

IP Alert | Responding to the COVID-19 Crises: A Look at Potential Patent Infringement Immunity in View of the PREP Act

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Many companies are eager to contribute to the fight against COVID-19 by making and distributing personal protective equipment (PPE) to healthcare workers. But the potential threat of a patent infringement suit may give companies pause. Banner Witcoff is proud to play a role in helping clients combat COVID-19 by advising them on ways to alleviate this threat.

One potential option is through the Public Readiness and Emergency Preparedness (PREP) Act enacted in 2005.^[i] The PREP Act is generally recognized as providing broad immunity from tort claims under federal and state law. Although the PREP Act does not specifically refer to immunity from specific causes of action, the breadth of the PREP Act suggests that it may extend to patent infringement claims.

The PREP Act authorizes the Secretary of Health and Human Services (HHS) to issue a “Declaration” that (a) recommends the manufacture, development, and distribution of certain “covered countermeasures,” and (b) invokes the liability protections provided by the PREP Act.^[ii]

In response to COVID-19, Secretary Alex Azar issued a PREP Act Declaration on March 10, 2020, that is retroactive to February 4, 2020.^[iii] The Declaration generally provides that “covered persons” who manufacture, test, develop, distribute, administer or use “covered countermeasures” cannot be sued for “any claim of loss caused by, arising out of, relating to, or resulting from” these activities.^[iv]

The Declaration defines “covered persons” to include manufacturers and distributors, among others,^[v] and “covered countermeasures” to include, for example, drugs or devices used to treat, prevent, or mitigate COVID-19.^[vi] The PREP Act defines “loss” as “any type of loss,” including: death; physical, mental, or emotional injury, illness, disability, or condition; fear of physical, mental, or emotional injury, illness, disability, or condition, including any need for medical monitoring; and loss of or to damage to property, including business interruption loss.^[vii]

Neither the PREP Act nor the Declaration specifically refer to patent infringement. That said, patent infringement claims arise under federal law, and patent infringement is generally considered a tort.^[viii] Accordingly, while the law is not settled and notwithstanding Constitutional challenges, patent infringement may be considered “loss

of or damage to [intellectual] property” that has a “causal relationship” with the design, development, manufacture, and distribution of covered countermeasures under the PREP Act.

Importantly, while the PREP Act and Declaration provide broad protections that potentially encompass patent infringement claims, there are limitations. For example:

- The covered countermeasures must be “qualified pandemic or epidemic products,” “security countermeasures,” or drugs, biological products, or devices authorized for investigational or emergency use, as those terms are defined in the PREP Act, the Federal Food, Drug, and Cosmetic Act, and the Public Health Service Act.^[ix]
- Liability immunity does not apply to death or serious physical injury proximately caused by “willful misconduct.”^[x]
- Liability immunity is limited to certain defined activities involving covered countermeasures related to: (1) present or future federal contracts or other federal agreements, or (2) activities authorized by authorities in accordance with the public health and medical response of the federal, state, and local authorities to prescribe, administer, deliver, distribute, or dispense the covered countermeasures following an emergency declaration.^[xi]

If a company wants to make and distribute PPE, but is concerned about patent infringement claims, it should seek legal advice to explore options to alleviate those concerns. Among many other options, the PREP Act is one option that should be explored. Banner Witcoff attorneys are experienced in these issues and ready to assist clients’ efforts to combat COVID-19.

For more information about the content in this alert or if you have questions about the business and legal implications of the COVID-19 situation, please contact a Banner Witcoff attorney.

[i] 42 U.S.C. § 247d-6d.

[ii] § 247d-6d(b)(1).

[iii] “Declaration for Public Readiness and Emergency Preparedness Act Coverage for medical countermeasures against COVID-19,” <https://www.phe.gov/Preparedness/legal/prepact/Pages/COVID19.aspx> (Mar. 10, 2020).

[iv] Id. §§ III–V.

[v] Id. § V.

[vi] Id. § VI.

[vii] § 247d-6d(a)(2).

[viii] 35 U.S.C. § 271; *Carbice Corp. of America v. America Patents Development Corp.*, 283 U.S. 27, 33(1931) (“Infringement, whether direct or contributory, is essentially a tort, and implies invasion of some right of the patentee”); *In re Cambridge Biotech Corp.*, 186 F.3d 1356, 1371 (Fed. Cir. 1999) (“Patent infringement is properly classified as a tort, albeit one created by federal statute.”).

[ix] PREP Act Declaration § VI; § 247d-6b(i).

[x] § 247d-6b(d).

[xi] PREP Act Declaration § VII.

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