MAY 2020 | VOLUME 43 • NUMBER 10

THE JOURNAL
OF THE DELAWARE STATE BAR ASSOCIATION

THE PRACTICE OF LAW IN THE TIME OF COVID-19

Presorted Std.
U.S. Postage
PAID
Permit No. 408
Wilmington, DE

Litigating Intellectual Property Rights Created in Response to COVID-19

BY FREDERICK L. COTTRELL III, ESQUIRE, AND VALERIE CARAS, ESQUIRE

As companies race to develop vaccines, medical products, and other treatments to combat the COVID-19 pandemic, these advances will likely engender litigation related to the protection of intellectual property rights. Given the District of Delaware's national prominence as a preeminent patent litigation venue, a sizeable portion of such litigation may proceed in a Delaware courtroom. A few of the IP issues that may arise in the pandemic's wake are previewed below.

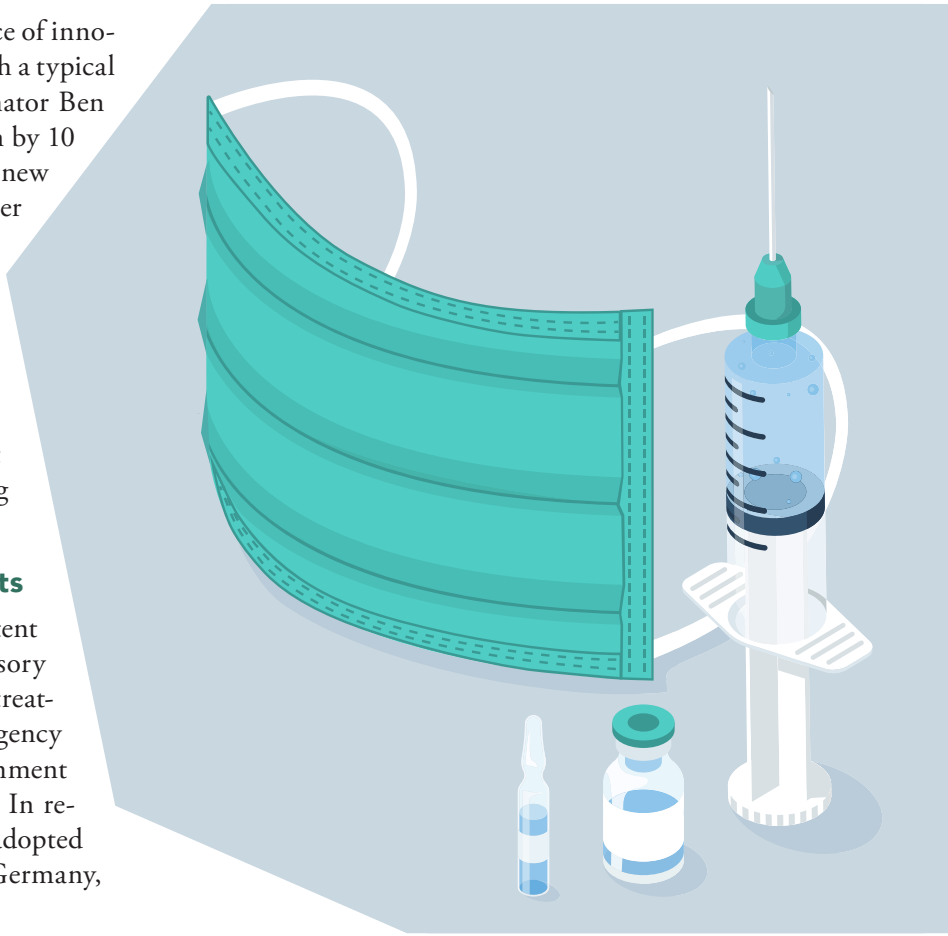
Exclusivity Terms

Under the United States' patent regime, the price of innovation is rewarded by the promise of exclusivity, with a typical patent term lasting 20 years.[1] In March, U.S. Senator Ben Sasse (R-NE) introduced a bill extending that term by 10 additional years for patent owners who develop "a new or existing pharmaceutical, medical device, or other process, machine, manufacture, or composition of matter, or any new and useful improvement thereof used or intended for use in the treatment" of COVID–19.[2] The patent term for such an innovation would not begin until the national emergency concludes.[3] Such a bill could, at a minimum, spawn litigation as to what constitutes an improvement of an existing product for purposes of treating COVID–19.

Compulsory Licensing and March-In Rights

Related to the question of exclusivity is the extent to which governments may require the compulsory licensing of patents to make medical devices and treatments widely available so long as the national emergency persists. Such schemes typically permit the government or private entities to produce patented inventions. In response to the pandemic, this approach has been adopted internationally by countries including Canada, Germany, France, and Israel.[4]

To date, the United States has not taken such an approach. To the extent statutory authority for compulsory licensing exists, 28 U.S.C. § 1498 permits the federal government to produce a patented invention without a license so long as it provides "reasonable and entire compensation for such use and manufacture" to the owner.[5] Additionally, 35 U.S.C. § 203 gives the federal government so-called "march-in rights": if the patented invention was developed with federal dollars, the government may either take a license on the patented invention, or otherwise grant a license to a third-party.[6] Against a 200-year-old backdrop reinforcing IP



as a constitutional property right, the government's use of compulsory licenses has been called "rare" by the Supreme Court,[7] and it does not appear that the federal government has ever used its march-in rights.

The recently-passed COVID-19 relief bill — the CARES Act — does not address compulsory licensing or march-in rights, but rather broadly permits the Secretary of the Department of Health and Human Services to "take such measures authorized under current law to ensure that vaccines, therapeutics, and diagnostics developed from funds provided in this Act will be affordable in the commercial market."[8]

PREP Act Immunity from Patent Infringement Claims

Another issue that could be litigated in the pandemic's wake is the extent to which the Public Readiness and Emergency Preparedness ("PREP") Act creates immunity for patent infringement claims arising from products used in fighting COVID-19.[9] The PREP Act generally immunizes "from suit and liability under Federal and State law" losses incurred by "entities and individuals involved in the development, manufacture, testing, distribution, administration, and use of medical countermeasures."[10] The Secretary of the Department of Health and Human Services recently invoked the PREP Act to fight COVID-19, conferring immunity upon companies for losses arising from producing qualifying medical devices and treatments.[11] No court has addressed whether "losses" under the PREP Act include patent infringement claims.

Why Delaware?

Given that the judges within the District of Delaware have accumulated the kind of expertise in patent litigation respected by both sides of the bar, and given that multiple pharmaceutical, medical device, and life sciences companies are incorporated in Delaware, it is unlikely that patent litigation will slow in the First State any time soon. As the fight against COVID-19 concludes, new fights related to IP rights are likely to begin.

Notes:

1. U.S. CONST. Art. I. § 8; 35 U.S.C. § 154.
2. *A Bill to provide certain limitations on liability for actions taken by health care providers to combat COVID-19*, 116th Cong. (2020).
3. *Id.*
4. Adam Houldsworth, *The key covid-19 compulsory licensing developments so far*, IAM (Apr. 7, 2020), https://www.iam-media.com/coronavirus/the-key-covid-19-compulsory-licensing-developments-so-far.
5. 28 U.S.C. § 1498.
6. 35 U.S.C. § 203 (the "Bayh-Doyle Act.").
7. *See, e.g., Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 215 (1980).
8. The CARES Act, H.R. 748, 116th Cong. (2020).
9. *PREP Act Q&As*, U.S. DEP'T OF HEALTH AND HUMAN SERVICES, https://www.phe.gov/Preparedness/legal/prepact/Pages/prepqa.aspx (last updated Sept. 5, 2019).
10. *Id.*
11. *Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID–19*, 85 Fed. Reg. 15198 (March 17, 2020).

Frederick L. Cottrell III is a director and **Valerie Caras** is an associate of Richards, Layton & Finger, P.A. The views expressed herein are the views of the authors and are not necessarily the views of the firm or its respective clients. Frederick L. Cottrell III can be reached at Cottrell@RLF.com and Valerie Caras can be reached at Caras@RLF.com.