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Patents and COVID-19 Testing

Patents made the news in a horrible way last week when it was reported that a test manufacturer was being sued for developing tests for COVID-19. Making the optics even worse, the patents were originally owned by Theranos, a testing company based on a "massive fraud," according to the SEC. This news casts the patent system in an unsavory light, where it appears to impede progress rather than promote it. However, it can also illustrate the crucial role of the patent system in healthcare. Despite the bad optics created by one patent litigant in the midst of this COVID-19 crisis, Congress should (in the future) enact legislation to make patents more available for inventions related to diagnostic tests.

On March 9, 2020, Labrador Diagnostics sued BioFire and its parent company bioMérieux, alleging that BioFire's FilmArray products infringed two U.S. patents. After a flood of criticism and revulsion, Labrador announced on March 17 that it will offer a royalty-free license for COVID-19 testing, and it insisted that it did not know BioFire was developing COVID-19 tests. Labrador and BioFire have agreed to extend the date for BioFire's response to June 30, 2020.

Outrage over Labrador's suit was intensified because Labrador does not make COVID-19 tests itself, nor has it announced any plans to do so. Labrador was formed on March 6 and does not have any facilities of its own. Since Labrador is not practicing its patented technology, some called it a "patent troll," an ugly creature demanding money in the form of royalties to let others pass. But that

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pejorative term can obscure that many non-practicing entities (such as universities, non-profit research centers, and the National Institutes of Health) regularly make crucial inventions, even though they themselves do not manufacture or distribute those inventions. Instead, the patents covering those inventions are licensed to companies for widespread distribution.

Yet patents are involved in another, less-publicized way in the Labrador story, in that they are used by the test makers to protect their innovation. BioFire's virtual patent marking page lists numerous U.S. patents covering its FilmArray instruments, kits and materials for medical testing. bioMérieux's annual reports confirm the importance of patents to the field of diagnostics:

"Diagnostic systems, which are underpinned by a combination of instrumentation, IT and biology, are heavily reliant on the protection of intellectual property; the players in the sector therefore seek to obtain strong positions in matters of patents."[1]

"The Company continues to deploy its intellectual property policy. It actively protects its research findings via patents (around 30 new patent applications per year) and monitors its competitors for any infringements of its patents."[2]

bioMérieux's statements reflect the primary economic purpose of patents in providing incentives for innovators. The promise of patent protection encourages them to invest in costly research and development (R&D), affording a later opportunity to reap the rewards of their innovations. If bioMérieux and other diagnostic developers lose faith in the patent system, their R&D investments and efforts for diagnostic testing are likely to decline.

The COVID-19 crisis is shining a spotlight on the critical role of diagnostic tests in public health and medical care. However the availability of U.S. patents for diagnostic testing has been drastically diminished over the past decade. Since 2012, the U.S. Supreme Court has

expanded the long-standing exceptions to the patent eligibility for "laws of nature" and "natural phenomena" to strike down patents related to diagnostic testing. Congress has considered legislation to reverse this expansion and heard testimony from leading life science innovators about the problem:

In recent years, decisions from the federal courts have cast ***a cloud of uncertainty over our work in the field of diagnostic tests and life sciences****. On multiple occasions, the federal courts have ruled that patents we received from the United States Patent and Trademark Office (USPTO) were invalid, even arguing that guidance issued by the USPTO did not carry legal weight. These decisions have created uncertainty that can* ***deter investment from new products that could have a significant impact on patient care****.[3]*

Even judges from the federal appellate court that decides patent cases have voiced concern over the current state of the law:

The math is simple, you need not be an economist to get it: Without patent protection to recoup the enormous R&D cost, investment in diagnostic medicine will decline. To put it simply, this is bad. It is bad for the health of the American people and the health of the American economy.[4]

In May 2019, a bipartisan group of legislators stated they were working on legislation to revise the patent statutes and eliminate the expanded use of judicial exceptions to strike down patents. Congress undoubtedly has a tremendous number of worries at the moment, but when the COVID-19 crisis subsides, it should resume its consideration of how to make the patent system provide greater incentives for diagnostic testing.

If you have any questions regarding patents or your intellectual property portfolio, please do not hesitate to

contact Michael Harlin or your Neal Gerber Eisenberg attorney.

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[1] bioMérieux, 2018 Registration Document and Annual Financial Report, p. 45.

[2] *Id.*

[3] Testimony of Peter O'Neill, Executive Director of Cleveland Clinic Innovations, to the U.S. Senate Committee on the Judiciary, Subcommittee on Intellectual Property, June 11, 2019.

[4] *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 927 F.3d 1333, 1358, 2019 BL 246748, 24 (Fed. Cir. 2019) (Moore, J., dissenting from denial of *en banc* rehearing).