and copyrights are typically considered torts and fall under federal law (for copyrights and patents) and to a limited extent under state law (for copyrights). *Cf. Carbice Corp. of America v. America Patents Development Corp.*, 283 US 27 (1931) (“Infringement, whether direct or contributory, is essentially a tort, and implies invasion of some right of the

patentee”). Accordingly, it would appear that acts falling within the declaration would be immune from patent and copyright liability.

The immunity extends not only to COVID-19-fighting drugs, but also to any products or technologies intended to enhance the use or effect of a drug, biological product, or device that may be used to diagnose, mitigate, prevent, treat, or cure a pandemic or otherwise limit the harm the pandemic might otherwise cause. Those entitled to claim immunity include manufacturers and distributors.

Countermeasures must be FDA approved or cleared, investigational under the FDCA, or otherwise licensed or authorized for emergency under the Emergency Use Authorization (“EUA”) process. Many of the tests now deployed for COVID-19 were authorized using the EUA pathway. Companies wanting to contribute to the fight against COVID-19 by supplying gloves, masks, gowns, or even ventilators can use the EUA process for devices not previously approved or cleared by FDA.

An application for an EUA for a device must be submitted through the Center for Devices and Radiological Health at the FDA. In applying for an EUA, the sponsor must satisfy

these four categories: Serious or Life-Threatening Disease or Condition, Evidence of Effectiveness, Risk Benefit Analysis, and No Alternatives.

For the FDA to issue an EUA, there must be no adequate, approved, and available alternative to the candidate product for diagnosing, preventing, or treating the disease or condition. A potential alternative product may be considered “unavailable” if there are insufficient supplies of the approved alternative to fully meet the emergency need.

The immunity extends through **October 1, 2024**, or longer if any given product is “obtained for the national stockpile.”

Blank Rome’s [Coronavirus \(“COVID-19”\) Task Force](#) is continuing to monitor the COVID-19 crisis and will provide further updates for patent and trademark applicants and registrants as they become available.

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