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By Jorge L. Contreras, JD

The U.S. patent system gives inventors a 20-year exclusive right to their inventions to incentivize the creation of new technologies.

But what if you have a great idea for a new technology, but never actually create it, test it, or determine that it works? Is that patentable? Conversely, should the U.S. Patent and Trademark Office (PTO) grant patents covering imaginary, fraudulent and otherwise non-existent inventions? Probably not, but it happens with alarming frequency, and it is causing serious problems.

For example, on March 3, 2020, the *Wall Street Journal* reported that French manufacturer bioMérieux, among others, was developing a new fast-acting DNA-based diagnostic test for COVID-19.

Six days later, a patent holding company called Labrador Diagnostics sued bioMérieux and its Utah-based subsidiary BioFire Diagnostics for patent infringement. Labrador alleged that

BioFire's FilmArray® products, which analyze blood samples for hundreds of different respiratory, gastrointestinal and other pathogens including, most recently, the COVID-19 virus, infringe U.S. patents 8,283,155 and 10,533,994. In addition to unspecified monetary damages, Labrador sought an injunction to stop sales of the allegedly infringing products.

News of Labrador's lawsuit sparked a wave of negative publicity that quickly persuaded its parent company Fortress to end the lawsuit and offer royalty-free licenses to anyone conducting COVID-19 testing.

Even more remarkable than Labrador's poor judgment in targeting COVID-19 test suppliers in the midst of a global pandemic is the source of the patents that it asserted. Both patents were originally held by Theranos Inc., the infamous blood testing company founded by Stanford wunderkind Elizabeth Holmes in 2003.

At its peak, Theranos was valued at more than $9 billion; it promised a multifunctional, automated testing system that worked with no more than a pinprick of blood. But as John Carreyrou at the *Wall Street Journal* first reported in 2015, and compellingly portrayed in his 2018 book *Bad Blood: Secrets and Lies in a Silicon Valley Startup*, Theranos was perhaps "Silicon Valley's greatest fraud." Despite its high flying reputation and blue chip Board, the company had simply not produced the blood testing technology that it had advertised.

By 2017, Theranos was on the brink of collapse. At that point, Fortress loaned Theranos $100 million, secured in part by the company's sizable patent portfolio. When Theranos finally ceased operations in March 2018, Fortress took possession of more than 700 Theranos patents worldwide.

Fortress, which is in the business of acquiring and asserting patents for profit, is sometimes referred to as a "patent troll," though more formally classified as a "patent assertion entity" (PAE) or a "non-practicing entity" (NPE) – and, given its size, has recently earned the new honorific "Mega-NPE." Fortress then transferred some Theranos patents to its tactical subsidiary Labrador, which seemingly began to assert them in 2020. Holmes, who is currently under federal indictment for multiple counts of criminal fraud, is the lead inventor on both patents asserted against bioMérieux and BioFire.

Assuming that the charges against Holmes and Theranos are proven, one might reasonably ask how a company that never developed its claimed technology, and went to great lengths to conceal its failures, could have obtained hundreds of patents protecting that non-existent technology.

Unfortunately, Theranos's aspirational blood testing apparatus is not the only allegedly fraudulent technology to have been patented. For example, in 2014, the USPTO granted a patent to disgraced South Korean scientist Hwang Woo-suk, who was convicted of fraud for falsifying experimental results relating to the cloning of human stem cells – the very subject of his patent. In fact, there are patents covering any number of never-achieved, unworkable inventions from cold fusion to anti-gravity-driven spacecraft.

The problem of patents covering non-existent inventions does not end with applicants who are fraudulent or delusional. The PTO receives a far larger number of applications from inventors who are simply mistaken (or only mildly dishonest). These are patents based on scientific findings that have been formally retracted from the journals in which they were originally

published. Professor Janet Freilich and Soomi Kim studied a large sample of patents based on retracted scientific papers and report (in a forthcoming article) that retraction of the underlying paper had little or no effect on the examination, issuance and later citation of those patents. This work supports prior research by Professor Freilich demonstrating, based on the methodological soundness of experiments reported in a large sample of patent documents that, in reality, "most [patented] inventions likely do not work."

What is going on here? Patents are supposed to reward inventors for conceiving and reducing to practice new and useful innovations. Inventions that are fraudulent, imaginary, or simply unsupported by scientific evidence clearly do not meet these criteria.

The Patent Act seeks to prevent these sort of inventions from being patented through a doctrine called the "enablement" requirement. Essentially, each patent application must contain a detailed written description of how to make and use the claimed invention. It is (supposedly) not enough to say, "it would be very nice to run a DNA test for hundreds of different pathogens using a single drop of blood – and that's my invention!" The inventor must actually tell the PTO, and the world, how to make and use the claimed invention.

So why isn't this system working as it should? One reason is that an applicant can cram a patent application full of legitimate-sounding scientific references, diagrams and descriptions of how one might *wish* the invention worked, without ever having checked that it actually did work.

Or, in the case of Theranos, allegedly covering up the fact that the technology never worked, despite years of genuine effort to develop it. And the patent examiner who evaluates the application need not perform any experiments or build any prototypes to verify what the applicant says. Examiners must simply take the written description provided by the applicant at face value, judging only that it discloses the invention in enough detail that someone "skilled in the art" would be able to produce it without undue experimentation. But that is simply an assessment of the application's level of detail, not its scientific or technical validity.

Is this the fault of the PTO or its examiners? We can't reasonably expect patent examiners to do their own confirmatory experiments – most of them are telecommuters who work from home under intense time pressure; they don't have laboratories, equipment or reagents at their disposal, nor even the luxury to read much of the scientific literature in the field. So what can be done to improve the system?

There are several administrative possibilities. First, at the examination stage, the PTO could track inventor names against lists of authors of retracted papers, individuals indicted in criminal proceedings and subject to securities investigations, disciplined for research misconduct, and accused of other behavior that could give rise to questions about the assertions made in an application. A match could trigger a need for heightened examination, peer review, or some other verification.

The PTO could also adopt more stringent enablement standards in high risk areas, including any medical innovation that is touted as overly revolutionary or miraculous (from 1994 to 2015 the PTO flagged and delayed prosecution of unlikely inventions including panacea cures for conditions ranging from AIDS to baldness; it is unclear why this program was eliminated). In addition, as Freilich has proposed, after such patents are issued, public interest challenges

could be allowed on the basis of lack of enablement (a challenge that is not currently permitted under the PTO's *inter partes review* procedure).

Some might argue that such reform is not needed, as little harm is caused by patents on inventions that do not really exist. Commenting on the ludicrous 2005 anti-gravity spacecraft patent noted above, one PTO advisor blithely opined that the consequences of such patents are not serious "because the patents are useless."

But that is clearly not the case, as Labrador's infringement suit against bioMérieux and BioFire demonstrates. First, even if the holder of a patent never succeeded in developing the patented technology, others might have, and they are vulnerable to claims that they are infringing the patent. Second, even if a patent can eventually be challenged and invalidated in court, as many presumably should, patent litigation is a costly proposition well beyond the means of most small and medium sized enterprises. The threat of patent suits, particularly by non-practicing entities, is a frightening prospect for most companies, and many would probably rather settle for a modest sum than take their chances in court. Finally, the threat of patent litigation can itself dampen enthusiasm for a new product market, deterring market entrants and the proliferation of product improvements and competition, which can be particularly damaging in the midst of a public health crisis.

For all of these reasons, we should care about the issuance of patents on fraudulent, imaginary and non-existent inventions, and urge Congress to enact reforms to the patent system that will more closely tie patents to inventions that are real.

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Jorge L. Contreras is a Presidential Scholar and Professor of Law at the University of Utah with an adjunct appointment in the Department of Human Genetics. His research focuses on intellectual property, technical standards and science policy, and he is one of the co-founders of the Open COVID Pledge, a framework for contributing intellectual property to the COVID-19 response. Professor Contreras is the editor of six books and the author of more than 100 scholarly articles and chapters appearing in scientific, legal and policy journals including Science, Nature, Georgetown Law Journal, NYU Law Review, Iowa Law Review, Harvard Journal of Law and Technology and Antitrust Law Journal. He has served as a member of the National Institutes of Health (NIH) Council of Councils, the Advisory Councils of the National Human Genome Research Institute (NHGRI) and the National Center for Advancing Translational Sciences (NCATS), and as the Co-Chair of the National Conference of Lawyers and Scientists. He is a graduate of Harvard Law School (JD) and Rice University (BSEE, BA).